(3) EPA APPROVED MECKLENBURG COUNTY REGULATIONS—Continued

State citation	Title/subject	State effective date	EPA approval date	Explanation
* *	*	*	* *	*
Section 2.0400 Ambient Air Quality Standards				
Rule 2.0401	Purpose	12/18/2018	11/17/2021, [Insert citation of publication].	
Rule 2.0402	Sulfur Oxides	12/18/2018	11/17/2021, [Insert citation of publication].	
Rule 2.0403	Total Suspended Particulates	12/15/2015	11/17/2021, [Insert citation of publication].	
Rule 2.0404	Carbon Monoxide	12/18/2018	11/17/2021, [Insert citation of publication].	
Rule 2.0405	Ozone	12/18/2018	11/17/2021, [Insert citation of publication].	
Rule 2.0407	Nitrogen Dioxide	12/18/2018	11/17/2021, [Insert citation of publication].	
Rule 2.0408	Lead	12/18/2018	11/17/2021, [Insert citation of publication].	
* *	*	*	* *	*
Rule 2.0410	$PM_{2.5}$ Particulate Matter	12/18/2018	11/17/2021, [Insert citation of publication].	
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[FR Doc. 2021–24942 Filed 11–16–21; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 73

[Docket No. CDC–2021–0119]

RIN 0920–AA79

Possession, Use, and Transfer of Select Agents and Toxins—Addition of 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 to the HHS List of Select Agents and Toxins

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

ACTION: Interim final rule.

SUMMARY: The Centers for Disease Control and Prevention (CDC) located within the Department of Health and Human Services (HHS) is amending its select agents and toxins regulations to add 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 to the list of HHS select agents and toxins. HHS/CDC intends to regulate this agent and to require the regulated entity to obtain prior approval from CDC to conduct deliberate manipulation of SARS–CoV–2 to incorporate nucleic acids coding for SARS–CoV virulence factors because these chimeric viruses have the potential to pose a severe threat to public health and safety.

DATES: *Effective date:* The interim final rule is effective on November 17, 2021.

Comments due date: Written comments must be submitted on or before January 18, 2022.

Applicability dates: By December 17, 2021, all entities that possess 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 must provide notice to the Federal Select Agent Program regarding their possession of this agent. By February 15, 2022, all entities that possess, use, or transfer this agent must register (or amend an existing registration) and obtain a certificate of registration (or an amended certificate of registration) that includes this agent, in accordance with 42 CFR 73.7 and 73.7(i), respectively, and must meet all of the requirements of select agent regulations.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2021–0119 or Regulation Identifier Number (RIN) 0920–AA79, by either of the methods listed below. Do not submit comments by email. CDC does not accept comments by email.

- *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, Mailstop H21–7, Atlanta, Georgia 30329, ATTN: RIN 0920–AA79.

Instructions: All submissions received must include the agency name and RIN for this rulemaking. All relevant comments received will be posted without change to *http://www.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.*

FOR FURTHER INFORMATION CONTACT: Samuel S. Edwin, Ph.D., Director, Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Road NE, Mailstop H21–7, Atlanta, Georgia 30329. Telephone: (404) 718–2000. Email: *lrsat@cdc.gov.*

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

SUPPLEMENTARY INFORMATION:

I. Public Participation

Interested persons or organizations are invited to participate in this rulemaking by submitting written views, recommendations, and data. Using the criteria enumerated below, HHS/CDC invites comments specifically, based on the following criteria, as to whether 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 should be regulated as a select agent:

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

(2) The degree of contagiousness of the agent and the methods by which the agent 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; and

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

In addition, HHS/CDC invites comments specifically on any virulence factors found in SARS–CoV that would increase virulence in SARS–CoV–2.

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(42 U.S.C. 262a).

Title II, 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). Accordingly, HHS has promulgated regulations requiring individuals or entities that possess, use, or transfer select agents and toxins to register with CDC. See 42 CFR part 73.

