

**Recommendation of the ZKBS on the risk assessment of the
Zika virus (ZIKV) as a donor or recipient organism according to Art. 5 Paragraph 1 of
the German Genetic Engineering Safety Regulation (GenTSV)**

General considerations

The *Zika virus* (ZIKV) belongs to the *Flaviviridae* family (genus *Flavivirus*). Like all flaviviruses it has an envelope and a linear, single-strand RNA genome of positive polarity. Its closest relatives are, among others, the *Spondweni virus*, the *Kedougou virus* and the *West Nile virus* [1].

ZIKV was first isolated in Uganda in 1947 from a rhesus monkey. Until 2007, it appeared sporadically in parts of Asia and Africa. Since then, cases were increasingly reported on the Pacific islands of Micronesia and Polynesia, currently also from wide stretches of South and Central America and the Caribbean [1; 2]. Apart from humans and primates, antibodies against ZIKV were identified in rodents living in the wild. Whether other vertebrates also belong to the host spectrum is uncertain at this time. Neither has the natural reservoir of the virus been identified yet [3; 4].

ZIKV is transmitted by several species of mosquitoes of the *Aedes* genus. The occurrence of ZIKV infections is predominantly limited to tropical and subtropical regions due to the distribution of the mosquitoes [4]. Sporadically, however, travel-related cases of infection also emerge outside these regions [5; 6]. Furthermore, rare cases of sexual transmission, transmission by blood transfusion as well as an intrauterine transmission between mother and fetus have also been observed [4; 6 – 9].

An infection with ZIKV often progresses either asymptotically or is associated with mild symptoms, in particular mild fever, exanthemas, myalgia, arthralgia and conjunctivitis. Typically, these symptoms last up to one week. However, an increase of severe neurological diseases such as microcephaly among newborns and the autoimmune disease Guillain-Barré syndrome (GBS) were observed during the recent outbreaks in Brazil and French Polynesia. The first case-control study on GBS in French Polynesia was able to confirm the association between the disease and a ZIKV infection. However, the incidence rate of 0.24 cases per 1,000 ZIKV-infected persons is low. A similar incidence of GBS was observed after infections with *Campylobacter jejuni* (0.25 – 0.65 per 1,000) [10]. A causal relationship

between ZIKV and microcephaly is likely and currently under investigation [11 – 13]. A neurotropism, including the passage through the blood-brain barrier, was demonstrated in the mouse [8].

Recommendation

According to Art. 5 Paragraph 1 of the German Genetic Engineering Safety Regulation (GenTSV) in conjunction with the criteria in Annex I of the GenTSV the *Zika virus* as a donor or recipient organism for genetic engineering operations is assigned to **risk group 2**.

Reasons

ZIKV causes mostly either mild clinical symptoms lasting up to one week, or no symptoms at all. The incidence of the Guillain-Barré syndrome or microcephaly after an infection with ZIKV is probably low. In addition, a transmission under laboratory conditions is unlikely as ZIKV is not spread through the air.

Notice

The Maternity Protection Act (MuSchG) must be observed when handling the Zika virus.

Literature

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