VOC emissions may have little or no effect on future ozone levels.

EPA has reviewed GA EPD's January 22, 2015, SIP revision to remove Stage II requirements for the Area, and is proposing to determine that the associated technical analysis is consistent with EPA's guidance on removing Stage II requirements from a SIP. EPA is also making the preliminary determination that GA EPD's SIP revision is consistent with the CAA and with EPA's regulations related to removal of Stage II requirements from the SIP.

V. Proposed Action

EPA is proposing to approve Georgia's January 22, 2015, SIP revision that changes Georgia's Stage II rule, 391–3–1–.02(2)(zz), to allow for the removal of the Stage II requirement and the orderly decommissioning of Stage II equipment. EPA is proposing this approval because the Agency has made the preliminarily determination that Georgia's January 22, 2015, SIP revision related to the State's Stage II rule is consistent with the CAA and with EPA's regulations and guidance.

VI. Statutory and Executive Order Reviews

Under the CAA, the Administrator is required to approve a SIP submission that complies with the provisions of the Act and applicable federal regulations. *See* 42 U.S.C. 7410(k); 40 CFR 52.02(a). Thus, in reviewing SIP submissions, EPA's role is to approve state choices, provided that they meet the criteria of the CAA. Accordingly, this proposed action merely proposes to approve state law as meeting federal requirements and does not impose additional requirements beyond those imposed by state law. For that reason, this proposed action:

- Is not a ''significant regulatory action'' subject to review by the Office of Management and Budget under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011);
- does not impose an information collection burden under the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*);
- is certified as not having a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*);
- does not contain any unfunded mandate or significantly or uniquely affect small governments, as described in the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4);
- does not have Federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999);
- is not an economically significant regulatory action based on health or safety risks subject to Executive Order 13045 (62 FR 19885, April 23, 1997);
- is not a significant regulatory action subject to Executive Order 13211 (66 FR 28355, May 22, 2001);
- is not subject to requirements of Section 12(d) of the National Technology Transfer and Advancement Act of 1995 (15 U.S.C. 272 note) because application of those requirements would be inconsistent with the CAA; and
- does not provide EPA with the discretionary authority to address, as appropriate, disproportionate human health or environmental effects, using practicable and legally permissible methods, under Executive Order 12898 (59 FR 7629, February 16, 1994).

In addition, the SIP is not approved to apply on any Indian reservation land or in any other area where EPA or an Indian tribe has demonstrated that a tribe has jurisdiction. In those areas of Indian country, the rule does not have tribal implications as specified by Executive Order 13175 (65 FR 67249, November 9, 2000), nor will it impose substantial direct costs on tribal governments or preempt tribal law.

List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Incorporation by reference, Nitrogen dioxide, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

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

Dated: June 18, 2015.

Heather McTeer Toney,

Regional Administrator, Region 4.

[FR Doc. 2015–16076 Filed 7–15–15; 8:45 am]

BILLING CODE 6560–50–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 73

[Docket No. CDC–2015–0050]

RIN 0920–AA58

Possession, Use, and Transfer of Select Agents and Toxins; Addition of Certain Influenza Virus Strains to the List of Select Agents and Toxins

AGENCY: Centers for Disease Control and Prevention, Department of Health and Human Services.

ACTION: Notice of proposed rulemaking and request for comments.

SUMMARY: The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) is proposing to add certain influenza virus strains to the list of HHS select agents and toxins. Specifically, we are proposing to add the influenza viruses that contain the hemagglutinin (HA) from the Goose Guangdong/1/96 lineage (the influenza viruses that contain the hemagglutinin (HA) from the A/Gs/Gd/1/96 lineage), including wild-type viruses, as a non-Tier 1 select agent. We are also proposing to add any influenza viruses that contain the HA from the A/Gs/Gd/1/96 lineage that were made transmissible among mammals by respiratory droplets in a laboratory as a Tier 1 select agent. We have determined that these influenza viruses have the potential to pose a severe threat to public health and safety.

DATES: Comments should be received on or before September 14, 2015.

