German Genetic Engineering Legislation Related to Contained Use

Prepared by the Federal Republic of Germany

1. The following text is intended to give a short overview of the subject by highlighting some key safety-related aspects of the relevant German legislation.

2. Contained use means genetic engineering operations in genetic engineering installations, that is any activity in which organisms, especially micro-organisms, are genetically modified or in which such GMOs are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with the general population and the environment.


4. The purpose of this legislation is firstly to protect the life and health of human beings, animals and plants as well as the symbiotic structure of the environment at large and also material goods from any possible risks involved in genetic engineering procedures and products of genetic engineering and to prevent the emergence of such risks and secondly to provide for the legal framework for the research into, the development, use and promotion of the scientific, technical and economic possibilities inherent in genetic engineering. For serving this purpose, the provisions regulating the contained use are building a comprehensive science-based legal framework with differentiated administrative procedures and control mechanisms, including preemptive and repressive measures, as well as sanctions.

5. The starting point is the legal principle of a preemptive prohibition with the reservation of granting permission. That means that everybody who plans to construct or to operate genetic engineering installations where genetic engineering operations are performed or who wants to carry out genetic engineering operations in such installations, i.e. the operator, has to notify it in advance to the competent authority or has to apply for an authorization.
6. The specific administrative procedures to follow, the specific obligations to be fulfilled and the specific safety measures to be taken are dependent on the risk level of the planned activities. For this purpose a classification system has been developed. On the basis of the current scientific knowledge, the activities are classified into four safety levels according to their estimated risk potential to human health or the environment with level one comprising activities of no risk, level two comprising activities of low risk, level three comprising activities of moderate risk and level four comprising activities of high risk. The classification is the result of a thorough risk assessment based on a detailed list of criteria concerning in specific the characteristics of the donor and the recipient organisms, of the inserted genetic material, the vectors used and the GMOs originating from the genetic engineering operations as well as the characteristics of the activity. In the case of doubts which safety level would be appropriate the activity will be classified into the higher level for precautionary reasons.

7. The specific safety measures are tailored to meet the requirements identified in the respective risk assessment. The provisions dealing with the safety measures comprise general obligations for all genetic engineering operations and specific obligations for genetic engineering operations in laboratories, in production facilities, in greenhouses and for the keeping of laboratory animals involved in genetic engineering operations. The general obligations include first of all measures to ensure the health and safety of the employees. All employees have to be sufficiently skilled and instructed. All employees, the works committee and the doctor responsible for the workplace have to be informed about the risks of the genetic engineering operations and the safety measures to be taken. Employees working with human pathogenic organisms of safety class two or higher get obligatory or optional medical examinations. In addition to that, the general obligations contain specific technical provisions, e. g. concerning the treatment of sewage and waste. The specific obligations consist of detailed lists of requirements for the construction and the technical equipment of the laboratories, production facilities, greenhouses or premises for keeping laboratory animals as well as specific rules of conduct for the employees.

8. Responsible for the fulfilment of these obligations and the observation of all safety measures is the project manager. That is the person nominated by the operator who, as part of his/her professional responsibilities, performs the direct planning, management or supervision of a genetic engineering operation. The project manager has to furnish proof of sufficient knowledge especially of classic and molecular genetics, practical experiences in the handling of micro-organisms, plants or animals and appropriate knowledge of safety measures and measures to ensure the health and safety at work. Apart from the project manager, after consultation with the works committee the operator has to nominate one or several biosafety officers. The biosafety officers are entitled and obliged to check whether the project manager complies with his/her responsibilities and to advise the operator, the works committee and the responsible persons in the risk assessment, in the planning, construction and operation of genetic engineering installations, in the choice and testing of safety equipment and before the introduction of procedures to use GMOs. The biosafety officers have to furnish proof of the same skills as the project manager.

9. The fulfilment of all these safety-related obligations and of other legal requirements is controlled on a regular basis by the competent authorities. In the field of contained use of GMOs the authorities of the Länder, the federal states, are competent for the performance of the whole administrative procedures. That means that they are competent for checking the notifications and applications for authorization by the operators planning to construct and operate genetic engineering installations or to carry out genetic engineering operations in such installations, they are competent for granting the authorizations and they perform the necessary controls of the
genetic engineering installations and they are entitled to take the necessary measures to ensure compliance with the legal obligations. These measures may include, if necessary, the removal or shut-down of a genetic engineering installation. Moreover, the breach especially of the obligations to notify or to apply for an authorization is subject to administrative fines or even penal sanctions.

