Order 13045, entitled ''Protection of Children from Environmental Health Risks and Safety Risks'' (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* nor does it require any special considerations under Executive Order 12898, entitled ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations'' (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemptions from the requirement of a tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal governments, on the relationship between the National Government and the States or Tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled ''Federalism'' (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled ''Consultation and Coordination with Indian Tribal Governments'' (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

V. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a ''major rule'' as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 174

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: December 4, 2024.

Edward Messina,

Director, Office of Pesticide Programs.

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

PART 174—PROCEDURES AND REQUIREMENTS FOR PLANT-INCORPORATED PROTECTANTS

■ 1. The authority citation for part 174 continues to read as follows:

Authority: 7 U.S.C. 136–136y; 21 U.S.C. 321(q), 346a and 371.

■ 2. Add §§ 174.551 and 174.552 to subpart W to read as follows:

Subpart W—Tolerances and Tolerance Exemptions

* * * * *

§ 174.551 *Brevibacillus laterosporus* Mpp75Aa1.1 protein; exemption from the requirement of a tolerance.

Residues of *Brevibacillus laterosporus* Mpp75Aa1.1 protein in or on the food and feed commodities of corn: corn, field; corn, sweet; and corn, pop are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in corn.

§ 174.552 *Bacillus thuringiensis* Vpb4Da2 protein; exemption from the requirement of a tolerance.

Residues of *Bacillus thuringiensis* Vpb4Da2 protein in or on the food and feed commodities of corn: corn, field; corn, sweet; and corn, pop are exempt from the requirement of a tolerance when used as a plant-incorporated protectant in corn.

[FR Doc. 2024–29133 Filed 12–16–24; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 73

[Docket No. CDC–2020–0024]

RIN 0920–AA71

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

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

ACTION: Final rule.

SUMMARY: This rule finalizes updates to the HHS list of select agents and toxins that could pose a severe threat to public health and safety. These updates were proposed along with other changes to the select agent and toxin regulations, which will be addressed in a separate regulatory action. In a companion document published in this issue of the **Federal Register**, the U.S. Department of Agriculture (USDA) is making parallel regulatory changes.

DATES: This final rule is effective January 16, 2025.

FOR FURTHER INFORMATION CONTACT: Daniel A. Singer, MD, Acting Director, Division of Regulatory Science and Compliance, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21–4, Atlanta, Georgia 30329. Telephone: (404) 553–8266.

SUPPLEMENTARY INFORMATION: The final rule is organized as follows:

I. Background

A. Legal Authority

Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Response Act), the HHS Secretary must, by regulation, establish and maintain a list of biological agents and toxins that have the potential to pose a severe threat to public health and safety (42 U.S.C. 262a(a)(1)). In determining whether to include a biological agent or toxin on the list, the Bioterrorism Response Act requires that the HHS Secretary consider the following criteria:

- 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
- any other criteria, including the needs of children and other vulnerable populations, that the HHS Secretary considers appropriate (42 U.S.C. 262a(a)(1)(B)).

Under 42 U.S.C. 262a(a)(2), the HHS Secretary must review and republish the list of HHS select agents and toxins at least biennially.

In the preparation of this rulemaking, HHS/CDC considered the statutory criteria and evaluated each agent and toxin based on the following:

- *Effect on human health:*
  - the degree of pathogenicity (ability of an organism to cause disease);
  - long-term health effects;
  - severity of illness;
  - case fatality rate;
  - status of host immunity (*e.g.,* whether an individual has already been exposed to the agent and generated an immune response);
  - vulnerability of special populations;
- *Degree of contagiousness:*
  - dissemination efficacy;
  - aerosol stability;
  - rate of transmission;
- *Availability and effectiveness of pharmacotherapies:*
  - available treatment;
- *Other Criteria:*
  - decontamination and restoration (the extent remediation efforts are needed due to agent persistence in the environment and population);
  - matrix stability;
  - ease of production;
  - ability to genetically manipulate or alter;
  - the burden or impact on the health care system.

The Federal Select Agent Program (FSAP) is the collaboration of the CDC, Division of Regulatory Science and Compliance (previously known as the Division of Select Agents and Toxins), and the USDA Animal and Plant Health Inspection Service (APHIS), Division of Agricultural Select Agents and Toxins. These two agencies administer the HHS and USDA select agent and toxin regulations and coordinate Federal oversight of select agents and toxins in a manner to minimize the administrative burden on the regulated community.

The list of HHS select agents and toxins is divided into two sections—agents and toxins regulated solely by HHS and agents that are regulated by both HHS and USDA. The biological agents and toxins listed in 42 CFR 73.3 (HHS select agents and toxins) have the potential to pose a severe threat to human health and safety and are regulated only by HHS. The biological agents listed in § 73.4 (overlap select agents and toxins) have the potential to pose a severe threat to human health and safety, as determined by HHS, and a severe threat to animals and animal products, as determined by the USDA, pursuant to USDA's authority under the Agriculture Bioterrorism Protection Act of 2002 (7 U.S.C. 8401). Accordingly, these biological agents are jointly regulated by HHS and USDA as ''overlap'' select agents. The Bioterrorism Response Act defines the term ''overlap agents and toxins'' to mean biological agents and toxins that are listed pursuant to 42 U.S.C. 262a(a)(1) and listed pursuant to 7 U.S.C. 8401(a)(1). If HHS/CDC removes any overlap select agents from its list, these agents might still be regulated as USDA select agents dependent on the outcome of the USDA biennial review.

B. 2024 Proposed Rule

On March 17, 2020, CDC published an advance notice of proposed rulemaking (ANPRM) (85 FR 15087) seeking public comments on potential changes to the current list of HHS and overlap select agents and toxins that are regulated by both HHS and USDA. The received comments broadly supported removal of the *Brucella* species—of the 335 comments received, 325 supported removal of one or more species of *Brucella.* Only two commenters were in favor of retaining the *Brucella* species.

HHS/CDC engaged the Intragovernmental Select Agents and Toxins Technical Advisory Committee (ISATTAC) to review and consider the public comments. The committee reviewed the public comments over a series of seven meetings held between June 12, 2020, and December 11, 2020. Other Federal subject-matter experts were invited to the meetings to address questions from the committee. The ANPRM also requested input on removal of other agents from the list (*e.g., Coxiella burnetii, Rickettsia prowazekii, Bacillus anthracis* [Pasteur strain]). After considering public comments, ISATTAC advisory input, and Federal subject-matter experts' input, CDC proposed changes to the select agent and toxin list and removal of three species of *Brucella.*

On January 30, 2024, HHS issued a proposed rule entitled ''Possession, Use, and Transfer of Select Agents and Toxins; Biennial Review of the List of Select Agents and Toxins'' (89 FR 5823). The proposed rule included two sets of proposals: (1) regulatory changes related to the select agents and toxins on the list (*i.e.,* remove three species of *Brucella* from the list of overlap select agents and toxins, raise one toxin's exclusion amounts, rename three viruses, designate a current agent as a Tier 1 agent, and remove the designation of Tier 1 status from one agent), and (2) regulatory changes related to the administration of FSAP. This second set of proposals included adding definitions and provisions to clarify inactivation of select agents, adding requirements to report discoveries of select agents and toxins, and codifying policies regarding effluent decontamination systems and biosafety provisions for facility verification requirements for registered biosafety level 3 and animal biosafety level 3 laboratories.

HHS/CDC has elected to finalize the January 30, 2024, proposed rule in two separate rulemakings—one final rule focused on changes to the select agents and toxins list (this final rule), and a second final rule focused on regulatory changes to the administration of the FSAP discussed above. This final rule will focus solely on removing three select agents, raising one toxin's exclusion limit, updating nomenclature, and designating an agent as Tier 1. HHS/CDC is proceeding with two final rules for clarity and to avoid any unnecessary delay in finalizing the revised select agents and toxins list. HHS/CDC will publish another regulatory action focused on the proposed rule's administrative and programmatic changes at a later date. Like HHS/CDC, USDA/APHIS is also

proceeding with two separate final rules for this rulemaking.

