Act on the Regulation of Genetic Engineering (Genetic Engineering Act - GenTG)

GenTG

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"Genetic Engineering Act in the version promulgated on 16 December 1993 (Federal Law Gazette I p. 2066), as last amended by Article 8(7) of the Act of 27 September 2021 (Federal Law Gazette I p. 4530)."

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Footnote

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(+++ Text reference from: 24.6.1990 +++)
(+++ Changes due to EinigVtr cf. § 41a +++)
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The Act as Article 1 G 2121-60-1 of 20.6.1990 I 1080 (GenTRG) was passed by the Bundestag with the consent of the Bundesrat; the Act was promulgated on 23.6.1990. Provisions of the Act, which are required for the enactment of
and general administrative provisions shall enter into force on the day after promulgation in accordance with Art. 8 sentence 1. Otherwise, the Act shall enter into force on 1 July 1990 in accordance with Art. 8 sentence 2 of the Act of 20 June 1990 I 1080.

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Part Three

Part One
General provisions

§ 1 Purpose of the Act

The purpose of this Act is,

1. to protect human life and health, the environment, animals, plants and material goods from the harmful effects of genetic engineering processes and products, taking into account ethical values, and to take precautions against the occurrence of such hazards,
2. to ensure that products, in particular food and feed, can be produced and placed on the market conventionally, organically or using genetically modified organisms,
3. to create the legal framework for the research, development, use and promotion of the scientific, technical and economic possibilities of genetic engineering.

§ 2 Scope of application

(1) This law applies to

1. genetic engineering facilities,
2. genetic engineering work,
3. Releases of genetically modified organisms and
4. the placing on the market of products containing or consisting of genetically modified organisms; animals shall be deemed to be products within the meaning of this Act.

(2) The Federal Government is hereby empowered, in order to implement the decisions or resolutions of the European Communities or of the European Union in accordance with Article 21 of Council Directive 90/219/EEC of 23 April 1990 on the contained use of genetically modified micro-organisms (OJ EC No. L 117 p. 1), as last amended by Commission Decision 2005/174/EC of 28 February 2005 (OJ EU No. L 59 p. 20), on Annex II, Part C, to carry out, after consultation of the Commission, by ordinance with the consent of the Bundesrat, genetic engineering operations with types of genetically modified micro-organisms. modified microorganisms in whole or in part from the provisions of this Act. Sections 32 to 37 shall remain unaffected. The statutory instrument shall include a notification obligation to the competent authority, which shall be limited to identifying the type of genetically modified micro-organism used, the place where it is worked with and the person responsible. The competent authority shall keep a register of these notifications and evaluate it at regular intervals.

(2a) The Federal Government shall be empowered, after consulting the Commission, to carry out genetic engineering work with types of genetically modified organisms by ordinance with the consent of the Bundesrat,

which are not micro-organisms and which are safe for human health and the environment in application, mutatis mutandis, of the criteria specified in Part B of Annex II to Directive 90/219/EEC, in installations in which containment measures are applied which are suitable for limiting the contact of the organisms used with humans and the environment, shall be exempted in whole or in part from the provisions of Parts Two and Four of this Act. Paragraph 2, sentences 3 and 4 shall apply mutatis mutandis.

(3) This Act does not apply to the use of genetically modified organisms on humans.

(4) This Act is without prejudice to more extensive requirements for the placing of products on the market under other legislation.

§ 3 Definitions

For the purposes of this Act

1. Organism
   any biological entity capable of reproducing or transferring genetic material, including microorganisms,

1a. Microorganisms
   Viruses, viroids, bacteria, fungi, microscopic unicellular or multicellular algae, lichens, other eukaryotic unicellular organisms or microscopic multicellular animal organisms as well as animal and plant cell cultures,

2. genetic engineering operations
   a) the production of genetically modified organisms,
   b) the propagation, storage, destruction or disposal, as well as the in-house transport of genetically modified organisms and their use in any other way, insofar as no authorisation has yet been granted for the release or placing on the market for the purpose of subsequent release into the environment,

3. genetically modified organism
   an organism, other than a human being, whose genetic material has been modified in a way that does not occur under natural conditions by crossing or natural recombination; a genetically modified organism is also an organism that has been produced by crossing or natural recombination between genetically modified organisms or with one or more genetically modified organisms, or by other means of propagation of a genetically modified organism, provided that the genetic material of the organism has characteristics that are attributable to genetic engineering operations,

3a. Methods of modifying genetic material in this sense are in particular
   a) Nucleic acid recombination techniques in which new combinations of genetic material are formed by introducing nucleic acid molecules generated outside an organism into viruses, viroids, bacterial plasmids or other vector systems and introducing them into a host organism in which they do not occur under natural conditions,
   b) Procedures involving the direct introduction into an organism of genetic material that has been produced outside the organism and does not occur naturally therein, including microinjection, macroinjection and microencapsulation,
   c) Cell fusion or hybridisation processes in which living cells with new combinations of genetic material not found in them under natural conditions are formed by the fusion of two or more cells using methods not found under natural conditions,

3b. not be considered as a method of modifying genetic material
   a) In vitro fertilisation,
   b) natural processes such as conjugation, transduction, transformation,
   c) Polyploidy induction,

   unless genetically modified organisms are used or recombinant nucleic acid molecules produced in the sense of numbers 3 and 3a are used.

Furthermore, the following are not considered to be methods of modifying genetic material

a) Mutagenesis and

b) Cell fusion (including protoplast fusion) of plant cells from organisms that can exchange genetic material using conventional breeding techniques,

unless genetically modified organisms are used as donors or recipients, 3c. unless it is a project of release or placing on the market and provided that
no genetically modified organisms are used as donors or recipients, the following apply
Furthermore, it is not a method of modifying genetic material.

a) Cell fusion (including protoplast fusion) of prokaryotic species that exchange genetic material via known physiological processes,

b) Cell fusion (including protoplast fusion) of cells of eukaryotic species, including the generation of hybridomas and the fusion of plant cells,

c) Self-cloning of non-pathogenic, naturally occurring organisms consisting of

aa) the collection of nucleic acid sequences from cells of an organism,

bb) the reintroduction of all or part of the nucleic acid sequence (or a synthetic equivalent) into cells of the same species or into cells of phylogenetically closely related species that can exchange genetic material through natural physiological processes, and

cc) any preceding enzymatic or mechanical treatment.

Self-cloning can also include the use of recombinant vectors if they have been used safely in that organism for a long time,

4. genetic engineering facility
Facility in which genetic engineering operations as defined in point 2 are carried out in a contained system and in which specific containment measures are applied to limit the contact of the organisms used with humans and the environment and to ensure a level of safety appropriate to the hazard potential,

5. Release
the deliberate release of genetically modified organisms into the environment, insofar as a marketing authorisation has not yet been granted for the purpose of subsequent release into the environment,

6. Placing on the market
the supply of products to third parties, including making them available to third parties, and the introduction into the area of application of the Act, insofar as the products are not intended for genetic engineering work in genetic engineering facilities or for authorised releases; however, the following shall apply

a) Transit traffic carried out under customs supervision,

b) the provision to third parties, the supply as well as the bringing into the area of application of the Act for the purpose of an authorised clinical trial

not as placing on the market,

6a. Dealing with genetically modified organisms
The use, propagation, cultivation, storage, transport and disposal, as well as consumption and other use and handling of products containing or consisting of genetically modified organisms authorised for placing on the market,

6b. Risk management
the process of weighing alternatives in the avoidance or control of risks, which is distinct from risk assessment,

7. Operator
a legal or natural person or an unincorporated association of persons which sets up or operates a genetic engineering facility under its name, carries out genetic engineering work or releases or places products containing or consisting of genetically modified organisms on the market for the first time; if an authorisation has been granted in accordance with section 16 subsection (2) which, in accordance with section 14 subsection (1) sentence 2, also permits the placing on the market of progeny or propagating material, only the authorisation holder shall be the operator in this respect,

8. Project Manager
a person who, within the scope of his professional duties, directly plans, directs or supervises a genetic engineering work or a release,

9. Biological Safety Officer
a person or a majority of persons (Biosafety Committee) to review the performance of the tasks of the project manager and to advise the operator,

10. Security levels
Groups of genetic engineering work according to their hazard potential,

11. Laboratory safety measures or production safety measures
specified working techniques and specified equipment of genetic engineering facilities,

12. biological safeguard
the use of recipient organisms and vectors with certain hazard-reducing properties,

13. Vector
a biological carrier that introduces nucleic acid segments into a new cell.

13a. Managers
a legal or natural person or an unincorporated association of persons having the power of disposal and actual physical control over an area for the cultivation of genetically modified organisms.

14. Pupils, students and other persons carrying out genetic engineering work are equivalent to employees as defined in Section 2 (2) of the Occupational Health and Safety Act.