ADDRESSES: You may submit comments, identified by Regulatory Information Number (RIN), 0920–AA58 or Docket No. CDC–2015–0050 in the heading of this document by any of the following methods:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop A–46, Atlanta, Georgia 30329, ATTN: RIN 0920–AA58.

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.

Docket Access: For access to the docket to read background documents or comments received or to download an electronic version of the NPRM, go to *http://www.regulations.gov.* Comments will be available for public inspection Monday through Friday, except for legal holidays, from 9 a.m. until 5 p.m. at 1600 Clifton Road NE., Atlanta, GA 30329. Please call ahead to 1–866–694–4867 and ask for a representative in the Division of Select Agents and Toxins to schedule your visit. Our general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet as they are received and without change.

FOR FURTHER INFORMATION CONTACT: Robbin Weyant, Director, Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop A–46, Atlanta, Georgia 30329. Telephone: (404) 718–2000.

SUPPLEMENTARY INFORMATION: The preamble to this notice of proposed rulemaking is organized as follows:

I. Public Participation

Interested persons or organizations are invited to participate in this rulemaking by submitting written views, recommendations, and data. We are establishing a docket to provide an opportunity for interested persons to submit comments, research data, and other information that will better inform us about the effect the regulation of these two viruses will have. Comments are invited on any topic related to this rulemaking, but in particular, we welcome comment on the following questions:

(1) Are there any vaccine candidates that include the HA from the A/Gs/Gd/1/96 lineage that should be considered for an exclusion from the regulation?

(2) What are the criteria that could be used for exclusion of attenuated strains which could include vaccine candidates?

(3) What criteria or experimental conditions should be considered in defining transmissibility among mammals via respiratory droplets?

(4) What criteria or experimental conditions should be used to define an appropriate mammalian model of influenza transmission?

(5) What is the impact of designating as a Tier 1 select agent any influenza virus that contains the HA from the A/Gs/Gd/1/96 lineage that was made transmissible among mammals by respiratory droplets in the laboratory?

(6) Is the potential for influenza A H5 viruses that contain the HA from the A/Gs/Gd/1/96 lineage to be a low pathogenic avian influenza (LPAI) (by design or nature) but still pose a severe threat to public health and safety significant enough to regulate as a select agent?

II. Background

A. Historical Background for This Proposed Rulemaking

Since late 2003, the World Health Organization (WHO) has reported over 600 cases of human infection with highly pathogenic avian influenza (HPAI) H5N1 viruses with a mortality rate that exceeds 50 percent in hospitalized patients (Ref 1). Current epidemiologic evidence indicates that, once transmitted into a human host, H5N1 viruses may result in more severe disease in humans than other subtypes of influenza.

One important factor that can account for some of the increased pathogenicity is the hemagglutinin (HA) molecule. Cleavage of the HA molecule by host proteases (enzymes that can break amino acid bonds) enables influenza viruses to productively infect cells (*i.e.,* replicate). For human influenza viruses, replication is generally restricted to the respiratory tract. However, HPAI H5N1 viruses contain a polybasic amino acid sequence in the HA molecule that is not found in human influenza viruses. This feature allows the molecule to be cleaved by a wider variety of proteases throughout the body.

Extrapulmonary dissemination of HPAI H5N1 virus has been documented among some fatal human HPAI H5N1 virus infections. The HA molecule mediates binding of the influenza virus to host cells in the respiratory tract. Human influenza viruses preferentially bind to different receptors than avian influenza viruses (Ref 2). While human influenza virus receptors are more prevalent in the upper respiratory tract, the receptors that bind avian viruses are present in the lower respiratory tract of humans. The ability of H5N1 viruses to bind and infect cells within the lung may contribute to the severity of H5N1 induced viral pneumonia (Ref 3–5). Furthermore, a change from avian- to human-type receptor-binding specificity, as seen with the pandemic strains of 1918 (H1N1), 1957 (H2N2), and 1968 (H3N2), is thought to be a critical step in the adaptation of avian influenza viruses to humans and the ability to transmit efficiently among humans (Ref 6–8). In two independent studies (Ref 9–10), investigators have shown that laboratory modified HPAI H5N1 influenza viruses with certain mutations can be transmitted via the respiratory route between ferrets. Ferrets are widely considered to provide the best animal model for exploring these aspects of influenza virus pathogenicity as they might relate to human infection (Ref 11).