Interested persons or organizations were invited to participate by submitting written views, recommendations, and data. HHS/CDC invited general comments as to whether there are additional biological agents or toxins that should be added or removed from the HHS list of select agents and toxins based on the following criteria outlined under 42 U.S.C. 262a(a)(1)(B):

(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 toxin;'' and

(4) ''any other criteria, including the needs of children and other vulnerable populations, that the Secretary considers appropriate''.

Comments were also requested on the following specific proposed changes to the list of HHS select agents and toxins:

- Removal of *Brucella abortus, Brucella melitensis,* and *Brucella suis:* Proposal to remove *Brucella abortus, Brucella melitensis,* and *Brucella suis* from the select agent list.
- Updates to nomenclature of select agents: To change ''SARS coronavirus (SARS–CoV)'' to ''Severe acute respiratory syndrome coronavirus (SARS–CoV)'' to correct the nomenclature; to remove the exclusion regarding South American genotype of Eastern Equine Encephalitis virus as this terminology is no longer the correct nomenclature; and to rename Ebola virus to *Ebolavirus* in accordance with the recent taxonomic change by the International Committee on Taxonomy of Viruses (ICTV) (this was initially included as its own section in the proposed rule but moved under this section for nomenclature changes).
- Updates to nomenclature of monkeypox virus: Proposal to update the terminology of ''monkeypox virus,'' which was initially proposed to be updated to ''Mpox Clade I.''
- Removal of the Designation of Botulinum neurotoxin producing species of *Clostridium* as a Tier 1 Agent: Proposal to retain botulinum neurotoxin producing species of *Clostridium* as an HHS select agent, but no longer list it as a Tier 1 agent.
- No Addition of Hantaviruses: Proposal to not add Sin Nombre virus (SNV), Andes virus (ANDV), Hantaan virus (HTNV), and Dobrava virus (DOBV) to the select agent list.
- Toxin Review: Changes to Exclusion Limits for Short, Paralytic Alpha Conotoxins: Proposal to increase the exclusion amount for short, paralytic alpha conotoxins from 100 mg to 200 mg.
- Designation of Nipah virus as a Tier 1 Select Agent: Proposal to designate Nipah virus as a Tier 1 select agent.
- Addition of a Footnote to the HHS Select Agent List on the FSAP website: Proposal to add a footnote to the list for HHS and Overlap select agents indicating that the current nomenclature will be available on the FSAP website (*https://www.selectagents.gov*) to harmonize the list of select agent viruses with ICTV nomenclature.

The public comment period for the proposed rule ended on April 1, 2024. HHS/CDC received 44 unique comments from individuals, stakeholders, and groups and carefully reviewed and considered the comments in this preparation of the final rule. Of these 44 comments, 37 include discussion of the list of select agents discussed in this final rule. A summary of the comments relevant to the content of this final rule and responses to those comments are found at section II, below. Public comments addressing other topics from the proposed rule will be addressed in a separate regulatory action.

II. Responses to Comments and Provisions of the Proposed Rule

The following is a section-by-section discussion of the changes HHS/CDC is making to the list of select agents and toxins in 42 CFR 73.3 and 73.4 after consideration of public comments. As previously stated, the changes proposed in the proposed rule will be finalized in two separate rules. This final rule addresses changes to the list of select agents and toxins in 42 CFR 73.3 and 73.4. All other revisions to definitions, policies, and regulatory requirements addressed in the proposed rule will be addressed in a separate final rule.

A. Removal of Brucella abortus, Brucella melitensis, and Brucella suis

Regarding the request for comment on whether to remove three species of *Brucella* (*B. abortus, B. melitensis, and B. suis*) from the select agent and toxins list, HHS/CDC received 37 comments from individuals, animal health groups, regulated entities, and public health associations that fully supported removing the three agents. No public comments proposed maintaining these agents on the select agent and toxins list.

Individuals and animal health groups stated that they support removing *B. abortus, B. melitensis,* and *B. suis* to allow for more robust studies on alternative methods of surveillance, effective delivery mechanisms for wildlife vaccination, and techniques to limit disease spread, such as contraception and novel sustained-release antibiotics in conjunction with immuno-contraception. Commenters stated the etiology and pathophysiology of the *Brucella* species make it poorly suited to cause a severe threat to human health. Commenters further noted that the disease is extremely rare in North America and has limited capacity for human-to-human transmission. The same commenters stated maintaining the *Brucella* species as select agents causes considerable burden to the research community, impairing necessary scientific developments of diagnostic tools and vaccine delivery methods. Regulatory constraints on *Brucella* species were further correlated to fewer individuals entering the field of *Brucella* research. The commenters agreed removal of these agents would not affect the nationally recognized biosafety measures used by U.S. researchers in handling these agents. Commenters also noted that, regardless of the FSAP's regulation of these agents, *Brucella* species remain endemic worldwide. This change would, however, enhance proactive measures for research and diagnostics.

State veterinarians, state agriculture departments, and livestock associations also support the removal of the *Brucella* species and believe delisting these agents will allow for faster production of improved diagnostics. These groups believe delisting ultimately will reduce the cost for ranching families and other taxpayers when performing the required testing on domestic livestock. These groups stated that current tests often cross-react or result in false positives that threaten animal agribusinesses; the benefits to delist the *Brucella* species are numerous; and the perceived risk to national security is not supported by peer-reviewed science. One group stated removal of these agents is a step toward using a modernized risk-based approach for biosafety and security.

Regulated entities (*i.e.,* entities registered with FSAP under 42 CFR 73.7) reported similar support for removing *B. abortus, B. melitensis,* and *B. suis* and included that they have no concerns with maintaining work using BSL–3/ABSL–3 practices. Commenters stated that guidance will be needed for the regulated community currently registered for these agents on how to remove registered space and/or removal of *Brucella* species from registration while active work is ongoing with *Brucella.*

Public health associations commented that *B. abortus, B. melitensis,* and *B. suis* should be removed because of the low mortality rate and because current molecular and diagnostic methods allow for the effective detection of the agents. Comments stated delisting these agents will remove substantial regulatory requirements on individuals, specifically the Responsible Official and Alternate Responsible Official, and allow for an expanded work staff to contribute to testing. Further, antibiotic treatment regimens are effective and well-established for treating brucellosis due to infections with *B. abortus, B. melitensis,* or *B. suis.*

In accordance with the proposed rule and public comments, HHS/CDC is removing *B. abortus, B. melitensis,* and *B. suis* from the select agent and toxins list upon publication of the final rule. This decision is based on the criteria and considerations outlined in 42 U.S.C. 262a, including the low mortality rate, rare human-to-human transmission, and availability of therapeutics, and is supported by the strong and unanimous support received through public comments in favor of removing these agents (Olsen et al., 2018). Please note that all entities currently working with *B. abortus, B. melitensis,* or *B. suis* will need to remove these agents from their APHIS/CDC Form 1 (registration), including Sections 3, 7A/C (and associated attachments), and 7B. FSAP will be reaching out to affected entities upon publication of this final rule. Further guidance can be found at *https://www.selectagents.gov/efsap/using/form1/docs/eFSAP_Form_1_Amendments_Guidance_508.pdf.*

For brucellosis case reporting and national notification, please visit *https://www.cdc.gov/brucellosis/hcp/surveillance/index.html.*

Additionally, BSL–3/ABSL–3 laboratory safety and containment recommendations for *Brucella* species are outlined in the Biosafety in Microbiological and Biomedical Laboratories (BMBL) found at *https://www.cdc.gov/labs/bmbl/index.html.*

B. Nomenclature and Other Changes in the Select Agent and Toxin List

HHS/CDC proposed to amend the select agent list by updating ''monkeypox virus'' to the regulated virus variant ''Mpox virus (clade I).'' Initially, HHS/CDC based this change on the World Health Organization (WHO) recommendation to adopt a new disease name from monkeypox to mpox (*https://www.who.int/news/item/28-11-2022-who-recommends-new-name-for-monkeypox-disease*). This was updated in the International Classification of Diseases (ICD) system (*https://icd.who.int/browse/2024-01/mms/en#160886685*).