§ 4 Commission for Biological Safety

(1) An expert commission shall be established at the competent higher federal authority under the name "Central Commission for Biological Safety" (Commission). The Commission is composed of:

1. twelve experts with special and, if possible, international experience in the fields of microbiology, cell biology, virology, genetics, plant breeding, hygiene, ecology, toxicology and safety engineering; of these, at least seven must work in the field of the recombination of nucleic acids; each of the fields mentioned must be represented by at least one expert, the field of ecology by at least two experts;
2. one competent person each from the fields of trade unions, occupational health and safety, business, agriculture, environmental protection, nature conservation, consumer protection and research-promoting organisations.

For each member of the Commission, an alternate member shall be appointed from the same field. To the extent necessary for the proper performance of the tasks, up to two experts may be appointed as additional alternate members in individual areas after consultation of the Commission.

(2) The members of the Commission shall be appointed by the Federal Ministry of Food and Agriculture in agreement with the Federal Ministries of Education and Research, of Economic Affairs and Energy, of Labour and Social Affairs, of Health and of the Environment, Nature Conservation and Nuclear Safety for a period of three years. Reappointment is permissible.

(3) The members and deputy members are independent in their activities and are not bound by instructions. They are bound to secrecy.

(4) The Commission shall report annually to the public in a general manner on its work.

(5) The Federal Government shall be empowered to regulate by ordinance, with the consent of the Bundesrat, the details of the appointment and procedure of the Commission, the use of external experts and the cooperation of the Commission with the authorities responsible for the enforcement of the Act. By ordinance with the consent of the Bundesrat, it may also be stipulated that the decision on appointment pursuant to paragraph 2 shall be taken in consultation with the Land governments.

(6) The Länder shall reimburse the expenses incurred by the Commission within the framework of the notification, registration and approval procedure. The expenses shall be determined on a case-by-case basis; in this context, the following may apply

fixed rates or framework rates determined on the basis of the average personnel and material costs.

§ 5 Tasks of the Commission

The Commission shall examine and evaluate safety-relevant issues in accordance with the provisions of this Act, make recommendations in this regard and advise the Federal Government and the Länder on safety-relevant issues relating to genetic engineering. In making its recommendations, the Commission shall also take due account of the state of international developments in the field of genetic engineering safety. The Commission shall publish general statements on frequently carried out genetic engineering work with the underlying criteria of comparability in each case in the Federal Gazette. Insofar as the general statements address questions
of occupational health and safety, the Committee on Biological Agents must be consulted beforehand in accordance with Section 19 of the Biological Agents Ordinance.

§ 5a (omitted)

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§ 6 General duties of care and record-keeping, hazard prevention

(1) Any person who sets up or operates genetic engineering installations, carries out genetic engineering work, releases genetically modified organisms or places products containing or consisting of genetically modified organisms on the market as an operator shall comprehensively assess the associated risks to the legal interests referred to in § 1 No. 1 in advance (risk assessment) and shall review this risk assessment and the safety measures at regular intervals and, if necessary according to the result of the review, revise them, but without delay, if

1. the safety measures applied are no longer appropriate or the safety level assigned to the genetic engineering work is no longer applicable, or
2. there is a reasonable assumption that the risk assessment no longer reflects the latest scientific and technical knowledge.

In the risk assessment by the competent higher federal authority, the use of antibiotic resistance markers in genetically modified organisms that confer resistance to antibiotics used in medical or veterinary treatment shall be considered with regard to the identification and phasing out of the use of antibiotic resistance markers in genetically modified organisms.
organisms that may have harmful effects on human health or the environment to be given special consideration for placing on the market by 31 December 2004 and for release by 31 December 2008.

(2) In accordance with the result of the risk assessment, the operator shall take the necessary precautions according to the state of the art in science and technology and adapt them without delay in order to protect the legal interests specified in Article 1 No. 1 from possible hazards and to prevent the occurrence of such hazards. The operator shall ensure that, even after the cessation of operation, no hazards can emanate from the installation for the legal interests referred to in Article 1 No. 1.

(3) The operator shall keep records of the performance of genetic engineering work and of releases and submit them to the competent authority at its request. The Federal Government shall regulate by statutory instrument with the consent of the Bundesrat and after consulting the Commission, the details of the form and content of the records and the obligations to keep and submit them.

(4) Anyone who carries out genetic engineering work or releases is obliged to appoint project managers and Biosafety Officers or Committees.

Part Two
Genetic engineering work in genetic engineering facilities

§ 7 Security levels, security measures

(1) Genetic engineering work is divided into four safety levels:

1. Safety level 1 is assigned to genetic engineering work which, according to the state of scientific knowledge, is not expected to pose a risk to human health and the environment.

2. Safety level 2 is assigned to genetic engineering work for which a low risk to human health or the environment can be assumed according to the state of scientific knowledge.
3. Safety level 3 is assigned to genetic engineering work for which a moderate risk to human health or the environment can be assumed according to the state of scientific knowledge.
4. Safety level 4 is assigned to genetic engineering work which, according to the state of scientific knowledge, must be assumed to pose a high risk or a justified suspicion of such a risk to human health or the environment.

The Federal Government shall be empowered, after consultation of the Commission, to regulate by ordinance, with the consent of the Bundesrat, the assignment of certain types of genetic engineering work to safety levels in order to achieve the purposes specified in Section 1 No. 1. The assignment shall be made on the basis of the risk potential of the genetic engineering work, which is determined by the characteristics of the recipient and donor organisms, the vectors and the genetically modified organism. Possible effects on employees, the population, farm animals, cultivated plants and the other environment, including the availability of suitable countermeasures, shall be taken into account.

(1a) If there is any doubt as to which safety level is appropriate for the proposed genetic engineering work, the genetic engineering work shall be assigned to the higher safety level. In individual cases, the competent authority may, on application, approve safety measures of a lower safety level if sufficient protection of human health and the environment is demonstrated.

(2) Certain safety measures must be observed when carrying out genetic engineering work. After consulting the Commission, the Federal Government shall regulate by ordinance, with the consent of the Bundesrat, the safety measures required for the different safety levels in accordance with the state of the art in science and technology for the laboratory and production area, for animal husbandry rooms and greenhouses and the requirements for the selection and safety assessment of recipient organisms and vectors used in genetic engineering work.

§ 8 Approval, notification and registration of genetic engineering installations and initial genetic engineering work

(1) Genetic engineering work may only be carried out in genetic engineering facilities. The erection and operation of genetic engineering facilities in which genetic engineering work of safety level 3 or 4 is require approval (plant permit). The permit authorises the performance of the genetic engineering work specified in the notice of approval.

(2) The construction and operation of genetic engineering installations in which genetic engineering work of safety level 1 or 2 is to be carried out and the intended first genetic engineering work shall be notified by the operator to the competent authority before the intended start of construction or, if the installation has already been constructed, before the intended start of operation in the case of safety level 1 and notified in the case of safety level 2. By way of derogation from the above, the operator of a facility in which genetic engineering work of safety level 2 is to be carried out may apply for a facility permit in accordance with paragraph 1, sentence 2.

(3) Approval may be granted on application for

1. the construction of a genetic engineering facility or part of such a facility, or
2. the construction and operation of part of a genetic engineering facility (partial authorisation).

(4) The substantial modification of the location, nature or operation of a genetic engineering facility in which genetic engineering work of safety level 3 or 4 is to be carried out requires a facility permit. For substantial changes to the location, nature or operation of a genetic engineering plant genetic engineering facility in which genetic engineering work of safety level 1 or 2 is to be carried out, paragraph 2 shall apply accordingly.

§ 9 Further genetic engineering work

(1) Further genetic engineering work at safety level 1 can be carried out without notification.

(2) The operator shall notify the competent authority of any further genetic engineering work at safety level 2 before the intended start of the work. Notwithstanding sentence 1, the operator may apply for a permit.

(3) Further genetic engineering work at safety level 3 or 4 requires a permit.

(4) Further genetic engineering work which is to be assigned to a higher safety level than the work covered by the licence under Section 8(1), second sentence, or by the notification or notification under Section 8(2), first sentence, may only be carried out in accordance with its safety level on the basis of a new licence under Section 8(1), second sentence, or a new notification under Section 8(2), first sentence.

(4a) If genetic engineering work of safety levels 2 and 3 that has already been notified, notified or approved is to be carried out in another notified or approved genetic engineering facility of the same operator in which corresponding genetic engineering work may be carried out, this shall be notified by the operator to the competent authority before the work commences.

(5) Other genetic engineering operations of safety level 2, 3 or 4 carried out by an international depository for the purpose of fulfilling the requirements under the Budapest Treaty of 28 April 1977 on the International Recognition of the Deposit of Microorganisms for the Purposes of patent procedure (Federal Law Gazette 1980 II p. 1104, 1984 II p. 679) shall be notified to the competent authority by the operator immediately after the start of the work.

(6) Further genetic engineering work at the instigation of the competent authority for the development of the detection methods required for the sample examination or for the examination of a sample within the framework of the monitoring pursuant to § 25 may be carried out by way of derogation from paragraph 2.

§ 10 Approval procedure

(1) The approval procedure requires a written application.

