

**Recommendation of the ZKBS on the risk assessment of
Middle East respiratory syndrome-related coronavirus
as donor or recipient organism according to Article 5 paragraph 1 GenTSV**

General

The *Middle East respiratory syndrome-related coronavirus* (MERS-CoV) is an enveloped virus with a non-segmented RNA genome of positive polarity. Within the order *Nidovirales* it is assigned to the family *Coronaviridae*.

MERS-CoV was first isolated in June 2012 in Saudi Arabia from the sputum of a 60-year-old male with severe respiratory disease [1]. Since then, 2040 confirmed cases of MERS-CoV infection have been reported, of which 710 were fatal (case fatality rate 35%). Cases of illness have so far mainly occurred in Saudi Arabia and other countries in the Middle East. Occasionally, travel-related cases were reported in Europe, Asia, Africa and North America. In total, 27 countries were affected so far [2; 3].

In about 20% of those infected, MERS-CoV infection was asymptomatic or with mild, flu-like symptoms. In contrast, approximately 50% of patients have a severe disease progression. This is particularly characterised by pneumonia up to acute respiratory distress syndrome. These symptoms are often accompanied by diarrhoea and kidney failure. Based on the available data, people with chronic pre-existing medical conditions seem to be predisposed in particular to a severe, often fatal course of disease. Neither antiviral agents nor a vaccine are currently available [2; 3].

The natural host of MERS-CoV seems to be the dromedary. More than 80% of adult dromedary serum samples from Africa and the Middle East, of which some had already been taken 30 years ago, showed neutralising antibodies against MERS-CoV [4; 5]. In addition, alpacas kept in close proximity to dromedaries but not any other farm animals such as sheep, goats, cattle, horses or poultry were seropositive [4; 6]. Lamas and pigs can also be infected experimentally [6].

In experimentally infected seronegative, adult dromedaries, MERS-CoV triggers a mild disease characterised by a slight increase in body temperature, increased formation of nasal secretions and mild bronchitis. A natural MERS-CoV infection typically does not lead to symptomatic disease in dromedaries. In rare cases, infected young animals show an increased nasal discharge [5; 7].

The paths of transmission of MERS-CoV are not yet fully understood. For most index patients, however, direct contact between the infected and dromedaries or their blood or untreated milk could be reconstructed. Furthermore, a human-to-human transmission with low efficiency is possible. There have been several nosocomial outbreaks, of which the largest in South Korea has led to 180 secondary cases from a single infected traveller. However, there is no evidence of a continuous human-to-human transmission chain [2 – 4].

Recommendation

According to Article 5 paragraph 1 GenTSV in conjunction with the criteria in Annex I GenTSV, *Middle East respiratory syndrome-related coronavirus* is assigned to **risk group 3** as donor and recipient organism for genetic engineering operations.

Reasoning

MERS-CoV can cause a severe, potentially fatal disease associated with pneumonia and kidney failure in humans. A direct human-to-human transmission is possible with a low efficiency. Transmission by droplets and/or aerosols is likely.

References

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