B. Background

Coronavirus disease 2019 is a highly contagious disease caused by severe acute respiratory syndrome coronavirus 2 (SARS–CoV–2). As of October 18, 2021, SARS–CoV–2 has infected approximately 44,857,861 individuals and resulted in at least 723,205 deaths in the United States. It should be noted that SARS–CoV–2 is not currently a select agent. However, SARS coronavirus (SARS–CoV), a related virus, is a select agent.

HHS/CDC is regulating, as a non-Tier 1 select agent 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. SARS–CoV virulence factors include but are not limited to those involved in inflammasome activation during infection, which could be introduced into SARS–CoV–2 and create a chimeric virus with increased virulence. HHS/CDC is also requiring prior approval from the HHS Secretary to conduct this type of work because these viruses have the potential to pose a severe threat to public health and safety. HHS/CDC believes that regulatory oversight of these experiments and the resulting chimeric viruses is essential to protecting the public from the potential consequences of a release of these viruses. The SARS–CoV/SARS–CoV–2 chimeric viruses that result from deliberate manipulation of SARS–CoV–2 to incorporate SARS–CoV virulence factors will be designated as a select agent and subject to strict regulatory controls on the possession, use, and transfer of these viruses.

HHS/CDC has determined that 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 are being listed as an HHS select agent because:

- Virulence factors from SARS–CoV including, but not limited to, those involved in inflammasome activation during infection, could be introduced into SARS–CoV–2 and create a chimeric virus with increased virulence.
- There is significant potential risk of merging a select agent virus and pandemic virus and creating a chimeric virus with the transmissibility of SARS–CoV–2 and the pathogenicity of SARS–CoV.

III. Rationale for an Interim Final Rule

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (42 U.S.C. 262a) requires the regulation of biological agents that have the potential to pose a severe threat to public health and safety. 5 U.S.C. 553 (Rulemaking) waives the requirement to publish a notice of proposed rulemaking ''when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest'' (5 U.S.C. 553(b)(B)). HHS/CDC believes that advance public notice and the opportunity to comment are impracticable [and contrary to the public interest] and there is good cause to issue an interim final rule with comment because there is no current regulatory oversight involving these experiments. As a result, HHS/CDC is unable to predict the potential infectiousness or virulence of the SARS–CoV/SARS–CoV–2 chimeric viruses and believes the resulting chimeric viruses have the potential to pose a severe threat to public health and safety. In addition, a release of this modification of a non-select agent with nucleic acids from a select agent would require a complicated and expensive emergency response effort. This effort could include extensive public health measures, such as quarantine, preventative treatment, and diagnostic testing for large numbers of potentially exposed persons, and extensive decontamination. Substantial costs could be incurred by hospitals and other medical facilities and institutions of government at all levels. A release, or widespread fear of one, also would create significant secondary effects. It could disrupt business, transportation, and many other aspects of normal behavior, on both a short-term and potentially a long-term basis. As a result, the regulation is needed to protect the American public from the potential consequences of a release of these viruses.

IV. Required Regulatory Analyses

A. Executive Orders 12866 and 13563

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

and safety. HHS/CDC has analyzed the IFR as required by these Executive Orders and has determined that it is consistent with the principles set forth in the Executive Orders and the Regulatory Flexibility Act, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA). We anticipate that the rule will create minimal cost impact, but that it could potentially result in benefits to the extent that it could reduce the probability of an accidental or intentional release of the 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. Such an event is a low probability, but potentially extremely high-cost outcome. This rule has been determined to be a ''significant regulatory action'' as defined by Executive Order 12866, section 3(f). However, this rule is not an economically significant regulatory action, as it will not 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. This rule has been reviewed by the Office of Management and Budget (OMB) pursuant to Executive Orders 12866 and 13563.