10. Apart from the competent authorities the Central Commission for Biosafety plays an important role in the administrative procedures. The Central Commission for Biosafety is an independent advisory committee consisting of 16 members: ten experts with particular and ideally international experience in the fields of microbiology, cell biology, virology, genetics, hygiene, ecology and safety technology, at least six of these working in the field of recombinant nucleic acids and at least two representing the field of ecology, and six qualified persons from the fields of trade unions, occupational safety, industry, protection of the environment, consumer protection and the research-promoting organizations. The members of the Commission are appointed at a maximum two times for a period of three years by the competent federal ministry in consultation with other relevant federal ministries. The general function of the Commission is to consider and evaluate safety-related issues in the light of the provisions of the Act on Genetic Engineering, make pertinent recommendations and advise the Federal Government and the Länder governments on safety-related issues specific to genetic engineering. In particular, the Commission is involved in the development of the general system of safety classification and publishes general comments on frequently effected genetic engineering operations specifying the criteria of comparability applying in each case. If genetic engineering operations are not comparable to those already evaluated and classified by the Commission, the Commission is entitled and obliged to issue a statement on the safety-related classification of the genetic engineering operations planned and the measures requisite in terms of safety technology for every single notification or application for authorization. The competent authorities have to take the Commission’s statement into account. Where the decision of the competent authorities differ from the Commission’s statement, they have to set forth their reasons in writing.

11. As said above, the administrative procedures to follow are dependent on the safety level of the genetic engineering operations and whether the genetic engineering operations are the first ones or are further operations. The construction and operation of genetic engineering installations where genetic engineering operations at safety level one or two are to be performed and the first genetic engineering operations at safety level one or two envisaged require only a notification by the operator to the competent authority. Upon application by the operator, an authorization may be granted. The construction and operation of genetic engineering installations where genetic operations at safety level three or four are to be performed and the first genetic engineering operations at safety level one or two envisaged are subject to an authorization. Also further genetic engineering operations at safety level three or four require an authorization whereas further genetic engineering operations at safety level one can be performed without any notification and further genetic engineering operations at safety level two are subject to a notification or upon application by the operator to an authorization.

12. In the authorization procedure for genetic engineering operations at safety level three or four to be performed for commercial purposes, the competent authority has to hold a consultation with the general public. Together with the annual public report of the Central Commission for Biosafety and exhaustive public data bases run by the competent authorities, which provide information on all genetic engineering installations and operations, this is part of the information and participation of the public contributing to transparent administrative procedures.
13. The written **application** for an authorization of genetic engineering operations performed for the first time **has to contain the following information**, in particular:

i. the location of the genetic engineering installation as well as the name and address of the operator,

ii. the name of the project manager and proof of the expert knowledge required,

iii. the name of the biosafety officer and proof of the expert knowledge required,

iv. a description of the genetic engineering installation and its operation, particularly of the equipment and the precautions critical for safety and occupational safety,

v. the risk assessment and a description of the genetic engineering operations envisaged, specifying the characteristics of the donor and recipient organisms used, the vectors and the GMO in terms of the safety level required and their possible safety-related impacts on the life and health of human beings, animals and plants as well as the symbiotic structure of the environment at large and also material goods and the precautions provided for,

vi. a description of the techniques available for recording, identifying and monitoring the GMOs,

vii. information about staff number and training, emergency response plans and about accident prevention measures,

viii. information about waste and sewage management.

14. The notification of first genetic engineering operations requires similar detailed information whereas the notification as well as the authorization of further genetic engineering operations require less detailed information.

15. The **authorization** is to be **granted**

i. in the absence of any facts that may give rise to doubts over the reliability of the operator and the persons responsible for the construction and management of the installation as well as for the supervision of the latter’s operation,

ii. if it is ensured that the project manager as well as the biosafety officer(s) possess the expert knowledge requisite for their functions and are able to fulfil the duties incumbent on them at all times,

iii. if it is guaranteed that the applicant will comply with the duties regarding the performance of the genetic engineering operations envisaged,

iv. if it is ensured that the precautions necessary for the safety level required according to state-of-the-art-knowledge have been taken and that, hence, detrimental impacts on the life and health of human beings, animals and plants as well as the symbiotic structure of the environment at large and also material goods are not to be expected,


vi. unless any other provisions under public law and the requirements of occupational safety impair the construction and operation of the genetic engineering installation.
16. These requirements also apply to the notification procedure in so far as the competent authority can prohibit a genetic engineering operation subject to a notification when these requirements are not fulfilled any more.

17. Consequently, the German genetic engineering legislation related to the contained use of GMOs is intended to ensure a high level of safety by a comprehensive science-based approach and by requiring and checking full compliance with the necessary safety measures and the relevant national and international regulations, including the BWC.