(2) An application for approval of a genetic engineering facility shall be accompanied by the documents required for the examination of the prerequisites for the approval, including the official decisions covered under Section 22(1). In particular, the documents shall contain the following information:

1. the location of the genetic engineering facility and the name and address of the operator,
2. the name of the project manager and proof of the required expertise,
3. the name of the Biosafety Officer(s) and proof of the required expertise,
4. a description of the existing or planned genetic engineering facility and its operation, in particular the facilities and precautions relevant to safety and occupational health,
5. the risk assessment pursuant to § 6, paragraph 1, and a description of the intended genetic engineering operations, showing the properties of the donor and recipient organisms used or the source organisms or, where applicable, host vector systems used, as well as the vectors and the genetically modified organism with regard to the required safety level, as well as their possible safety-relevant effects on the legal interests specified in § 1, No. 1, and the necessary facilities and precautions, in particular the measures for the protection of employees,
6. a description of the techniques available for the detection, identification and monitoring of the genetically modified organism,
7. Information on the number and training of personnel, emergency plans and information on measures to prevent accidents and operational incidents,
8. Information on waste and wastewater disposal.

(3) An application for a permit to carry out further genetic engineering work shall be accompanied by the documents required to verify the conditions of the permit. The documents shall contain in particular the following information:

1. a description of the planned genetic engineering work in accordance with paragraph 2, sentence 2, no. 5,

1a. a description of the techniques available for the detection, identification and monitoring of the genetically modified organism,

2. a statement by the project leader as to whether and, if so, how the information pursuant to paragraph 2 sentence 2 nos. 1 to 3 has changed,
3. Date and file number of the notice of approval for the construction and operation of the genetic engineering facility or of the confirmation of receipt of the notification pursuant to § 12 para. 3,
4. a description of any necessary changes to the safety-related facilities and precautions, in particular the measures to protect employees,
5. Information on waste and wastewater disposal.

(4) The competent authority shall without delay acknowledge receipt of the application and the attached documents in writing to the applicant and verify whether the application and the documents are sufficient for the assessment of the permit conditions. If the application or the documents are not complete or do not permit an assessment, the competent authority shall without delay request the applicant to supplement the application or the documents within a reasonable period of time.

(5) A decision on an application under Section 8(1), sentence 2, (2), sentence 2, (3) or (4) or under Section 9(4) shall be taken in writing within a period of 90 days. In the case of approval of a genetic engineering facility in which genetic engineering work of safety level 2 is to be carried out, the competent authority shall decide on decide on the application without delay, at the latest after 45 days, if the genetic engineering work is comparable to genetic engineering work already classified by the Commission; subsection 7, sentences 1 to 4, shall not apply. If the construction or operation of the genetic engineering facility in which genetic engineering work of safety level 2 is to be carried out requires further official decisions in accordance with Section 22, paragraph 1, the period specified in sentence 2 shall be extended to 90 days. The time limits shall be suspended as long as a hearing procedure according to
§ Section 18(1) is carried out or the authority awaits the completion of the application or the documents or until the required opinion of the Commission on the safety classification of the intended genetic engineering work and on the necessary safety measures has been received.

(6) A decision on an application in accordance with Section 9, Paragraph 2, Sentence 2 or Paragraph 3 shall be taken in writing within a period of 45 days. In the case of approval of further genetic engineering work of safety level 2, the competent authority shall decide on the application without delay, at the latest after 45 days, if the genetic engineering work is comparable to genetic engineering work already classified by the Commission; subsection 7, sentences 1 to 4 shall not apply. The time limit shall be suspended for as long as the authority has not
of the application or the documents or until the required opinion of the Commission on the safety classification of the proposed genetic engineering operations and on the necessary safety measures has been received.

(7) Before deciding on an authorisation, the competent authority shall obtain a statement from the Commission on the safety classification of the planned genetic engineering work and on the necessary safety measures via the competent higher federal authority.
The Commission shall deliver its opinion without delay. The opinion shall be taken into account in the decision. Where the decision of the competent authority differs from the opinion of the Commission, it shall state the reasons in writing. The competent authority shall also seek the opinions of the authorities whose responsibilities are affected by the project.

(8) Prior to the filing of an action before an administrative court, no preliminary proceedings shall take place in the case of a decision on an application for authorisation to construct and operate a genetic engineering facility, provided that a hearing procedure pursuant to section 18 has been conducted.

§ 11 Licensing requirements

(1) Approval for the construction and operation of a genetic engineering facility shall be granted if

1. there are no facts giving rise to concerns about the reliability of the operator and the persons responsible for the construction and for the management and supervision of the operation of the installation,
2. it is ensured that the project leader as well as the biosafety officer(s) have the necessary expertise for their tasks and are able to fulfil the obligations incumbent upon them at all times,

3. it is ensured that the applicant fulfils the obligations arising from § 6, paras. 1 and 2 and the ordinances according to § 30, para. 2, nos. 2, 4, 5, 6 and 9 for the performance of the intended genetic engineering work,
4. it is ensured that the facilities required for the required safety level according to the state of the art in science and technology are available and precautions have been taken and that therefore no harmful effects on the legal interests specified in § 1 No. 1 are to be expected,
5. there are no facts which would violate the prohibitions of Article 2 of the Act of 21 February 1983 on the Convention of 10 April 1972 on the Prohibition of the Development, Production and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction (Federal Law Gazette 1983 II p. 132) and the provisions on the prohibition of biological and chemical weapons in the implementing law on Article 26, paragraph 2 of the Basic Law (Law on the Control of War Weapons in the version promulgated on 22 November 1990 (Federal Law Gazette I p. 2506), last amended by Article 17 of the Law of 21 December 1992 (Federal Law Gazette I p. 2150)), and
6. other regulations under public law and occupational health and safety concerns do not conflict with the construction and operation of the genetic engineering facility.

(2) Partial approval under Section 8(3) shall be granted if a preliminary examination shows that the requirements of subsection (1) will be met with regard to the construction and operation of the entire genetic engineering facility and that there is a legitimate interest in granting partial approval.

(3) The authorisation according to section 9, paragraph 2, sentence 2 or paragraph 3 shall be granted if the prerequisites according to paragraph 1, nos. 1 to 5 for the performance of the intended further genetic engineering work are fulfilled.

§ 12 Notification and registration procedure

(1) Notification and registration must be in writing.

(2) When notifying a facility in which genetic engineering work of safety level 1 is to be carried out, the following must be submitted:

1. the documents pursuant to § 10 para. 2 sentence 2 nos. 1 to 3 and 8,
2. a general description of the genetic engineering facility,
3. a summary of the risk assessment pursuant to § 6 para. 1,
4. a description of the type of genetic engineering work envisaged.

When registering a facility in which genetic engineering work of safety level 2 is to be carried out, the documents pursuant to Section 10 para. 2 sentence 2 nos. 1 to 8 shall be submitted.

(2a) When notifying further genetic engineering work of safety level 2 in accordance with § 9 para. 2, the following shall be submitted:

1. a summary of the risk assessment pursuant to section 6 sub-section 1 as well as a description of the intended genetic engineering work in accordance with section 10 sub-section 2 sentence 2 no. 5,
2. a statement by the project leader as to whether and how the information pursuant to § 10 para. 2 sentence 2 nos. 1 to 3 and 6 has changed,
3. File number and date of the notice of approval for the construction and operation of the genetic engineering facility or of the confirmation of receipt of the application in accordance with § 12 Para. 3,
4. a description of the required changes to the safety-related facilities and precautions,
5. Information on waste disposal.

(3) The competent authority shall without undue delay acknowledge receipt of the notification and the accompanying documents in writing to the notifier and examine whether the notification and the documents are sufficient for the assessment of the notification. If the notification or the documents are not complete or do not permit an assessment, the competent authority shall without delay request the notifier to supplement the notification or the documents within a reasonable period of time. Sentences 1 and 2 shall apply mutatis mutandis to the notification.

(4) In the case of safety level 2, the competent authority shall, via the competent higher federal authority,

obtain an opinion from the Commission on the safety classification of the intended genetic engineering.

The Commission shall give its opinion without delay if the genetic engineering work is not comparable to a genetic engineering work already classified by the Commission. The Commission shall issue its opinion without delay. The opinion shall be taken into account in the decision. If the competent authority deviates from the opinion when taking a decision, it shall explain the reasons in writing.

(5) In the case of safety level 2, the operator may commence the construction and operation of the genetic engineering facility and the performance of the initial genetic engineering work 45 days after receipt of the notification by the competent authority or, with its consent, earlier. The expiry of the time limit shall be deemed to constitute consent to the construction and operation of the genetic engineering facility and to the performance of the genetic engineering work. The time limit shall be suspended while the authority awaits the completion of the documents or until the required opinion of the Commission on the safety classification of the intended genetic engineering work and on the necessary safety measures is available.

