**Regulatory environment for contained use activities**

**involving genetically modified organisms**

**in Germany**

Legal Background

In the European Union, the central directive regulating the handling of genetically modified micro-organisms in contained use is the Directive 2009/41/EC of the European Parliament and of the Council of 6 May 2009 on the contained use of genetically modified micro-organisms (BCH Record ID # 101047). It is translated into german law by the German Gene Technology Act (Gentechnikgesetz, GenTG, BCH Record ID # 39280), which aims both at protecting against potential risks arising from the application of genetic engineering as well as facilitating exploitation and exploration of genetic engineering. Essentially, the German Gene Technology Act regulates activities of development and application of not only genetically modified micro-organisms but all kinds of genetically modified organisms (GMOs), in laboratories for example, and also governs deliberate releases of GMOs into the environment.

The German Gene Technology Act is practically implemented in the legal German regulations (BCH Record IDs # 40586, # 40587, # 40588, # 40589, # 40590, # 40591, # 40592, # 40594, # 40595, # 102194). They determine legal procedures relating to application procedures, public consultations, the charging of fees, the preparation of external emergency plans, the security levels and safety measures requested and how to keep adequate records.

Regulation of contained use activities

Competent authorities for the regulation of contained use activities in Germany are the federal states, the “Bundesländer”, which authorize and oversee genetic engineering operations and facilities. Genetic engineering operations are classified into four biosafety levels according to their risk to the life and safety of humans, the environment, animals, plants and material goods. Genetic engineering operations of biosafety level 1 are not expected to pose any risk, whereas genetic engineering operations of biosafety level 4 pose a high risk (e. g. genetic engineering operations with pathogens both highly dangerous and contagious like the Ebola virus).

The term “genetic engineering operation” primarily covers the creation and handling of GMOs. Depending on the required biosafety, i. e. containment level, genetic engineering operations have to be registered or approved by the appropriate federal state authorities and carried out in a genetic engineering facility that also has to be registered or approved depending on the required containment level. Genetic engineering facilities can be laboratories, production plants, greenhouses or facilities for keeping animals.

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| **Table 1** Genetic engineering facilities in Germany (as of December 2015) | |
| **Containment level** | **Number** |
| S1 | 4751 |
| S2 | 1604 |
| S3 | 106 |
| S4 | 4\* |
| **Σ** | **6461** |
| \* Two genetic engineering facilities at containment level 4 are already in service, two additional facilities are under construction. | |

In Germany, a total of 6461 genetic engineering facilities have operating approval (as of December 2015). Table 1 lists the genetic engineering facilities according to the level of safety measures for the facilities.

Additional information on genetic engineering operations and genetic engineering facilities as well as on classification of micro-organisms as donor- or acceptor organisms for genetic engineering operations, cell lines, vectors and oncogenes is provided on the BVL website: [http://www.bvl.bund.de](http://www.bvl.bund.de/).

For each genetic engineering operation, a project leader is required. He/She is responsible for applying and for planning, observing and leading the genetic engineering operations. The project leader has to adhere to the relevant legal requirements regarding species conservation, animal welfare, pest management and protection against human and animal diseases. In addition, she/he is responsible for ensuring that administrative obligations are followed, that laboratory staff is sufficiently qualified and that the biological safety officer is kept informed.

Each operator of facilities for genetic engineering (i. e. universities or companies) is obliged to appoint a biological safety officer(s) for all genetic engineering facilities. The biological safety officer himself is responsible for advising project leaders and monitoring that the relevant legal requirements are observed. In addition, he/she is the contact person for the federal state authorities for all questions relating to biosafety of genetic engineering facilities of the respective university or company.

In order to be recognized as project leader or biological safety officer, the applicant needs to prove his/her qualification to the federal state authority. She/He is required to have completed university education in the natural, medical or veterinary sciences and to have three years of practical experience in the field of genetic engineering. Furthermore the applicant is required to have attended a certified advanced training course informing on risk potentials of organisms in genetic engineering operations, on safety measures for genetic engineering laboratories and for deliberate releases and on the legal regulations relevant for genetic engineering operations as well as deliberate releases and placing on the market of GMOs.

For genetic engineering operations of biosafety levels 2 (if comparable genetic engineering operations have not been evaluated yet), 3 and 4, the respective authorities in the federal states are required to obtain a position statement of the national independent advisory committee on biosafety, the Central Committee on Biological Safety (ZKBS).

The ZKBS is an expert committee comprising twenty members and twenty deputy members. The members are experts from various specialist fields and their deputies are experts from the same specialist background. The ZKBS examines and evaluates questions relevant to biosafety according to the regulations of the German Gene Technology Act and advises the Federal Government and federal states. The ZKBS provides position statements for the appropriate authorities, particularly on safety or containment level assignment for genetic engineering operations, required safety measures in genetic engineering facilities and possible risks associated with deliberate release or placing on the market of GMOs. In its recommendations, it takes into account international developments in the area of biosafety. The position statements of the ZKBS, which are of general interest, can be found in the BCH (BCH Record IDs # 102193, # 103660, # 103663, # 103664, # 103673, # 103674, # 103675, # 104464, # 104465, 104466, # 104557, # 104558). The members of the ZKBS and their deputies perform their activities voluntarily.

The ZKBS is based at the Federal Office of Consumer Protection and Food Safety (BVL), which belongs to the operating area of the Federal Ministry for Food and Agriculture (BMEL). The members of the ZKBS and their deputies are appointed for the duration of three years by the BMEL.