

## Federal Select Agent Program: SA Gram/IP Gram

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**DATE:** June 5, 2017

**TO:** Responsible Officials and Alternate Responsible Officials

**SUBJECT:** Permits for Asian lineage H7N9 strains

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On February 18, 2017, the OIE (World Organisation for Animal Health) reported samples obtained from live bird markets in China, sent to the National Reference Laboratory for Avian Influenza by the Guangdong veterinary authorities, tested positive for H7N9 **highly pathogenic** avian influenza virus<sup>[1]</sup> (HPAIV). Retrospectively, samples were identified as H7N9 HPAIV in Guangdong extending back to as early as October 2016. This Asian lineage H7N9 HPAIV is **not** related to the recent finding of North American wild bird lineage H7N9 HPAIV in United States (US) poultry during March 2017.

The Asian H7N9 lineage was first reported in February 2013 as a low pathogenic avian influenza virus (LPAIV) which continues to circulate primarily in live bird markets in China, and causes human morbidity and mortality. As of April 2017, the Asian lineage H7N9 HPAIV has been isolated from poultry, the environment, and from people ([http://www.fao.org/ag/againfo/programmes/en/empres/h7n9/situation\\_update.html](http://www.fao.org/ag/againfo/programmes/en/empres/h7n9/situation_update.html)).

In light of these recent findings, additional supporting information will now be required for facilities requesting Asian lineage H7N9 strains in order to differentiate LPAIV from HPAIV. HPAIV is a USDA VS Select Agent, and may only be possessed, used or transferred in the United States by entities registered with the Federal Select Agent Program.

In general, any request to receive low pathogenicity avian influenza A viruses for import and/or interstate transportation requires a **VS 16-6 permit** from the National Import Export Service (NIES), Organisms and Vectors (OV) Unit ([www.aphis.usda.gov/animal-health/organisms-vectors](http://www.aphis.usda.gov/animal-health/organisms-vectors)). This permit can be requested via the **VS 16-3 permit application**.

As of the date of this notice, facilities requesting to receive **Asian lineage H7N9 LPAIV** will also be required to obtain a *letter of exclusion* at the time of the **VS 16-3 permit application** submission, which indicates that the material requested demonstrates a low pathogenicity phenotype. To obtain a *letter of exclusion*, provide either **A**) HA-gene sequence data consistent with H7N9 LPAIV genotype, and *in vivo* testing per OIE indicating a low pathogenic phenotype (either intravenous pathogenicity index [IVPI] of <1.2, or chicken lethality assay), or **B**) next generation full genome sequence data with depth of

coverage >1000-fold to aid in excluding the potential of co-infection/ contamination with a high pathogenicity genotype, and duplicate plaque characterization testing using chicken embryo fibroblast cells (or other suitable cell line) with and without trypsin. Data should be sent to [Agsas@aphis.usda.gov](mailto:Agsas@aphis.usda.gov).

A facility requesting to receive Asian lineage H7N0 LPAIV will also be required to request a *letter of exclusion* from APHIS (indicating that the material requested demonstrates a low pathogenicity phenotype) at the time of the **VS 16-6 permit** application submission.

**Permit application** requests to Centers for Disease Control (CDC) for the importation of **Asian lineage H7N9** strains will be held by CDC until an approved **APHIS VS 16-6 permit** is submitted to the CDC Import Permit program as supporting documentation.

Movement of all other HPAI material requires an APHIS/CDC Form 2 “Request to Transfer Select Agents and Toxins” <https://www.selectagents.gov/form2.html>.

Additional information related to avian influenza viruses can be found at [https://www.selectagents.gov/resources/Guidelines for Avian Influenza Viruses 2011-11-4.pdf](https://www.selectagents.gov/resources/Guidelines%20for%20Avian%20Influenza%20Viruses%202011-11-4.pdf).

If you have any questions regarding this notice, please contact the Federal Select Agent Program at 301-851-3300 option 3 (8:00 am to 4:30 pm Eastern) or [agsas@aphis.usda.gov](mailto:agsas@aphis.usda.gov) for APHIS/AgSAS entities, and 404-718-2000 or [LRSAT@CDC.gov](mailto:LRSAT@CDC.gov) for CDC/DSAT entities.

<sup>1</sup>There are molecular and biologic criteria, specific to chickens, which define an avian influenza virus as either low or high pathogenicity. Such criteria do not address infectivity nor pathogenicity in humans.

Respectfully,

Freeda Isaac and Samuel Edwin

Directors

Federal Select Agent Program