Under section 307(b)(1) of the CAA, petitions for judicial review of this action must be filed in the United States Court of Appeals for the appropriate circuit by May 2, 2023. Filing a petition for reconsideration by the Administrator of this final rule does not affect the finality of this action for the purposes of judicial review nor does it extend the time within which a petition for judicial review may be filed, and shall not postpone the effectiveness of such rule or action. This action may not be challenged later in proceedings to enforce its requirements. (See section 307(b)(2).)

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Carbon monoxide, Incorporation by reference, Intergovernmental relations, Lead, Nitrogen dioxide, Ozone, Particulate matter, Reporting and recordkeeping requirements, Sulfur oxides, Volatile organic compounds.

Dated: January 30, 2023.

Earthea Nance,

Regional Administrator, Region 6.

For the reasons stated in the preamble, the Environmental Protection Agency amends 40 CFR part 52 as follows:

PART 52—APPROVAL AND PROMULGATION OF IMPLEMENTATION PLANS

■ 1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401 *et seq.*

Subpart GG—New Mexico

■ 2. In § 52.1620(c), the first table titled ''EPA Approved New Mexico Regulations'' is amended by revising the entry for ''Part 7'' to read as follows:

§ 52.1620 Identification of plan.

* * * * *

(c) * * *

EPA APPROVED NEW MEXICO REGULATIONS

State citation	Title/ subject	State approval/ effective date	EPA approval date	Comments
New Mexico Administrative Code (NMAC) Title 20—Environment Protection Chapter 2—Air Quality				
*	*	*	*	* * *
Part 7	Excess Emissions.	7/10/2008, 10/13/2016	9/14/2009, 74 FR 46910, 3/3/2023 [Insert **Federal Register** citation].	Sections 20.2.7.111 NMAC, 20.2.7.112 NMAC, 20.2.7.113 NMAC, 20.2.7.6(B) NMAC, 20.2.7.110(B)(15) NMAC, 20.2.7.115 NMAC, and 20.2.7.116 NMAC are no longer in SIP, 3/3/2023.
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[FR Doc. 2023–03887 Filed 3–2–23; 8:45 am]

BILLING CODE 6560–50–P

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: Final rule.

SUMMARY: The Centers for Disease Control and Prevention (CDC) located within the Department of Health and Human Services (HHS) has amended the 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. With this final rule, regulated entities are required 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 March 3, 2023.

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 H21–4, Atlanta, Georgia 30329. Telephone: (404) 718–2000. Email: *lrsat@cdc.gov.*

SUPPLEMENTARY INFORMATION: The final rule is organized as follows:

I. Background and Legal Authority

On November 17, 2021, HHS/CDC published an interim final rule (IFR) (86 FR 64075) that amended the 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 [1] to the list of HHS select agents and toxins. The IFR also required the regulated entity obtain prior approval from CDC to conduct deliberate manipulation of SARS–CoV–2 to incorporate nucleic acids coding for SARS–CoV virulence factors and vice versa, because these chimeric viruses have the potential to pose a severe threat to public health and safety.

Legal Authority:

[1] Virulence factors are genes or gene modifications that are associated with virulence. Virulence factors determine a pathogen's ability to replicate, modify host defenses, spread within the host and to other individuals, and produce products that are toxic to the host. These factors may impact infectivity, transmissibility, immunity, vaccine sensitivity, pathogenicity, and disease severity. Viral virulence factors (*e.g.,* structures, molecules, and regulatory systems) can impact features of viral pathogenicity including infectivity, replication, host tropism, the ability to evade the host response, and/or resistance to medical countermeasures, among other viral characteristics.

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.

II. Summary of Public Comments and Response to Comments

The IFR solicited public comments, based on the following criteria, regarding 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 invited comments specifically on any virulence factors found in SARS–CoV that would increase virulence in SARS–CoV–2.

HHS/CDC received three comments regarding the IFR.

