population who, as a result of their location, cultural practices, or other factors, may have atypical or disproportionately high and adverse human health impacts or environmental effects from exposure to the pesticides discussed in this document, compared to the general population.

II. What action is the Agency taking?

EPA is announcing receipt of a pesticide petition filed under section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA), (21 U.S.C. 346a), requesting the establishment or modification of regulations in 40 CFR part 180 for residues of pesticide chemicals in or on the food commodity, wheat, grain. The Agency is taking public comment on the request before responding to the petitioner. EPA is not proposing any particular action at this time. EPA has determined that the pesticide petition described in this document contains data or information prescribed in FFDCA section 408(d)(2); however, EPA has not fully evaluated the sufficiency of the submitted data at this time or whether the data supports granting of the pesticide petition. After considering the public comments, EPA intends to evaluate whether and what action may be warranted. Additional data may be needed before EPA can make a final determination on this pesticide petition.

Pursuant to 40 CFR 180.7(f), a summary of the petition that is the subject of this document, prepared by the petitioner, is included in a docket EPA has created for this rulemaking. The docket for this petition is available online at *http://www.regulations.gov.*

As specified in FFDCA section 408(d)(3), (21 U.S.C. 346a(d)(3)), EPA is publishing notice of the petition so that the public has an opportunity to comment on this request for the establishment or modification of regulations for residues of pesticides in or on the food commodity, wheat, grain. Further information on the petition may be obtained through the petition summary referenced in this unit.

EPA has received a pesticide petition (PP #1F7955) from Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419 proposing, pursuant to section 408(d) of FFDCA, 21 U.S.C. 346a(d), to amend 40 CFR 180.559 by amending the tolerances for residues of the herbicide, clodinafop-propargyl (propanoic acid, 2-[4-(5-chloro-3-fluoro-2-pyridinyl)oxy]phenoxy]-,2-propynyl ester, (2R)-) and its acid metabolite (propanoic acid, 2-[4-[5-chloro-3-fluoro-2-pyridinyl)oxy]phenoxy]-, (2R)-), in or on the raw agricultural commodity wheat, grain from 0.1 parts per million (ppm) to 0.02 ppm.

List of Subjects

Environmental protection, Agricultural commodities, Feed additives, Food additives, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: October 4, 2012.

Lois Rossi,

Registration Division, Office of Pesticide Programs.

[FR Doc. 2012–25549 Filed 10–16–12; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 73

[Docket: CDC–2012–0010]

Influenza Viruses Containing the Hemagglutinin from the Goose/Guangdong/1/96 Lineage

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

ACTION: Request for information and comment.

SUMMARY: The Centers for Disease Control and Prevention (CDC) within the Department of Health and Human Services (HHS) announces the opening of a docket to obtain information and comments from the public to questions concerning highly pathogenic avian influenza (HPAI) H5N1 viruses that contain a hemagglutinin (HA) from the Goose/Guangdong/1/96 lineage, and their potential to pose a severe threat to public health and safety. This information will be considered in a determination of whether such viruses should be listed as HHS select agents, by revising the HHS Select Agent Regulations (42 CFR Part 73).

DATES: Electronic or written comments should be received on or before December 17, 2012.

ADDRESSES: You may submit comments identified by Docket Number CDC–2012–0010, 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 30333, Attn: Docket Number: CDC–2012–0010.

Instructions: All submissions received must include the agency name and docket number (CDC–2012–0010) for this notice. All relevant comments received will be posted without change to *www.regulations.gov,* including any personal information provided. For access to the docket to read background documents or comments received, go to *www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: Dr. Robbin Weyant, Director, Division of Select Agents and Toxins, Centers for Disease Control and Prevention, 1600 Clifton Road NE., Mailstop A–46, Atlanta, Georgia 30333. Telephone: (404) 718–2000.

SUPPLEMENTARY INFORMATION:

I. Background

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 (chemicals that can break amino acid bonds) enables influenza viruses to productively infect cells (i.e., replicate). For human influenza viruses, replication is 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 and consequently, HPAI H5N1 viruses can replicate systemically in avian species.

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 recent independent studies (Ref 9 and Ref 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 clades found in humans to date have been derived from the Goose/Guangdong/1/96 lineage, and the HA molecule enables the virus to infect a host cell. Thus, we are interested in receiving information and comments on whether the influenza viruses that contain a hemagglutinin (HA) from the Goose/Guangdong/1/96 lineage have the potential to pose a severe threat to public health and safety (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 and safety. Listing influenza viruses that contain an HA from the goose/Guangdong/1/96 lineage as an HHS select agent will ensure that the focus of regulation will also be on the potential impact of these viruses on human health as well as agriculture. While USDA sets biosafety measures that may also be more generally beneficial to public health, its focus with respect to select agent designation is primarily on risks to agricultural animals, rather than direct effects on human health. There is precedence (e.g., *Bacillus anthracis*) for including agents that have both human and agricultural impacts on both the HHS and USDA Select Agent Lists. Designating HPAI containing an HA from the Goose/Guangdong/1/96 lineage an HHS select agent, in addition to its status as a USDA select agent, may help to ensure that HPAI strains that have the greatest potential for major direct effects on human health will be regulated with a focus on protection of human health.

