DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Docket No. CDC–2015–0006]

42 CFR Part 73

RIN 0920–AA59

Possession, Use, and Transfer of Select Agents and Toxins; Biennial Review of the List of Select Agents and Toxins and Enhanced Biosafety Requirements

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

ACTION: Notice of Proposed Rulemaking (NPRM).

SUMMARY: In accordance with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Response Act), the Centers for Disease Control and Prevention (CDC) in the Department of Health and Human Services (HHS) has reviewed the list of biological agents and toxins that have the potential to pose a severe threat to public health and safety and proposes to amend and republish the list. Specifically, we are proposing to remove six biological agents; add provisions to address the inactivation of select agents; add specific provisions to the section of the regulations addressing biosafety; and clarify regulatory language concerning security, training, incident response, and records.

DATES: Submit written or electronic comments by March 21, 2016.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2015–0006 or RIN 0920–AA59 by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Road NE., MS–A46, Atlanta, Georgia 30329, Attn: Docket CDC–2015–0006.

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. Dan Sosin, Acting 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 NPRM is organized as follows:

I. Public Participation

Interested persons or organizations are invited to participate in this rulemaking by submitting written views, recommendations, and data. Comments are invited on any topic related to this rulemaking.

In addition, HHS/CDC invites comments specifically as to whether there are biological agents or toxins that should be added or removed from the HHS list of select agents and toxins based on the following criteria:

(1) The effect on human health of exposure to the agent or toxin;

(2) The degree of contagiousness of the agent or toxin and the methods by which the agent or toxin is transferred to humans;

(3) The availability and effectiveness of pharmacotherapies and immunizations to treat and prevent any illness resulting from infection by the agent or exposure to the toxin; and

(4) Any other criteria, including the needs of children and other vulnerable populations that the commenter considers appropriate.

HHS/CDC also invites comments on the following questions:

(1) Are there other methods that should be required to validate the rendering of a select agent non-viable or regulated nucleic acids that can produce infectious forms of any select agent virus non-infectious?

(2) Should there be changes to the toxin permissible limits for excluded toxins?

(3) Should Diacetoxyscirpenol (DAS) and T–2 be removed from the select toxin list because they do not have the potential to pose a severe threat to public health and safety?

(4) Does seven calendar days provide a sufficient amount of time for the entity to destroy or transfer the select agents or toxins after identification?

(5) Are there any specific biosafety measures that should be required to prevent laboratory acquired infections (LAIs) or accidental release of the select agents and toxins from an entity into the community?

(6) What alternative regulatory requirement could be constructed such that a registered entity would know whether it had a theft or loss of a select agent or toxin without that registered entity first having ''an accurate, current inventory for each select agent . . . held in long term storage''?

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 carefully consider all comments submitted in preparation of a final rule.

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).

B. Historical Background to This Rulemaking

Subtitle A 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 have the potential to pose a severe threat to public health and safety (select agents and toxins). Subtitle B 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 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 the CDC or the 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 (FSAP) is the collaboration of the CDC, Division of Select Agents and Toxins (DSAT) and the APHIS Agriculture Select Agent Services (AgSAS) to administer the select agent regulations in a manner that minimizes the administrative burden on persons subject to the select agent regulations. The FSAP administers the select agent regulations in close coordination with the Federal Bureau of Investigation's Criminal Justice Information Services Division (CJIS).

The Bioterrorism Response Act also requires the HHS Secretary to establish by regulation a list of biological agents and toxins that have the potential to pose a severe threat to public health and safety. In determining whether to include an agent or toxin on the list, the HHS Secretary considers criteria such as the effect on human health of exposure to an agent or toxin; the degree of contagiousness of the agent and the methods by which the agent or toxin is transferred to humans; the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent illnesses resulting from an agent or toxin; and the needs of children and other vulnerable populations. The current list of HHS select agents and toxins can be found at 42 CFR 73.3 (HHS select agents and toxins) and 42 CFR 73.4 (Overlap select agents and toxins). The list of HHS and Overlap select agents and toxins is also available at: *http://www.selectagents.gov/SelectAgentsandToxinsList.html.*

The HHS Secretary last republished the list of HHS select agents and toxins in the **Federal Register** on October 5, 2012 (77 FR 61084). The list of HHS select agents and toxins is divided into two sections. The select agents and toxins listed in section 73.3 (HHS select agents and toxins) are those regulated only by HHS under the authority of the Bioterrorism Response Act (42 U.S.C. 262a). The select agents and toxins listed in section 73.4 (Overlap select agents and toxins) are those regulated by HHS under the authority of the Bioterrorism Response Act and also regulated by the U.S. Department of Agriculture under the authority of the Agricultural Bioterrorism Protection Act of 2002 (7 U.S.C. 8401).

The Bioterrorism Response Act requires the HHS Secretary to review and republish the list of select agents and toxins on at least a biennial basis. Using government subject matter experts, HHS/CDC conducts the biennial review process in consultation with the HHS/CDC Intragovernmental Select Agents and Toxins Technical Advisory Committee (ISATTAC). The ISATTAC is comprised of Federal government employees from CDC, Biomedical Advanced Research and Development Authority (BARDA) within the Office of the Assistant Secretary for Preparedness and Response, 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 Bioterrorism Response Act, the ISATTAC considered the following criteria in their review of the HHS and Overlap lists of select agents and toxins: 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, acute morbidity (illness), mortality, available treatment, status of host immunity, vulnerability of special populations, and the burden or impact on the health care system.

On February 27, 2015, HHS/CDC published an advance notice of proposed rulemaking (80 FR 10656) in which we requested public comment on (1) whether there are biological agents or toxins that should be added or removed from the HHS list of select agents and toxins; and (2) whether HHS/CDC should remove the following six select agents from the HHS list of select agents and toxins: *Coxiella burnetti, Rickettsia prowazekii, Bacillus anthracis* Pasteur strain, *Brucella abortus, Brucella melitensis*, and *Brucella suis.*

III. Summary of Proposed Changes

The following changes to the list of HHS select agents and toxins are proposed based on comments received to the advance notice of proposed rulemaking (80 FR 10656) referenced above, recommendations from the ISATTAC, information from the DHS Material Threat Determinations (DHS–MTD) of biological agents and toxins (*https://www.medicalcountermeasures.gov/phemce/dhs.aspx*), and the expertise of federal agencies and staff responsible for the oversight of the possession, use, and transfer of select agents and toxins. We are also proposing specific changes to the current regulations, as discussed below, addressing biosafety; clarifying regulatory language concerning security, training, incident response, and records; correcting an omission from the technical amendment (appeal process for exclusion); and revision of the select agent list with current taxonomic names.

A. Definitions

We are proposing to add two new terms to section 73.1 (Definitions) of the regulations. We are proposing to define the term ''*Inactivation''* as ''a method to render a select agent non-viable but retain characteristic of interest for future use, or to render any nucleic acids that can produce infectious forms of any select agent virus non-infectious for future use.'' We are also proposing to define the term ''*Kill curve''* as ''the results of a dose-response experiment where a select agent is subjected to increasing amounts of the inactivating treatment to determine the minimum conditions required to render it non-viable or to render any nucleic acids that can produce infectious forms of any select agent virus as non-infectious.'' The new definitions will help clarify proposed regulatory language in section 73.12 (Biosafety).

B. Proposed Changes to the List of Select Agents

On February 27, 2015, HHS/CDC published an advance notice of proposed rulemaking (ANPRM) (80 FR 10656) in which we requested public comment specifically on whether there are biological agents or toxins that should be added or removed from the HHS list of select agents and toxins.

In that same docket, HHS/CDC also requested public comments as to whether biological agents specifically listed in the February 27, 2015 ANPRM should be removed or remain on the list. The listed agents were *Coxiella burnetti, Rickettsia prowazekii, Bacillus anthracis* Pasteur strain, *Brucella abortus, Brucella melitensis*, and *Brucella suis.* We are now proposing that these agents be removed from the

HHS list of select agents based on the twenty-two comments received in response to the February 27, 2015 ANPRM, recommendations from the ISATTAC, and our review of current scientific data regarding these biological agents.