Comment: One commenter, from academia, asked whether there is a need to create a new rule specific to SARS–CoV/SARS–CoV–2 chimeras because the regulation of the chimeras is covered in the ''Guidance on the Regulation of Select Agents and Toxin Nucleic Acids'' document. The commenter also stated that they did not support the addition of SARS–CoV/SARS–CoV–2 chimeric viruses to the HHS select agents list because the action would be an incremental step that could result in decreased scientific advances and thus reduced preparedness at the detriment of public health broadly. Finally, the commenter stated that the IFR does not adhere to federal standards set forth for rulemaking, and the goals of the IFR can be accomplished using existing regulatory infrastructure.

Response: HHS/CDC made no changes based on the comment. The ''Guidance on the Regulation of Select Agents and Toxin Nucleic Acids'' document includes information provided by HHS/CDC to assist registered entities with achieving regulatory compliance with the select agent and toxin regulations. SARS–CoV–2 is not a select agent and, previously, the select agent and toxins regulations only applied to nucleic acids capable of producing infectious select virus, which would be the majority of the genome and not a gene in isolation. The select agent and toxins regulations did not apply to specific genes or nucleic acids in isolation or non-select agent viruses. The Guidance document includes information on complying with the regulations for regulated genetic material, not for unregulated material or the genetic components of unregulated material. Further, a guidance document does not have the force and effect of law.

The basis for listing 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 is that:

- 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.

Comment: Two commenters, one from academia and one from industry, requested more robust definitions or guidance to clarify ''virulence factor'' and ''chimera'' to explicitly define ''virulence factors of concern.''

Response: HHS/CDC agreed with the commenters.

Virulence factors are genes or gene modifications that are associated with virulence. Virulence factors determine a pathogen's ability to replicate, modify host defenses, spread within the host and to other individuals, and produce products that are toxic to the host. These factors may impact infectivity, transmissibility, immunity, vaccine sensitivity, pathogenicity, and disease severity.

SARS–CoV/SARS–CoV–2 chimeric viruses result from any intentional manipulation of SARS–CoV–2 to include nucleic acids coding for SARS–CoV virulence factors. They are select agents and entities are required to obtain prior approval from CDC's Division of Select Agents and Toxins (DSAT) to possess, use, or transfer these agents. Additionally, experiments to create these chimeric viruses must be submitted to the Federal Select Agent Program for prior approval.

Additional Guidance has also been developed that provides examples of virulence factors found in SARS–CoV/SARS–CoV–2 and provides examples of experiments that may meet the definition of a restricted experiment. Guidance can be found at the Supporting Materials tab of the docket and at *www.selectagents.gov.*

II. Required Regulatory Analyses

A. Executive Orders 12866 and 13563

HHS/CDC has examined the impacts of the final rule 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 final rule 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 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 an 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 this regulation.

Analysis of Costs and Benefits

Costs

As of September 7, 2022, CDC has not received any requests from already registered entities to amend their registration to work with this agent. In addition, CDC has not received any applications from new entities to register with CDC and work with this agent. Thus, as of this date, CDC has not observed any costs associated with the IFR or for this final rule. If an entity chooses to work with this agent in the future, the below estimates of costs and benefits would apply.

In the following analysis, HHS/CDC looked at two different types of entities that may incur additional costs because of this rulemaking. They are described below as: (1) A registered entity that applies to amend its registration to add the agent; or (2) An unregistered entity that seeks to register to work with the agent. HHS/CDC also estimated the costs for CDC to work with an entity to amend its registration or to register because of this final rule. 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) *A registered entity that applies to amend its registration for the agent.*

As of September 7, 2022, none of the entities already registered with CDC to work with select agents and toxins have amended their registries to work with this agent. This final rule requires 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 apply for an amendment using 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, 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 cost of having HHS/CDC amend an entity's registration for the agent is estimated to be $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
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) *An unregistered entity will apply to register in order to work with the agent (The entity is NOT currently registered).*

As of September 7, 2022, no unregistered entities notified CDC, as required by the IFR, that they plan to work with select agents and toxins and have amended their registries to work with this agent. For unregistered 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 agent is estimated at $59,600. This estimate from the Regulatory Impact Analysis for the 2005 Select Agent Regulations Final Rule [2] was adjusted to 2020 U.S. dollars value using the Consumer Price Index

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

(CPI) Inflation Calculator.[3] This results in an adjusted value of $78,994 for each additional registered, medium-size BSL–⅔ research institute laboratory (range: $41,087 to $936,528) (Table 2).

