

Recommendation of the ZKBS on the risk assessment of Influenza viruses as donor and recipient organisms for genetic engineering operations according to § 5 (1) GenTSV

Viruses of the genera *Alphainfluenzavirus*, *Betainfluenzavirus*, *Gammainfluenzavirus* and *Del-tainfluenzavirus* are classified in risk groups 2 and 3 in accordance with the Worker Protection Directive 2000/54/EC (amended by Directive (EU) 2019/1833 of 24 October 2019). Since 2005, the ZKBS has classified various subtypes and strains of influenza viruses into risk groups, including some in risk group 3. These are viruses that pose an increased pandemic risk because of insufficient immunity in the population, or subtypes and strains that are generally associated with particularly severe disease in humans or poultry.

Recommendation

In accordance with § 5 paragraph 1 GenTSV in conjunction with the criteria in Annex 1 of the GenTSV, the following influenza A viruses are assigned to **risk group 3** as donor and recipient organisms for genetic engineering operations as a precautionary measure:

- variant of the H1N1 subtype of the 1918 Spanish flu
- highly pathogenic avian influenza A viruses (HPAIV)
- novel avian influenza A virus of subtype H7N9
- non-circulating (non-contemporary) influenza A viruses of subtype H2N2
- bat influenza virus of subtype H9N2 (strain A/bat/Egypt/381 OP/2017)

Additional safety measures

When performing genetic engineering operations with influenza A viruses of risk group 3, the wearing of respiratory protective equipment with a retention capacity of class P3 (e.g. FFP3 mask) is recommended in addition to the common level 3 safety measures.

When performing genetic engineering operations with the H1N1 subtype of the 1918 Spanish flu virus, it is also recommended to shower when leaving the laboratory. This includes changing clothes.

Notes

Reference is made to the following further ZKBS recommendations on influenza viruses:

- [Evaluation of the Influenza A virus mutant "Delta NS1"](#) (2001), Ref. 6790-10-71
- [Risk assessment of Highly pathogenic avian Influenza virus A strains of the subtypes H5 and H7 and derived laboratory strains](#) (2015), Ref. 6790-05-02-34
- [Risk assessment of Influenza A virus strains SC35 and SC35M](#) (2015), Ref. 45242.0116
- [Risk assessment of the novel avian Influenza A virus H7N9](#) (updated 2013), Ref. 45242.0103
- [Classification of genetic engineering operations with highly pathogenic avian Influenza A viruses \(HPAIV\) which possess the potential for efficient airborne transmission between mammals](#) (2013), Ref. 45310.0108
- [Risk assessment of genetic engineering operations with recombinant Influenza A viruses](#) (updated 2019), Ref. 45310.0113
- [Risk assessment of Influenza A viruses of subtype H5N8](#) (2017), Ref. 45242.0145
- [Risk assessment of Influenza A virus A/bat/Egypt/381 OP/2017 H9N2](#) (2024), Ref. 45242.0216
- [Risk assessment of Influenza D virus](#) (2020), Ref. 45242.0176