Coxiella burnetii (42 CFR 73.3)

In response to the February 27, 2015 ANPRM, we received 11 comments concerning *Coxiella burnetii.* Only two commenters recommended that *C. burnetii* remain on the list because ''antibiotic treatment should not be considered for removing the agent.'' The other nine commenters argued that *C. burnetii* should not be included as a select agent based on the following assertions:

- Five commenters stated it is not easily transmitted from person to person.
- Three commenters referenced that even in the absence of antibiotic treatment, Q fever (the disease with acute and chronic stages caused by the bacteria *C. burnetii*) is generally a self-limited flu-like illness with low mortality (Ref. 1).
- All commenters acknowledged that most infections are inapparent and most seropositive individuals cannot remember an infection consistent with Q fever.
- Six commenters agreed that *Coxiella* is susceptible to a number of readily available antibiotics. Preferred treatments include tetracycline or doxycycline. Quinolones have also been used successfully and Co-trimoxazole is recommended in specific situations such as pregnancy.

The ISATTAC recommended the removal of *C. burnetii* from the HHS list of select agents and toxins because:

- It has a low mortality rate with antibiotic treatment and most seropositive individuals cannot remember an infection consistent with Q fever (Ref. 2); and
- A whole-cell killed vaccine (Q-Vax) with nearly 100% efficacy is licensed in Australia and has been used to vaccinate U.S. researchers whom were at risk (Ref. 3).

We are now proposing to remove C. *burnetii* from the HHS list of select agents (42 CFR 73.3). As discussed above, our proposal is supported by comments we received in response to the February 27, 2015 ANPRM and the recommendations of the ISATTAC. Both the commenters and the ISATTAC supported their recommendations with the scientific references noted above. We further conclude that, based on recent information provided by DHS–MTD, *C. burnetii* does not pose a severe threat to public health and safety. We are, however, still seeking comment from those who may believe that C. *burnetii* remains a severe threat to public health and safety and accordingly should be retained as a HHS select agent.

Rickettsia prowazekii (42 CFR 73.3)

In response to the February 27, 2015 ANPRM, we received eight comments concerning *Rickettsia prowazekii.* Only one commenter recommended to retain *Rickettsia prowazekii* because ''antibiotic treatment should not be considered for removing the agent.'' The other seven commenters supported removal based on the following reasons:

- The risk of mass casualties is low because *R. prowazekii* can be treated with a single dose of doxycycline when symptoms are present;
- Transmissibility from person to person is low due to the fact that R. *prowazekii* is usually transmitted via blood, although it can be spread through inhalation of louse feces;
- The agent has poor environmental stability; and
- The difficulty in growing and purifying substantial quantities of these agents *in vitro.*

The ISATTAC recommended the removal of *R. prowazekii* from the HHS list of select agents and toxins because:

- It is treatable with available antibiotics (Ref. 4 and 5);
- The risk of mass casualties is low because *R. prowazekii* can be treated with a single dose of doxycycline when symptoms are present (Ref. 4 and 5); and
- Transmissibility from person to person is low due to the fact that *R. prowazekii* is usually transmitted via blood, although it can be spread through inhalation of louse feces (Ref. 5).

We are now proposing to remove *R. prowazekii* from the HHS list of select agents (42 CFR 73.3). As discussed above, our proposal is supported by the comments we received in response to the February 27, 2015 ANPRM and the recommendations of the ISATTAC. Both the commenters and the ISATTAC supported their recommendations with the scientific references noted above. We further conclude that, based on recent information provided by DHS–MTD, *R. prowazekii* does not pose a severe threat to public health and safety. We are, however, still seeking comment from those who may believe that *R. prowazekii* remains a severe threat to public health and safety and accordingly should be retained as a HHS select agent.

Bacillus anthracis Pasteur Strain (42 CFR 73.4)

We received six comments to the February 27, 2015 ANPRM with all commenters agreeing that *Bacillus anthracis* Pasteur strain should not be included as a select agent based on *B. anthracis* Pasteur strain lacks the plasmid that encodes the toxin genes causing disease. The *B. anthracis* Sterne strain, which lacks the plasmid that encodes for the capsule, was excluded from the requirements of the regulations effective on February 27, 2003.

The ISATTAC recommended the removal of *B. anthracis* Pasteur strain from the overlap list of select agents and toxins because:

- *B. anthracis* Pasteur strain lacks the plasmid that encodes the toxin genes causing disease (Ref. 6);
- *B. anthracis* Sterne strain, which lacks the plasmid that encodes for the capsule, was excluded from the requirements of the regulations effective on February 27, 2003 (Ref. 7–8); and
- Historically, the *B. anthracis* Pasteur strain has been retained as a select agent to allow for continued oversight of laboratories in which the accidental (or intentional) combination of this strain with the Sterne strain could occur to produce *de novo* the wild type phenotype *B. anthracis.* However, a recent study indicates that bacterial transformation of *B. subtilis* with plasmid DNA is inefficient; indicating that transformation with plasmid pXO1 into closely related bacteria such as the *Bacillus anthracis* Pasteur strain would also be inefficient (Ref. 9).

We agreed with the commenters and ISATTAC. We propose to remove *B. anthracis* Pasteur strain because the transformation of a virulence plasmid from one *Bacillus* strain to another is difficult.

Brucella abortus, B. melitensis, and B. suis (42 CFR 73.4)

Responses were received from 16 commenters to the February 27, 2015 ANPRM, that addressed the retention of the three *Brucella* species (*B. abortus, B. melitensis, and B. suis*) currently on the overlap select agent list. Only two commenters recommended to retain these species because ''antibiotic treatment should not be considered for removing the agent.'' The other 14 commenters supported removal based on the rationale provided in the ANPRM.

The ISATTAC recommended the removal of *B. abortus, B. melitensis,* and *B. suis* from the overlap list of select agents and toxins because:

- *B. abortus* has a low human mortality rate (Ref. 10);

• *B. abortus, B. melitensis, and B. suis* are treatable with antibiotics (Ref. 10); and

• Human-to-human transmission is extremely rare, and wildlife carriers in the United States often come into contact with humans without significant transmission (Ref. 10).

We agreed with the commenters and ISATTAC. We propose to remove *B. abortus, B. melitensis,* and *B. suis* because although *Brucella* has a low infectious dose, it is treated, mortality is low, efficacy of treatment is good for all three *Brucella* strains.

C. Inactivation of a Select Agent

We are proposing to add specific requirements to the biosafety section of the regulations (42 CFR 73.12) to address the requirements for rendering a select agent or an nucleic acids that can produce infectious forms of any select agent virus ''non-viable.''

Sections 73.3 (HHS select agents and toxins) and 73.4 (Overlap select agents and toxins) both provide that a ''non-viable'' select agent is excluded from the requirements of the select agent regulations. We are proposing that for an agent to be ''non-viable,'' or to render a nucleic acids that can produce infectious forms of any select agent virus non-infectious for future use, an entity must use a validated method. A validated method means that the method must be scientifically sound such that method will produce consistent results each time the method is used. As outlined in our guidance for ''Non-viable Select Agents and Nonfunctional Select Toxins and Rendering Samples Free of Select Agents and Toxins'' (*http://www.selectagents.gov/guidance-nonviable.html*), an inactivation procedure may include (1) use of the exact conditions of an accepted method that has been validated, such as autoclaving, (2) a published method with adherence to the exact published conditions, or (3) for in-house methods, validation testing should include the specific conditions used and appropriate controls.

As part of the inactivation procedure, an entity would be required to develop a site specific kill curve to identify conditions of inactivation for each select agent or regulated nucleic acids that can produce infectious forms of any select agent virus. If there are strain-to-strain variations in resistance of a select agent to the inactivation procedure, then a specific kill curve would be required to be developed for each strain that undergoes the inactivation procedure. A new kill curve would also be required to be created upon any change in procedure or inactivation equipment. In addition, a validated sterility testing protocol to ensure that the inactivation method has rendered a select agent non-viable or regulated nucleic acids that can produce infectious forms of any select agent virus non-infectious would be required to be conducted.

We are also proposing that written records be kept for a select agent or extracts that have been subjected to a procedure to render them non-viable or regulated nucleic acids that can produce infectious forms of any select agent virus that have been subjected to a procedure to render them non-infectious.

We are also soliciting ideas as to whether there are other methods that should be required to validate the rendering of a select agent non-viable or regulated nucleic acids that can produce infectious forms of any select agent virus non-infectious.