We recognize that all HPAI H5N1 influenza virus HA clades found in humans to date descended from the A/Gs/Gd/1/96 HA lineage (Ref 12). Currently, all HPAI H5 subtype viruses are regulated by the U.S. Department of Agriculture (USDA) Animal and Plant Health Inspection Service (APHIS) whose oversight focuses on the threat to animal health. We conclude that (1) designating as a non-Tier 1 HHS select agent any influenza viruses that contain an HA from the A/Gs/Gd/1/96 lineage and (2) designating as a Tier 1 HHS select agent any influenza viruses that contain the HA from the A/Gs/Gd/1/96 lineage that were made transmissible among mammals by respiratory droplets in a laboratory, will expand the regulatory oversight of this agent to address the potential threat of these viruses to human health. We conclude this expanded oversight is needed because while the USDA required biosafety measures for the HPAI H5 subtype viruses may also be generally beneficial to public health; their regulatory oversight is focused primarily on risks to agricultural animals rather than direct effects on human health.

According to Federal government influenza subject matter experts, it is possible for an influenza virus that contains the HA from the A/Gs/Gd/1/96 lineage to be classified as LPAI, and therefore not be regulated as a select agent by USDA, but still be capable of causing severe disease in humans. Designating these viruses as HHS select agents will ensure that influenza strains with the greatest potential for major direct effects on human health will be regulated with a focus on protection of human health. This approach would include LPAI viruses with the polybasic amino acid sequence removed from the HA molecule that may not pose a severe threat to avian species but could pose a severe threat to public health and safety.

Whether the (1) influenza viruses that contain an HA from the A/Gs/Gd/1/96 lineage and (2) influenza viruses that contain the HA from the A/Gs/Gd/1/96 lineage that were made transmissible among mammals by respiratory droplets in a laboratory should be regulated as a HHS select agent was considered by HHS/CDC's Intragovernmental Select Agents and Toxins Technical Advisory Committee (ISATTAC). The ISATTAC is comprised of Federal government scientists from HHS/CDC, the Biomedical Advanced Research and Development Authority (BARDA) within the Office of the Assistant Secretary for Preparedness and Response (HHS/ASPR) in HHS, the

National Institutes of Health (HHS/NIH), the Food and Drug Administration (HHS/FDA), USDA/APHIS, the USDA/Agricultural Research Service, the USDA/Center for Veterinary Biologics, the Department of Homeland Security, and the Department of Defense. The criteria used by the ISATTAC in its review were the degree of pathogenicity, communicability, ease of dissemination, route of exposure, environmental stability, ease of production, ability to genetically manipulate or alter, long-term health effects, acute morbidity, acute mortality, available treatment, status of host immunity, vulnerability of special populations, and the burden or impact on the health care system. The ISATTAC recommended that (1) the influenza viruses containing an HA from the A/Gs/Gd/1/96 lineage should be regulated as an HHS select agent (non-Tier 1), and (2) the influenza viruses that contain the HA from the A/Gs/Gd/1/96 lineage that were made transmissible among mammals by respiratory droplets in a laboratory should be regulated as a Tier 1 HHS select agent. In making its recommendations, the ISATTAC considered both the historical data regarding the A/Gs/Gd/1/96 lineage and data from current *in vitro* and *in vivo* animal studies. The virulence of viruses of this lineage, the data showing transmissibility of genetically modified H5N1 viruses among ferrets, together with the fact that the level of immunity in the general population is low, were all considered. In addition, the ISATTAC recommended limiting the Tier 1 status to only those viruses that were made transmissible among mammals by respiratory droplets. Transmission by respiratory droplets would be the most similar route to normal human-to-human transmission, as opposed to transmission by other respiratory routes such as intra nasal exposure which is not a normal route of human infection. In addition, the ISATTAC voiced concern that an influenza pandemic caused by viruses containing an HA from the A/Gs/Gd/1/96 lineage, could potentially overwhelm the health care system.