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

Need for the Regulation

There is no current regulatory oversight involving 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. Under the current regulatory baseline, the 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 would not be regulated as a select agent. As a result, existing entities that are already registered to handle select agents and toxins would not need to amend their registrations. In addition, other entities that are not currently registered to handle select agents and toxins would not need to invest in upgrading their facilities to qualify to handle select agents or toxins or to go through the process to register with HHS/CDC. However, in the absence of such activities, the risk of release of the 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 would be increased. An intentional or accidental release of this agent could impose significant costs on entities other than those directly working with the chimeric viruses. Thus, HHS/CDC is regulating this agent as a select agent because of its potential to pose a threat to public health and safety.

HHS/CDC analyzed the expected costs and benefits of this IFR by comparing the pre-IFR baseline to the provisions of this IFR.

Analysis of Costs and Benefits

Costs

In the following analysis, HHS/CDC looked at two different types of entities that may incur additional costs as a result of this rulemaking. They are described below: (1) A registered entity who wishes to amend their registration to add the agent; or (2) A new unregistered entity who will register in order to work with the agent. HHS/CDC also estimated the costs for HHS/CDC to work with entities to amend their registration or to be registered as a result of this IFR. All costs and benefits for this analysis are reported in 2020 U.S. dollars. Further, HHS/CDC assumed that all costs would be incurred within a one-year time period corresponding to the expected period of time in which experiments with these chimeric viruses would be performed.

(1) An entity is already registered and will amend the registration for the agent.

This IFR will require such an entity to amend its registration using relevant portions of APHIS/CDC Form 1 (Registration for Possession, Use, and Transfer of Select Agents and Toxins). The estimated time to amend this form is one hour for one select agent (Table 1). To account for uncertainty in the estimate, a range of 75% to 125% of this estimate is used as the lower bound and the upper bound estimates, respectively. HHS/CDC used a median hourly respondent labor rate of $49.83 for managerial staff (occupation code 11–1021 general and operations manager) as the upper bound estimate and $16.98 for clerical staff (occupation code 43–9061 office clerks, general) as the lower bound estimate. These rates were obtained from the Bureau of Labor Statistics, from the 2020 Occupational Employment Statistics Survey by Occupation (*http://www.bls.gov/oes/*). HHS/CDC assumed that the hourly burden would be evenly split between managerial staff and clerical staff as a base case. The hourly respondent labor rate for the base case was the average of these two figures ($33.41 per hour). The base salary is multiplied by an overhead multiplier of 100% to account for non-wage benefits and other overhead costs for supporting each employee. The estimated cost per already registered entity to amend their registration for this agent was $66.81 (range: $25.47 to $124.58).

The additional time for HHS/CDC's review of the amended registration for the already registered entities will also generate additional costs. HHS/CDC estimated that one staff at the GS–13 (step 5) level is required to review the amended registration application. The hourly wage of a Federal Employee at GS–13 (step 5) from the 2020 General Schedule (GS) locality pay table for Atlanta (where CDC has its headquarters), $52.20 per hour, was used to estimate the hourly base salary (Table 1). The base salary is multiplied by an overhead multiplier of 100% to account for non-wage benefits and other overhead costs for supporting each employee. HHS/CDC estimated that the review of the amendment application takes two hours (range: 1.5 hours to 2.5 hours) for HHS/CDC. The estimated HHS/CDC's cost per entity to amend their registration for the agent was $209 (range: $157 to $261).

TABLE 1—ESTIMATED COSTS PER ALREADY REGISTERED ENTITY TO AMEND THEIR REGISTRATION FOR THE AGENT

[2020 U.S. Dollars]

	Base case	Lower bound	Upper bound
Entity:			
Number of employees working on the amendment (A)	1	1	1
Hourly wage (B)	$33.41	$16.98	$49.83

TABLE 1—ESTIMATED COSTS PER ALREADY REGISTERED ENTITY TO AMEND THEIR REGISTRATION FOR THE AGENT—Continued

[2020 U.S. Dollars]

	Base case	Lower bound	Upper bound
Overhead multiplier (C)	100%	100%	100%
Time required per staff (hours) (D)	1	0.75	1.25
Estimated costs per entity (E) = (A) × (B) × ((C) + 1) × (D)	$66.81	$25.47	$124.58
HHS/CDC:			
Number of staff required for the review of the amendment application (F)	1	1	1
Hourly wage (G)	$52.20	$52.20	$52.20
Overhead multiplier (H)	100%	100%	100%
Time required for the amendment per staff (hour) (I)	2	1.5	2.5
Estimated costs per entity (J) = (F) × (G) × ((H) + 1) × (I)	$209	$157	$261

(2) A new entity will register in order to work with the select agent (The entity is NOT currently registered).