D. Toxins

Due Diligence

Section 73.3(d)(3) of the select agent regulations (42 CFR 73.(d)(3))specifies the select toxin amounts under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor that are excluded from the requirements of the select agent regulations. However, this exclusion applies to the transfer of select toxins ''only after the transferor uses due diligence and documents that the recipient has a legitimate need . . . to handle or use such toxins'' (42 CFR 73.3(d)(3)(i)). This provision was added to the select agent regulations to address the concern that someone might be able to covertly stockpile toxins by receiving multiple orders below the excluded amount. The toxin ''due diligence'' provision requires a person transferring toxins in amounts which would otherwise be excluded from the provisions to: (1) Use due diligence to assure that the recipient has a legitimate need to handle or use such toxins; and (2) report to the FSAP if they detect a known or suspected violation of Federal law or become aware of suspicious activity related to the toxin.

''Due diligence'' is generally understood to be such a measure of prudence, activity, or assiduity, as is properly to be expected from, and ordinarily exercised by, a reasonable and prudent person under the particular circumstances; not measured by any absolute standard, but depending on the relative facts of the specific case.

We are proposing to add a more specific documentation requirement to the toxin exclusion provision to require the transferor to document the identity of the recipient and the legitimate need (*i.e.,* prophylactic, protective, bona fide research, or other peaceful purpose) claimed by the transferee. Information required to be documented would also include the name of the toxin and the total amount transferred. Identity information of the person requesting and using the toxins would include the individual's name, institution name, address, telephone number, and email address.

Toxin Permissible Limits

In conjunction with this biennial review, the FSAP solicited input from biological toxin subject matter experts to review the listed exclusion limits for select toxins in the HHS select agent regulations. To assess the amount necessary to weaponize a biological toxin, DHS developed toxin parameters and attack scenarios for potential inhalation and ingestion exposures to select toxins. DHS used the formulas described below to estimate ingestion scenarios while employing the ''NIST CONTAM Multizone Modeling'' software (*http://www.bfrl.nist.gov/IAQanalysis/*) for inhalation scenarios. To estimate the amount of toxin for each scenario, DHS analyzed a range of release sizes (in mg) for each biological toxin in order to estimate the number of people that would be exposed to LD–50 (lethal dose, 50% or median lethal dose, the amount of the substance required (usually per body weight) to kill 50% of the test population); or TD–50 (the median toxic dose of a toxin is the dose at which toxicity occurs in 50% of cases) levels of each toxin amount by ingestion of milk (using published TD–50 or LD–50) and/or indoor inhalation (using published LD–50). The inhalation models analyzed toxin releases in three different indoor public facilities that experience heavy commuter volume (population details for these facilities are given in Table 1). One hundred scenarios were generated for each facility using 1–10μm particle sizes. The models used 10 random locations within each facility (potential release locations and population evenly spaced throughout occupied area) at 10 random times. The inhalation models assumed:

• No immediate symptoms, so no changes in population movement due to attack

• Respiration rate 10L/min

• All people assumed to have the same mass = 70 kg (*e.g.,* did not account for lower doses required for children)

TABLE 1—SUMMARY OF FACILITY POPULATION AND RESIDENCE TIMES

Facility	2008 Annual passenger traffic (people)	Simulation transient hourly population	Simulation transient average residence time (minutes)
High throughput transportation facilities	255,500,000	43,750	10
High throughput transportation facilities	219,000,000	37,500	15
High throughput transportation facilities	64,300,000	11,005	60

The ingestion models investigated biological toxins introduced into a fluid (*e.g.,* milk) that was purchased and consumed by consumers over a two day period. Production details and specifics of how the toxins were introduced were not considered. In particular, the largest scenarios involve contaminating greater than ten million servings, which was determined to be implausible in practice. The ingestion models made the following assumptions:

- Milk containing specified quantity of active toxin (1 mg to 1 kg) reaches store shelves.
- Milk is consumed over six days at a uniform rate.
- Contaminated milk is consumed daily until supply is depleted or a health advisory is issued.
- Milk contamination discovered and health advisory issued a minimum of one day, and a maximum of >1 week post attack (at which point all contaminated milk has been consumed).
- For toxins other than saxitoxin and tetrodotoxin, the attacker chooses a toxin concentration such that a person in the 45+ years old age group will consume 1 LD–50 (or TD–50) over 6 day consumption period.
- Since saxitoxin and tetrodotoxin are largely excreted in approximately one day after consumption, the attacker chooses a saxitoxin or tetrodotoxin concentration such that a person in the 45+ years old age group will consume 1 LD–50 (or TD–50) over a one day consumption period.
- Total volume of milk contaminated equals the number of grams of toxin available divided by the toxin concentration (*i.e.,* total volume of milk contaminated depends on the mass of toxin assumed to be available (which varies from 1 mg to 1 kg) and the toxin ingestion LD–50 (or TD–50)).
- If the toxin ingestion LD–50 (or TD–50) is given by a range, the geometric mean of this range is used.
- Range of total volumes of milk contaminated is less than 1 L to approximately 10^8 L.
- The amount of milk contaminated is assumed to depend on how much toxin the attacker has available (*i.e.,* the total volume of milk contaminated equals the number of grams of toxin available divided by the toxin concentration). For example, for a 1 g attack, with a toxin that has an LD–50 of 1mg/kg, the volume of milk contaminated would be 1000 mg/(0.056 mg/mL*1000 mL/L) = 18 L of milk.
- For small attack sizes, it is assumed the attacker would target appropriately-sized small holding tanks or containers, while for large attack sizes, the attacker would target large holding tanks or silos.
- If the toxin is degraded due to pasteurization or storage, the amount of toxin introduced pre-processing would have to be correspondingly larger than these masses.

Proposed Increase of Regulatory Exclusion Limits

Based on the data generated by the models described above, we are proposing the following exclusion limits based on the amounts estimated to expose less than 10 people by inhalation or less than 100 people by ingestion to the LD–50 or TD–50 levels of toxin:

- Increase the regulatory exclusion limit of Botulinum neurotoxin (BoNT) from 0.5 mg to 1 mg;
- Increase the regulatory exclusion limit of Staphylococcal enterotoxins from 5 mg to 100 mg;
- Increase the regulatory exclusion limit of saxitoxin from 100 mg to 500 mg;
- Increase the regulatory exclusion limit of tetrodotoxin from 100 mg to 500 mg;
- Increase the regulatory exclusion limit of abrin from 100 mg to 1,000 mg;
- Increase the regulatory exclusion limit of ricin from 100 mg to 1,000 mg; and
- Increase the regulatory exclusion limit of DAS from 1,000 mg to 10,000 mg.
- Increase the regulatory exclusion limit of T–2 from 1,000 mg to 10,000 mg.

We are, however, still seeking comment from those who may believe that we should retain the current exclusion limits. In addition, we are interested in receiving comments from the public on whether DAS and T–2 have the potential to pose a severe threat to public health and safety or whether these two toxins should be removed from the select toxin list given the high exclusion limit for DAS and T–2.

Proposed Removal of Select Toxins

Short, Paralytic Alpha-Conotoxins

We are proposing short, paralytic alpha-conotoxins containing the following amino acid sequence ($X_1CCX_2PACGX_3X_4X_5X_6CX_7$) be removed as a select toxin for the following reasons:

- The DHS model reported LD–50 value for inhalation delivery of alpha-conotoxin is 20 μg/kg, which is a low toxicity compared to other select toxins;
- A regulatory exclusion limit of 10,000 mg would require the depletion of the cone snail population to achieve this quantity.

Therefore, based on the low toxicity of short, paralytic alpha-conotoxins and the high dosage required for inhalation exposure, we are proposing that the alpha-conotoxin be removed from the select toxin list (Ref. 32).

Toxins: Exclusion of Original Food Samples and Clinical Samples

Original food samples and clinical samples are those specimens that are submitted to laboratories for diagnosis or verification purposes to identify or verify a biological agent or toxin. For example, an original food sample could be a container of potato salad or juice. An original clinical sample could be serum or stool from a patient. Laboratories that test food sample and clinical samples for the presence of toxins generally do not know the level of toxin in a sample and do not extract and purify a toxin as part of their studies. Therefore, we are proposing to exclude the original food sample or clinical sample identified to contain an HHS select toxin to be consistent with the rationale for the current exclusion for animals exposed to toxins (42 CFR 73.3(d)(4)). The proposed exclusion is based upon input from biological toxin subject matter experts and our determination that quantifying the

amount of toxin in these samples is problematic because (1) the amount of toxin is highly variable, which would require large amounts of food and clinical samples to quantify or purify, (2) laboratory procedures to extract toxin from samples are inefficient with most extractions producing low yields; (3) the resources that would be required to quantify toxins in clinical samples and food samples make sample quantification prohibitively expensive; and (4) procedures in these laboratories, based on the requirements of their public health mission, are designed only for toxin detection and not for purification and quantification. Therefore, we are interested in comments regarding our rationale that the original food sample or clinical sample identified to contain an HHS select toxin should be excluded from the select agent regulation.