Global experts, including the International Committee on the Taxonomy of Viruses, assigned new names to the monkeypox virus variants but not to the virus itself. The virus variants became known as monkeypox virus Clade I (formerly Congo Basin, Central African clade) and Clade II (formerly West African Clade) (*https://www.who.int/news/item/12-08-2022-monkeypox--experts-give-virus-variants-new-names*). These efforts were in part to align the disease name and virus variants with current best naming practices.

FSAP issued guidance during the 2022 mpox outbreak to assist individuals and entities to comply with select agent and toxin regulations after they identified monkeypox virus in diagnostic samples. The guidance clarified that when materials are identified as being or containing monkeypox virus, and the clade is unknown, the materials are considered select agents. The guidance also explained when regulatory exemptions and exclusions would apply. This guidance was issued based on current diagnostic assays not being specific to the monkeypox virus clade.

Based on these considerations and recognition that this change would have implications beyond a change in nomenclature, HHS/CDC will not change the listed agent from ''monkeypox virus'' to ''Mpox virus (clade I).'' The decision to retain the existing listing is to ensure consistency in nomenclature and the regulation of select agent material. FSAP does not include clade-specific designations for other select agents, but the regulations provide exclusions when appropriate. This ensures select agent material is possessed, used, and transferred in accordance with the regulations, which is critically important when clade-specific assays are generally used. Therefore, HHS/CDC is retaining the current listing and monkeypox virus, meaning monkeypox virus with clade unknown is a select agent. Likewise, monkeypox virus identified as clade I is a select agent. The decision to retain the current listing means no changes are made to the regulation of this select agent or the applicable exclusions and exemptions.

As mentioned above, monkeypox virus contains two virus variants, or clades. In 2012, HHS/CDC excluded the West African Clade of monkeypox virus from the select agent regulatory requirements (*https://www.selectagents.gov/sat/exclusions/hhs.htm*). Excluded select agents have been determined to not pose a severe threat to public health and safety and are not regulated as select agents. Though not explicitly proposed in the proposed rule, HHS/CDC has decided to rename the excluded West African Clade monkeypox virus to clade II monkeypox virus. This nomenclature change aligns with WHO recommendations (Ulaeto et al., 2023, *https://www.who.int/news/item/28-11-2022-who-recommends-new-name-for-monkeypox-disease*). This change promotes consistent terminology in global and public health and will not impact regulated entities.

Additionally, HHS/CDC proposed to change SARS coronavirus (SARS–CoV) to ''Severe acute respiratory syndrome coronavirus (SARS–CoV),'' which is the correct nomenclature. This nomenclature change was also supported by two comments and is finalized as proposed.

Though ''Eastern equine encephalitis virus'' is an HHS select agent, the regulations exclude any South American genotype of Eastern Equine Encephalitis Virus from the requirements. HHS/CDC proposed to remove the exclusion regarding South American genotype of Eastern Equine Encephalitis virus as this no longer reflected the appropriate nomenclature, but did not provide the updated virus name. The updated nomenclature of the South American genotype of Eastern Equine Encephalitis virus is ''Madariaga virus.'' HHS/CDC received two comments requesting clarification on whether Madariaga virus would be excluded from regulatory requirements and one comment in favor of this exclusion. The nomenclature of the excluded South American genotype of Eastern Equine Encephalitis virus is finalized as ''Madariaga virus.'' For clarity, 42 CFR 73.3(d)(12) will now read as excluding ''Madariaga virus'' from the regulatory requirements.

Lastly, HHS/CDC proposed the renaming of Ebola virus to the genus *Ebolavirus.* HHS/CDC received 10 public comments that supported renaming Ebola virus to the genus *Ebolavirus* to align with the International Committee on Taxonomy of Viruses (ICTV). None of the commenters provided evidence or rationale for their support of this change. One commenter stated that HHS/CDC should also make it clear that any strain that is similar enough to this genus, whether naturally discovered or artificially derived, should be regarded as a select agent. HHS/CDC will not make any changes based on this comment but does note that any virus

(including separate strains or species) that is classified as being a member of the genus *Ebolavirus* would be subject to the requirements of this part. The renaming of *Ebolavirus* is finalized as proposed.

C. Additional Comments Received

HHS/CDC also received three public comments recommending the removal of monkeypox virus (clade I) from the HHS list of select agents and toxins. One commenter stated that given the virulence and transmission patterns of circulating strains of clade I combined with the similarity of prophylaxis and treatment measures for both clade I and II, they did not feel it should be regarded as a select agent any longer. Another commenter stated that the risk of a severe monkeypox virus (clade I) outbreak in the United States is likely minimal, given the low risk of casual human-to-human transmission; mild clinical symptoms for immunocompetent people; low mortality rate; an FDA-approved, effective vaccine; availability of pharmacotherapy treatment; and a robust healthcare infrastructure and public health response. The final commenter recommended removal of monkeypox virus (clade I), as its status as a select agent could potentially restrict early detection via wastewater surveillance and may lead to unnecessary burdens on healthcare facilities, particularly in under-resourced communities. This commenter stated that removing monkeypox virus (clade I) from the select agent list would remove barriers to rapid diagnosis, ensure equitable access to care, and streamline public health response efforts by increasing accessibility to testing in the event monkeypox virus (clade I) begins to circulate in the United States. The select agent regulations include provisions that exempt diagnostic laboratories from the requirements, as long as these laboratories secure, destroy, and report positive samples. This exemption allows for continued rapid diagnosis, equitable access to care, and a robust public health response effort. As new data from current outbreaks are collected and analyzed, HHS/CDC will take these comments along with future data into consideration during the next biennial review. The review process considers how the agent affects human health, the degree of transmissibility, if there are effective medical countermeasures available, and the needs of vulnerable populations. Appropriate departments and agencies with scientific experts will also be consulted. At present, more data would be needed to support the removal of monkeypox virus from the select agent list, so monkeypox virus will remain on the list as an HHS-only select agent, and monkeypox virus (clade I) will remain a regulated variant.

Additionally, one commenter stated that they do not support the addition of SARS–CoV/SARS–CoV–2 chimeric viruses, which were previously added as a select agent on November 17, 2021. HHS/CDC is not making changes to the final rule based on this comment. A final rule published on March 3, 2023 (88 FR 13322), outlines the basis for adding SARS–CoV/SARS–CoV–2 chimeric viruses resulting from any deliberate manipulation of SARS–CoV–2 to incorporate nucleic acids coding for SARS–CoV virulence factors as an HHS select agent.

One commenter inquired why H2N2 (a subtype of Influenza A virus) was not considered a select agent, especially since NIAID's Laboratory of Infectious Diseases published that the 1957 pandemic strain of H2N2 would most likely cause a pandemic. As mentioned above, changes to the list of select agents and toxins are carefully considered using specific criteria and in consultation with appropriate departments, agencies, and scientific experts. This review also takes into account current data to support changes to the list. FSAP will continue assessing changes to the select agent and toxin list as part of its ongoing biennial review process, but HHS/CDC is not making any changes based on this comment at this time.

Another commenter stated that, given the further development of reverse genetics systems, FSAP should consider oversight of the nucleic acids, in part or in whole, that could be used to create select agents. HHS/CDC is not making any changes based on this comment but does understand that the ability to synthetically create agents capable of posing a severe threat to public health and safety is becoming less difficult because of newer technologies. HHS/CDC will further review the risks posed by these technologies.

One additional public commenter thanked the Federal Government for transparency regarding the criteria for adding/delisting agents and toxins and strongly supported the continued use of these criteria and processes. Another commenter stated that a list-based approach no longer adequately addresses the current biological threat landscape, which includes unknown, accidental, engineered, and naturally occurring hazardous biological agents and toxins. To address the current biological threat landscape, the commenter stated that FSAP should take into account transmissibility, not just pathogenicity, and should move toward a ''tiered, risk-based program'' and away from a ''list-based program.'' HHS/CDC thanks these commenters for their thoughts. HHS/CDC does evaluate transmissibility in the assessments of whether to include an agent in our list, specifically under the direction of the statute that includes contagiousness as a criterion for inclusion. Also, FSAP derives its regulatory authority from section 351A(a)(1) of the Public Health Service Act (42 U.S.C. 262a(a)(1)), which states that HHS/CDC must maintain a list of select agents and toxins. HHS/CDC may consider additional tiering to the list of select agents and toxins at the next biennial review.