(5a) The operator may commence with the construction and operation of the genetic engineering facility and with the performance of the initial genetic engineering work in the case of safety level 1 and with the performance of further genetic engineering work in the case of safety level 2 immediately after receipt of the notification by the competent authority. The competent authority may prohibit the performance or provisionally prohibit the continuation of the genetic engineering work until the expiry of 21 days after receipt of the supplementary documents requested under paragraph 3 or of the opinion of the Commission to be obtained under paragraph 4, insofar as this is necessary to ensure the purposes specified in Section 1 No. 1.

(6) The competent authority may make the performance of the notified or registered genetic engineering operations subject to conditions, impose time limits or impose conditions, insofar as this is necessary to ensure the purposes specified in § 1 No. 1; § 19, third sentence, shall apply mutatis mutandis.

(7) The competent authority may prohibit the performance of the notified or registered genetic engineering work if the requirements specified in Section 11(1) Nos. 1 to 5 are not or are no longer complied with or if occupational health and safety concerns are opposed thereto. The decision must be made in writing.

§ 13

(omitted)

Part Three
Release and placing on the market

§ 14 Release and placing on the market

(1) Approval by the competent higher federal authority is required for anyone who

1. releases genetically modified organisms,
2. places products on the market which contain or consist of genetically modified organisms,
3. places on the market products containing or consisting of genetically modified organisms for a purpose other than their intended use,
4. places on the market products derived or produced from released genetically modified organisms which are not covered by an authorisation pursuant to Number 2.

The authorisation for a release or placing on the market may also cover the progeny and the reproductive material of the genetically modified organism. The authorisation for a placing on the market may be restricted to certain uses. The modification of a release shall not require approval if the competent higher federal authority determines that the modification does not have any significant effect on the assessment of the requirements under section 16 subsection (1). § Section 19 sentences 2 and 3 shall remain unaffected.

(1a. A marketing authorisation shall not be required for the placing on the market of products containing or consisting of genetically modified organisms which are

1. have been produced using processes referred to in § 3 No. 3c and
2. are discharged into a facility in which containment measures are applied in accordance with sentence 2.

3. (omitted)

The containment measures shall be suitable to limit the contact of the products with humans and the environment and to ensure a level of safety appropriate to the hazard potential. Furthermore, the containment measures shall correspond to the safety measures pursuant to Article 7(2) in conjunction with the ordinance referred to therein. Insofar as products pursuant to sentence 1 do not require a marketing authorisation, the other provisions of this Act and of the ordinances on marketing issued on the basis of this Act shall also not apply.

(2) Insofar as the placing on the market is regulated by legal provisions which are at least equivalent to the provisions of this Act and the ordinances issued on the basis of this Act concerning risk assessment, risk management, labelling, monitoring and information of the public, the provisions of this Act and the ordinances issued on the basis of this Act shall apply.
are equivalent, the provisions of Part Three shall not apply, with the exception of sections 16a and 16b and sections 17b(1) and 20(2).

(2a) to (2d) (omitted)

(3) A permit may cover the release of a genetically modified organism or a combination of genetically modified organisms at the same site or at different sites, provided that the release is for the same purpose and within a period specified in the permit.

(4) In order to implement Commission Decision 94/730/EC of 4 November 1994 establishing simplified procedures for the deliberate release of genetically modified plants pursuant to Article 6(5) of Council Directive 90/220/EEC (OJ EC No. L 292, p. 31), the Federal Government may, after consulting the Commission, determine by ordinance with the consent of the Bundesrat that a simplified procedure deviating from the procedure laid down in Part Three of this Act shall apply to the release, provided that sufficient experience has been gained with the release of organisms with regard to the protective purposes specified in Section 1, No. 1.

(4a) The Federal Government may, in order to implement the decisions or resolutions of the European Communities or of the European Union in accordance with Article 7 paragraph 3 in conjunction with Article 30 paragraph 2 of Directive 2001/18/EC, after consulting the Commission, determine by ordinance with the consent of the Bundesrat that

1. a simplified procedure that deviates from the procedure in Part Three of this Act applies to the authorisation of the release,
2. paragraph 3 shall apply mutatis mutandis to approvals pursuant to number 1,

insofar as sufficient experience has been gained with the release of organisms with regard to the requirements under section 16 subsection (1). The statutory instrument may, in particular, contain provisions on consultation that deviate from section 18 subsection (2) sentence 1 and subsection (3), also in conjunction with the statutory instrument referred to therein.

(5) Authorisations granted by authorities of other Member States of the European Union or other States party to the Agreement on the European Economic Area in accordance with their provisions implementing Directive 2001/18/EC shall be deemed equivalent to marketing authorisations granted by the competent higher federal authority. The Federal Government shall be empowered to issue, by ordinance with the consent of the Bundesrat, regulations on the notification of authorisations treated as equivalent in accordance with sentence 1.

§ 15 Application for authorisation in the case of release and placing on the market

(1) The application for approval of a release shall be accompanied by the documents required for examination. In addition to the information described in § 10 para. 2 sentence 2 nos. 2 and 3, the documents must contain the following information in particular:

1. the name and address of the operator,
2. the description of the release project in terms of its purpose and location, timing and period,
3. the description, in accordance with the state of the art, of the safety-relevant properties of the organism to be released and of the circumstances relevant to its survival, reproduction and

The documents on previous work in a genetic engineering facility and on releases shall be enclosed,

4. a risk assessment pursuant to § 6 para. 1 and a statement of the safety precautions envisaged, 4a.

   a plan for determining the effect of the organism to be released on human health, and health and the environment,

5. a description of the planned monitoring measures as well as information on residual substances arising and their treatment as well as on emergency plans,

6. a summary of the application dossier as required by Council Decision 2002/813/EC of 3 October 2002 establishing, pursuant to Directive 2001/18/EC of the European Parliament and of the Council, the summary information format for notifications concerning the deliberate release into the environment of genetically modified organisms for purposes other than for placing on the market (OJ EC No. L 280 p. 62).

(2) (omitted)

(3) Any person submitting an application for marketing authorisation must be established in a Member State of the European Union or appoint a representative established there. The application shall be accompanied by the documents necessary for the examination of the conditions of the marketing authorisation. The documents shall contain in particular the following information:

1. the name and address of the operator,

2. the name and a description in accordance with the state of scientific knowledge of the product to be placed on the market with regard to the specific genetically modified properties; Documents on previous work in a genetic engineering facility and on releases must be enclosed,

3. A description of the expected types of use and the planned spatial distribution, 3a. Information on the requested period of validity of the authorisation,

4. a risk assessment pursuant to § 6 para. 1 including a statement of the potential adverse effects,

5. a description of the measures planned to control the further behaviour or quality of the product to be placed on the market, the residues arising and their treatment, and the contingency plans,

5a. a monitoring plan taking into account the obligation to monitor pursuant to § 16c, including information on its duration,

6. a description of specific conditions for handling the product to be placed on the market and a proposal for its labelling and packaging,

7. a summary of the application dossier as required by Council Decision 2002/812/EC of 3 October 2002 establishing, pursuant to Directive 2001/18/EC of the European Parliament and of the Council - of the Summary Notification Information Format for the placing on the market of genetically modified organisms as or in products (OJ EC No. L 280 p. 37).

(4) The application for an extension of the marketing authorisation shall be submitted at the latest nine months before the expiry of the marketing authorisation (cut-off period). The application must be accompanied by the documents required for the examination. The documents must contain the following information in particular:

1. a copy of the marketing authorisation,

2. a report on the results of the observation,

3. new information going beyond the report according to number 2 which has come to the knowledge of the applicant with regard to the risks posed by the product to the legal interests mentioned in § 1 number 1.

If, on the basis of the information available to him, the applicant considers it necessary to amend the previous content of the permit, in particular with regard to the observation plan or the period of validity of the permit, he shall indicate this in the application.

§ 16 Authorisation for release and placing on the market

(1) Approval for a release shall be granted if

1. the requirements according to § 11 para. 1 nos. 1 and 2 are met,
2. it is ensured that all safety precautions required by the state of the art in science and technology are taken,
3. according to the state of scientific knowledge in relation to the purpose of the release, unacceptable harmful effects on the legal interests specified in § 1 No. 1 are not to be expected.

(2) The marketing authorisation shall be granted or renewed if, according to the state of scientific knowledge and in relation to the purpose of the placing on the market, unacceptable adverse effects on the legal interests specified in § 1 No. 1 are not to be expected. In the case of an application for an extension of the marketing authorisation, the placing on the market shall be deemed to have been provisionally authorised until completion of the administrative procedure in accordance with the provisions thereof, provided that such an application was submitted in good time.

(3) A decision on an application for authorisation of a release shall be taken in writing within a period of 90 days after receipt of the application. Before a decision is taken on an application for marketing authorisation, an assessment report shall be drawn up by the competent higher federal authority within 90 days of receipt of the application and shall be notified to the applicant; the application shall be decided on after completion of the procedure in accordance with Articles 14, 15 and 18 of Directive 2001/18/EC (EU-participation procedure) without delay, but at the latest within 30 days, in writing. The time limits specified in sentences 1 and 2 shall be suspended as long as the competent higher federal authority is awaiting further information, documents or samples requested by the applicant; if a public participation procedure is initiated in accordance with
§ section 18(2) is carried out, the time limit shall be extended by the period during which the hearing is held, but by no more than 30 days. Before deciding on an application for an extension of the marketing authorisation, an assessment report shall be drawn up by the competent higher federal authority and communicated to the applicant; a decision on the application shall be taken in writing without delay after completion of the procedure in accordance with Article 17 of Directive 2001/18/EC, but within 30 days at the latest.