On July 2, 2010, the President signed Executive Order 13546, ''Optimizing the Security of Biological Select Agents and Toxins in the United States'' that directed the Secretaries of HHS and USDA to designate a subset of the select agents and toxins list (Tier 1) that presents 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. Executive Order 13546 also established the Federal Experts Security Advisory Panel (FESAP) to advise the HHS and USDA Secretaries on the designation of Tier 1 agents and toxins. In December of 2010, the FESAP provided recommendations on the composition of the HHS and USDA select agent and toxin lists, including a subset of agents and toxins recommended for Tier 1 designation.

In accordance with Executive Order 13546, HHS/CDC published a final rule (77 FR 61084) on October 5, 2012 which designated those select agents and toxins that present the greatest risk of deliberate misuse with the most significant potential for mass casualties or devastating effects to the economy, critical infrastructure, or public confidence as ''Tier 1'' agents; established new security requirements for entities possessing Tier 1 agents, including the requirement to conduct pre-access and ongoing suitability assessments of personnel with access to Tier 1 agents and toxins; and made revisions to the regulations to clarify regulatory language concerning security, training, biosafety, and incident response.

On October 17, 2012, HHS/CDC published a request for information and comment (RFI) (77 FR 63783) to provide an opportunity for interested persons to submit comments, research data, and other information to better inform us about the risk to public health and safety posed by HPAI H5N1 influenza viruses containing the HA from the A/Gs/Gd/1/96 lineage.

We received responses from thirty-one commenters associated with academic, private and commercial institutions and professional societies. The majority of the commenters addressed the specific questions found in the request for information.

Twenty-seven of the thirty-one commenters asserted that influenza viruses of this lineage (1) exhibit high lethality in humans (exceeds 50% mortality rate, (Ref 1), (2) exhibit efficient aerosol transmissibility and retention of virulence in mammals following experimental adaptation to mammals in a laboratory setting, and (3) potentially may acquire efficient aerosol transmissibility in mammals and retention of virulence through natural adaptation to mammals in nature. The commenters concluded that HPAI H5N1 influenza viruses containing the HA from the Goose/Guangdong/1/96 lineage pose a severe threat to public health and safety and warrant regulation as HHS select agents. One commenter stated that listing these viruses as HHS select agents would ''enable the regulatory process to evaluate, and to respond to, impacts on human health as well as impacts on agriculture.''

Twenty commenters also stated that HPAI H5N1 viruses that contain the HA from the A/Gs/Gd/1/96 lineage should not be designated as Tier 1 agents. The commenters believed that select agent biosafety and security requirements currently in place in regards to HPAI are adequate to protect against a release (accidental or intentional) or theft (13). However, some commenters also stated that any laboratory generated influenza viruses that contain the hemagglutinin (HA) from the A/Gs/Gd/1/96 lineage that are mammalian transmissible by the respiratory route should be regulated as a Tier 1 HHS select agent due to the combination of (1) high human virulence (presumed from that of their precursors), (2) potentially high human-to-human transmissibility, (3) nonexistence in the wild, and (4) lack of adequate control measures to contain its spread if released in the environment. The same twenty commenters felt that the mammalian-transmissible H5N1 strains are a unique or nearly unique threat to public health and therefore warrant Tier 1 status.

HHS/CDC also asked if there were other influenza strains containing HA from Goose/Guangdong/1/96 lineage that would pose a severe threat to public health and safety. None of the commenters was aware of any other strains that would pose a severe threat to public health and safety.

