Bundesamt für
Verbraucherschutz und
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Position statement of the ZKBS on introducing recombinant DNA into animals

In recent times recombinant DNA has been introduced directly into animals, for example for immunization against microorganisms or in preliminary experiments for genetic therapy procedures. The methods used include intramuscular injection of recombinant DNA in salt solution, intravenous injection of recombinant DNA using liposomes, shooting gold particles covered in the recombinant DNA at the epidermis or other organs, etc. With each of these procedures it can be assumed that some somatic cells absorb recombinant DNA. This is the required goal of the procedure, which is expression of the introduced nucleic acid fragment in somatic cells. For the procedures above there is as yet no comprehensive information available that allows anything to be said about whether the introduced DNA only ends up in the target tissue (e.g. muscle cells) or if other cells can be affected, or if the introduced DNA is stably integrated in the cell's chromosomes. So far it remains open as to whether the introduced DNA – even if only with a low probability – can be passed on from the animal.

A hazard potential is not assumed when applying the above procedure in animals under the following conditions:

- introducing nucleic acid fragments from mammals into animals of risk group 1 (non-infected)
- introducing viral nucleic acid fragments that code for virus structural proteins into animals from risk group 1 (non-infected)

In the application of methods described above, it is provisionally assumed that stable integration does not occur in germ cells. To date, there is no publication that supports any change from this assumption. Operations that do not have the modification of germ cells as the primary goal are therefore not considered as procedures that modify the genetic material. However, the ZKBS provisionally recommends not using the experimental animals for breeding purposes.

If the goal of such operations is the stable integration of introduced DNA into germ cells, i.e. creating transgenic animals, such operations are considered as procedures for modifying genetic material according to the Genetic Engineering Act (GenTG).

The ZKBS considers examining and assessing safety relevant aspects as particularly required if the nucleic acid fragments introduced into animals can be expected to create new organisms (e.g. viruses) in these animals.

This can be particularly relevant if

- viral or bacterial nucleic acid fragments are introduced into such animals that due to infection or genetic modification can release microorganisms of risk group 2 - 4, and if
- complete virus genomes are introduced

Such operations are also to be considered as procedures for modifying genetic material according to the GenTG.