(4) The decision on a release shall be taken in consultation with the Federal Agency for Nature Conservation and the Robert Koch Institute and the Federal Institute for Risk Assessment; a statement by the Julius Kühn Institute, Federal Research Centre for Cultivated Plants, and, insofar as genetically modified vertebrates or genetically modified microorganisms used on vertebrates are concerned, shall be submitted beforehand, also be obtained from the Friedrich-Loeffler-Institute. Before granting an authorisation for a release, an opinion of the competent Land authority shall be obtained. Decisions on the granting or renewal of a marketing authorisation, including the submission of assessment reports and opinions on assessment reports of competent authorities of other Member States, shall be taken by the competent national authority. in consultation with the Federal Agency for Nature Conservation, the Robert Koch Institute and the Federal Institute for Risk Assessment; a statement by the Julius Kühn Institute, Federal Research Institute for Environmental Health, shall be submitted beforehand.
The Commission shall obtain the approval of the Friedrich Loeffler Institute and the Paul Ehrlich Institute as far as genetically modified vertebrates or genetically modified micro-organisms used on vertebrates are concerned.

(5) Before granting the licence, the Commission shall examine and evaluate the application with regard to possible dangers to the legal interests specified in § 1 No. 1, in the cases referred to in paragraph 1 taking into account the planned safety precautions, and shall make recommendations in this respect. § Section 10, paragraph 7, sentences 3 and 4 shall apply accordingly.

(5a. The provisions of a marketing authorisation shall also be complied with by other parties involved in the placing on the market or handling of the product, insofar as they relate to the intended use or handling of the product, in particular its application, transport or storage, provided that the authorisation has been made public.

(6) The Federal Ministry of Food and Agriculture is hereby empowered to determine by ordinance, with the consent of the Bundesrat, the procedure for the participation of the European Commission and the Member States of the European Union and the other Contracting States to the Agreement on the European Economic Area in relation to the release of genetically modified organisms and the placing on the market of products containing or consisting of genetically modified organisms and the obligation of the competent authority to take into account any comments made by the Member States of the European Union and the other States party to the Agreement on the European Economic Area or to implement any decision or decision of the European Commission, in so far as this is necessary for the implementation of the Council

Directive on the deliberate release into the environment of genetically modified organisms.

organisms into the environment, as amended from time to time. The statutory instrument pursuant to the first sentence may provide that a permit shall be granted or refused, also in derogation of the provisions of this Act, to the extent provided for in a decision or resolution of the European Commission; this shall apply mutatis mutandis to the suspension of a permit pursuant to section 20 subsection (2) and a prohibition pursuant to section 26 subsection (5) third sentence.

(7) Prior to filing an administrative court action, preliminary proceedings shall not take place in the case of a decision on an application for authorisation of a release, provided that a hearing procedure pursuant to section 18 has been conducted.

§ 16a Location register

(1) For the purpose of monitoring any effects of genetically modified organisms on the legal interests and concerns referred to in § 1 Nos. 1 and 2 and for the purpose of informing the public, the information to be notified pursuant to paragraph 2 on releases of genetically modified organisms shall be
and the information on the cultivation of genetically modified organisms to be notified pursuant to paragraph 3 shall be recorded in a federal register. The register shall be maintained by the competent higher federal authority and shall record the information notified in accordance with paragraph 2 or paragraph 3 for the entire federal territory. The register shall be generally accessible in accordance with paragraph 4.

(2) The operator shall notify the competent higher federal authority of the actual implementation of the approved release of genetically modified organisms no later than three working days before the release. The notification shall include the following information:

1. the name of the genetically modified organism,
2. its genetically modified properties,
3. the site of the release and the size of the release area,
4. the release period.

Changes in the information as well as the termination of the release project shall be notified without delay.

(3) The cultivation of genetically modified organisms shall be notified to the competent higher federal authority by the person cultivating the area at least three months prior to cultivation. The notification shall include the following information:

1. the name and unique identifier of the genetically modified organism,
2. its genetically modified properties,
3. the name and address of the person cultivating the area,
4. the plot of land of the cultivation as well as the size of the

cultivated area. Any changes in the information must be reported

immediately.

(4) The generally accessible part of the register includes:

1. the name and unique identifier of the genetically modified organism,
2. its genetically modified properties,
3. the plot of land of the release or cultivation and the size of the area.

Information from the generally accessible part of the register shall be provided by way of automated retrieval via the internet.

(5) The competent higher federal authority shall also provide information on personal data from the part of the register that is not generally accessible, insofar as the person making the request substantiates a justified interest and there is no reason to assume that the person concerned has an overriding interest worthy of protection in the exclusion of the information.

(5a) The authority of a Land responsible for the implementation of this Act may, for the purpose of monitoring, retrieve the data stored in the part of the register that is not generally accessible by means of an automated procedure, insofar as a plot of land located within its area of responsibility is concerned. Responsibility for the permissibility of the individual retrieval shall be borne by the body to which the data are transmitted. The storing agency shall only check the permissibility of the retrievals if there is reason to do so. The storing agency shall ensure that the transfer of personal data is at least adequately protected by

suitable

(c) the data can be ascertained and verified by means of sampling procedures. If a complete set of personal data is retrieved or transmitted, the guarantee of ascertainment and verification shall only relate to the permissibility of the retrieval or transmission of the complete set. § Section 29, paragraph 1a, sentences 2 and 4 shall apply accordingly.

(6) The competent higher federal authority shall take state of the art measures to ensure data security and data protection, in particular to guarantee the integrity of the data and the confidentiality of the data stored in the part of the register that is not generally accessible; in the case of the use of generally accessible data networks for information pursuant to subsection 5
encryption procedures shall be used. The data of the Federal Register shall be deleted after 15 years have elapsed since they were first stored.

(7) Articles 12(5) and 15(1)(a), (c) and (g) of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of individuals with regard to the processing of personal data, on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation) (OJ L 119, 4.5.2016, p. 1; L 314, 22.11.2016, p. 72; L 127, 23.5.2018, p. 2). L 119, 4.5.2016, p. 1; L 314, 22.11.2016, p. 72; L 127, 23.5.2018, p. 2) and Section 34 of the Federal Data Protection Act, as amended, shall apply mutatis mutandis to legal persons.

(8) (omitted)

§ 16b Handling of products placed on the market

(1) Any person who cultivates, processes or, in the case of animals, keeps products containing or consisting of genetically modified organisms authorised for placing on the market, or who
places on the market commercially, on a commercial basis or in a comparable manner, shall ensure that the legal interests and concerns referred to in § 1 Nos. 1 and 2 are not substantially impaired by the transfer of properties of an organism based on genetic engineering work, by admixture or by other inputs of genetically modified organisms. With regard to the interests referred to in § 1 No. 2, he shall not be obliged to observe this obligation vis-à-vis another person,
than the latter has waived his protection by written agreement with him or has not provided him with the information required for his protection within one month upon request and the obligation in the respective individual case serves exclusively the protection of the other. In the written agreement or the request, the other party shall be informed of the legal consequences of the agreement or of the failure to provide the information and shall be informed that it must observe third party rights to be protected. The permissible deviation from the requirements of good professional practice shall be notified to the competent authority in due time before sowing or planting.

(1a) The manager shall, in addition to the information pursuant to § 16a para. 3 sentence 2

1. the fact of the conclusion of an agreement within the meaning of paragraph 1 sentence 2 or
2. the fact of not having received information from the neighbour in response to an enquiry within the meaning of subsection (1) sentence 2, insofar as the neighbour intends to deviate from the requirements of good professional practice due to a failure to provide information,

to the competent higher federal authority at the latest one month before the cultivation, indicating the plot of land concerned. The generally accessible part of the register pursuant to § 16a para. 1 sentence 1 shall include, in addition to the information pursuant to § 16a para. 4 sentence 1 no. 3, the information pursuant to sentence 1 relating to the plot of land concerned. Otherwise, § 16a shall apply mutatis mutandis.

(2) In the cultivation of plants, in other handling of plants and in the keeping of animals, the precautionary obligation under paragraph 1 shall be fulfilled by compliance with good professional practice.

(3) Good professional practice shall include, to the extent necessary to fulfil the precautionary duty pursuant to paragraph 1, in particular

1. when handling genetically modified organisms, compliance with the provisions of the marketing authorisation pursuant to § 16 para. 5a,
2. when cultivating genetically modified plants and when producing and applying fertilisers containing genetically modified organisms, measures to prevent entries into other properties and to prevent cross-pollination into other crops on neighbouring land and further spread by wild plants,

3. in the case of the keeping of genetically modified animals, the prevention of escape from the area intended for keeping and of the entry of other animals of the same species into that area,
4. in the transport, storage and further processing of genetically modified organisms, the prevention of losses and of mixing and admixture with other products.

