Position statement of the ZKBS on infection of animals with genetically modified organisms of risk group 2

Introduction

Increasingly, the ZKBS is faced with the question if the containment level for handling a genetically modified microorganism assessed for safety of handling in the laboratory, also applies to the infection of animals and the handling of the infected animal in the animal facilities.

Risk assessment of the genetically modified organisms is according to § 5 of the GenTSV, and the containment level allocation for the operations to be carried out with the GMOs are derived from § 7 of the GenTSV.

When handling GMOs of risk group 1 the allocation of containment levels and approval of the safety measures to be adhered to in the laboratory and animal facilities is performed by the approval authorities without participation of the ZKBS.

If GMOs of risk group 2 are constructed and available in the laboratory the approval authorities responsible can agree to the genetic engineering operations and specify the safety measures without participation of the ZKBS, so long as the genetic engineering operations are comparable to genetic engineering operations already classified by the ZKBS. If they are not comparable then approval authorities are to request the ZKBS to provide a position statement on classifying the planned genetic engineering operations and on the necessary safety measures.

Safety measures for the laboratory areas and animal facilities are listed in Appendix III and V of the GenTSV. Only the local approval authorities or the monitoring authorities can check whether the safety measures are adhered to.

If GMOs of risk group 2 constructed in the laboratory are later used on animals in the animal facilities, it is not sure whether the ZKBS should make a new position statement on classifying the genetic engineering operations (animal experiments) and on safety measures in the animal facilities.

Position statement

If genetic engineering operations of containment level 2 have already been approved by the ZKBS or an approval authority, and laboratory safety measures of level 2 been stipulated, and if the GMO is used later in infection experiments in animals, then in changing the safety measures from the laboratory to the animal facilities a renewed position statement from the ZKBS from the factual point of view is not required, as long as the following conditions apply:

- Recombination between the nucleic acids of the GMO and the infected animal is not expected.
- The creation and production of a new GMO is not expected.

This particularly applies to genetically modified bacteria or fungi and is usually independent of the experimental animal used.
• use of vectors with poor mobility in the genetic engineering operations with bacteria as recipient organisms.

If the GMO is an attenuated bacteria strain the possibility of losing the attenuation is to be taken into account. In this case the ZKBS considers individual examination of the situation is required.

If it concerns a genetically modified virus then the position statement of the ZKBS on the replication of genetically modified viruses of risk groups 2 – 4 in eukaryotic cells is to be observed.

The use of mobilizable vectors with a broad host range in the construction of the GMO, when used with animals (e.g. oral administration) means that possible creation of new GMOs through nucleic acid exchange with the natural microorganism flora of the animal cannot be excluded. In this case the ZKBS recommends individual examination of the planned experiments.

Similarly, the ZKBS recommends that it is informed when in animal experiments new safety relevant aspects arise that make additional safety measures necessary, or when certain safety measures can be anticipated.