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 an application would take two hours (range: 1.5 hours to 2.5 hours). The estimated HHS/CDC cost per entity to review an application was $384 (range: $263 to $522).

Registration also will require an inspection by CDC to assess the applicant's ability to comply with the select agents and toxins regulations. 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 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 final rule will occur during the first year after the final rule is published and that the final rule will not affect costs for registered entities in following years. This may result in an over-estimate of the costs to register an entity if that entity were to decide to continue to work with select agents and toxins in future years.

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

[2020 U.S. dollars]

	Base case	Lower bound	Upper bound
Entity			
Estimated costs for registration per entity (A)[4]	$78,994	$41,087	$936,528
HHS/CDC			
Application review (time) costs per entity.			
Number of staff required for the review of the application (B)	2	2	2
Hourly wage (C)	$48.05	$43.90	$52.20
Overhead multiplier (D)	100%	100%	100%
Time required for the application per staff (hour) (E)	2	1.5	2.5
Estimated costs associated with a 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
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) = (G) × (H) × ((I) + 1) × (J)	$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

As of September 7, 2022, none of the entities already registered with CDC to work with select agents and toxins have amended their registries to work with this agent. The base case is the assumption for the final rule that only one registered entity would amend their registration for the agent and no unregistered entities would undergo the registration process 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 FINAL RULE

	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

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

[4] The estimates from the Regulatory Impact Analysis for the 2005 Select Agent Regulations Final Rule (Regulatory Impact Analysis, 42 CFR Part 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 U.S. dollars value using the Consumer Price Index (CPI) Inflation Calculator (*https://www.bls.gov/data/inflation_calculator.htm*).

The total costs associated with the final rule 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 FINAL RULE

[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 unregistered entities to work with this agent, which are associated with the final rule 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 UNREGISTERED ENTITIES TO WORK WITH THE SARS–COV/SARS–COV–2 CHIMERIC VIRUSES ASSOCIATED WITH THE FINAL RULE

[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
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 final rule 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 an unregistered 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 FINAL RULE 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 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 rule will reduce the risk of human exposure to these 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 are commensurate with the risk of the agent given its intended use,

(2) Develop and implement a written security plan and measures in place that are sufficient to safeguard the 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 of either accidental or intentional release of the modification of a non-select agent with nucleic acids from a select agent, however, the benefits are difficult to quantify. The cost of such an event in morbidity and mortality could be very high. In addition, a release of such a chimera or chimeric virus that is composed of the modification of a non-select agent with nucleic acids from a select agent may 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 final rule. However, implementation of the final rule will provide a means of determining where the modification of a non-select agent with nucleic acids from a select agent is taking place; 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 agent and the consequent avoidance of costs associated with such a release.

This final rule 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 final rule are likely to exceed the estimated costs associated with this final rule.

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

We have examined the impacts of the 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 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 section 804 of the SBREFA. 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 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 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 apply for registration. This represents a non-material/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

D. E.O. 12988: Civil Justice Reform

This rule has been reviewed under E.O. 12988, Civil Justice Reform. Once the rule was 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 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, Packaging and containers, Penalties, Reporting and Recordkeeping requirements, Transportation.

■ For the reasons stated above in the preamble, HHS/CDC adopts the interim final rule which was effective November 17, 2021 (86 FR 64075) as final without change. In accordance with the interim final rule, 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 an HHS select agent. Any individual or entity that possesses SARS–CoV/SARS–CoV–2 chimeric viruses on or after November 17, 2021 must provide notice to CDC regarding their possession and must secure the agent against theft, loss, release, or unauthorized access; and by November 17, 2021, an individual or entity that intends to continue to possess, use, or transfer this agent is required to either register in accordance with 42 CFR part 73 or amend their current registration in accordance with 42 CFR 73.7(h) and meet all of the requirements of select agent regulations (42 CFR part 73). Further, 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 are restricted experiments and require prior approval in accordance with 42 CFR 73.13(a)(3).

Dated: February 27, 2023.