HHS/CDC asked if special precautions (*i.e.,* safety and containment measures) should be considered when working with diagnostic specimens suspected of containing HPAI H5N1 influenza viruses containing the HA from the A/Gs/Gd/1/96 lineage (*i.e.,* any precautions versus none at all, precautions beyond those usual for clinical samples and/or laboratory microbes, etc.). The commenters varied on their recommendations. Some commenters recommended that diagnostic work with this virus should be performed in BSL–3 laboratories. Other commenters recommended that diagnostic work be carried out in BSL–2 facility with special precautions (face masks, etc.) or in an enhanced BSL–2 facility, which would include performing all open container work and aerosol-producing procedures in a Class II biological safety cabinet.

HHS/CDC asked if special precautions (*i.e.,* safety and containment measures) should be considered when working with strains of HPAI containing the HA from the A/Gs/Gd/1/96 lineage that have been shown to be transmissible between mammals beyond those

recommended for non-mammalian transmissible strains. The commenters varied on their recommendations. Commenters recommended that work with mammalian aerosol-transmissible H5N1 strains should be performed only using the highest physical containment and operational procedures (*i.e.,* BSL–4 containment and procedures) and only after an open, transparent, and independent process of risk-benefit assessment and risk mitigation. Some commenters recommended that work with diagnostic specimens suspected of containing mammalian-transmissible H5N1 virus should be treated under BSL–3+ or BSL–4 conditions where possible (and consistent with the need for rapid diagnosis), and in any case should be handled only by individuals with training and experience with high-containment pathogens. Some commenters recommended that H5N1 vaccination of those working with transmissible H5N1 viruses should probably be required, but an increase in containment level is not necessary.

HHS/CDC, with advice from the ISATTAC and from public input received in response to the RFI, published in CDC's Morbidity and Mortality Weekly Report (MMWR) (June 28, 2013/62(RR06);1–7) Biosafety Guidelines for Working with Influenza Viruses Containing an HA from the A/goose/Guangdong/1/96 lineage which can be found at *http://www.cdc.gov/mmwr/preview/mmwrhtml/rr6206a1.htm?s_cid=rr6206a1_w.*

Based on the public comments to the RFI and in consultation with the ISATTAC, we are proposing a tiered approach to the regulation of influenza viruses containing the HA from the A/Gs/Gd/1/96 lineage. Under our proposal, influenza viruses that contain the HA from the A/Gs/Gd/1/96 lineage, including wild-type and laboratory-derived viruses, will be regulated as a non-Tier 1 select agent. This designation recognizes the public health threat posed by the high mortality rate, lack of a readily available vaccine, and the absence of immunity in the population. The USDA regulates avian influenza virus, although the USDA regulations exclude any ''low pathogenic strains of avian influenza virus . . . provided that the individual or entity can identify that the agent is within the exclusion category'' (Ref 13). Accordingly, all reported human infections with influenza viruses containing the HA from the A/Gs/Gd/1/96 lineage are considered to be HPAI by the USDA and therefore are regulated as select agents by USDA. However, influenza subject matter experts have indicated that there is a possibility that influenza viruses that contain the HA from the A/Gs/Gd/1/96 lineage could be classified as LPAI, as a result of mutation or genetic manipulation and yet cause severe disease in humans. Under the current paradigm, these strains would not be regulated as select agents. Our regulatory strategy would address this potential gap in select agent oversight. We do not anticipate this listing to have a significant impact on the select agent stakeholder community as most entities working with this agent are already registered to work with select agents.

We are also proposing the regulation as a Tier 1 HHS select agent influenza viruses that contain the HA from the A/Gs/Gd/1/96 lineage that were made transmissible among mammals by respiratory droplets in a laboratory. Designating these viruses as Tier 1 recognizes the higher public health risk posed by these viruses and establishes security requirements above those currently proscribed by the USDA for HPAI. This strategy also recognizes that HHS considers these types of experiments with these viruses to be of a significant public health concern and is consistent with recent United States Government policy regarding dual use research of concern and gain-of-function research, and the framework for ''Guiding US HHS Funding Decisions about Research Proposals with the Potential for Generating Highly Pathogenic Avian Influenza H5N1 Viruses that are Transmissible among Mammals by Respiratory Droplets'' (February 2013); and therefore warranting increased oversight (Ref 14–16). Designating these agents as HHS select agents also addresses a potential gap in current select agent oversight since laboratory-generated viruses that are capable of causing human disease do not necessarily have to be HPAI.