(4) Any person who handles products containing or consisting of genetically modified organisms for commercial, industrial or comparable purposes shall possess the reliability, knowledge, skills and equipment to be able to fulfil the precautionary obligation under paragraph 1.

(5) Any person who places on the market products containing or consisting of genetically modified organisms shall supply product information containing the provisions of the authorisation insofar as they relate to the handling of the product and indicating how the obligations under paragraphs 1 to 3 can be fulfilled.

(6) The Federal Government is hereby empowered to specify in more detail by ordinance, with the consent of the Bundesrat, the principles of good professional practice within the meaning of paragraph 3, including the exchange of information with neighbours and authorities, the suitability of persons and equipment pursuant to paragraph 4 and the content of product information pursuant to paragraph 5.

§ 16c Observation

(1) Any operator who places on the market products consisting of or containing genetically modified organisms shall thereafter continue to monitor them in accordance with the authorisation in order to identify possible effects on the legal interests referred to in § 1 No. 1.

(2) The aim of the observation is to,

1. confirm that an assumption about the occurrence and effect of any adverse effect of a genetically modified organism or its use in the risk assessment is correct (case-specific observation), and
2. identify the occurrence of adverse effects of the genetically modified organism or its use on human health or the environment that were not anticipated in the risk assessment (general surveillance).

(3) The Federal Government is hereby empowered, with the consent of the Bundesrat, to regulate the general principles of the monitoring of genetically modified organisms by the operator in a statutory instrument, in particular with regard to the definition of minimum standards of monitoring, the involvement of third parties and the inclusion of federal authority monitoring activities.

§ 16d Decision of the authority in the case of placing on the market

(1) Within the framework of the authorisation to place a product on the market which contains or consists of genetically modified organisms, the competent higher federal authority shall decide on the following

1. the intended use,
2. the special conditions for handling the product and its packaging,
3. the conditions for the protection of particular ecosystems, environmental conditions or geographical areas,
4. the labelling,
5. the requirements for the details of the observation based on the risk assessment, the duration of the observation plan,
6. the obligation to submit control samples.

(2) The marketing authorisation shall be granted for a maximum of ten years. The authorisation shall be renewed for a period of ten years. The extension may be granted for a shorter or longer period for special reasons. In the case of a genetically modified organism to be placed on the market exclusively as seed or propagating material, the period referred to in the first sentence shall commence with the notification of the registration of the first seed or propagating material containing that organism.
Plant variety in an official national plant variety catalogue in accordance with Council Directive 2002/53/EC.

of 13 June 2002 on the common catalogue of varieties of agricultural plant species (OJ EC No. L 193 p. 1), last amended by Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003 (OJ EU No. L 268 p. 1), and Council Directive 2002/55/EC of 13 June 2002 on the marketing of vegetable seed (OJ EC No. L 193 p. 33), as last amended by Regulation (EC) No. 1829/2003 of the European Parliament and of the Council of 22 September 2003 (OJ EU No. L 268 p. 1). If the marketing of forest reproductive material is authorised, the period referred to in the first sentence shall commence with the notification of the entry in an official national register of basic material in accordance with Council Directive 1999/105/EC of 22 December 1999 on the marketing of forest reproductive material (OJ EC 2000 No. 11 p. 17). The operator shall immediately notify the competent higher federal authority of the announcement of the entry pursuant to sentences 3 and 4.

(3) The competent higher federal authority may, insofar as this is necessary to prevent unjustifiable harmful effects on the legal interests specified in section 1 no. 1 in relation to the purpose of placing the product on the market in accordance with the state of scientific knowledge, subsequently amend the decision taken in accordance with subsection 1 sentence 1 no. 5, insofar as this is necessary to adapt the observation methods, the sampling or analysis procedures to the state of scientific knowledge or to take account of findings only obtained in the course of the observation. Sections 48 and 49 of the Administrative Procedure Act shall remain unaffected.

§ 16e Exemptions for seed not subject to labelling requirements

Sections 16a and 16b shall not apply to seed if the seed does not have to be labelled with an indication of the genetic modification on the basis of a threshold value laid down in legal acts of the European Union and their implementation by section 17b subsection (1) sentence 2 or, if it were placed on the market, would have to be labelled.

Part Four
Common rules

§ 17 Use of documents

(1) documents pursuant to § 10 para. 2 sentence 2 no. 5, para. 3 sentence 2 no. 4, also in conjunction with § 12 para. 2, pursuant to § 12
Para. 2a sentence 2 nos. 1 and 4, Article 15 para. 1 sentence 2 nos. 2 and 4, para. 3 sentence 2 nos. 2, 4 and 5 shall not be required if the competent authority has sufficient knowledge. In this respect, the operator may also refer to documents submitted by him or a third party in a previous procedure, unless the documents are confidential documents of the third party and the third party has not given his consent to their use. If findings that require animal experiments are derived from documents of a third party, the operator shall inform the third party.
the competent authority shall inform the third party and the notifier or applicant which documents of the third party it intends to use for the benefit of the notifier or applicant, together with the name and address of the other party. If animal testing is not a prerequisite, the use of confidential documents of a third party shall require the written consent of the third party. Sentences 3 and 4 shall not apply if the notification or authorisation dates back more than ten years.

(2) The third party may object to the use of his documents in the case of paragraph 1, sentence 3 within a period of 30 days after receipt of the notification under paragraph 1, sentence 3. In the event of an objection, the application or authorisation procedure shall be suspended for a period of five years after the application or filing of the
The application for authorisation shall be suspended until the expiry of ten years after the filing of the application or the authorisation of the third party at the latest. If the applicant would need a shorter period of time to provide his own documents, the application or authorisation procedure shall be suspended only for that period of time. Before suspending the application or approval procedure, the applicant or person requesting it and the third party shall be heard.

(3) If an application is filed or, in the case referred to in paragraph 2, an authorisation is granted before the expiry of ten years from the date of filing or granting of the authorisation of the third party using his documents, he shall be entitled to compensation from the applicant or declarant amounting to 50 % of the expenses saved by the applicant or declarant through such use. The third party may prohibit the applicant from placing the product on the market as long as the applicant has not paid the fee or provided adequate security for it.

(4) Where several notifiers or applicants submit at the same time to a competent authority documents of the same content which require animal testing, the competent authority shall inform the notifiers or applicants

known to it which documents shall be submitted jointly by them,
and the name and address of each of the other parties involved. The competent authority shall provide the

The competent authority shall give the applicants or proposers the opportunity to agree, within a time limit to be fixed by the competent authority, on who will submit the documents. If no agreement is reached, the competent authority shall decide and
shall immediately inform all parties concerned thereof. Unless they withdraw their application or request or the conditions of their obligation to apply or request otherwise cease to apply, they shall be obliged to reimburse the person who submitted the documents for the proportionate expenses incurred in preparing them; they shall be jointly and severally liable.

§ 17a Confidentiality of information

(1) Information which constitutes a trade or business secret shall be marked as confidential by the operator. The operator shall justify that disclosure of the trade or business secrets could be detrimental to the operator's business or operations. If the competent authority considers the labelling to be unjustified, it shall hear the applicant before deciding which information is to be treated as confidential and inform the applicant of its decision. Personal data shall be treated as trade and business secrets and shall be kept confidential.

(2) The following shall not be covered by industrial and commercial secrecy within the meaning of paragraph 1

1. general characteristics or description of the genetically modified organisms,
2. Name and address of the operator,
3. Location of the genetic engineering facility or release and the purpose of the

release, 3a. Intended use,

4. Security level and security measures,
5. Methods and plans for monitoring the genetically modified organisms and for emergency measures,
6. Risk assessment.

(3) Insofar as a hearing procedure pursuant to section 18 is to be carried out, the contents of the documents shall, insofar as the information contains trade or business secrets or personal data and insofar as it can be done without disclosing such protected data, be presented in sufficient detail to enable third parties to assess whether and to what extent they are affected by the effects of the project.

(4) If the notifier or applicant withdraws the notification or application for authorisation, the competent authorities shall respect confidentiality.

§ 17b Labelling

(1) Products containing or consisting of genetically modified organisms and placed on the market shall be labelled with the words "This product contains genetically modified organisms" on a label or in an accompanying document in accordance with the provisions on labelling issued on the basis of section 30 subsection (2) No. 14. The Federal Government may, for the purpose of implementing an Article 21
(2), second sentence, in conjunction with Article 30 (2) of Directive 2001/18/EC, shall exempt from the labelling obligation by ordinance, with the consent of the Bundesrat, those products in which adventitious or technically unavoidable presence of genetically modified organisms cannot be excluded.