For new entities, which will register for working with the agent, HHS/CDC expects per facility costs to vary based on the entity type, laboratory size, and biosafety level (BSL). The first-year cost per facility for a medium-size BSL–2/3 research institute to register to work with the select agent is estimated at $59,600. This estimate from the Regulatory Impact Analysis for the 2005 Select Agent Regulations Final Rule [1] was adjusted to 2020 U.S. dollars value using the Consumer Price Index (CPI) Inflation Calculator.[2] This results in an adjusted value of $78,994 for each additional registered, medium-size BSL–2/3 research institute laboratory (range: $41,087 to $936,528) (Table 2). The provisions of this IFR will reduce the risk of human exposure to the chimeric viruses by ensuring that laboratory facilities employ adequate security and safety measures including:

(1) Develop and implement a written biosafety plan and measures in place that is commensurate with the risk of the select agent given its intended use,

(2) Develop and implement a written security plan and measures in place that is sufficient to safeguard the select agent against unauthorized access, theft, loss, or release,

(3) Develop and implement a written incident response plan based upon a site-specific risk assessment,

(4) Have an adequate training program for handling select agents, and

(5) Maintain an inventory of select agents.

Two HHS/CDC staff, GS–12 (step 5) would perform the initial review of the application with the final review conducted by GS–13 (step 5). HHS/CDC estimated the upper bound hourly wage for a Federal Employee at the GS–13 (step 5) from the 2020 General Schedule (GS) locality pay table for Atlanta, $52.20 per hour. The lower bound was estimated using the hourly wage for a GS–12 (step 5) employee, $43.90 per hour (Table 2). The mean of these two wage rates was used as the base case. The base salary is multiplied by an overhead multiplier of 100% to account for non-wage benefits and other overhead costs for supporting each employee. HHS/CDC estimated that the review of a new application would take two hours (range: 1.5 hours to 2.5 hours). The estimated HHS/CDC cost per entity to review a new application was $384 (range: $263 to $522).

The new registration also will require a site visit by CDC to investigate the adequacy of the laboratory to handle select agents and toxins. HHS/CDC assumed that two CDC investigators, GS–12 (step 5) or GS–13 (step 5) would travel to the laboratory and that the visit would require 3 days (1 day for outbound trip to the laboratory, 1 day for the investigation, and 1 day for the return trip) and 8 work hours per day inclusive of report writing. The estimated travel costs were $1,200 per trip for two CDC investigators. The total estimated costs associated with laboratory investigation per entity are $5,183 (range: $5,414 to $6,211). The estimated total costs for CDC per new registered entity are $6,197 (range: $5,678 to $6,733) for application review and laboratory investigation.

HHS/CDC assumed that all costs associated with the IFR will occur during the first year after the IFR is published and that the IFR will not affect costs for registered entities in following years. This may result in an over-estimate of the costs to register a new entity if that entity were to decide to continue to work with select agents and toxins in future years.

TABLE 2—ESTIMATED COSTS PER NEW ENTITY, WHICH WILL REGISTER IN ORDER TO WORK WITH THE AGENT

[2020 U.S. dollars]

	Base case	Lower bound	Upper bound
Entity:			
Estimated costs for new registration per entity (A) [3]	$78,994	$41,087	$936,528
HHS/CDC:			
New application review (time) costs per entity:			
Number of staff required for the review of the new application (B)	2	2	2
Hourly wage (C)	$48.05	$43.90	$52.20
Overhead multiplier (D)	100%	100%	100%
Time required for the new application per staff (hour) (E)	2	1.5	2.5
Estimated costs associated with a new registration application review (F) = (B) × (C) × ((D) + 1) × (E)	$384	$263	$522
Lab investigation costs per entity:			
Number of staff required for the lab investigation (G)	2	2	2

[1] Regulatory Impact Analysis, 42 CFR parts 73: Possession, Use, and Transfer of Select Agents and Toxins Final Rule, Centers for Disease Control and Prevention, February 3, 2005.