We recognize that this new regulatory paradigm could have implications on the development of vaccines needed during an influenza outbreak in the human population. We understand the importance of vaccine development and availability. Accordingly, we are seeking comments on how to best accommodate the need of vaccine development while protecting the public health and safety from the accidental or intentional release of these viruses. We are interested in receiving comments on criteria that could be used for the exclusion of vaccine reassortants such as those well-characterized vaccine strains or backbones (*e.g.,* PR8) that have been demonstrated to not pose a severe threat to public health and safety.

B. Legal Authorities

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Response Act) requires the HHS Secretary to establish by regulation a list of biological agents and toxins that have the potential to pose a severe threat to public health and safety. In determining whether to include an agent or toxin on the list, the HHS Secretary considers criteria such as the effect on human health of exposure to an agent or toxin; the degree of contagiousness of the agent and the methods by which the agent or toxin is transferred to humans; the availability and effectiveness of pharmacotherapies and immunizations to treat and prevent illnesses resulting from an agent or toxin; and the needs of children and other vulnerable populations. The current list of HHS select agents and toxins can be found at 42 CFR 73.3 (HHS select agents and toxins) and 42 CFR 73.4 (Overlap select agents and toxins). The list of HHS and Overlap select agents and toxins is available at: *http://www.selectagents.gov/SelectAgentsandToxinsList.html.*

III. Alternatives Considered

After we published the request for information and comment (RFI) (77 FR 63783) on October 17, 2012, we reviewed all comments received regarding the risk to public health and safety posed by HPAI H5N1 influenza viruses containing the HA from the A/Gs/Gd/1/96 lineage. Even though all HPAI H5 subtype viruses are regulated by USDA/APHIS, whose oversight focuses on the threat to animal health, the majority of commenters believed that HPAI H5N1 influenza viruses containing the HA from the Goose/Guangdong/1/96 lineage pose a severe threat to public health and safety and warrant regulation as HHS select agent. Given the recent research that has identified specific determinants of transmission for H5N1 influenza viruses in ferrets, we conclude that listing influenza viruses that contain an HA from the A/Gs/Gd/1/96 lineage as an HHS select agent would allow us to focus on biosafety measures that would mitigate the risk to public health and safety.

In researching the proposed change, we also reviewed how USDA/APHIS designated the avian influenza virus (highly pathogenic) as a non-Tier 1 agent. We conclude that (1) listing influenza viruses that contain an HA from the A/Gs/Gd/1/96 lineage as a non-Tier 1 HHS select agent and (2) listing any influenza viruses that contain the

HA from the A/Gs/Gd/1/96 lineage that were made transmissible among mammals by respiratory droplets in a laboratory as a Tier 1 HHS select agent, will ensure that the regulatory oversight of this agent will expand to include the potential threat of these viruses to human health.

III. Regulatory Analyses

A. Executive Orders 12866 and 13563

Executive Orders 12866 (Regulatory Planning and Review) and 13563 (Improving Regulation and Regulatory Review) 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). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility.

Under E.O. 12866 HHS must determine whether a regulatory action is ''significant.'' A ''significant regulatory action'' under E.O. 12866 is defined as (1) an action that is likely to result in a rule that may have an annual effect on the economy of $100 million or more, or adversely and materially affects a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities (or an economically significant action); (2) creates a serious inconsistency or otherwise interferes with an action taken or planned by another agency; (3) materially alters the budgetary impact of entitlements, grants, user fees or loan programs or the rights and obligations of recipients; or (4) raises novel legal or policy issues.