(2) Genetically modified organisms which are made available to another person for genetic engineering work in genetic engineering facilities, for work in facilities within the meaning of Section 14 sub-section 1a or for a release shall be labelled with the indication "This product contains genetically modified organisms". The provisions on the labelling of genetically modified organisms issued on the basis of section 30 subsection (2) No. 14 shall apply mutatis mutandis insofar as they are applicable to organisms according to sentence 1 by their nature. The Federal Government may, in order to implement the implementing provisions of the European Community or the European Union in accordance with Article 26 paragraph 2 in conjunction with Article 30 paragraph 2 of Directive 2001/18/EC shall, after consulting the Commission in accordance with section 4, determine by ordinance with the consent of the Bundesrat how the labelling of these products is to be carried out.

(3) The requirements for the labelling and packaging of products containing or consisting of genetically modified organisms authorised for the placing on the market shall not apply to products intended for immediate processing containing authorised
genetically modified organisms does not exceed 0.9 per cent, provided that this proportion is adventitious or

is technically unavoidable. The Federal Government may set a lower threshold value determined in accordance with Article 21(3) in conjunction with Article 30(2) of Directive 2001/18/EC by ordinance with the consent of the Bundesrat.

§ 18 Hearing procedure

(1) Before deciding on the construction and operation of a genetic engineering facility in which genetic engineering work of safety levels 3 or 4 is to be carried out for commercial purposes, the competent authority shall conduct a consultation procedure. For the approval of genetic engineering facilities,
in which genetic engineering work of safety level 2 is to be carried out for commercial purposes, a hearing procedure must be carried out if a licensing procedure in accordance with Section 10 of the Federal Immission Control Act would be required. In the case of § 8 para. 4, a hearing procedure shall not be required if there is no reason to fear that the alteration will result in additional or other hazards to the legal interests specified in § 1 no. 1.

(2) A hearing procedure shall be conducted prior to the decision on the authorisation of a release. § Section 14 para. 4a sentence 2 shall remain unaffected.

(3) The Federal Government shall regulate the hearing procedure by ordinance with the consent of the Bundesrat. The procedure shall comply with the requirements of section 10 subsections (3) to (8) of the Federal Immission Control Act. In the case of procedures pursuant to subsection (2) above, section 10 subsection (4) No. 3 and subsection (6) of the Federal Immission Control Act shall not apply; objections to the project may be raised and substantiated in writing or in writing within one month of the expiry of the display period at the licensing authority or at the office where the application and documents are displayed for inspection.

§ 19 Ancillary provisions, subsequent conditions

The competent authority may attach ancillary provisions to its decision insofar as this is necessary to ensure that the licensing requirements are met. In particular, certain procedural sequences or safety precautions or a certain quality or equipment of the genetic engineering facility may be ordered by means of conditions. The subsequent inclusion of ancillary provisions or conditions is permissible under the conditions of sentence 1.

§ 20 Interim suspension

(1) If the prerequisites for the continuation of the operation of the genetic engineering facility, the genetic engineering work or the release have subsequently ceased to exist, the temporary cessation of the activity may be ordered in accordance with the provisions of the Administrative Procedure Acts instead of the withdrawal or revocation of the authorisation until the operator proves that the prerequisites are again fulfilled.

(2) If, after the granting of a marketing authorisation, including an equivalent marketing authorisation under Section 14(5), there are justifiable grounds for assuming, on the basis of new or additional information having an impact on the risk assessment, or on the basis of a reassessment of the available information on the basis of new or additional scientific knowledge, that the genetically modified organism constitutes a risk to human health or the environment, the following may be authorised
the competent higher federal authority shall order the suspension of the authorisation in whole or in part until a decision has been taken or until a decision has been taken by the European Communities or the European Union in accordance with Article 23 in conjunction with Article 30(2) of Directive 2001/18/EC.

§ 21 Obligations to notify

(1) The operator shall notify in advance any change in the assignment of the project leader, the Biosafety Officer or a member of the Biosafety Committee to the competent authority responsible for a notification, the granting of a permit and the competent authority responsible for monitoring. In the event of an unforeseen change, the notification shall be made without delay. The notification shall be accompanied by proof of the required expertise.

(1a) (omitted)

(1b) If the operator intends to discontinue the operation of an installation, he shall immediately notify the competent authority responsible for supervision thereof, stating the date of discontinuation. The notification shall be accompanied by documents on the measures envisaged by the operator to fulfil the obligations resulting from § 6 para. 2 sentence 2.

(2) Notification shall also be given of any intended modification of the safety-related facilities and precautions of a genetic engineering facility, even if, as a result of the modification, the genetic engineering facility continues to meet the requirements of the safety level necessary for the performance of the notified, notified or approved work.

(2a) The competent higher federal authority shall be notified of any intended or known unintentional change to a release which may have an effect on the assessment of the requirements under Section 16(1).

(3) The operator shall immediately notify the authority responsible for notification, notification, granting of authorisation and the authority responsible for monitoring of any occurrence which does not correspond to the expected course of the genetic engineering work or of the release or placing on the market and which gives rise to the suspicion of a risk to the legal interests specified in § 1 No. 1. All information necessary for the safety assessment as well as planned or taken emergency measures shall be reported.

(4) After completion of a release, the operator shall notify the competent higher federal authority of the results of the release, insofar as they have knowledge of a risk to the species referred to in § 1 No. 1. legal interests can be inferred. This shall also apply to hazards resulting from placing on the market if this is intended. The duration of the obligation to notify shall be decided in the authorisation. Decisions or resolutions of the European Communities or of the European Union in accordance with Article 10 in conjunction with Article 30, paragraph 2 of Directive 2001/18/EC, which specify the form of the notifications in accordance with paragraph 4 and are published by the Federal Ministry of Food and Agriculture in the Federal Gazette, shall be taken into account in the preparation of the notifications.

(4a) The operator shall report to the competent higher federal authority on the observation of the placing on the market in accordance with the marketing authorisation.

(5) If the operator receives new information on risks to human health or the environment, he shall notify the competent authority without delay.

(5a) If the operator receives new information on risks to the legal interests and concerns referred to in § 1 Nos. 1 and 2, he shall, as far as the release and the placing on the market are concerned, report these to the competent
the higher federal authority without delay. Sentence 1 shall apply mutatis mutandis to the other parties involved in placing the product on the market or handling it.

(6) A notification under paragraphs 5 and 5a may not be used for the criminal prosecution of the notifier or for proceedings under the Administrative Offences Act against the notifier.

§ 22 Other official decisions

(1) The installation permit includes other official decisions concerning the genetic engineering installation, in particular public-law approvals, authorisations, awards, permits and licences, with the exception of official decisions based on nuclear regulations.

(2) Provisions under which public-law authorisations, approvals, conferrals, permits and licences are granted shall not apply to genetic engineering installations for which a notification procedure is to be carried out under this Act, or to genetic engineering work, releases or placing on the market which are subject to notification or authorisation under this Act, insofar as protection against the specific hazards of genetic engineering is concerned; provisions on placing on the market under Section 14(2) shall remain unaffected.

(3) § Section 35 of the Federal Nature Conservation Act shall remain unaffected.

§ 23 Exclusion of defence claims under private law

On the basis of claims under private law, not based on special titles, for the defence against adverse effects from one plot of land on an adjacent plot of land, the cessation of the operation of the genetic engineering facility, the genetic engineering work or the termination of a release, the approval of which is incontestable and for which a hearing procedure has been carried out in accordance with section 18, cannot be demanded; only precautions which exclude the adverse effects can be demanded. Insofar as such

precautions are not feasible according to the state of the art or are not economically justifiable, only compensation for damages can be claimed.

§ 24 (omitted)

§ Section 25 Monitoring, Obligation to Provide Information, Obligation to Tolerate

(1) The competent authorities shall monitor the implementation of this Act, of the statutory instruments issued on the basis of this Act, of the directly applicable legal acts of the European Communities or of the European Union within the scope of this Act and of the official orders and decrees based thereon.

(2) The operator, the responsible persons within the meaning of § 3 Nos. 8 and 9 and any person who handles products containing or consisting of genetically modified organisms commercially, on a commercial basis or in a comparable manner shall, upon request, immediately provide the competent authority with the information required for monitoring and shall make available the necessary tools, including control samples, within the scope of their availability.

(3) The persons charged with monitoring are authorised,

1. to enter and inspect properties, business premises and business premises during operating and business hours,
2. carry out all tests necessary for the performance of their duties, including the taking of samples,
3. to inspect the documents necessary for the performance of their duties and to make copies or transcripts thereof.

In order to prevent urgent hazards to public safety and order, measures pursuant to sentence 1 may also be taken in living quarters and at any time of day or night. The operator and any person who commercially, commercially or in a comparable manner handles products containing or consisting of genetically modified organisms shall be obliged to tolerate measures pursuant to sentence 1 nos. 1 and 2 and sentence 2, to assist the persons charged with monitoring to the extent necessary for the performance of their duties, and to submit the necessary business documents. The fundamental right of inviolability of the home (Article 13 of the Basic Law) is restricted in this respect.