D. Retaining Tier 1 Designation of Botulinum Neurotoxin Producing Species of Clostridium

Botulinum neurotoxin, which causes botulism, is a Tier 1 select toxin, and botulinum neurotoxin producing species of *Clostridium* are a Tier 1 select agent, regulated by HHS/CDC. In the 2024 proposed rule, HHS/CDC requested comment on the proposal to retain botulinum neurotoxin producing species of *Clostridium* as an HHS select agent, but no longer designate it as a Tier 1 agent because the organism itself does not normally cause disease. Botulinum neurotoxin would still be designated as a Tier 1 toxin. HHS/CDC received mixed reactions and a total of 14 comments on whether to downgrade botulinum neurotoxin producing species of *Clostridium* from a Tier 1 agent, while keeping it as an HHS select agent.

Nine commenters supported downgrading the agent from Tier 1, three opposed the change, and two comments requested clarification of when nucleic acids that encode for toxic forms of botulinum neurotoxin would be considered Tier 1 or non-Tier 1. One commenter stated the most compelling rationale for no longer designating the agent as Tier 1 is that public health outbreaks with this organism are not likely or projected to be particularly disruptive.

Three commenters did not support the change. They stated that no longer designating botulinum neurotoxin producing species of *Clostridium* as a Tier 1 select agent—while keeping botulinum neurotoxin as a Tier 1 toxin—would introduce ambiguity to procedures related to storage, possession, use, and in the event of an accidental release. One commenter stated that if the neurotoxin remains as

a Tier 1 agent and regulatory requirements are only reduced for the organism, it could potentially cause violations relating to an entity producing the toxin in an unregulated manner.

One commenter recommended that if botulinum neurotoxin remains a Tier 1 agent, then botulinum neurotoxin producing species of *Clostridium* should also remain as Tier 1. Another commenter pointed out that HHS/CDC would need to provide extensive guidance regarding differentiating between experiments or steps in experiments that include both the agent and toxin that require Tier 1 personnel and practices versus non-Tier 1 personnel and practices if this change were to take effect. Both commenters recommended that the agent, toxin, and regulated nucleic acids all be regulated as either non-Tier 1 or Tier 1 because regulating the related materials differently would create a substantial administrative burden to registered entities.

HHS/CDC agrees that public health outbreaks are unlikely to occur with botulinum neurotoxin producing species of *Clostridium.* Per Executive Order 13546, ''Optimizing the Security of Biological Select Agents and Toxins in the United States,'' botulinum neurotoxin producing species of *Clostridium* do not pose a great risk of deliberate misuse with the most significant potential for mass casualties, and therefore do not meet the standard of Tier 1. However, in accordance with several other comments, HHS/CDC agrees that downgrading the agent (or nucleic acids encoding for toxic forms of botulinum neurotoxin) from Tier 1, while continuing to regulate botulinum neurotoxin as a Tier 1 toxin would require registered entities to differentiate between the applicable regulatory requirements, which may cause confusion. Likewise, establishing different regulatory standards for the select agent and related toxin would create challenges for HHS/CDC in assessing compliance. The agent has the inherent ability to produce Tier 1 toxin. In consideration of the logistical challenges raised in the comments referenced above, HHS/CDC will continue to regulate botulinum neurotoxin producing species of *Clostridium* as a Tier 1 select agent.

E. No Addition of Hantaviruses

In response to the 2024 proposed rule, HHS/CDC received nine public comments that unanimously supported the proposal to not add Hantaviruses [Sin Nombre virus (SNV), Andes virus (ANDV), Hantaan virus (HTNV), and Dobrava virus (DOBV)] to the select agent and toxins list. Eight commenters did not offer a rationale or evidence for their stance; however, one commenter stated that because there is no evidence of sustained person-to-person transmission of SNV, ANDV, HTNV, or DOBV, they concurred with the proposal not to add these viruses to the select agent list. Given the limited direct person-to-person transmission and difficulty propagating in a laboratory setting, it is unclear whether Hantaviruses would pose a severe threat to public health and safety. In accordance with the criteria and considerations for determining whether to include an agent or toxin on the list as articulated in 42 U.S.C. 262a, as proposed and in addition to the unanimous support for not adding these agents via public comment, HHS/CDC will not be adding SNV, ANDV, HTNV, and DOBV as HHS select agents.

F. Toxin Review: Changes to Exclusion Limits for Short, Paralytic Alpha Conotoxins

In response to the 2024 proposed rule, HHS/CDC received eight public comments that unanimously supported the proposal to increase the exclusion amount for short, paralytic alpha conotoxins from 100 mg to 200 mg. HHS/CDC proposed this change based on assessments of lethal doses of conotoxin compared to other regulated toxins and the amount of the toxin that would be needed if a bad actor sought to weaponize it. To assess the amount necessary to weaponize a biological toxin, the Department of Homeland Security (DHS) developed toxin parameters and attack scenarios for potential inhalation and ingestion exposures to select toxins. The DHS models determined the impact of the dissemination of varying concentrations of toxins on public health. HHS/CDC reviewed the DHS models, and the lethal doses of conotoxins are comparable to other regulated toxins with a much higher permissible amount. Based on the DHS model and the public comments mentioned above, HHS/CDC is raising the exclusion limit for conotoxin from 100 mg to 200 mg as proposed.

G. Designation of Nipah virus as a Tier 1 Select Agent

In the 2024 proposed rule, HHS/CDC sought public comment on whether Nipah virus should be identified as a Tier 1 select agent because of its human transmissibility, high case fatality rate, low infectious dose, high severity of illness, and severity of long-term effects.

HHS/CDC received a total of 10 comments on this proposal. One commenter was in favor of designating Nipah virus as a Tier 1 select agent, especially given the known person-to-person transmissibility of the virus. There were nine commenters against this change. Eight of these commenters stated the justification is not sufficient support for designating Nipah virus as a Tier 1 select agent over other agents on the select agent list that are Risk Group 4 pathogens. One commenter thought it was unclear what value the Tier 1 designation would have for Nipah virus.

CDC disagrees with these commenters. Executive Order 13546, ''Optimizing the Security of Biological Select Agents and Toxins in the United States,'' directs the HHS Secretary to designate a subset of select agents and toxins as Tier 1 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. Nipah virus has high human transmissibility; a high case fatality rate (estimated between 40–100%); a low infectious dose (ranging from $10^1 - 10^7$ plaque forming units depending on route of infection); high severity of illness; and severe long-term effects, including neurological complications including encephalopathy, cranial nerve palsies, and dystonia (Sejvar et al., 2007 and Lo et al., 2008).

For these reasons, HHS/CDC is designating Nipah virus as a Tier 1 select agent.

H. Addition of a Footnote to the HHS Select Agent and Overlap Select Agent List

In the 2024 proposed rule, HHS/CDC received one public comment that supported the proposal to add a footnote to the list of HHS and Overlap select agents indicating that the current ICTV nomenclature for select agent viruses, if different from that published in the HHS regulations, will be available on the FSAP website (*https://www.selectagents.gov*). This commenter stated that the FSAP website is a good place to provide this information. As proposed, HHS/CDC will proceed with adding a footnote to the list for HHS and Overlap select agents for this purpose.