The question of whether the influenza viruses that contain an HA from the Goose/Guangdong/1/96 lineage pose a severe threat to public health and safety 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 (DHS), and the Department of Defense (DOD). 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. ISATTAC made the recommendation that the influenza viruses containing an HA from the Goose/Guangdong/1/96 lineage do have the potential to pose a severe threat to public health and safety. In making its recommendation to HHS/CDC, the ISATTAC considered both the historical data regarding the Goose/Guangdong/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. Further, in its recommendation the ISATTAC voiced concern that an influenza pandemic caused by viruses containing an HA from the Goose/Guangdong/1/96 lineage, could potentially overwhelm the health care system. The ISATTAC also recognized that the study of the Goose/Guangdong/1/96 lineage-derived viruses could lead to significant public health benefits for understanding pandemic influenza, improved diagnostics, and the development of more effective countermeasures. Therefore, the risks posed by these viruses need to be weighed against any adverse impact that a regulation will have on legitimate research.

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. The 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 the HHS and USDA Select Agent regulatory programs with recommendations on updating the HHS and USDA Select Agent and Toxin lists, including a subset of agents and toxins recommended for Tier 1 designation.

On October 3, 2011, HHS/CDC published a notice of proposed rulemaking (76 FR 61206) in which we proposed a list of select agents and toxins that should be considered Tier 1 select agents and toxins. The proposed Tier 1 agents and toxins that were based on Executive Order 13546 and the recommendations from FESAP were scored against 20 criteria by over 60 Subject Matter Experts representing the Federal life sciences, public health, law enforcement, security, and intelligence communities. The criteria included:

- The relative ease with which a particular select agent or toxin might be disseminated or transmitted from one human to another or into the environment where it could produce a deleterious effect upon human health;
- The potential for a high mortality rate;
- The potential for a major human health impact;
- Select agents or toxins whose misuse might result in public panic or other social or economic disruption; and
- Select agents or toxins whose use might require Federal, State, and/or local officials to take special action in planning for major human health disasters.

We proposed that the following agents should be designated as Tier 1 agents: *Bacillus anthracis,* Botulinum neurotoxin, Botulinum neurotoxin producing species of *Clostridium, Burkholderia mallei, B. pseudomallei, Francisella tularensis,* Marburg virus, Variola major virus, Variola minor virus, and *Yersinia pestis.* On the same day, USDA/APHIS published a companion rule in the **Federal Register** proposing its list of select agents and toxins that should be considered Tier 1 select agents and toxins. Although USDA/APHIS regulates HPAI viruses as select agents, they did not propose to designate HPAI viruses as Tier 1 select agents. Given the above criteria used by the FESAP, we would welcome comment on whether HPAI H5N1 influenza viruses containing the HA from the Goose/Guangdong/1/96 lineage should be listed as a Tier 1 select agent. The final determination of whether or not to designate this particular lineage

of H5N1 HPAI as Tier 1 would be a collaborative process between HHS and USDA. HHS and USDA would continue to work closely together whether or not both HHS and USDA designate these viruses as Tier 1 Select Agents.

II. Establishment of a Docket and Request for Specific Input on Certain Topics

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 risk posed by HPAI H5N1 influenza viruses containing the HA from the Goose/Guangdong/1/96 lineage to public health and safety. In particular, we welcome comment on the following questions:

(1) Do HPAI H5N1 influenza viruses containing the HA from the Goose/Guangdong/1/96 lineage pose a severe threat to public health and safety?

(2) Are there other influenza strains containing HA from Goose/Guangdong/1/96 lineage that would also pose a severe threat even if they were not fully of HPAI H5N1 origin?

(3) Are there any other HPAI H5N1 influenza strains that have been identified to pose a severe threat to public health and safety?

(4) Should these viruses be regulated as HHS select agents?

(5) If these viruses should be regulated as HHS select agents, should these viruses be designated as Tier 1 select agents?

(6) Should special precautions (i.e., safety and containment measures) be considered when working with diagnostic specimens suspected of containing HPAI H5N1 influenza viruses containing the HA from the Goose/Guangdong/1/96 lineage (i.e., any precautions versus none at all, precautions beyond those usual for clinical samples and/or laboratory microbes, etc.)? and

(7) Should special precautions (i.e., safety and containment measures) be considered when working with strains of HPAI containing the HA from the Goose/Guangdong/1/96 lineage that have been shown to be transmissible between mammals beyond those recommended for non-mammalian transmissible HPAI (Ref 13 and Ref 14)?

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13. *Guidelines for Avian Influenza Viruses* (*http://www.selectagents.gov/resources/Guidelines%20for%20Avian%20Influenza%20Viruses_2011-11-4.pdf*).
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Dated: October 9, 2012.

Kathleen Sibelius,

Secretary.

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