[2] *https://www.bls.gov/data/inflation_calculator.htm.*

TABLE 2—ESTIMATED COSTS PER NEW ENTITY, WHICH WILL REGISTER IN ORDER TO WORK WITH THE AGENT—Continued

[2020 U.S. dollars]

	Base case	Lower bound	Upper bound
Hourly wage (H)	$48.05	$43.90	$52.20
Overhead multiplier (I)	100%	100%	100%
Time required for the amendment per staff (hour) (J)	24	24	24
Estimated time costs for lab investigation per entity (K) = (F) × (G) × ((H) + 1) × (I)	$4,613	$4,214	$5,011
Number of trips required per lab investigation (L)	1	1	1
Travel associated costs per trip (M)	$1,200	$1,200	$1,200
Travel associated costs per lab investigation (N) = (L) × (M)	$1,200	$1,200	$1,200
Estimated costs associated with lab investigation (O) = (K) + (N)	$5,813	$5,414	$6,211
Estimated total costs for HHS/CDC per entity (P) = (F) + (O)	$6,197	$5,678	$6,733

HHS/CDC is only aware of one registered entity that is interested in generating this agent and would likely amend their registration to work with this agent. The base case is that only one registered entity would amend their registration for the agent and no unregistered entities would undergo the registration process in order to work with this agent. The lower bound is the same as the base case. For the upper bound, HHS/CDC assumed that two registered entities would amend their registration to work with this agent and one unregistered entity would undergo the registration process to work with this agent (Table 3).

TABLE 3—NUMBERS OF ENTITIES THAT WILL BE AFFECTED BY THE IFR

	Base case	Lower bound	Upper bound
Registered entities, which want to amend the registration for the agent	1	1	2
Unregistered entities, which want to be registered for the agent	0	0	1

The total costs associated with the IFR for the entities working with this agent are estimated at $67 (range: $25 to $936,777) (Table 4).

TABLE 4—TOTAL ESTIMATED COSTS FOR ENTITIES TO WORK WITH THE SARS–COV/SARS–COV–2 CHIMERIC VIRUSES ASSOCIATED WITH THE IFR

[2020 U.S. dollars]

	Base case	Lower bound	Upper bound
Registered entities, which want to amend their registrations to work with the agent:			
Number of entities (A)	1	1	2
Estimated costs per entity (B)	$67	$25	$125
Estimated costs (C) = (A) × (B)	$67	$25	$249
Unregistered entities, which would pursue registration to work with this agent:			
Number of entities (D)	0	0	1
Estimated costs per entity (E)	$78,994	$41,087	$936,528
Estimated costs (F) = (D) × (E)	$0	$0	$936,528
Total estimated costs for entities to comply with HHS/CDC requirements to work with this agent (G) = (C) + (F)	$67	$25	$936,777

The total estimated costs for HHS/CDC to review applications to amend registrations or to register new entities to work with this agent, which are associated with the IFR are $209 (range: $156 to $7,255) (Table 5).

