

**General position statement of the ZKBS
on safety measures for handling retroviruses of risk group 3****

The following retroviruses are allocated to risk group 3**.

- Human immunodeficiency viruses (HIV-1 and HIV-2)
- Human T-cell leukemia viruses (HTLV-1 and HTLV-2)
- Simian immunodeficiency viruses (SIV)

(see: Appendix III of the directive 2000/54/EG of the European Parliament and the council from September 18 2000 on the protection of employees against hazards from biological materials and the list of risk assessed donor and recipient organisms for genetic engineering operations according to Appendix 4 of the Genetic Engineering Safety Regulations in the released version from 14.03.1995.)

The symbol ** means that the risk of infection is limited, since infection via the respiratory tract normally cannot occur. This makes it possible to do without specific safety measures that are designed to prevent spread via the respiratory tract.

Retroviruses of all risk groups are usually not transmissible via the respiratory tract. The reason for this is primarily their instability. Retroviruses are viruses with viral envelopes. In addition to the viral capsid, they possess an envelope derived from the cytoplasmic membrane of the host cell, in which the viral envelope proteins, comprising two associated subunits, are embedded. Mainly due to the labile association of these two subunits, retroviral particles show a high degree of physical (1) as well as thermal instability (2) and rapidly lose their infectivity. These properties are also retained in recombinant retroviruses.

The Technical Rules for Biological Materials (TRBA) 100 allow for flexibility in the stipulation of safety measures for handling organisms of risk group 3**. Also according to the Genetic Engineering Safety Regulations (GenTSV) certain safety measures of containment level 3 are not required in individual cases.

In principle, the ZKBS considers the building measures for containment level 2, according to Appendix III of the GenTSV, to be sufficient for the handling of retroviruses of risk group 3**. According to Appendix III level 3 of the GenTSV and TRBA 100, the ZKBS takes the following position on the safety measures for containment level 3 for genetic engineering operations with retroviruses of risk group 3**:

- An airlock is not necessary.
- Negative pressure in the laboratory is not necessary.
- The possibility to seal the laboratory for the purpose of room disinfection is not necessary.
- Filtration of extract air from the laboratory is not necessary.
- An autoclave or an equivalent sterilization unit in the laboratory is not necessary. Such equipment must be available in the same building and the transport of the waste there must take place in accordance with GenTSV Appendix III part A III containment level 3 sentence 15.
- The treatment of liquid and solid waste is carried out according to the requirements for genetic engineering operations of the containment level 2 as outlined in § 13 para. 1 to 4 GenTSV.

- Higher fire resistance of the walls, windows and doors compared to genetic engineering installations with containment level 2 safety measures is not necessary.

Note:

The ZKBS already listed the most substantial safety measures, which can be omitted, in their general statement for handling retrovirus of risk group 3** from June 2003. In this amended version further safety measures were included, which can be omitted too, due to the limited infection risk.

[1] Andreadis, S.T. et al., (1999).

Large scale processing of recombinat retroviruses for gene therapy

Biotechnolog. prog. 15: 1-11.

[2] Einarsson, M., et al., (1989).

Heat inactivation of human immunodeficiency virus in solutions of antithrombin III.

Transfusion 29:148-152.