Exclusion of Toxin Produced as a Byproduct

Laboratories that are only registered for BoNT-producing species of *Clostridium* do not normally have a need to account for BoNT produced during the culturing of *Clostridium* since studying the toxin is not part of their work objective. Therefore, we propose to exclude toxins that are produced only as a byproduct to a study of the toxin producing host organism so long as the toxin has not been intentionally collected, purified, or otherwise extracted, and the material containing the toxin is inactivated and properly disposed of within 30 days of the initiation of the culture. The 30 day disposal time was recommended by biological toxin subject matter experts based on the time it would take to grow the organism and perform the extraction process. This exclusion allows laboratories whose purpose does not include purification of the toxin to more effectively conduct outbreak investigations, food studies, and molecular characterization of agents which produce toxin. In the case of BoNT, these laboratories would still be regulated for the BoNT-producing species of *Clostridium* and in the case of all other HHS select toxins the laboratories would be regulated if they wished to keep the material containing toxins for longer than 30 days from the initiation of culture of the toxin producing host organism. If at any time an entity manipulated the material that contains the select toxin, such as intentional collection, purification or extraction of the toxin from culture supernatant, such activities would void this exemption, and the entity would be required to be registered for the select toxin and meet all applicable select agent and toxin regulatory requirements.

E. Exemptions for Select Agents and Toxins

Informing Specimen Provider

Since a registered or certified reference laboratory typically confirms the identification of a select agent or toxin for public health and agriculture, clinical and diagnostic laboratories, we are proposing to require the registered or certified reference laboratory inform the specimen provider of the identification. This will ensure that the reference laboratory notifies the specimen provider of the identification of the select agent or toxin so that the specimen provider is aware that they are in possession of the agent or toxin and must meet the requirements outlined in 42 CFR 73.5, 73.6.

Identification of Toxin

Once a clinical or diagnostic laboratory has identified a select toxin-positive specimen, an APHIS/CDC Form 4 (Report of the Identification of a Select Agent or Toxin) must be submitted to the FSAP. The select agent regulations currently require the laboratory to transfer or destroy the material within seven days of identification (42 CFR 73.5(a), 73.6(a)) because we determined through input from technical experts that the seven calendar days provides a sufficient amount of time for the entity to destroy or transfer the select agents or toxins after identification. In the past, we have received comments that argued that the seven day requirement for transferring or destroying select agents or toxins used for diagnosis or testing is too short a time limit. Therefore, we are seeking comments to determine if seven calendar days provides a sufficient amount of time for the entity to destroy or transfer the select agents or toxins after identification.

In addition, we are seeking comments to extend the exemption time period to 30 days for BoNT and Staphylococcal enterotoxin (Subtypes A–E) to allow clinical and diagnostic laboratories sufficient time to complete their investigations without having to transfer or destroy the sample. Laboratories would still be required to report the identification of BoNT immediately and Staphylococcal enterotoxin (Subtypes A–E) within seven days. We are proposing to amend the language in 42 CFR 73.5(a), and 42 CFR 73.6(a)to read: ''Unless directed otherwise by the HHS Secretary, within seven calendar days after identification of the select agent and toxin (except for Botulinum neurotoxin and/or Staphylococcal enterotoxin (Subtypes A–E)), or within thirty calendar days after identification of Botulinum neurotoxin and/or Staphylococcal enterotoxin (Subtypes A–E), the select agent or toxin is transferred in accordance with § 73.16 or destroyed on-site by a recognized sterilization or inactivation process,''

Patient Care

To clarify how the select agent regulations apply to activities associated with the diagnosis and care for individuals infected with a select agent or exposure to a select toxin, we are proposing to add provisions that HHS/CDC will not regulate material containing a select agent or toxin when it is in a patient care setting and is not being otherwise collected, tested or retained for non-patient care purposes. However, once delivery of patient care for an illness associated with a select agent or toxin has concluded these specimens would become subject to the regulatory requirements. An entity unable to meet all of the regulatory requirements necessary to retain the material will then have the option of transferring the material containing the select agent or toxin in accord with the select agent regulations or destroying the materials within seven calendar days of the conclusion of patient care.

We also are proposing to clarify that FSAP does not regulate waste generated during the delivery of patient care.

F. Registration

We are codifying in regulations the current FSAP policy that an entity is required to meet all of the regulatory requirements for those select agents and toxins listed on the entity's registration regardless of whether the select agent or toxin is in the actual possession of the entity; and without regard to the actual amounts of toxins in the possession of the entity.

G. Responsible Official (RO)

Section 73.9(a)(6) of the select agent regulations currently states that the Responsible Official must ensure that an annual inspection is conducted for each laboratory where select agents and toxins are stored or used. This requirement also provides that the results of each inspection must be documented, and any deficiencies identified during an inspection must be corrected. We are adding a requirement that the Responsible Official must also document the corrective actions taken by the entity to address any identified deficiencies.

HHS or USDA Office of the Inspector General Hotline

In response to a recommendation in the December 2014 Federal Experts Security Advisory Panel report, we are adding a requirement that the Responsible Official must ensure that individuals are provided the contact information of the HHS or USDA Office of Inspector General Hotline so that individuals are able to anonymously report a safety or security concern related to select agents and toxins. In its December 2014 report, the Federal Experts Security Advisory Panel recommended adding a specific requirement to include how individuals are informed so that they can access the HHS or USDA Office of Inspector General Hotline to anonymously report a safety or security concern.

H. Visitor Access to Select Agents and Toxins

Section 73.10(e) of the select agent regulations currently provides that a person with a valid approval from the HHS Secretary or APHIS Administrator to have access to select agents and toxins may request, through his or her Responsible Official, that the HHS Secretary or APHIS Administrator provide their approved access status to another registered individual or entity for a specified period of time. This allows a scientist registered to work with a select agent at a registered entity to work with the select agent at another registered entity. To ensure that the Responsible Official of the entity hosting the visitor is aware if a visiting individual loses approval for access to select agents and toxins, we are proposing to add a requirement that the Responsible Official at the home entity must immediately notify the Responsible Official of the visiting entity if the person's access to select agents or toxins has been terminated.

I. Security, Biosafety, and Incident Response Plans

The select agent regulations require a registered entity to develop and implement a number of plans in order to ensure the safety and security of the select agents they handle. These are:

- A security plan that provides for measures sufficient to safeguard the select agent or toxin against unauthorized access, theft, loss, or release (42 CFR 73.11);
- A biosafety plan that provides for measures sufficient to contain the select agent or toxin (*e.g.,* physical structure and features of the entity, and operational and procedural safeguards) (42 CFR 73.12); and
- An incident response plan that provides for measures that the registered entity will implement in the event of theft, loss, or release of a select agent or toxin; inventory discrepancies; security breaches (including information systems); severe weather and other natural disasters; workplace violence; bomb threats and suspicious packages; and emergencies such as fire, gas leak, explosion, power outage, etc. The response procedures must account for hazards associated with the select agent or toxin and appropriate actions to contain such agent or toxin. (42 CFR 73.14)

Drills or exercises must be conducted at least annually to test and evaluate the effectiveness of the plans. The plans must be reviewed and revised, as necessary, after any drill or exercise and after any incident. We are proposing to require that these drills or exercises be documented to include how the drill or exercise tested and evaluated the plan, any problems identified and corrective actions that were taken, and the names of the individuals who participated in the drill or exercise. This will provide a more thorough accounting of required activities via testing and entity-directed improvements.

Similar to the existing requirement for the security plan, we are also proposing to add a requirement that the biosafety and incident response plans be submitted for initial registration, renewal of registration, or when requested by FSAP.

Biosafety

We are proposing to amend the regulatory language in section 73.12 to update the name change of the National Institutes of Health (NIH) *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (Ref. 31).

Prior to the publication of the 5th edition of CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories* (Ref. 3), the Occupational Safety and Health Administration (OSHA) regulations in 29 CFR 1910.1200 and 1910.1450 provided specific requirements for handling hazardous chemicals in the laboratories. This regulation also provided recommendations for safely working with chemical including toxins and gave non-mandatory recommendations for prudent practices in laboratories handling chemical hazards. As such, we included this reference for entities to consider when developing biosafety plans for those facilities working with toxins. Since the current edition of the CDC/NIH *Biosafety in Microbiological and Biomedical Laboratories* Appendix I provides guidelines for work with toxins of biological origin, we have removed the reference to the OSHA regulations in 29 CFR 1910.1200 and 1910.1450. It should be noted that regulated entities must still meet the OSHA regulatory requirements where applicable.