TABLE 5—TOTAL ESTIMATED COSTS FOR HHS/CDC TO REVIEW ENTITIES' APPLICATIONS TO AMEND THEIR REGISTRATIONS OR TO REGISTER NEW ENTITIES TO WORK WITH THE SARS–COV/SARS–COV–2 CHIMERIC VIRUSES ASSOCIATED WITH THE IFR

[2020 U.S. dollars]

	Base case	Lower bound	Upper bound
Registered entities, which want to amend the registration for the agent:			
Number of entities (A)	1	1	2
Estimated costs per entity (B)	$209	$157	$261

[3] The estimates from the Regulatory Impact Analysis for the 2005 Select Agent Regulations Final Rule (Regulatory Impact Analysis, 42 CFR Parts 73: Possession, Use, and Transfer of Select Agents and Toxins Final Rule, Centers for Disease Control and Prevention, February 3, 2005) was adjusted to 2020 US dollars value using the Consumer Price Index (CPI) Inflation Calculator (*https://www.bls.gov/data/inflation_calculator.htm*).

TABLE 5—TOTAL ESTIMATED COSTS FOR HHS/CDC TO REVIEW ENTITIES' APPLICATIONS TO AMEND THEIR REGISTRATIONS OR TO REGISTER NEW ENTITIES TO WORK WITH THE SARS–COV/SARS–COV–2 CHIMERIC VIRUSES ASSOCIATED WITH THE IFR—Continued

[2020 U.S. dollars]

	Base case	Lower bound	Upper bound
Estimated costs (C) = (A) × (B)	$209	$157	$522
Unregistered entities, which want to be registered for the agent:			
Number of entities (D)	0	0	1
Estimated costs per entity (E)	$6,197	$5,678	$6,733
Estimated costs (F) = (D) × (E)	$0	$0	$6,733
Total estimated costs for HHS/CDC (G) = (C) + (F)	$209	$156	$7,255

Summary of Costs

In summary, the total estimated costs associated with the IFR are $276 (range: $182 to $944,032) (Table 6). All costs are one-time costs, and the follow-up costs are assumed to be minimal. The upper bound cost estimate includes the cost to register a new entity to work with select agents and toxins, which may not be pursued. Even this upper bound estimate is less than $1 million.

TABLE 6—SUMMARY OF TOTAL ESTIMATED COSTS ASSOCIATED WITH THE IFR TO ADD THE 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 TO HHS/CDC'S LIST OF SELECT AGENTS AND TOXINS

[2020 U.S. dollars]

	Base case	Lower bound	Upper bound
Total estimated costs to entities working with the agent (A)	$67	$25	$936,777
Total estimated costs to HHS/CDC (B)	209	157	7,255
Total estimated costs (C) = (A) + (B)	276	182	944,032

Benefits

The agents and toxins placed on the HHS/CDC select list have the potential to pose severe threats to public health and safety. The benefits of the HHS/CDC interim final rule derive from the strengthened prevention against the accidental or intentional release of 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. The provisions of this IFR will reduce the risk of human exposure to the chimeric viruses by ensuring that laboratory facilities employ adequate security and safety measures including:

(1) Develop and implement a written biosafety plan and measures in place that is commensurate with the risk of the select agent given its intended use,

(2) Develop and implement a written security plan and measures in place that is sufficient to safeguard the select agent against unauthorized access, theft, loss, or release,

(3) Develop and implement a written incident response plan based upon a site-specific risk assessment,

(4) Have an adequate training program for handling select agents, and

(5) Maintain an inventory of select agents.

The benefits to public health and safety from the implementation of the rule result from the strengthened prevention that the rules provide against the either accidental or intentional release of the modification of a non-select agent with nucleic acids from a select agent but are difficult to quantify. The cost of such an event in morbidity and mortality could be very high. In addition, a release of this modification of a non-select agent with nucleic acids from a select agent would require a complicated and expensive emergency response effort. This effort could include extensive public health measures, such as quarantine, preventative treatment, and diagnostic testing for large numbers of potentially exposed persons, and extensive decontamination. Substantial costs could be incurred by hospitals and other medical facilities and institutions of government at all levels. A release, or widespread fear of one, also would create significant secondary effects. It could disrupt business, transportation, and many other aspects of normal behavior, on both a short-term and potentially a long-term basis.