I. Summary of Final Rule Provisions

In summary of the discussions in section II. of this rule, HHS/CDC is finalizing these revisions to the Federal Select Agent Program at 42 CFR part 73:

- Remove *Brucella abortus, Brucella melitensis,* and *Brucella suis* from the select agent list.
- Update the nomenclature of select agents:
  - Change ''SARS coronavirus (SARS–CoV)'' to ''Severe acute respiratory syndrome coronavirus (SARS–CoV)'' to correct the nomenclature;
  - Rename the exclusion of ''South American genotype of Eastern Equine Encephalitis virus'' to ''Madariaga virus'';
  - Rename the exclusion of ''West African Clade of Monkeypox virus'' to ''clade II monkeypox virus'';
  - Rename Ebola virus to *Ebolavirus* in accordance with the recent taxonomic change by the International Committee on Taxonomy of Viruses (ICTV);
- Retain nomenclature of monkeypox virus;
- Retain designation of botulinum neurotoxin producing species of *Clostridium* as a Tier 1 agent;
- No addition of Hantaviruses: specifically not adding Sin Nombre virus (SNV), Andes virus (ANDV), Hantaan virus (HTNV), and Dobrava virus (DOBV) to the select agent list;
- Increase the exclusion amount for short, paralytic alpha conotoxins from 100 mg to 200 mg;
- Designate Nipah virus as a Tier 1 Select agent;
- Add a footnote to the list for HHS and Overlap select agents indicating that the current nomenclature will be available on the FSAP website (*https://www.selectagents.gov*).

III. Alternatives Considered

Under 42 U.S.C. 262a(a)(2), the HHS Secretary must review and republish the list of HHS select agents and toxins at least biennially. This ensures scientific advancements and gained knowledge are applied to each agent and toxin on the list.

Below are reasonable regulatory alternatives considered regarding key individual provisions listed in this final rule.

This final rule contains several updates to outdated nomenclature of agents, including monkeypox virus, Severe acute respiratory syndrome coronavirus (SARS–CoV), and Ebolavirus. Retaining outdated nomenclature is not scientifically accurate and causes confusion when organizations seek to be in compliance with the regulations. Retaining outdated nomenclature can also cause discrepancies between HHS/CDC and other global health organizations. There is a low, one-time cost associated with updating nomenclature. The alternative of finalizing the rule without the proposed changes, *i.e.,* retaining outdated nomenclature, is not feasible or accurate.

Several changes in this final rule also ensure continued compliance with E.O. 13546.

If HHS/CDC were to retain Nipah virus without a Tier 1 designation, the select agent and toxin list would have an agent that has a great risk of deliberate misuse with the potential for mass casualties, like other Tier 1 select agents, but without the additional provisions outlined for Tier 1 select agents and toxins. These additional provisions include advanced security even compared to non-Tier 1 agents, laboratory personnel enrollment in an entity-specific Occupational Health Program, and that entity-specific risk assessments include Nipah virus as a Tier 1 agent. Not having Nipah virus designated as Tier 1 select agent could potentially result in entities or personnel handling the agent incorrectly, causing public health, biosafety, and biosecurity concerns. It also would not enable FSAP to ensure and require compliance with the enhanced Tier 1 biosafety and biosecurity requirements provided for in the regulations.

All entities currently registered with FSAP for Nipah virus are also registered for other Tier 1 select agents and toxins. Therefore, these entities have Tier 1 provisions in place already that can be applied to Nipah virus. If HHS/CDC were to retain Nipah virus as a select agent without Tier 1 designation, the department and agency would be out of compliance with E.O. 13546. It could also potentially cause public health and biosecurity concerns in that the agent is not handled appropriately. Nipah virus has high human transmissibility; a high case fatality rate (estimated between 40–100%); a low infectious dose; high severity of illness; and severe long-term effects.

Along similar reasoning, new models from DHS illustrate the lethal doses of conotoxins are comparable to other regulated toxins with a much higher permissible amount. The alternative to not raising the permissible toxin limit for short, paralytic alpha conotoxins would lead to irregularities of regulatory application as it pertains to select toxins. Keeping the permissible toxin limit at 100 mg for short, paralytic alpha conotoxins could prevent research and advancement of understanding the select toxin, with no advancement on biosafety and biosecurity. The raised permissible toxin limit of 200 mg will allow more research to occur with the select toxin with no effect on public health and safety. It is important that HHS/CDC considers new data while reviewing the select agent and toxin list to ensure the list is in accordance with criteria and considerations as articulated in 42 U.S.C. 262a.

Similarly, the final rule does not include adding Hantaviruses (*i.e.,* Sin Nombre virus (SNV), Andes virus (ANDV), Hantaan virus (HTNV), and Dobrava virus (DOBV)) to the list as was initially proposed in the ANPRM. Adding Hantaviruses to the list would lead to the agency regulating agents that are not proven to pose a severe threat to public health and safety. Hantaviruses have limited direct person-to-person transmission and are difficult to propagate in a laboratory setting. At this time, research shows it is not certain that Hantaviruses require any regulation in accordance with the criteria and considerations as articulated in 42 U.S.C. 262a. If FSAP were to begin regulating Hantaviruses, there would be costs associated with onboarding, inspecting, and managing those entities that would be required to register with FSAP, with no current need to regulate the agents.

The most significant impact of this rule is the delisting of *Brucella* species, and HHS/CDC has carefully considered the alternative of delisting the agents, which would be retaining the agents on the list and continuing regulating these agents.

Retaining the *Brucella* species on the list has several economic, agricultural, and economic effects with little biosecurity benefit. Most notably, retaining *Brucella* species on the list prevents researchers from progressing advancement of science with regards to study of the agents and development of countermeasures for this agent by subjecting these laboratories to FSAP's regulatory authority. These agents are designated as Risk Group 3 agents, meaning entities and organizations will continue working with these agents at the appropriate biosafety level (Biosafety Level 3), as outlined in the national standard Biosafety in Microbiological and Biomedical Laboratories, 6th edition.

Continuing regulation of *Brucella melitensis, suis,* and *abortus* has a one-time cost of approximately $29k to an entity that wishes to register with FSAP for work with these agents. This cost to the regulated community, due to the reasons listed above, does not enhance biosafety and biosecurity, and may be a regulatory burden to entities that wish to advance understanding of the agent and research medical countermeasures.

There is no alternative to foregoing review of the select agent and toxin list.

This rulemaking is intended to meet the regulatory mandate under 42 U.S.C. 262a(a)(2) where the HHS Secretary must review and republish the list of HHS select agents and toxins at least biennially. CDC conducts the biennial review in consultation with CDC's Intragovernmental Select Agents and Toxins Technical Advisory Committee (ISATTAC). An alternative to the rule was to not delist three select agents, not raise the exclusion amount of a regulated toxin, not update nomenclature, and not add the Tier 1 designation to a select agent. Retaining the *Brucella* species would maintain the current status quo; it does not consider that these agents no longer pose a severe threat to public health and safety, does not promote better research and vaccine development, and does not align with USDA's decision to delist the *Brucella* agents. Additionally, the alternative to not amend the select agent list is inconsistent with USDA's rule, creating regulatory conflict. In addition, this option is not consistent with the public comment received to support amending the select agent list.

After carefully considering the technical input of subject-matter experts, both within the Federal Government and from public comments, and recommendations from Federal advisory groups, HHS/CDC is finalizing the changes listed in section II, part I (Summary of Final Rule Provisions) above to the list of select agents and toxins.

IV. Required Regulatory Analyses

The HHS/CDC modifications to the list of select agents and toxins addressed in this rule will benefit producers, research and reference laboratories, and state and Federal oversight agencies, while also maintaining adequate program oversight of select agents and toxins. Specifically, HHS/CDC is removing *Brucella abortus, Brucella melitensis,* and *Brucella suis* from the select agent and toxin list; updating the nomenclature for several select agents (''SARS coronavirus (SARS–CoV),'' removing the exclusion regarding ''South American genotype of Eastern Equine Encephalitis virus,'' renaming the exclusion regarding ''West African Clade of Monkeypox virus,'' and ''Ebola virus''); retaining the nomenclature of Monkeypox virus; retain the Tier 1 designation of Botulinum neurotoxin producing species of *Clostridium;* no addition of Hantaviruses to the current select agent and toxin list; increase the exclusion amount for short, paralytic alpha conotoxins from 100 mg to 200 mg; and designating Nipah virus as a Tier 1 Select Agent. HHS/CDC is also adding a footnote to the list for HHS and Overlap select agents indicating that the current nomenclature will be available on the website (*www.selectagents.gov*).

Currently, 236 entities are registered with the Federal Select Agent Program (FSAP). Of these entities, there are 13 private entities, 30 Federal entities, 42 commercial entities, 84 academic entities, and 67 state entities (registered with either APHIS or CDC, depending on the select agents and toxins they work with). Less than 4 percent of all firms operating within these North American Industry Classification categories are considered to be small entities. This final rule will not have a significant economic impact on a substantial number of small entities.

