

## Biosafety Clearing-House (BCH)

BIOSAFETY LAW, REGULATION, GUIDELINES AND  
AGREEMENTS (LAW)

BCH-LAW-DE-261456-2 |

EN

DE

LAST UPDATED: 17 NOV 2022

### Amendment

Is this an amendment to a law, regulation, guideline or agreement already published on the BCH?

No

### General Information

Country submitting a law, regulation, guideline or agreement

Germany

Title

General statement of the ZKBS on genetic engineering work carried out frequently with the underlying criteria of comparability: Genetic engineering work with RNA viruses derived from Minigenomes, replicons and virus-like particles for introduction into human or animal cells

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### Legislative details

Type of Law / Regulation

Guidelines

Area of jurisdiction

National / Federal

Subject areas

Contained use

Types of organisms addressed

Viruses

Brief description of the document including objective and scope

This ZKBS statement describes various systems for the production of viral minigenomes,

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viral replicons and virus-like particles derived from RNA viruses. These systems are intended to be introduced into human or animal cells and to be able to study the RNA viruses without having to work with the often very pathogenic wild-type viruses themselves.

The replication-defective systems each represent only individual aspects of the viral life cycle; infectious viruses are not produced in the process, which is why it is possible to work with these systems with significantly reduced safety measures.

The statement summarises the relevant criteria for the safety classification of genetic engineering work with viral minigenomes, viral replicons and virus-like particles and then specifically names criteria that enable a safety classification of genetic engineering work based on comparability.

Date of entry into force

01 Feb 2021

## Document details

Document text

[45310.0118\\_Gentechnische Arbeiten mit von RNA-Viren abgeleiteten Minigenomen, Replikons und virusähnlichen Partikeln zum Einbringen in humane oder tierische Zellen \[ German \]](#)

Unofficial Documents

[45310.0118\\_Genetic engineering work with RNA viruses derived from Minigenomes, replicons and virus-like particles for introduction into human or animal cells \[ English \]](#)

## Regulatory contact information

Competent National Authority(ies) and/or Supplementary Protocol Competent Authority(ies)

- **COMPETENT NATIONAL AUTHORITY:** | [BCH-CNA-DE-12096-7](#)

### **COMPETENT NATIONAL AUTHORITY:**

Federal Office of Consumer Protection and Food Safety (BVL)

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## Additional Information

The Central Committee on Biological Safety (ZKBS) is an expert scientific committee made up of 20 members and 20 deputy members, who represent different specialist areas or spheres of

corporate interest. Its offices are based at the Federal Office of Consumer Protection and Food Safety (BVL). Its members and deputy members are appointed by the Federal Ministry for Food and Agriculture (Bundesministerium für Ernährung und Landwirtschaft, BMEL) for three years. The ZKBS evaluates GMOs for possible risk potential, assigns genetic engineering operations to a biosafety level and recommends suitable safety measures. The German federal states obtain ZKBS position statements for genetic engineering operations in safety categories 3 and 4 and for operations in a lower safety category, whose classification is not clear. The ZKBS also evaluates approval applications for releases and for the placing of GMOs on the market and also issues a report to the BVL. An activity report is published annually.

Other relevant website addresses and/or attached documents

[Homepage of the ZKBS \[ English \]](#)

[Internetseiten der ZKBS \[ German \]](#)

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## Further Information

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Questions about the Cartagena Protocol on Biosafety or the operation of the Biosafety Clearing-House may be directed to the Secretariat of the Convention on Biological Diversity.

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Convention on Biological  
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