

**Position statement of the ZKBS
on criteria for assessing and categorizing plant viruses,
phytopathogenic fungi and phytopathogenic bacteria as donor and recipient
organisms in genetic engineering operations**

I. Introduction

The ZKBS decided at its 75th meeting in November 1997 to revise the criteria for the assessment and safety classification of phytopathogenic organisms as donor or recipient organisms in genetic engineering operations. Revision was required due to a number of changes in the statutory position. The classification criteria that proved valid over the past few years were retained.

II: Allocation criteria of the ZKBS

Criteria for allocating plant viruses, phytopathogenic fungi and phytopathogenic bacteria as donor and recipient organisms for genetic engineering operations to **risk groups 1 or 2**:

1. Plant viruses are allocated to **risk group 1** if:

- they are wide-spread in Germany or directly neighbouring countries,
- their host plants are not wide-spread in Germany or directly neighbouring countries,
- the vectors necessary for transferring the plant virus, if applicable, are not wide-spread in Germany or directly neighbouring countries.

2. Phytopathogenic fungi and/or phytopathogenic bacteria are allocated to **risk group 1** if they are not infectious for healthy humans or animals, and if:

- they are wide-spread in Germany or directly neighbouring countries,
- their host plants are not wide-spread in Germany or directly neighbouring countries.

Potential allergens and/or ability to form toxins do not lead to a higher group allocation for a phytopathogenic fungi and/or phytopathogenic bacterium.

3. Plant viruses are allocated to **risk group 2** if:

- the plant virus is not wide-spread in Germany or directly neighbouring countries, but its host plants and, if applicable, vectors necessary for transferring the plant virus are wide-spread,
- there is not enough information about the biology of a virus to allocate a safety level.

There are currently no plant viruses known that require a safety level allocation higher than **risk group 2**.

4. Phytopathogenic fungi and/or phytopathogenic bacteria are allocated to **risk group 2** if:

- the phytopathogenic fungus and/or phytopathogenic bacterium are pathogenic for humans or animals,
- the phytopathogenic fungus and/or phytopathogenic bacterium are not wide-spread in Germany or directly neighbouring countries, but their host plants are wide-spread,
- there is not enough information about the biology of the phytopathogenic fungi and/or phytopathogenic bacteria to allocate a safety level.

Phytopathogenic fungi and/or phytopathogenic bacteria with a particular risk potential for humans, animals or the environment may necessitate allocation to **risk group 3**.

III. Reasons

Plant viruses, phytopathogenic fungi and phytopathogenic bacteria as donor or recipient organisms for genetic engineering operations can also be allocated to **risk group 1** based on the criteria in Appendix I No. 1 of the Genetic Engineering Safety Regulations (GenTSV).

Humans and animals consume numerous different plant viruses in large amounts through their food and fodder. Damage to the health of humans and animals is as yet unknown. Therefore, what is decisive in allocating plant viruses to a risk group is whether the escape of these viruses into the environment is expected to put wild or cultivated plants at risk, e.g. by a significant increase in infection events.

Handling phytopathogenic fungi and/or phytopathogenic bacteria potentially dangerous for humans, animals or plants must be performed in such a way as to ensure these fungi or bacteria present no risk to humans, animals or plants.

In particular, it must be avoided that plant viruses, phytopathogenic fungi or phytopathogenic bacteria reach an environment where they do not occur naturally, but where they are able to infect plants and cause damage by their spread.

IV. Notes

For the general handling of phytopathogenic organisms the ZKBS refers to the regulations of the Plant Virus Safety Act, particularly regulations pertaining to the Plant Inspection Decree and the Plant Quarantine Directive 2000/29/EG from May 8, 2000.