In addition, we want to ensure that laboratory personnel that are working with select agents and toxins are aware of the risks associated with these agents. As such, we are proposing to add a requirement that a laboratory-specific biosafety manual must be accessible to individuals. This is consistent with guidance provided by the CDC/NIH publication, *Biosafety in Microbiological and Biomedical Laboratories.* This requirement is proposed to foster an enhanced culture of responsibility by ensuring that appropriate biosafety resources are available to all staff with access to select agents and toxins within a select agent laboratory.

The current regulations require that the biosafety plan be written using performance standards. In the aftermath of recent biosafety incidents involving select agents, we are proposing that the biosafety plan should be designed according to a site-specific risk assessment in accordance with the risk of a select agent, given its intended use by adding specific provisions to the biosafety section that would require a written risk assessment for each registered select agent or toxin; written safety procedures to protect entity personnel, the public, and the environment from exposure to the select agent or toxin; written decontamination procedures; and written waste management procedures.

The FSAP would also like to solicit ideas regarding any specific biosafety measures that should be required to prevent LAIs or accidental or intentional release of the select agents and toxins from an entity into the community.

Security

We are proposing to amend the requirement that the security plan contain a description of how the entity authorizes the means of entry into areas where select agents or toxins are stored or used, to include a requirement that the security plan must include a description of centralized access control management systems (*e.g.,* keycards) and/or key management (mechanical keys).

Paragraphs (d)(7)(i) through (d)(7)(v) of section 11 of the select agent regulations encompass a list of events that individuals with access approval from the APHIS Administrator or the

HHS Secretary must immediately report to the Responsible Official. We are proposing to add a new requirement that the Responsible Official must be notified of any loss of computer, hard drive, or other data storage device containing information that could be used to gain access to select agents or toxins. We believe that such notification will facilitate notification of the Federal Bureau of Investigation if deemed necessary by the Responsible Official as the loss of such equipment may be criminal in nature.

J. Training

We are proposing to amend section 15 of the select agent regulations which concerns the provision of training for staff and visitors who work in or visit areas where select agents or toxins are handled or stored. Since individuals need to understand hazards associated with the select agents and toxins that they will be working with in the laboratory or are in the area they will be visiting, we are proposing to require that all individuals who have received approval to have access to select agents and toxins have training that address the particular needs of the individual and the risks posed by the select agent or toxin regardless of whether they have access to the select agents or toxins. The training would have to be completed within 12 months of that individual's anniversary of receiving access approval or prior to his or her entry into an area where any select agents and toxins are used or stored, whichever occurs first. This change is necessary in order to codify our policy regarding which individuals at registered entities are required to receive training.

We are also proposing to add a new paragraph (e) to section 15, which would require the entity's Responsible Official to provide contact information for the USDA or HHS Office of the Inspector General Hotline. Details of the proposed addition may be found under the heading ''Responsible Official.''

K. Records

Based on inspections of registered entities, we observed that entities are maintaining records of the destruction of select agents even though section 73.17 of the select agent regulations currently does not include a requirement for documenting when a select agent is destroyed. To ensure the proper tracking of a select agent from acquisition to destruction and to incorporate into the regulations what entities are currently doing, we are proposing to add the requirement for records to be created and maintained for the destruction of a select agent held in long-term storage to include the quantity (*i.e.,* number of vials) of select agent destroyed, the date of such action, and by whom.

Section 73.17 of the select agent regulations currently states that records and databases need to be accurate. To ensure that handwritten records are accurate, we are proposing to clarify that hand-written record must be legible (*i.e.,* capable of being read).

We are proposing to expand the scope of records required to be maintained to include any records that contain information related to the requirements of the regulations. Such records may include, but would not limited to, biocontainment certifications, laboratory notebooks, institutional biosafety and/or animal use committee minutes and approved protocols, and records associated with occupational health and suitability programs. We propose revision to the regulations will enhance the ability of FSAP to evaluate biosafety, security, and incident response programs and includes any record created under sections 73.5, 73.7, 73.9, 73.11, 73.12, 73.14, 73.15, 73.16, 73.17, and 73.19 of the select agent regulations.

Records for Long-term Storage

The FSAP continues to receive comments that are critical of that portion of the select agent regulations that require a registered entity to maintain ''an accurate, current inventory for each select agent . . . held in long term storage.'' The comments typically focus on the belief that a container based inventory requirement is not useful to track inventory of biological agents of which small amounts of samples from the container could be stolen without detection and used to grow larger quantities. In the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Congress requires the Secretaries of Health and Human Services and Agriculture to include in the select agent regulations a requirement for ''the prompt notification of the Secretary, and appropriate Federal, State, and local law enforcement agencies, of the theft or loss of listed agents and toxins.'' HHS/CDC is soliciting ideas on any alternative regulatory requirement that could be constructed such that a registered entity would know whether it had a theft or loss of a select agent or toxin without that registered entity first having ''an accurate, current inventory for each select agent . . . held in long term storage.''

V. Required Regulatory Analyses

A. Executive Orders 12866 and 13563

Under Executive Order 12866 (EO 12866), Regulatory Planning and Review (58 FR 51735, October 4, 1993) HHS/CDC is required to determine whether this regulatory action would be ''significant'' and therefore subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Orders. This order defines ''significant regulatory action'' as any regulatory action that is likely to result in a rule that may:

- Have an annual effect on the economy of $100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local, or tribal governments or communities;
- Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency;
- Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients; or,
- Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in EO 12866.

Executive Order 13563 (EO 13563), Improving Regulation and Regulatory Review, (76 FR 3821, January 21, 2011), updates some of the provisions of EO 12866 in order to promote more streamlined regulatory actions. This EO charges, in part, that, while protecting ''public health, welfare, safety, and our environment'' that regulations must also ''promote predictability and reduce uncertainty'' in order to promote economic growth. Further, regulations must be written in plain language and be easy to understand.

HHS/CDC has determined that this NPRM is a significant regulatory action as defined in EO 12866. However, the Office of Management and Budget has waived their review of the document.

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

We have examined the impacts of the proposed rule under the Regulatory Flexibility Act (5 U.S.C. 601–612). Unless we certify that the proposed 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. We certify that this proposed 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 proposed 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.*), HHS/CDC has determined that the Paperwork Reduction Act does apply to information collection and recordkeeping requirements included in this rule. We note that the information collection and recordkeeping requirements are already approved by the Office of Management and Budget (OMB) under OMB Control Number 0920–0576.

D. EO 12988: Civil Justice Reform

This rule has been reviewed under E.O. 12988, Civil Justice Reform. Once the 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 proposed 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.

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List of Subjects in 42 CFR Part 73

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

For the reasons discussed in the preamble, we propose to amend 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 201–2014, 221 and 231 of Title II of Public Law 107–188, 116 Stat 637 (42 U.S.C. 262a).

■ 2. Section 73.1 is amended by adding in alphabetical order, definitions of *inactivation* and *kill curve* to read as set forth below.

§ 73.1 Definitions.

* * * * *

Inactivation means a method to render a select agent non-viable but retain characteristic of interest for future use, or to render any nucleic acids that can produce infectious forms of any select agent virus non-infectious for future use.

* * * * *

Kill curve means the results of a dose-response experiment where a select agent is subjected to increasing amounts of the inactivating treatment to determine the minimum conditions required to render it non-viable or to render any nucleic acids that can produce infectious forms of any select agent virus as non-infectious.

* * * * *

■ 3. Section 73.3 is amended as follows:

■ a. By revising paragraph (b).

■ b. By adding new paragraphs (d)(2)(i), (ii), and (iii).

■ c. By revising paragraphs (d)(3) introductory text and (d)(3)(i).

■ d. By redesignating paragraph (d)(5) as paragraph (d)(7).

■ e. By adding new paragraphs (d)(5), (d)(6), and (d)(8).

■ f. By adding paragraph (e)(3) to read as set forth below.

The additions and revisions read as follows:

§ 73.3 HHS select agents and toxins.