The benefits of strengthened safeguards against the unintentional or deliberate release of a select agent or toxin greatly exceed the costs of complying with the regulatory requirements. As an example of losses that can occur due to a select agent release, the October 2001 anthrax attacks caused 5 fatalities and 17 illnesses, disrupted business and government activities (including $2 billion in lost revenues for the U.S. Postal Service) and required more than $23 million to decontaminate one Senate office building and $3 billion to decontaminate postal facilities and procure mail-sanitizing equipment. Deliberate introduction greatly increases the probability of a select agent becoming established and causing wide-ranging and devastating impacts to the economy, other disruptions to society, and diminished confidence in public and private institutions.

HHS has examined the impacts of this rule as required by Executive Order 12866 on Regulatory Planning and Review (September 30, 1993), Executive Order 13563 on Improving Regulation and Regulatory Review (January 18, 2011), Executive Order 14094, entitled ''Modernizing Regulatory Review'' (April 6, 2023), the Regulatory Flexibility Act (RFA) (September 19, 1980, Pub. L. 96–354), section 1102(b) of the Social Security Act, section 202 of the Unfunded Mandates Reform Act of 1995 (March 22, 1995; Pub. L. 104–4), and Executive Order 13132 on Federalism (August 4, 1999). This final rule does not meet the criteria set forth in 5 U.S.C. 804(2) under the Congressional Review Act.

A. Executive Orders 12866, 13563, and 14094

Executive Orders 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). Executive Order 14094 (the Modernizing E.O.) amends section 3(f) of Executive Order 12866 (Regulatory Planning and Review). The amended section 3(f) of Executive Order 12866 defines a ''significant regulatory action'' as an action that is likely to result in a rule: (1) having an annual effect on the economy of $200 million or more in any 1 year (adjusted every 3 years by the Administrator of Office of Information and Regulatory Affairs (OIRA) for changes in gross domestic product), 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, territorial, or Tribal governments or communities; (2) creating a serious inconsistency or otherwise interfering with an action taken or planned by another agency; (3) materially altering the budgetary impacts of entitlement grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) raise legal or policy issues for which centralized review would meaningfully further the President's priorities or the principles set forth in this Executive order, as specifically authorized in a timely manner by the Administrator of OIRA in each case. OIRA has determined that this rule is significant.

Statement of Need

As discussed above, HHS/CDC is removing *Brucella abortus, Brucella melitensis,* and *Brucella suis* from the select agent list; updating the nomenclature for several select agents (''SARS coronavirus (SARS–CoV),'' the exclusion regarding ''South American genotype of Eastern Equine Encephalitis virus,'' the exclusion regarding ''West African Clade of Monkeypox virus,'' and ''Ebola virus''); retaining the nomenclature of Monkeypox virus; retaining the Tier 1 designation of Botulinum neurotoxin producing species of *Clostridium;* not adding Hantaviruses to the current select agent list; increasing the exclusion amount for short, paralytic alpha conotoxins from 100 mg to 200 mg; and designating Nipah virus as a Tier 1 Select Agent. HHS/CDC is also adding a footnote to the list for HHS and Overlap select agents indicating that the current nomenclature will be available on the website (*www.selectagents.gov*).

Some of the regulatory changes described in the preamble and reported below are a minor in nature, and as

such, are expected to have minimal impact on the costs and benefits of current regulations, except for the one-time costs of updating official documents for CDC. These regulatory changes are the updates to the nomenclature for several select agents (''SARS coronavirus [SARS–CoV],'' the exclusion regarding ''South American genotype of Eastern Equine Encephalitis virus,'' the exclusion regarding ''West African Clade of Monkeypox virus.'' and ''Ebola virus); retaining the nomenclature of *Monkeypox virus,* retaining the Tier 1 designation of Botulinum neurotoxin producing species of *Clostridium;* no addition of Hantaviruses to the current select agent list*;* increasing the exclusion amount for short, paralytic alpha conotoxins from 100 mg to 200 mg; and designating Nipah virus as a Tier 1 Select Agent.

This final rule changes the regulatory baseline by removing *Brucella abortus, Brucella melitensis,* and *Brucella suis* from the select agent list. As of July 2024, of the 236 registered entities with FSAP, 112 were registered for select agents and toxins including *Brucella abortus, melitensis,* and/or *suis,* and three of those entities were registered for only *Brucella* species. CDC expects the three entities registered for only *Brucella* species will deregister from FSAP, which HHS/CDC expects will cause minimal savings for these laboratories, as well as CDC. The remaining 109 entities will likely submit amendments to their registrations to remove the delisted agents while maintaining the rest of their registration. Therefore, HHS/CDC expects no change in the costs for these entities; there is no cost to deregister with FSAP. Because of the small number of entities that will deregister due to the delisting of *Brucella* species, the cost-savings to the government will be minimal, roughly a net value (benefits-costs) of $8,795.78 in one-time cost savings.

Costs

This final rule does not impose any mandatory costs on the public and benefits laboratories who choose to develop research using *Brucella abortus, Brucella melitensis,* and *Brucella suis.* Nonetheless, the changes in this rule will have a minimal economic impact on CDC due to the process of updating official documentation for the implementation of the changes listed in this final rule.

To estimate the cost to CDC of including the changes listed in this final rule in official documents, HHS/CDC assumed that 1 GS–14, step 5 employee and one GS–15, step 5 employee each spend 40 hours (*i.e.,* 80 hours in total) for any updates to cite the language in this final rule. The hourly wage rates for two employees based in Washington-Baltimore-Arlington, DC-MD-VA-WV-PA are $75.70 (GS–14) and $89.03 (GS–15).[1] To account for the non-wage benefits, we multiplied the wage cost by two to result in a total cost estimate of $13,178 (table 1).

TABLE 1—SUMMARY OF THE ONE-TIME COSTS IN 2024 USD TO UPDATE OFFICIAL DOCUMENTS FOR DEPARTMENT OF STATE (DOS), CENTERS FOR DISEASE CONTROL AND PREVENTION (CDC) COSTS FROM UPDATING OFFICIAL DOCUMENTS WITH THE CHANGES IN THIS FINAL RULE

Agency	Cost components	Hourly wage rate[2]	Multiplier non-wage benefits and overhead	Total
CDC	80 hours split between GS–14, step 5, and GS–15, step 5 levels.	$82.4	2	$13,178
Total				13,178

The changes in this final rule that are minor in nature and should not result in an additional regulatory burden to regulated entities. Instead, they should help reduce costs by reducing confusion regarding the requirements for the possession, use, and transfer of biological select agents and toxins.

The elimination of *Brucella abortus, Brucella melitensis,* and *Brucella suis* from the select agents and toxins list should not result in additional regulatory burden for CDC or regulated entities as this change would imply less regulatory burden. However, one concern about this reduction in regulatory burden is that it could cause costs or losses to the general public by increasing the risk of *Brucella abortus, Brucella melitensis,* and *Brucella suis* being accessed without authorization, stolen, lost, or released. Although this cost cannot be measured until after the regulation has been applied, HHS/CDC expects that the risk of *Brucella abortus, Brucella melitensis,* and *Brucella suis* being accessed without authorization, stolen, lost, or released would be minimal as the current recommended best practices in place to mitigate these biosafety and biosecurity risks (*Biosafety in Microbiological and Biomedical Laboratories*) will remain in place. USDA's prevention and eradication efforts against Brucellosis from livestock in the United States through the National Bovine Brucellosis Surveillance Plan and the National Brucellosis Eradication program will continue even with the changes in this rule.

