

**ABSA**

American Biological Safety Association

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President-Elect

Paul J. Meechan, PhD, RBP, CBSP
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Division of Select Agents and Toxins
Center for Disease Control Prevention
1600 Clifton Road NE, Mailstop A-46
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Re: Federal Register Docket CDC-2012-0010

Ladies and Gentlemen,

Secretary

Melissa Morland, MS, RBP, CBSP
University of Maryland—Baltimore
Environmental Health & Safety
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The American Biological Safety Association (ABSA) is an international group of biological safety professionals and is known as one of the world's foremost resources on biological safety practices. ABSA has reviewed the Federal Register Docket CDC-2012-0010: Influenza Viruses Containing the Hemagglutinin from the Goose/Guangdong/1/96 Lineage, and would like to offer the following responses to the seven posed questions:

Treasurer

Rosamond Rutledge-Burns, MS, CBSP
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Question (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?*

HPAI H5N1 infection in humans is rare. In addition, H5N1 in its current form does not transmit efficiently from person to person. ABSA fully recognizes that HPAI H5N1 can, under certain circumstances, pose a significant concern for public health given the high case fatality rate once a person is ill with the virus; however, ABSA does not believe that H5N1 viruses containing the Hemagglutinin from the Goose/Guangdong/1/96 Lineage, in their current form, pose a severe threat to public health and safety.

Past-President

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Question (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?*

At this time, ABSA is not aware of any other strains that would pose a severe threat to public health and safety.

Councilors

Marian M. Downing, RBP, CBSP (13)
Robert A. Heckert, DVM, PhD, CBSP (14)
Domenica M. Zimmerman (15)
Scott Alderman, CBSP (15)

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

At this time, ABSA is not aware of any other strains that would pose a severe threat to public health and safety.

2013 Biosafety Conference Chairpersons

Scientific Program Committee
Dawn P. Wooley, PhD, RBP, CBSP
Exhibitors Advisory Committee
Stephen Sowa, MS
Local Arrangements Committee
Timothy Sturgis, RBP

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

These viruses are currently regulated as USDA select agents. Therefore, their possession, use and transfer require adherence to strict safety and security requirements. These requirements are essentially identical to the requirements for select agents regulated by HHS. ABSA believes there would be no added benefit to adding these viruses to the HHS list.

Executive Director

Edward J. Stygar, III, MBA, CAE
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Question (5): *If these viruses should be regulated as HHS select agents, should these viruses be designated as Tier 1 select agents?*

ABSA does not believe these viruses warrant regulation as Tier 1 select agents. The current regulation of these viruses as USDA select agents ensures proper safety and security. Regulation as Tier 1 select agents could discourage future research efforts related to these viruses.

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

Diagnostic laboratories play a critical role in the early detection of an outbreak. Such laboratories are typically equipped to operate at biosafety level-2 (BSL-2) and are staffed with technicians that are properly trained for work at this containment level. ABSA believes that clinical samples suspected of containing HPAI viruses can be safely handled at an enhanced BSL-2, which includes performing all open container work and aerosol-producing procedures in a Class II biological safety cabinet.

Question (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)?*

HPAI viruses are currently regulated by the USDA as select agents. The USDA requires BSL-3 containment plus numerous enhancements (i.e., respiratory protection for workers) for work with these viruses in the laboratory and ABSL-3 with enhancement when working with animals in negative pressure animal isolators and BSL-3 Ag containment when working with loose-housed animals. ABSA believes that BSL-3 and ABSL-3 containment plus the enhancements and BSL-3 Ag required by the USDA provide proper protection of workers and the environment for work with these strains in the laboratory and in animals.

ABSA appreciates the opportunity to provide comments on the docket.

Sincerely,



Barbara Fox Nellis, RBP, CBSP
President
American Biological Safety Association