ZKBS
Zentrale Kommission
für die Biologische Sicherheit

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ZKBS statement on genetic engineering activities with parasites

In accordance with Section 5 of the Genetic Engineering Safety Ordinance (GenTSV) the Central Committee on Biological Safety (ZKBS) assigns microorganisms as donor and recipient organisms in genetic engineering work in risk groups. According to the definition in § 3 No. 1a of the Genetic Engineering Act (GenTG), microorganisms include, among others, eukaryotic unicellular organisms, but also certain animal multicellular organisms, which are referred to as parasites in the following. These assignments are published in the 'list of organisms' in accordance with § 6 GenTSV.

Genetic engineering work with parasite-infected vectors

Many parasites can only infect humans or animals if they are transmitted by certain arthropods such as mosquitoes or heteropterans (typical bugs). This is the case for *Leishmania braziliensis*, *Leishmania donovani*, *Plasmodium falciparum* and *Trypanosoma brucei rhodesiense,* which are classified as risk group 3**. Genetic engineering work with vectors infected with such parasites is classified as safety level 3. Even if no ventilation system is required for genetic engineering work with vectors infected with risk group 3** parasites, specific technical, organisational and, if necessary, personal protective measures must be observed. The safety measures are adapted to the vector in order to prevent the escape of parasite-infected insects. This also applies to genetic engineering work involving vectors infected with risk group 2 parasites.

Genetic engineering work with infectious or non-infectious parasite stages or without vectors

Genetic engineering work with parasites that rely on vectors for host infection can be assigned to a lower safety level if the work is carried out in the absence of these vectors and if no nucleic acid segments are transferred that increase the parasites' risk potential. This applies to several parasites in risk group 2 and 3**. In the case of other parasites, only certain stages of the life cycle are infectious, such as the oocysts of *Eimeria falciformis*, while other life stages are non-infectious. Genetic engineering operations involving non-infectious stages also have a lower hazard potential than genetic engineering work involving infectious stages of these parasites.

Notes on the classification of parasites in the list of organisms

In the list of donor and recipient organisms for genetic engineering work according to § 6 GenTSV, it is not possible to differentiate between the use of parasites in genetic engineering work without or with vectors, or to list different stages of a parasite separately. Therefore, the

relevant entries in the list of organisms are indicated with the index **d**, which was defined by the ZKBS for this purpose. The index **d** has the following meaning:

“As natural part of our environment, some parasites infect other organisms permanently or temporarily. Genetic engineering work with these parasites may require special safety precautions, which are based on the specific hazard potential of the organisms. Parasites sometimes (i) have non-infectious stages and/or (ii) may depend on obligate vectors /intermediate hosts for transmission. After review by the ZKBS, genetic engineering work with these parasites may take place at a lower safety level, if the work is carried out with non-infectious stages and if the release of the GMOs into the original organisms habitat can be excluded. In particular, genetic engineering work that intends to alter the host specificity or to increase infectivity, virulence, resistance to therapeutic measures or the dissemination of the GMOs is to be evaluated by the ZKBS.”

The index is usually assigned by the ZKBS when parasites are reclassified as donor or recipient organisms according to § 5 GenTSV. It offers the possibility of downgrading genetic engineering work if it is not carried out with vectors or infectious parasites life stages. Genetic engineering work that is intended to alter the host specificity or increase the infectivity, virulence, resistance to therapeutic measures or the dissemination of the GMOs must be submitted to the ZKBS for a case-by-case assessment.