HHS/CDC is unable to predict the potential infectiousness or virulence of the SARS–CoV/SARS–CoV–2 chimeric viruses that are regulated according to the provisions of this IFR. However, implementation of the IFR will provide a means of determining where the modification of a non-select agent with nucleic acids from a select agent is located; ensure that transfer, storage, and use of the agent can be tracked; provide for the screening of personnel with access to such agent; and require that entities in possession of such agent develop and implement effective means of biosafety and physical security. The benefit of these provisions is a reduced likelihood of either an accidental or intentional release of the select agent and the consequent avoidance of costs associated with such a release.

This IFR addresses a risk associated with substantial economic consequences. The likelihood of these negative outcomes under a baseline scenario of no further regulatory action are low, but also highly uncertain and difficult to characterize. Based on this analysis, HHS/CDC believes the expected benefits of this IFR are likely to exceed the estimated costs associated with this IFR.

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

We have examined the impacts of the interim final rule under the Regulatory Flexibility Act (5 U.S.C. 601–612). The Regulatory Flexibility Act (RFA), as

amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA), requires agencies to analyze regulatory options that would minimize any significant economic impact of a rule on small entities. Based on our current knowledge of who may possess this agent, we certify that this interim final rule will not have a significant economic impact on a substantial number of small entities within the meaning of the RFA.

This regulatory action is not a major rule as defined by Sec. 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This interim final rule will not result in an annual effect on the economy of $100,000,000 or more; a major increase in cost or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

C. Paperwork Reduction Act of 1995

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in the current regulations are approved by the Office of Management and Budget (OMB) under OMB control number 0920–0576, expiration date 1/31/2024. This rulemaking includes a request for a nonmaterial/non-substantive change to account for small, potential increases in burden for a limited number of entities to submit amendments to their registrations.

We expect that the entities who will register for possession, use, or transfer of the select agent will already be registered with the Federal Select Agent Program because the entity would be registered to possess, use, or transfer SARS–CoV. This rulemaking will require such an entity to amend its registration with the Federal Select Agent Program using relevant portions of APHIS/CDC Form 1 (Registration for Possessing, Use, and Transfer of Select Agents and Toxins). Estimated time to amend this form is one hour for one select agent. Additionally, any registered entity that wishes to transfer the select agent will be required to submit information using APHIS/CDC Form 2 (Request to Transfer of Select Agent and Toxins). Estimated average time to complete this form is one hour. Based upon the limited publications on this agent at this time, we estimate that only one to five registered entities may add the select agent to their registration or transfer the select agent to another registered entity. Therefore, we calculate that there is no increase in the number of respondents that need to submit an application for registration, we estimate the total number of responses for entities to submit an amendment to their registration may increase by five, and the total burden hours may increase to five hours. This represents a nonmaterial/non-substantive change in burden for respondents to this approved information collection. The burden is outlined in the table below.

Section	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)	Total burden hours
Section 7	Application for Registration	3	1	5	15
Section 7	Amendment to a Certificate of Registration	254	5	1	1,270

D. E.O. 12988: Civil Justice Reform

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

E. E.O. 13132: Federalism

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

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 announcing this rule consistent with the Federal Plain Writing Act guidelines.

List of Subjects in 42 CFR Part 73

Biologics, Incorporation by reference, Packaging and containers, Penalties, Reporting and Recordkeeping requirements, Transportation.

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

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

Authority: 42 U.S.C. 262a; sections 201–204, 221 and 231 of Title II of Public Law 107–188 (42 U.S.C. 262a)

■ 2. In § 73.3 amend paragraph (b) by adding in alphabetical order an entry for ''SARS–CoV/SARS–CoV–2 chimeric viruses'' to read as follows:

§ 73.3 HHS select agents and toxins.

* * * * *

(b) * * *

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.

* * * * *

■ 3. Amend § 73.13 by adding paragraph (a)(3) to read as follows:

§ 73.13 Restricted experiments.

* * * * *

(a) * * *

(3) Experiments that involve the creation of 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 or vice versa.

* * * * *

Xavier Becerra,

Secretary, Department of Health and Human Services.

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