

## Biosafety Clearing-House (BCH)

BIOSAFETY LAW, REGULATION, GUIDELINES AND  
AGREEMENTS (LAW)

BCH-LAW-DE-262241-1 |

EN

DE

LAST UPDATED: 01 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

Opinion of the ZKBS on the risk assessment of the recombinant adenovirus-based vaccine virus Ad26.ZEBOV according to § 5 paragraph 1 GenTSV

EN

### Legislative details

Type of Law / Regulation

Guidelines

Area of jurisdiction

National / Federal

Subject areas

Contained use

Risk assessment and management

Types of organisms addressed

Viruses

Brief description of the document including objective and scope

Ad26.ZEBOV is a replication-defective human adenovirus of serotype 26 (Ad26) that contains the gene for the glycoprotein of Zaire ebolavirus (ZEBOV) and is used as a

EN

vaccine against ZEBOV. Ad26 belongs to the species *Human mastadenovirus D* and is assigned to **risk group 2** as a donor and recipient organism for genetic engineering work.

Compared to the wild-type virus, different deletions are present in Ad26.ZEBOV. According to § 5 paragraph 1 GenTSV in conjunction with the criteria in Appendix 1 GenTSV, the recombinant adenovirus Ad26.ZEBOV is assigned to **risk group 1** as a genetically modified organism.

Date of entry into force

01 Jul 2021

## Document details

Document text

[45242.0194\\_Stellungnahme der ZKBS zur Risikobewertung des rekombinanten Adenovirus-basierten Impfvirus Ad26.ZEBOV gemäß § 5 Absatz 1 GenTSV \[ \]](#)

Unofficial Documents

[45242.0194\\_Opinion of the ZKBS on the risk assessment of the recombinant adenovirus-based vaccine virus Ad26.ZEBOV according to § 5 paragraph 1 GenTSV \[ English \]](#)

## 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)

Mauerstrasse 39-42

Berlin

10117, Germany

Phone: +49-(0)3018-445-6500

Fax: +49-(0)3018-445-6099

Email: [german\\_bch@bvl.bund.de](mailto:german_bch@bvl.bund.de)

Website: [https://www.bvl.bund.de/EN/Home/home\\_node.html](https://www.bvl.bund.de/EN/Home/home_node.html), <https://www.bvl.bund.de>,  
[https://biosicherheit-bch.de/BCH/EN/Home/home\\_node.html](https://biosicherheit-bch.de/BCH/EN/Home/home_node.html), <https://biosicherheit-bch.de>

## 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

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

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

BCH-LAW-DE-262241-1

## Further Information

---

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.

**Secretariat of the  
Convention on Biological  
Diversity**

413 rue Saint-Jacques, suite  
800

Montreal, Québec, H2Y 1N9  
Canada

Fax: +1 514 288-6588

Email: [secretariat@cbd.int](mailto:secretariat@cbd.int)