* * * * *

(b) HHS select agents and toxins:

Abrin
Botulinum neurotoxins*
Botulinum neurotoxin producing species of *Clostridium**
Crimean-Congo hemorrhagic fever virus
Diacetoxyscirpenol
Eastern equine encephalitis virus
Ebola virus*
*Francisella tularensis**
Lassa fever virus
Lujo virus
Marburg virus*
Monkeypox virus
Reconstructed replication competent forms of the 1918 pandemic influenza A virus containing any portion of the coding regions of all eight gene segments (Reconstructed 1918 influenza A virus)
Ricin
SARS coronavirus (SARS-CoV)
Saxitoxin
South American hemorrhagic fever viruses:
Chapare
Guanarito
Junin
Machupo
Sabia
Staphylococcal enterotoxins (subtypes A–E)
T–2 toxin
Tetrodotoxin
Tick-borne encephalitis virus
Far Eastern subtype
Siberian subtype
Kyasanur Forest disease virus
Omsk haemorrhagic fever virus
Variola major virus (Smallpox virus) *
Variola minor virus (Alastrim) *
*Yersinia pestis**

* * * * *

(d)* * *

(2) Non-viable HHS select agents or nonfunctional HHS toxins.

(i) Unless waived by the HHS Secretary, a select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation process to remove viability or infectious form (*i.e.,* the ability to reproduce or produce disease, while maintaining cellular structure) is not excluded from the requirements of this part until an individual or entity:

(A) Develops a site-specific kill curve to define conditions of inactivation for each select agent or regulated nucleic acids that can produce infectious forms of any select agent virus. If there are strain-to-strain variations in resistance of a select agent to the inactivation procedure, then a specific kill curve must be developed for each strain that undergoes the inactivation procedure. A new kill curve must be created upon any change in procedure or inactivation equipment.

(B) Develops site-specific standard operating inactivation procedures to ensure that the material is inactivated by a safety margin determined by the kill curve.

(C) Subjects representative samples of inactivated select agents or any nucleic acids that can produce infectious forms of any select agent viruses to a validated sterility testing protocol to ensure that the inactivation method has rendered the select agent non-viable or regulated nucleic acids non-infectious.

(D) Any viability of a select agent or infectivity of regulated nucleic acids that can produce infectious forms of any select agent virus that was subjected to a validated inactivation protocol is reported to APHIS or CDC.

(E) Reviews annually, and revises as necessary, the following:

(*1*) The kill curve procedure and results;

(*2*) Site-specific standard operating procedures to ensure that select agents or regulated nucleic acids that can produce infectious forms of any select agent virus are inactivated by a safety margin; and

(*3*) The validated sterility testing protocol used to ensure that the inactivation method has rendered a select agent non-viable or regulated nucleic acids that can produce infectious forms of any select agent virus sample non-infectious.

(F) Reviews, and revises as necessary, documents listed in paragraph (d)(2)(i)(E) of this section after any change in principal investigator, change in protocol, or any reported viability of a select agent or infectivity of regulated nucleic acids that can produce infectious forms of any select agent viruses previously assessed as inactive.

(ii) Unless waived by the HHS Secretary, an extract from a select agent is not excluded from the requirements of this part until an individual or entity meets the following requirements:

(A) Any extract is subjected to a process that removes all viable cells, spores, or virus particles.

(B) Any extract is subjected to a validated sterility testing protocol to ensure that the inactivation method has rendered the extract free of a select agent.

(C) Any viability of an extract that was subjected to a validated inactivation protocol is reported to the Responsible Official.

(D) Any viability of a select agent or infectivity of regulated nucleic acids that can produce infectious forms of any select agent virus that was previously assessed as inactive by their validated sterility testing protocol is reported to APHIS or CDC.

(3) Except as required in § 73.16(l), the aggregate amount of the toxin under the control of a principal investigator, treating physician or veterinarian, or commercial manufacturer or distributor does not, at any time, exceed the following amounts: 1000 mg of Abrin; 1 mg of Botulinum neurotoxins; 10,000

mg of Diacetoxyscirpenol; 1000 mg of Ricin; 500 mg of Saxitoxin; 100 mg of Staphylococcal enterotoxins (subtypes A–E); 10,000 mg of T–2 toxin; or 500 mg of Tetrodotoxin.

(i) The toxin is transferred only after the transferor uses due diligence and documents the identification of the recipient and the legitimate need (*i.e.,* prophylactic, protective, bona fide research, or other peaceful purpose) claimed by the recipient to use such toxin. Information to be documented includes, but is not limited to, the recipient identity information, including the recipient's name, institution name, address, telephone number and email address; name of the toxin and the total amount transferred, and the legitimate need claimed by the recipient. Notwithstanding the provisions of paragraph (d) of this section, the HHS Secretary retains the authority to, without prior notification, inspect and copy or request the submission of the due diligence documentation to the CDC.

* * * * *

(5) An HHS select toxin identified in an original food sample or clinical sample.

(6) Select toxins that are produced as a byproduct in the study of the toxin producing host organism so long as the toxin has not been intentionally cultivated, collected, purified, or otherwise extracted, and the material containing the toxin is rendered non-functional and disposed of within 30 days of the initiation of the culture.

* * * * *

(8) Waste generated during the delivery of patient care from a patient infected with a select agent that is decontaminated with a validated method within seven calendar days of the conclusion of patient care,

(e) * * *

(3) An individual or entity may make a written request to the HHS Secretary for reconsideration of a decision denying an application for the exclusion of an attenuated strain of a select agent or a select toxin modified to be less potent or toxic. The written request for reconsideration must state the facts and reasoning upon which the individual or entity relies to show the decision was incorrect. The HHS Secretary will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision.

* * * * *

■ 4. Section 73.4 is amended as follows:

■ a. By revising paragraph (b).

■ b. By adding new paragraphs (d)(2)(i), (ii), and (iii).

■ c. By adding paragraph (d)(4).

■ d. By adding paragraph (e)(3).

The revision and additions read as follows:

§ 73.4 Overlap select agents and toxins.

* * * * *

(b) Overlap select agents and toxins:

*Bacillus anthracis**
*Burkholderia mallei**
*Burkholderia pseudomallei**
Hendra virus
Nipah virus
Rift Valley fever virus
Venezuelan equine encephalitis virus

* * * * *

(d) * * *

(2) * * *

(i) Unless waived by the APHIS Administrator or HHS Secretary, a select agent or regulated nucleic acids that can produce infectious forms of any select agent virus that has been subjected to a validated inactivation process to remove viability or infectious form (*i.e.,* the ability to reproduce or produce disease, while maintaining cellular structure) is not excluded from the requirements of this part until an individual or entity:

(A) Develops a site-specific kill curve to define conditions of inactivation for each select agent or regulated nucleic acids that can produce infectious forms of any select agent viruses. If there are strain-to-strain variations in resistance of a select agent to the inactivation procedure, then a specific kill curve must be developed for each strain that undergoes the inactivation procedure. A new kill curve must be created upon any change in procedure or inactivation equipment.

(B) Develops site-specific standard operating inactivation procedures to ensure that the material is inactivated by a safety margin determined by the kill curve.

(C) Subjects representative samples of inactivated select agents or nucleic acids that can produce infectious forms of any select agent viruses to a validated sterility testing protocol to ensure that the inactivation method has rendered a select agent non-viable or regulated nucleic acids non-infectious.

(D) Reports any viability of a select agent or infectivity of regulated nucleic acids that can produce infectious forms of any select agent virus that was subjected to a validated inactivation protocol to the Responsible Official.

(E) Reviews annually, and revises as necessary, the following:

(*1*) The kill curve procedure and results;

(*2*) Site-specific standard operating procedures to ensure that select agents or regulated nucleic acids that can produce infectious forms of any select agent viruses are inactivated by a safety margin; and

(*3*) The validated sterility testing protocol used to ensure that the inactivation method has rendered a select agent non-viable or regulated nucleic acids that can produce infectious forms of any select agent viruses non-infectious.

(F) Reviews, and revises as necessary, documents listed in paragraph (d)(2)(i)(E) of this section after any change in principal investigator, change in protocol, or any reported viability of a select agent or infectivity of regulated nucleic acids that can produce infectious forms of any select agent virus previously assessed as inactive.

(ii) Unless waived by the APHIS Administrator or HHS Secretary, an extract from a select agent is not excluded from the requirements of this part until an individual or entity meets the following requirements:

(A) Any extract is subjected to a process that removes all viable cells, spores, or virus particles.

(B) Any extract is subjected to a validated sterility testing protocol to ensure that the inactivation method has rendered the extract free of a select agent.

(C) Any viability of an extract that was subjected to a validated inactivation protocol is reported to the Responsible Official.