Based on a literature and database search, the current possessors are academic and government institutions. As such, we conclude that the majority of the viruses that will be regulated by HHS are already regulated by USDA. If it is determined that there are unregistered possessors of the agent as a result of the comments received from this proposed rule, we will include a grace period to allow these individuals to become compliant with the regulations prior to the full implementation. As a result of the search, we conclude that the addition of influenza viruses that contain an HA from the A/Gs/Gd/1/96 lineage to the HHS select agent list will not have an annual effect on the economy of $100 million or more, or adversely and materially affects a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or state, local or tribal governments or communities. We also believe that this change will not create a serious inconsistency or otherwise interferes with an action taken or planned by another agency; materially alters the budgetary impact of entitlements, grants, user fees or loan programs or the rights and obligations of recipients; or raises novel legal or policy issues. However, we would be interested in receiving any information from the public on the potential for an economic impact that might result from this proposal.

B. Regulatory Flexibility Act

We are continuing to assess the potential economic effects of this action on small entities, but based on a literature and database search that the current possessors are academic and government institutions, we conclude that this proposed rule will not have a significant economic impact on a substantial number of small entities.

C. Paperwork Reduction Act

In accordance with section 3507(d) of the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection and/or recordkeeping requirements included in this proposed rule have been approved by the Office of Management and Budget (OMB) under OMB control number 0920–0576 (expiration November 30, 2015).

Please send written comments on the new information collection contained in this proposed rule or requests for a copy of the data collection to Leroy A. Richardson, 1600 Clifton Road, MS–D74, Atlanta, GA 30329 or send an email to *omb@cdc.gov*.

Based on a literature and database search, the current possessors are academic and government institutions and are already regulated by USDA. Since entities who possess influenza viruses that contain an HA from the A/Gs/Gd/1/96 lineage and are HPAI are already regulated by USDA/APHIS, the proposed rule will require an entity to make an amendment to its registration with the Federal Select Agent Program using relevant portions of APHIS/CDC Form 1 (Application for Registration for Possession, Use, and Transfer of Select Agents and Toxins) to indicate the registration for the viruses regulated by HHS. Estimated time to amend this form is 45 minutes for one select agent. Since this agent is currently regulated by USDA/APHIS, we conclude that there is no increase in the number of respondents.

D. Executive Order 12988: Civil Justice Reform

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. This proposed rule: (1) Preempts all State and local laws and regulations that are inconsistent with this rulemaking; (2) has no retroactive effect; and (3) does not require administrative proceedings before parties may file suit in court challenging this rule.

E. Executive Order 13132: Federalism

This proposed rule has been reviewed under E.O. 13132, Federalism. The document does not propose any regulation that would expressly preempt State, local, and Indian Tribe requirements, or that would have any substantial direct effects on the States, or on the distribution of power and responsibilities among the various levels of government.

F. Plain Writing Act of 2010

Under Public Law 111–274 (October 13, 2010), executive branch Departments and Agencies are required to use ''clear Government communication that the public can understand and use.'' E.O. 13563 (Improving Regulation and Regulatory Review) states that ''[our regulatory system] must ensure that regulations are accessible, consistent, written in plain language, and easy to understand.'' HHS has attempted to use plain language in writing this proposed rule and seek comment from the public on our attempt to use plain language in this rulemaking.

V. References

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United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (*http://www.phe.gov/s3/dualuse/Documents/oversight-durc.pdf*).

List of Subjects

Biologics, Influenza viruses, Packaging and containers, Penalties, Select agents and toxins, Reporting and recordkeeping requirements, Transportation.

For the reasons stated in the preamble, the Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, proposes to amend 42 CFR part 73, as follows:

PART 73 [AMENDED]

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

Authority: 42 U.S.C. 262a; sections 201–204, 221 and 231 of Title II of Public Law 107–188, 116 Stat. 637 (42 U.S.C. 262a).

■ 2. Add two entries to the list in paragraph (b) of § 73.3 to read as follows:

§ 73.3 HHS select agents and toxins.

* * * * *

(b) * * *

Influenza viruses that contain the hemagglutinin (HA) from the Goose Guangdong/1/96 lineage,

Any laboratory generated Influenza viruses that contain the hemagglutinin (HA) from the A/Goose Guangdong/1/96 lineage that are mammalian transmissible by the respiratory route *

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Dated: July 8, 2015.

Sylvia M. Burwell,

Secretary.

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