31 January 2018

**Regarding: Submission of information requested in decision VIII/17 on Contained Use (Article 6)**

**Response to CBD notification ntf-2017-087 (Reference: SCBD/SPS/DC/MM/DA/86806)**

**Submission by GERMANY in addition to the submission of the European Union, January 2018**

This submission is meant to complement the submission of the European Union on notification ntf-2017-087. Please find enclosed details on practical guidance on specific measures for contained use of living modified organisms (LMO) that effectively limit their contact with and impact on the external environment as implemented in Germany.

In Germany, Directive 2009/41/EC[[1]](#footnote-2) is transmitted into national law by the Genetic Engineering Act[[2]](#footnote-3) established in 1990. Methodologies for classifying genetic engineering operations into one of four classes as well as specific containment measures are detailed in the Genetic Engineering Safety Ordinance (Gentechniksicherheitsverordnung, GenTSV)[[3]](#footnote-4).

In addition to Directive 2009/41/EC, GenTG and GenTSV not only cover contained use operations dealing with genetically modified microorganisms, but also with genetically modified plants and animals. These are currently also applied to contained use of genetically modified organisms resulting from new scientific developments, e.g. current developments in Synthetic biology or Gene drive systems. In the annexes of the GenTSV, specific containment measures for animal units as well as glasshouses are listed besides containment measures for laboratories and biotechnological production facilities. Furthermore, containment measures in the annexes of the GenTSV are specified in more detail and more precise recommendations regarding the type of technical equipment necessary for each class of genetic engineering operation are given, compared to Directive 2009/41/EC.

As of 2016, approximately 6750 genetic engineering facilities are registered in Germany. Genetic engineering facilities and operations are registered and authorized by the German federal states. Since 1990, the GenTG and the GenTSV have proven to be practical tools for efficiently regulating the safe use of genetically modified organisms under contained conditions.

As relatively specific containment measures are recommended in the GenTSV, it needs to be adapted regularly in reaction to the scientific and technological progress. Currently, this adaption is underway and foreseen to be finished in 2018.

Furthermore, it should be kept in mind that there is a long history and experience in handling of (non-genetically modified) (micro-) organisms under contained use. In Europe they are based on the Directive 2000/54/EC on biological agents which is transmitted into national law by the Biological Agents ordinance (BiostoffV) and corresponding technical rules for laboratories. Relevant manuals exist that provide practical guidance on biosafety techniques for use in laboratories at all biosafety levels, including the "Laboratory biosafety manual", published by the Word Health Organization (WHO) in all six UN and further languages (<http://www.who.int/csr/resources/publications/biosafety/WHO_CDS_CSR_LYO_2004_11/en/>).

1. BCH Record ID # 101047 (http://bch.cbd.int/database/record.shtml?documentid=101047) [↑](#footnote-ref-2)
2. BCH Record ID # 39280 (http://bch.cbd.int/database/record.shtml?documentid=39280) [↑](#footnote-ref-3)
3. BCH Record ID # 40587 (http://bch.cbd.int/database/record.shtml?documentid=40587) [↑](#footnote-ref-4)