(D) Any viability of a select agent or infectivity of regulated nucleic acids that can produce infectious forms of any select agent virus that was previously assessed as inactive by the validated sterility testing protocol is reported to APHIS or CDC.

(d) * * *

(4) Waste generated during the delivery of patient care from a patient infected with a select agent that is decontaminated with a validated method within seven calendar days of the conclusion of patient care.

(e) * * *

(3) An individual or entity may make a written request to the HHS Secretary or APHIS Administrator for reconsideration of a decision denying an application for the exclusion of an attenuated strain of a select agent or a select toxin modified to be less potent or toxic. The written request for reconsideration must state the facts and reasoning upon which the individual or entity relies to show the decision was incorrect. The HHS Secretary or APHIS Administrator will grant or deny the request for reconsideration as promptly as circumstances allow and will state, in writing, the reasons for the decision.

* * * * *

■ 5. Section 73.5 is amended as follows:
■ a. By revising paragraph (a)(1).
■ b. By redesignating paragraph (a)(3) as paragraph (a)(4) and revising newly redesignated paragraph (a)(4).
■ c. By adding new paragraph (a)(3).

The revisions and addition read as follows:

§ 73.5 Exemptions for HHS select agents and toxins.

(a) * * *

(1) Unless directed otherwise by the HHS Secretary, within seven calendar days after identification of the select agent and toxin (except for Botulinum neurotoxin and/or *Staphylococcal* enterotoxin (Subtypes A–E)), or within thirty calendar days after identification of Botulinum neurotoxin and/or *Staphylococcal* enterotoxin (Subtypes A–E), the select agent or toxin is transferred in accordance with § 73.16 or destroyed on-site by a recognized sterilization or inactivation process,

* * * * *

(3) Unless otherwise directed by the HHS Secretary, the clinical or diagnostic specimens collected from a patient infected with a select agent are transferred in accordance with § 73.16 or destroyed on-site by a recognized sterilization or inactivation process within seven days after delivery of patient care has concluded, and

(4) The identification of the agent or toxin is reported to CDC or APHIS, the specimen provider, and to other appropriate authorities when required by Federal, State, or local law by telephone, facsimile, or email. This report must be followed by submission of APHIS/CDC Form 4 to APHIS or CDC within 7 calendar days after identification.

* * * * *

■ 6. Section 73.6 is amended as follows:
■ a. By redesignating paragraph (a)(3) as paragraph (a)(4) and revising newly redesignated paragraph (a)(4).
■ b. By adding paragraph (a)(3).

The revision and addition read as follows:

§ 73.6 Exemptions for overlap select agents and toxins.

(a) * * *

(3) Unless otherwise directed by the HHS Secretary or Administrator, the clinical or diagnostic specimens collected from a patient infected with a select agent are transferred in accordance with § 73.16 or destroyed on-site by a recognized sterilization or inactivation process within seven days after delivery of patient care has concluded, and

(4) The identification of the agent or toxin is reported to CDC or APHIS, the specimen provider, and to other appropriate authorities when required by Federal, State, or local law by telephone, facsimile, or email. This report must be followed by submission of APHIS/CDC Form 4 to APHIS or CDC within 7 calendar days after identification.

* * * * *

■ 7. Section 73.7 is amended as follows:
■ a. By redesignating paragraphs (b) through (k) as paragraphs (c) through (l), respectively.
■ b. By adding a new paragraph (b) to read as follows:

§ 73.7 Registration and related security risk assessments.

* * * * *

(b) As a condition of registration, each entity is required to be in compliance with the requirements of this part for select agents and toxins listed on the registration regardless of whether the entity is in actual possession of the select agent or toxin. With regard to toxins, the entity registered for possession, use or transfer of a toxin must be in compliance with the requirements of this part regardless of the amount of toxin currently in possession.

* * * * *

■ 8. Section 73.9 is amended as follows:
■ a. In paragraph (a)(6) by removing ''laboratory'' and adding in its place ''registered space'' and adding ''and the corrections documented'' after ''corrected'' at the end of the sentence.
■ b. By adding paragraph (a)(7) to read as set forth below.

§ 73.9 Responsible Official.

(a) * * *

(7) Ensure that individuals are provided the contact information for the HHS or USDA Office of Inspector General Hotline so that they may anonymously report any safety or security concerns related to select agents and toxins.

* * * * *

■ 9. Section 73.10 is amended by adding a new sentence to the end of paragraph (e) to read as follows:

§ 73.10 Restricting access to select agents and toxins; security risk assessments.

* * * * *

(e) * * * A Responsible Official must immediately notify the Responsible Official of the visited entity if the person's access to select agents and toxins has been terminated.

* * * * *

■ 10. Section 73.11 is amended as follows:
■ a. In paragraph (c)(5) by adding ''keycards,'' between ''keys,'' and ''passwords'' and removing ''numbers'' and adding in its place ''permissions''.
■ b. By adding paragraph (c)(11).
■ c. By adding paragraph (d)(7)(vi).
■ d. By adding a sentence to the end of paragraph (h).

The additions read as follows:

§ 73.11 Security.

* * * * *

(c) * * *

(11) Describe how the entity authorizes the means of entry into areas where select agents or toxins are stored or used, to include centralized access control management systems (*e.g.,* keycards) and/or mechanical key management.

(d) * * *

(7) * * *

(vi) Any loss of computer, hard drive or other data storage device containing information that could be used to gain access to select agents or toxins.

* * * * *

(h) * * * Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and all individuals who participated in the drill or exercise.

■ 11. Section 73.12 is amended as follows:
■ a. By revising paragraph (a).
■ b. By removing paragraph (c)(2), redesignating paragraph (c)(3) as (c)(2), and in newly redesignated paragraph (c)(2), removing ''NIH Guidelines for Research Involving Recombinant DNA Molecules'' and adding in its place ''NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules''.
■ c. By adding a new sentence to the end of paragraph (e).

The revision and addition read as follows:

§ 73.12 Biosafety.

(a) An individual or entity required to register under this part must develop and implement a written biosafety plan that is commensurate with the risk of the select agent or toxin, given its intended use. The biosafety plan must contain sufficient information and documentation to describe the biosafety and containment procedures for the select agent or toxin, including any animals (including arthropods) or plants intentionally or accidentally exposed to or infected with a select agent. Biosafety and containment procedures specific to each registered laboratory must be available to each individual working in that laboratory. The current biosafety plan must be submitted for initial registration, renewal of registration, or

when requested. The biosafety plan must include the following provisions:

(1) A written risk assessment for each procedure involving a select agent or toxin that addresses the hazards associated with the agent or toxin.

(i) The hazardous characteristics of each agent or toxin listed on the entity's registration, including probable routes of transmission in the laboratory and in the environment, infective dose (if known), stability in the environment, host range, contribution of any genetic manipulations, and endemicity.

(ii) Hazards associated with laboratory procedures related to the select agent or toxin;

(2) Safeguards in place with associated work practices to protect registered entity personnel, the public, and the environment from exposure to the select agent or toxin including, but not limited to: Safety training requirements for registered entity personnel performing the procedure; required personal protective equipment and other safety equipment; required containment equipment including, but not limited to, biological safety cabinets, animal caging systems, and centrifuge safety containers; and required engineering controls and other facility safeguards.

(3) Written procedures for decontamination with a validated method, of all contaminated or potentially contaminated materials including, but not limited to: Cultures and other materials related to the propagation of select agents or toxins, items related to the analysis of select agents and toxins, personal protective equipment, animal caging systems and bedding, and animal carcasses or extracted tissues.

(4) Written procedures for decontamination, with a validated method, of laboratory surfaces and equipment using manufacturer's specification.

(5) Effluent decontamination procedures, with a validated method, that describe the treatment of effluent material contaminated with select agents and toxins.

(6) Procedures to respond to emergencies such as spills, sharps injury, or animal bites involving select agents and toxins.

(7) Procedures for the handling of select agents and toxins in the same spaces with non-select agents and toxins in order to prevent unintentional contamination.

* * * * *

(e) * * * Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and all individuals who participated in the drill or exercise.

■ 12. Section 73.14 is amended as follows:

■ a. By adding a new sentence to the end of paragraph (a).

■ b. By adding a new sentence to the end of paragraph (f).

The additions read as follows:

§ 73.14 Incident response.

(a) * * * The current incident response plan must be submitted for initial registration, renewal of registration, or when requested.