Another concern linked to the reduction in regulatory burden to agencies and laboratories is that it could increase cost to the general public by increasing the risk of *Brucella abortus, Brucella melitensis,* and *Brucella suis* becoming an agent of interest to be used as a bioweapon. Although this risk cannot be measured by HHS/CDC currently, HHS/CDC expects this risk to be minimal as recent literature indicates that *Brucella*'s ''minimal mortality, availability of treatment options, protracted inoculation period and the emergence of new, more virulent potential weapons means that its inclusion among agents of bioterrorism is nowadays mainly of historical significance.'' [3]

Increasing the exclusion limits for short paralytic alpha conotoxins will have a negligible impact on costs for regulated entities. There are only four registered entities currently working with these conotoxins, and increasing

[1] U.S. Office of Personnel and Management. *https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/2024/general-schedule-gs-salary-calculator/* accessed on September 4, 2024.

[2] U S Office of Personnel Management: General Schedule (*opm.gov*).

[3] Pappas, G., Panagopoulou, P., Christou, L., & Akritidis, N. (2006). Biological weapons: Brucella as a biological weapon. *Cellular and molecular life sciences CMLS, 63,* 2229–2236.

the exclusion limit will allow for additional research and testing without the additional burden of select agent and toxin regulatory requirements.

Change to the designation of Nipah virus as a Tier 1 select agent will have a negligible impact on costs for regulated entities. All eight of the entities that are currently registered for Nipah virus are already registered for other Tier 1 select agents; therefore they are already complying with the additional Tier 1 requirements and will not incur additional costs with this change.

Benefits

HHS found the benefits of this rulemaking to outweigh the costs to regulated entities as all the changes described in this final rule have a zero cost to regulated entities. Furthermore, these changes are likely to reduce regulated entities' costs by simplifying their processes and reducing some of the regulatory burden. HHS/CDC is unable to quantify the cost reductions to regulated entities due to the minor changes but expects this final rule will potentially simplify processes for them. Nonetheless, at a minimum, costs of these changes are zero for regulated entities, thus any simplification of processes coming out of this change implies a gain.

As of July 2024, of the 236 registered entities with APHIS and CDC, 112 were registered for select agents and toxins including *Brucella abortus, melitensis,* and/or *suis,* and three of those entities are registered for only *Brucella* species. CDC expects the three entities registered for only *Brucella* species will deregister from FSAP, which HHS/CDC expects to cause small savings for these entities. Although FSAP registration does not have a direct cost for regulated entities, HHS/CDC estimates that it takes 12 hours of labor a week for eight months to perform the registration processes required to get an FSAP registration. These activities are usually performed by a Responsible Official/Biosafety Officer or an Alternate Responsible Official/Biosafety Officer. The GS scale for these professionals typically ranges from GS–9 to GS–14. Assuming a GS–14 scale, the hourly wage rate based in Washington-Baltimore-Arlington, DC-MD-VA-WV-PA is $75.70. Thus, the estimated one-time cost of registration with FSAP for an entity is $29,069. This estimated one-time cost savings will apply to any entities not registered with FSAP that wish to work with *Brucella* species. Renewal of registration with FSAP is a negligible cost as the process takes less than 10 minutes. Because three entities are currently registered solely for *Brucella* species, the exclusion of *Brucella abortus, Brucella melitensis,* and *Brucella suis* from the select agent list means they will not need to participate in the registration renewal process, which is a negligible cost.

HHS/CDC expects that the deregistration of the three entities registered only for *Brucella* species with FSAP will also cause small one-time cost-savings to CDC, as CDC personnel will no longer follow these entities throughout the registration process. HHS/CDC estimates that CDC personnel spend about three hours a week for six months reviewing laboratories' Standard Operating Procedures (SOPs) for entity's registration applications to FSAP. Assuming that the CDC staff reviewing SOPs is GS–13 step 5, the hourly salary in 2024 dollars would be $64.06, thus the one-time cost savings to CDC of reviewing the SOPs required for one entity's registration is $1,153.08, and this implies a total of $3,459.24 in cost savings for CDC of not going through the registration process of the three entities that would deregister after the publication of this rule.

In addition to these cost savings CDC will also have cost savings from not having to perform inspections on the three entities that are ending their FSAP registrations as a result of the exclusion of *Brucella abortus, Brucella melitensis,* and *Brucella suis* from the select agent list. Assuming that the personnel performing the inspections are a GS–12 step 5, and a GS–13 step 5 inspectors, the hourly wage is $53.87, and $64.06, respectively. Using an overhead multiplier of 2 to take into account non-wage benefits, and considering the travel costs of inspections, HHS/CDC estimates one-time costs savings of $10,564.18 per inspection not performed per entity (table 2). Since each entity goes through at least one inspection during registration, HHS/CDC estimates CDC will have a cost savings of at least $31,692.54 due to inspections not performed for the three entities deregistering from FSAP.

TABLE 2—ESTIMATED ANNUAL CDC COST-SAVINGS IN 2024 USD FOR INSPECTION OF EACH FACILITY ONLY WORKING WITH BRUCELLA

Type of CDC staff	Number of staff	Number of inspections per year	Number of hours spent per inspection	Average hourly wage rate [4]	Overhead multiplier	One-time annual benefit
GS–12 (step 5)	1	0.5	40	$53.87	2	$4,309.6
GS–13 (step 5)	1	0.5	40	64.06	2	5,124.8
Total						9,438.4
Travel costs	Airfare [5]	417.79/per person	Hotel, food, lodging [6]	145.10/per person		1125.78
Total (Personnel + Travel).						10,564.18

Executive Order 14094 reaffirms the principles of E.O. 12866 and E.O. 13563 and states that regulatory analysis should facilitate agency efforts to develop regulations that serve the public interest, advance statutory objectives, and are consistent with E.O. 12866, E.O. 13563, and the Presidential Memorandum of January 20, 2021 (Modernizing Regulatory Review). Regulatory analysis, as practicable and appropriate, should recognize distributive impacts and equity, to the extent permitted by law. HHS/CDC developed this final rule in a manner consistent with these requirements. E.O. 13563 emphasizes further that regulations must be based on the best available science and that the rulemaking process must allow for public participation and an open

[4] U.S. Office of Personnel Management: General Schedule (opm.gov).

[5] Bureau of Transportation Statistics: Air Fares √ Bureau of Transportation Statistics (bts.gov).

[6] FY 2024 Federal Per Diem Rates: FY 2024 Federal Per Diem Rates (federalpay.org).

exchange of ideas. HHS/CDC developed this final rule in a manner consistent with these requirements. In administering FSAP, HHS, along with USDA, regularly interact with the affected registered entities via email, phone, online webinars, through the eFSAP information system, and through designated points of contact at registered entities. All changes result from entity questions received or interaction with registered entities who have contacted FSAP when they had questions or regulatory interpretation requests. Therefore, HHS/CDC believes this final rule serves the public interest. Additionally, HHS/CDC encouraged public participation and informed registered entities of the proposed rule via a Select Agent (SA) Gram and a GovD message to ensure they were aware and had a chance to provide public comments. The FSAP website (*www.selectagents.gov*) was updated to share the proposed changes and provided a link to web visitors so that they could review and provide comments on the proposed rule. Lastly, HHS/CDC emailed outreach notes summarizing the proposed rule directly to national partner organizations (*e.g.,* the Association of Public Health Laboratories, American Society for Microbiology, American Biological Safety Association) so that they could share among their constituents. As discussed above, HHS/CDC carefully reviewed and considered public comments in the development of this final rule.

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

HHS/CDC examined the impacts of this final rule under the Regulatory Flexibility Act (5 U.S.C. 601–612). Unless HHS/CDC certifies that the final rule is not expected to have a significant economic impact on a substantial number of small entities, the RFA, as amended by SBREFA, requires agencies to analyze regulatory options that would minimize any significant economic impact of a rule on small entities. Currently, 236 entities are registered with FSAP. Of these entities, there are 13 private entities, 30 Federal entities, 42 commercial entities, 84 academic entities, and 67 state entities (registered with either APHIS or CDC, depending on the select agents and toxins they work with). Less than 4 percent of all firms operating within these North American Industry Classification System (NAICS) categories are considered to be small entities. HHS/CDC estimates that 13 entities will be impacted by the changes in this rule. Of these 13 entities, which are not considered small, 4 are associated with colleges, universities, and professional schools; 2 are categorized as research and development in biotechnology; and 7 are part of research and development in the physical, engineering, and life sciences. Applying NAICS' estimation of less than 4 percent of entities classified as small, we find that not even one small entity will be affected by the changes in this rule. Based on our analysis as described above, we certify that this final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the RFA. In addition, no public comments were received from any small entities on the RFA section.

