

Bundesamt für Verbraucherschutz und Lebensmittelsicherheit

Ref. No.: 6790-10-91

March 2009

Position statement of the Central Biosafety Commission (ZKBS) on the risk assessment of GB virus C / hepatitis G virus (GBV-C/HGV) as a donor or recipient organism in genetic engineering operations according to § 5 paragraph 1 of the Genetic Engineering Safety Regulations

GB virus C (GBV-C) and hepatitis G virus (HGV) were first isolated from the serum of hepatitis patients in 1995 (1, 2, 3). They were found to be two isolates of the same virus, closely related to isolates from marmoset monkeys (GBV-A, GBV-B) that had been inoculated with serum from a patient with jaundice (4). For this reason GBV-C/HGV was initially thought to be associated with hepatitis.

GBV-C/HGV belongs to the Flaviviridae family of viruses.

GBV-C/HGV is widespread around the world. Basically, the virus has five genotypes which are prevalent in different geographic regions (5, 6, 7). 15 - 20% of the German population is sero-positive for GBV-C/HGV. Virus RNA can be detected in the blood of 1 - 2% of these individuals (8, 9). In immune-competent persons 25% of infections can take a chronic course (2, 8). The infection has not been associated with any known disease.

The virus replicates in cells of the haematopoeitic system (10). If HIV-positive persons are coinfected with GBV-C/HGV, a positive effect on the course of the HIV infection may result (3, 11).

According to Annex III of the European Council Directive 2000/54/EC of 18 September 2000, GBV-C/HGV is allocated to **risk group 3****.

Recommendation

As a donor and recipient organism in genetic engineering operations GBV-C/HGV is allocated to **risk group 1** in accordance with § 5 paragraph 1 of the Genetic Engineering Safety Regulations (GenTSV) in conjunction with the criteria in Appendix I (GenTSV).

Reasons

GBV-C/HGV is widespread throughout the world. The infection is not associated with any known disease.

Safety measures beyond level 1 are not required to safeguard the legally protected goods and interests listed in § 1 of the Genetic Engineering (Act GenTG).

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