* * * * *

(f) * * * Drills or exercises must be documented to include how the drill or exercise tested and evaluated the plan, any problems that were identified and corrective action(s) taken, and all individuals who participated in the drill or exercise.

■ 13. Section 73.15 is amended as follows:

■ a. In paragraph (a)(1) by removing ''before that individual has such access to select agents and toxins'' and adding in its place '', within 12 months of that individual's anniversary of receiving such approval or prior to his or her entry into an area where select agents or toxins are used or stored, whichever occurs first.''.

■ b. By adding paragraph (e) to read as set forth below.

§ 73.15 Training.

* * * * *

(e) The Responsible Official must ensure and document that individuals are provided the contact information of the HHS or USDA Office of Inspector General Hotline so that they may anonymously report any safety or security concerns related to select agents and toxins.

■ 14. Section 73.16 is amended by revising paragraph (l)(1) to read as follows:

§ 73.16 Transfers.

* * * * *

(l) * * *

(1) Transfer the amounts only after the transferor uses due diligence and documents that the recipient has a legitimate need (*i.e.,* prophylactic, protective, bona fide research, or other peaceful purpose) to handle or use such toxins. Information to be documented includes, but is not limited, to the recipient information, toxin and amount transferred, and declaration that the recipient has legitimate purpose to store and use such toxins.

* * * * *

■ 15. Section 73.17 is amended as follows:

■ a. In paragraphs (a)(1)(iii) and (a)(3)(v) by adding ''or other storage container'' after ''freezer''.

■ b. By adding paragraph (a)(1)(ix).

■ c. By adding paragraph (a)(8).

■ d . In paragraph (b) by adding ''legible,'' after ''are''.

■ e. By revising paragraph (c).

The revision and additions read as follows:

§ 73.17 Records.

(a) * * *

(1) * * *

(ix) If destroyed, the quantity (*e.g.,* containers, vials, tubes, etc.) of select agent destroyed, the date of such action, and by whom.

* * * * *

(8) For a select agent or an extract from a select agent that has been rendered non-viable or regulated nucleic acids that can produce infectious forms of any select agent virus that have been rendered non-infectious through inactivation:

(i) A written description of the inactivation process used for rendering a select agent non-viable or regulated nucleic acids that can produce infectious forms of any select agent virus non-infectious;

(ii) The sterility testing protocol used to verify non-viability of a select agent or non-infectivity of regulated nucleic acids that can produce infectious forms of any select agent virus and the results of the test, including investigation, of any inactivation process failures and the corrective actions taken;

(iii) The name of each individual performing the inactivation method and sterility testing protocols;

(iv) The date(s) the inactivation method and sterility testing protocols were completed;

(v) The location where the inactivated method and sterility testing protocols were performed; and

(vi) An inactivation certificate that includes the date of inactivation, method of inactivation, date of final sterility testing protocol result, and the Principal Investigator. A copy of the inactivation certificate must accompany any transfer of inactivated material.

* * * * *

(c) Any records that contain information related to the requirements of the regulations. Such records may include, but are not limited to, biocontainment certifications, laboratory notebooks, institutional biosafety and/or animal use committee minutes and approved protocols, and records associated with occupational

health and suitability programs. All records created under this part must be maintained for 3 years.

* * * * *

Dated: January 12, 2016.

Sylvia M. Burwell,

Secretary.

[FR Doc. 2016–00758 Filed 1–14–16; 4:15 pm]

BILLING CODE 4163–18–P

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 73 and 74

[MB Docket No. 13–249; FCC 15–142]

Revitalization of the AM Radio Service

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: In this document, the Commission adopted a Further Notice of Proposed Rulemaking (FNPRM), in which it sought comment on several proposals designed to revitalize the AM broadcast radio service, or to reduce burdens on AM broadcasters. The Commission further adopted a Notice of Inquiry (NOI), in which it sought comment on two proposals designed to revitalize the AM broadcast radio service. One of the proposals, regarding increased utilization of the AM expanded band, was suggested by several commenters in response to the NPRM in this proceeding, The second proposal, for relaxation of the Commission's main studio rules for AM stations, was suggested by a commenter and supported by others.

DATES: Comments may be filed on or before March 21, 2016 and reply comments may be filed on or before April 18, 2016. Written comments on the Paperwork Reduction Act proposed information collection requirements must be submitted by the public, Office of Management and Budget (OMB), and other interested parties on or before March 21, 2016.

ADDRESSES: You may submit comments, identified by MB Docket No. 13–249, by any of the following methods:

- *Electronic Filers:* Comments may be filed electronically using the Internet by accessing the Commission's Electronic Comment Filing System (ECFS), through the Commission's Web site *http://fjallfoss.fcc.gov/ecfs2/.* Filers should follow the instructions provided on the Web site for submitting comments. For ECFS filers, in completing the transmittal screen, filers should include their full name, U.S. Postal service mailing address, and MB Docket No. 13–249.
- *Paper Filers:* Parties who choose to file by paper must file an original and one copy of each filing. Filings can be sent by hand or messenger delivery, by commercial overnight courier, or by first-class or overnight U.S. Postal Service mail (although the Commission continues to experience delays in receiving U.S. Postal Service mail). All filings must be addressed to the Commission's Secretary, Office of the Secretary, Federal Communications Commission.

For detailed instructions for submitting comments and additional information on the rulemaking process, *see* the **SUPPLEMENTARY INFORMATION** section of this document.

FOR FURTHER INFORMATION CONTACT: Peter Doyle, Chief, Media Bureau, Audio Division, (202) 418–2700; Thomas Nessinger, Senior Counsel, Media Bureau, Audio Division, (202) 418–2700. For additional information concerning the Paperwork Reduction Act (PRA) information collection requirements contained in this document, contact Cathy Williams at 202–418–2918, or via the Internet at *Cathy.Williams@fcc.gov.*

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Further Notice of Proposed Rulemaking, FCC 15–142, adopted October 21, 2015, and released October 23, 2015.

Initial Paperwork Reduction Act of 1995 Analysis

The FNPRM contains proposed information collection requirements subject to the PRA, Public Law 104–13. OMB, the general public, and other Federal agencies are invited to comment on the proposed new and modified information collection requirements contained in this FNPRM.

Comments on the proposed information collection requirements should address: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the Commission, including whether the information shall have practical utility; (b) the accuracy of the Commission's burden estimates; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on the respondents, including the use of automated collection techniques or other forms of information technology. Pursuant to the Small Business Paperwork Relief Act of 2002, Public Law 107–198, see 44 U.S.C. 3506(c)(4), the FCC seeks specific comment on how it might ''further reduce the information collection burden for small business concerns with fewer than 25 employees.''

In addition to filing comments with the Secretary, a copy of any Paperwork Reduction Act comments on the information collection requirements contained herein should be submitted to Cathy Williams, Federal Communications Commission, Room 1–C823, 445 12th Street SW., Washington, DC 20554, or via the Internet to *Cathy.Williams@fcc.gov,* and to Nicholas A. Fraser, Office of Management and Budget (OMB), via the Internet to *Nicholas_A._Fraser@omb.eop.gov.*

To view a copy of this information collection request (ICR) submitted to OMB: (1) Go to the Web page *http://www.reginfo.gov/public/do/PRAMain,* (2) look for the section of the Web page called ''Currently Under Review,'' (3) click on the downward-pointing arrow in the ''Select Agency'' box below the ''Currently Under Review'' heading, (4) select ''Federal Communications Commission'' from the list of agencies presented in the ''Select Agency'' box, (5) click the ''Submit'' button to the right of the ''Select Agency'' box, (6) when the list of FCC ICRs currently under review appears, look for the Title of this ICR and then click on the ICR Reference Number. A copy of the FCC submission to OMB will be displayed.

The proposed information collections are as follows:

OMB Control Number: 3060–0075.

Title: Application for Transfer of Control of a Corporate Licensee or Permittee, or Assignment of License or Permit, for an FM or TV Translator Station, or a Low Power Television Station, FCC Form 345.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit entities; Not for profit institutions; Local or Tribal Government.

Number of Respondents and Responses: 1,700 respondents; 2,700 responses.

Estimated Time per Response: 0.084–1.25 hours.

Frequency of Response: Third party disclosure requirement and on occasion reporting requirement.

Total Annual Burden: 2,667 hours.

Total Annual Cost: $3,958,125.

Obligation to Respond: Required to obtain or retain benefits. The statutory authority for this collection of information is contained in Sections 154(i) and 310 of the Communications Act of 1934, as amended.