Based on the information above, this regulatory action is not a major rule as defined by sec. 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This 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 U.S.-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 determined that the Paperwork Reduction Act does apply to information collection and recordkeeping requirements included in this rule. This final rule focuses on the select agent and toxins list. Any changes to burden hours caused by the removal of *Brucella abortus, Brucella suis,* and *Brucella melitensis* from the list of select agents and toxins will be submitted for consideration by OMB under the existing approved PRA package (Possession, Use, and Transfer of Select Agents and Toxins (42 CFR part 73)). Other changes put forth in this final rule, *i.e.,* updating entity registrations to reflect the nomenclature updates to the list, will be instituted by FSAP, resulting in no additional paperwork for the regulated community.

D. E.O. 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. E.O. 13132: Federalism

HHS/CDC reviewed this final rule in accordance with Executive Order 13132 regarding federalism and 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 issuing this rule consistent with the Federal Plain Writing Act guidelines.

V. References

Government Accountability Office. 2023. Public Health Preparedness: HHS Could Improve Oversight of Research Involving Enhanced Potential Pandemic Pathogens (GAO–23–105455). *https://www.gao.gov/products/gao-23-105455*

Lo, M., et al. The Emergence of Nipah virus, a Highly Pathogenic Paramyxovirus. J Clin Virol, 2008. 43(4): p. 396–400.

Olsen, S., et al. *Biosafety Concerns Related to Brucella and its Potential Use as a Bioweapon.* Applied Biosafety, 2018. 23(2): p. 77–90. Biosafety Concerns Related to Brucella and Its Potential Use as a Bioweapon | Applied Biosafety (*liebertpub.com*).

Sejvar, J., et al. Long-term Neurological and Functional Outcome in Nipah virus Infection. Ann Neurol. 2007 Sep;62(3): p. 235–42.

Ulaeto, D., et al. New Nomenclature for mpox (monkeypox) and Monkeypox Virus Clades. The Lancet: Infectious Diseases, 2023. 23(3): pg 273–275. *https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(23)00055-5/fulltext.*

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, HHS amends 42 CFR part 73 as follows:

PART 73—SELECT AGENTS AND TOXINS

■ 1. The authority citation for part 73 is revised to read as follows:

Authority: 42 U.S.C. 262a.

■ 2. Section 73.3 is amended by:
■ a. Revising paragraph (b);
■ b. In paragraph (d)(7), removing the text ''100 mg of Conotoxins'' and adding in its place the text ''200 mg of Conotoxins''; and
■ c. Revising paragraph (d)(12).

The revisions read as follows:

§ 73.3 HHS select agents and toxins.

* * * * *

(b) HHS select agents and toxins [1] are:

(1) Abrin.

(2) *Bacillus cereus* Biovar *anthracis.**

(3) Botulinum neurotoxins.*

(4) Botulinum neurotoxin producing species of *Clostridium.**

(5) Conotoxins (Short, paralytic alpha conotoxins containing the following amino acid sequence $X_1CCX_2PACGX_3X_4X_5X_6CX_7$).[2]

(6) *Coxiella burnetii.*

(7) Crimean-Congo hemorrhagic fever virus.

(8) Diacetoxyscirpenol.

(9) Eastern equine encephalitis virus.

(10) *Ebolavirus* *

(11) *Francisella tularensis.**

(12) Lassa fever virus.

(13) Lujo virus.

(14) Marburg virus.*

(15) Monkeypox virus.

(16) 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).

(17) Ricin.

(18) *Rickettsia prowazekii.*

(19) Severe acute respiratory syndrome coronavirus (SARS–CoV).

(20) SARS–CoV/SARS–CoV–2 chimeric viruses resulting from any deliberate manipulation of SARS–CoV–2 to incorporate nucleic acids coding for SARS–CoV virulence factors.

(21) Saxitoxin.

(22) South American hemorrhagic fever virus: Chapare.

(23) South American hemorrhagic fever virus: Guanarito.

(24) South American hemorrhagic fever virus: Junin.

(25) South American hemorrhagic fever virus: Machupo.

(26) South American hemorrhagic fever virus: Sabia.

(27) Staphylococcal enterotoxins (subtypes A,B,C,D,E).

(28) T–2 toxin.

(29) Tetrodotoxin.

(30) Tick-borne encephalitis virus: Far Eastern subtype.

(31) Tick-borne encephalitis virus: Siberian subtype.

(32) Kyasanur Forest disease virus.

(33) Omsk haemorrhagic fever virus.

(34) Variola major virus (Smallpox virus).*

(35) Variola minor virus (Alastrim).*

(36) *Yersinia pestis.**

[1] Please refer to *https://www.selectagents.gov* for current information on historical or proposed nomenclature for the HHS select agents on the list.

[2] C = Cysteine residues are all present as disulfides, with the 1st and 3rd Cysteine, and the 2nd and 4th Cysteine forming specific disulfide bridges; The consensus sequence includes known toxins a-MI and a-GI (shown above) as well as a-GIA, Ac1.1a, a-CnIA, a-CnIB; X1 = any amino acid(s) or Des-X; X2 = Asparagine or Histidine; P = Proline; A = Alanine; G = Glycine; X3 = Arginine or Lysine; X4 = Asparagine, Histidine, Lysine, Arginine, Tyrosine, Phenylalanine or Tryptophan; X5 = Tyrosine, Phenylalanine, or Tryptophan; X6 = Serine, Threonine, Glutamate, Aspartate, Glutamine, or Asparagine; X7 = Any amino acid(s) or Des X and; ''Des X'' = ''an amino acid does not have to be present at this position.'' For example, if a peptide sequence were XCCHPA then the related peptide CCHPA would be designated as Des-X.

* * * * *

(d) * * *

(12) Madariaga virus and any Clade II Monkeypox provided that the individual or entity can identify that the agent is within the exclusion category.

* * * * *

■ 3. Section 73.4 is amended by revising paragraph (b) to read as follows:

§ 73.4 Overlap select agents and toxins.

* * * * *

(b) Overlap select agents and toxins [1] are:

(1) *Bacillus anthracis.**

(2) *Bacillus anthracis* Pasteur strain.

(3) *Burkholderia mallei.**

(4) *Burkholderia pseudomallei.**

(5) Hendra virus.

(6) Nipah virus.*

(7) Rift Valley fever virus.

(8) Venezuelan equine encephalitis virus.

[1] Please refer to *https://www.selectagents.gov* for current information on historical or proposed nomenclature for the Overlap select agents on the list.

* * * * *

Dated: December 11, 2024.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2024–29583 Filed 12–16–24; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

49 CFR Part 513

[Docket No. NHTSA–2023–0014]

RIN 2127–AL85

Implementing the Whistleblower Provisions of the Vehicle Safety Act

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Final rule.

SUMMARY: This final rule addresses an important source of motor vehicle safety information and fulfills a requirement in the Motor Vehicle Safety Whistleblower Act (Whistleblower Act) that NHTSA promulgate regulations on the requirements of the Act, in complement to NHTSA's existing whistleblower program. The Whistleblower Act authorizes the Secretary of Transportation to pay an award, subject to certain limitations, to eligible whistleblowers who voluntarily provide original information relating to any motor vehicle defect, noncompliance, or any violation or alleged violation of any notification or reporting requirement, which is likely to cause unreasonable risk of death or serious physical injury, if the information provided leads to the successful resolution of a covered action. This final rule defines certain terms important to the operation of the whistleblower program, outlines the procedures for submitting original information to NHTSA and applying for awards, discusses NHTSA's procedures for making decisions on award applications, and generally explains the scope of the whistleblower program to the public and potential whistleblowers.

DATES:

Effective date: This rule is effective January 16, 2025.

Petitions for Reconsideration: If you wish to submit a petition for reconsideration of this rule, your petition must be received by January 31, 2025.

ADDRESSES: Any petitions for reconsideration should refer to the docket number set forth above (NHTSA–2023–0014) and be submitted to the