Xavier Becerra,

Secretary, Department of Health and Human Services.

[FR Doc. 2023–04323 Filed 3–2–23; 8:45 am]

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DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Part 679

[Docket No. 220216–0049; RTID 0648–XC694]

Fisheries of the Exclusive Economic Zone Off Alaska; Pacific Cod by Catcher Vessels Less Than 50 Feet Length Overall Using Hook-and-Line Gear in the Central Regulatory Area of the Gulf of Alaska

AGENCY: National Marine Fisheries Service (NMFS), National Oceanic and Atmospheric Administration (NOAA), Commerce.

ACTION: Temporary rule; closure.

SUMMARY: NMFS is prohibiting directed fishing for Pacific cod by for catcher vessels less than 50 feet (15.2 meters (m)) length overall using hook-and-line (HAL) gear in the Central Regulatory Area of the Gulf of Alaska (GOA). This action is necessary to prevent exceeding the A season allowance of the 2023 total allowable catch (TAC) apportioned to catcher vessels less than 50 feet length overall using HAL gear in the Central Regulatory Area of the GOA.

DATES: Effective 1200 hours, Alaska local time (A.l.t.), February 28, 2023, through 1200 hours, A.l.t., June 10, 2023.

FOR FURTHER INFORMATION CONTACT: Obren Davis, 907–586–7241.

SUPPLEMENTARY INFORMATION: NMFS manages the groundfish fishery in the GOA exclusive economic zone according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson-Stevens Fishery Conservation and Management Act. Regulations governing fishing by U.S. vessels in accordance with the FMP appear at subpart H of 50 CFR part 600 and 50 CFR part 679.

The A season allowance of the 2023 Pacific cod TAC apportioned to catcher vessels less than 50 feet (15.2 m) length overall using HAL gear in the Central Regulatory Area of the GOA is 1,026 metric tons (mt) as established by the final 2022 and 2023 harvest specifications for groundfish in the GOA (87 FR 11599, March 2, 2022) and inseason adjustment (87 FR 80088, December 29, 2022).

In accordance with § 679.20(d)(1)(i), the Regional Administrator has determined that the A season allowance of the 2023 Pacific cod TAC apportioned to catcher vessels less than 50 feet (15.2 m) length overall using HAL gear in the Central Regulatory Area of the GOA will soon be reached. Therefore, the Regional Administrator is establishing a directed fishing allowance of 976 mt and is setting aside the remaining 50 mt as bycatch to support other anticipated groundfish fisheries. In accordance with § 679.20(d)(1)(iii), the Regional Administrator finds that this directed fishing allowance has been reached. Consequently, NMFS is prohibiting directed fishing for catcher vessels less than 50 feet (15.2 m) length overall using HAL gear in the Central Regulatory Area of the GOA.

While this closure is effective, the maximum retainable amounts at § 679.20(e) and (f) apply at any time during a trip.

Classification

NMFS issues this action pursuant to section 305(d) of the Magnuson-Stevens Act. This action is required by 50 CFR part 679, which was issued pursuant to section 304(b), and is exempt from review under Executive Order 12866.

Pursuant to 5 U.S.C. 553(b)(B), there is good cause to waive prior notice and an opportunity for public comment on this action, as notice and comment would be impracticable and contrary to the public interest, as it would prevent NMFS from responding to the most recent fisheries data in a timely fashion, and would delay the closure of Pacific cod by catcher vessels less than 50 feet (15.2 m) length overall using HAL gear in the Central Regulatory Area of the GOA. NMFS was unable to publish a notice providing time for public comment because the most recent, relevant data only became available as of February 27, 2023.

The Assistant Administrator for Fisheries, NOAA also finds good cause to waive the 30-day delay in the effective date of this action under 5 U.S.C. 553(d)(3). This finding is based upon the reasons provided above for waiver of prior notice and opportunity for public comment.

Authority: 16 U.S.C. 1801 *et seq.*

Dated: February 27, 2023.

Jennifer M. Wallace,

Acting Director, Office of Sustainable Fisheries, National Marine Fisheries Service.

[FR Doc. 2023–04366 Filed 2–28–23; 4:15 pm]

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