(4) Persons obliged to provide information may refuse to provide information to questions the answering of which would expose them or one of their relatives referred to in section 383, paragraph 1, nos. 1 to 3 of the Code of Civil Procedure to the risk of prosecution for a criminal offence or misdemeanour.

(4a) The operator's own expenses incurred in the fulfilment of obligations to provide information and to tolerate within the framework of notification and approval procedures and within the framework of monitoring shall not be reimbursed.

(5) Personal information collected in fulfilment of an obligation to provide information or to tolerate the provision of information under this Act or a statutory instrument issued on the basis of this Act may only be used to the extent necessary to implement this Act or to prosecute a criminal offence or to avert a threat to public safety.

(6) The risk assessment pursuant to § 6 para. 1 shall be submitted to the competent authority upon request.

(7) By way of derogation from paragraph 1, authorities which carry out statutory tests on genetically modified plants authorised for placing on the market or have such tests carried out shall themselves ensure compliance with the provisions of this Act, the statutory orders issued on the basis of this Act and the directly applicable legal acts of the European Communities or of the European Union within the scope of this Act. This shall apply to the municipalities and associations of municipalities only insofar as this task has been transferred to them by Land law.

§ 26 Official orders

(1) The competent authority may, in individual cases, make such orders as are necessary for the elimination of established violations or the prevention of future violations of this Act, of the regulations issued on the basis of this Act, or of the regulations issued on the basis of this Act.
legal ordinances or against directly applicable legal acts of the European Communities or the

European Union within the scope of this Act. In particular, it may prohibit the operation of a genetic engineering facility or genetic engineering work in whole or in part if

1. the required notification or registration has been omitted, a required permit or consent has not been obtained,
2. there is a ground for withdrawal or revocation of a permit under the Administrative Procedure Acts,
3. ancillary provisions or subsequent conditions pursuant to § 19 are violated,
4. the existing safety-related facilities and precautions are not or no longer sufficient.

(2) If the operator of a genetic engineering facility fails to comply with a requirement, an enforceable subsequent order or an obligation on the basis of a statutory instrument under section 30 and if the requirement, order or obligation relates to the nature or operation of the genetic engineering facility, the competent authority may prohibit operation in whole or in part until the requirement, order or obligation under a statutory instrument under section 30 has been complied with.

(3) The competent authority may order the complete or partial shutdown or removal of a genetic engineering facility which has been established, operated or substantially modified without the required notification or authorisation. It shall order the complete or partial removal if the legal interests referred to in § 1 No. 1 cannot be adequately protected in any other way.

(4) The competent authority shall prohibit a release if the requirements of paragraph 1, sentence 2, nos. 1 and 2 are met. It may prohibit a release if the requirements of paragraph 1, sentence 2, nos. 3 and 4 are met.

(5) The competent authority shall prohibit the placing on the market if the required authorisation has not been granted. It shall provisionally prohibit the placing on the market pending a decision or a decision of the European Communities or of the European Union in accordance with Article 23 in conjunction with Article 30(2) of Directive 2001/18/EC, insofar as the suspension of the marketing authorisation has been ordered. It may provisionally prohibit the placing on the market, in whole or in part, pending this decision or this order, if there is sufficient suspicion that the requirements for placing on the market are not met. The competent authority shall refrain from issuing orders pursuant to sentence 1 if the product containing genetically modified organisms not authorised for placing on the market is intended for direct processing and it is ensured that the product does not enter foodstuffs or animal feed either in an unprocessed or processed state, that the genetically modified organisms are destroyed after processing and that no harmful effects on the legal interests referred to in section 1 no. 1 occur.

§ Section 27 Expiry of the authorisation, invalidity of the application

(1) The authorisation shall expire if

1. the construction or operation of the genetic engineering facility or the release has not commenced within a period set by the approval authority, which may not exceed three years, or
2. a genetic engineering facility has not been operated for a period of more than three years.

(2) The approval, except in the cases of § 8 para. 2 sentence 2, shall furthermore expire insofar as the approval requirement is revoked.

(3) The licensing authority may, upon application, extend the time limits under subsection (1) by a maximum of one year for good cause, provided that the purpose of the Act is not jeopardised thereby.

(4) The notification of a facility in which genetic engineering work of safety level 1 or 2 is to be carried out shall become invalid if

1. has not commenced construction or operation of the genetic engineering facility within three years, or
2. the genetic engineering facility has not been operated for a period of more than three years.

(5) (omitted)

§ 28 Disclosure of information

(1) The competent authorities shall inform the competent higher federal authority without delay about

1. the decisions taken in the execution of this Act, insofar as they are relevant to the higher federal authority,
2. Findings and occurrences that may have an impact on the legal interests and concerns mentioned in § 1 nos. 1 and 2,
3. Infringements or suspected infringements of provisions of this Act and of statutory instruments issued on the basis of this Act, of directly applicable legal acts of the European Communities or of the European Union, and of permits and conditions within the scope of this Act.

(2) The competent higher federal authority shall make its findings known to the competent authorities insofar as they may be of significance for the implementation of the law.

§ 28a Informing the public

(1) The competent authority shall inform the public of orders under section 26 if they have become incontestable or their immediate enforcement has been ordered, including the precautionary measures ordered. Personal data may only be published insofar as this is necessary to avert danger.

(2) The competent authority shall inform the public of

1. the reasonable suspicion of a danger to the legal interests mentioned in § 1 no. 1 including the precautionary measures to be taken,
2. the results of the monitoring of the placing on the market in a general manner.

In the cases referred to in sentence 1, personal data may only be published if the person concerned has consented or if the public's interest in information worthy of protection outweighs the interest of the person concerned in the exclusion of publication. The person concerned shall be heard prior to the decision on publication.

(3) Information under paragraph 2 shall not be published,

1. insofar as the disclosure of the information may affect the confidentiality of the deliberations of public authorities or may cause a significant threat to public safety,
2. during the duration of legal proceedings, criminal investigations, disciplinary proceedings, administrative offence proceedings with regard to the data which are the subject of the proceedings,
3. insofar as the protection of intellectual property, in particular copyrights, conflicts with the right to information or
4. insofar as the information would disclose trade or business secrets or information relevant to competition that is equivalent in nature to trade secrets, unless certain information must be published, taking into account the overall circumstances, in order to ensure the protection of the safety and health of the public; in this context, a balancing exercise shall be carried out in accordance with paragraph 2 sentence 2.

Prior to the decision on publication, the persons concerned shall be heard in the cases of sentence 1 no. 3 or 4. Insofar as published information is marked as a trade or business secret, the competent authority shall, in case of doubt, assume that the person marking the information is affected.

(4) If the information provided by the Authority to the public subsequently turns out to be incorrect or the underlying circumstances to have been misrepresented, the Authority shall inform the public thereof in the same manner in which it previously disclosed the information concerned.

§ 28b Methodology

(1) The competent higher federal authority shall, in consultation with the authorities responsible for food and feed legislation, publish an official collection of procedures for the sampling and testing of samples carried out or used in the context of the monitoring of genetic engineering operations, genetic engineering facilities, releases of genetically modified organisms and the placing on the market.

(2) The procedures shall be established with the participation of experts from the fields of monitoring, science and the industry involved. The collection shall be kept up to date on an ongoing basis.

§ 29 Evaluation and provision of data

(1) The competent higher federal authority shall collect data in accordance with Section 28 that is collected in connection with the construction and operation of genetic engineering facilities, the performance of genetic engineering work, releases or
with a placing on the market collected by it or transmitted to it for the purpose of monitoring, collecting and evaluating facts which may have an impact on the legal interests and concerns referred to in Section 1 Nos. 1 and 2. It may transmit data on Commission opinions on the safety classification and safety measures of genetic engineering operations and on decisions taken by the competent authorities to the competent authorities for use in notification and authorisation procedures. The recipients may use the transmitted data only for the purpose for which they were transmitted.

(1a) The establishment of an automated retrieval procedure shall be permissible. When setting up the automated retrieval procedure, the competent higher federal authority and the competent authorities shall specify in writing the type of data to be transmitted and the necessary technical and organisational measures in accordance with Articles 24, 25 and 32 of Regulation (EU) 2016/679. The establishment of the automated retrieval procedure shall require the approval of the Federal Ministry of Food and Agriculture. in agreement with the Federal Ministry for Economic Affairs and Energy. The Federal Commissioner for Data Protection shall be informed of the establishment of the retrieval procedure and of the specifications pursuant to sentence 2. The recipient shall be responsible for the permissibility of the individual retrieval. The competent higher federal authority shall only check the permissibility of the retrievals if there is cause to do so. It shall ensure that the transmission of the data can be determined and verified.

(2) The legal provisions on secrecy shall remain unaffected. The transmission of factual information within the meaning of § 17a to departments of the European Union and authorities of other states may only take place if the requesting body demonstrates that it has taken precautions to protect operational and
The Act provides that the competent authorities of a Member State shall take measures to protect business secrets and personal data that are equivalent to the corresponding provisions within the scope of application of this Act.

(3) Personal data may only be processed by the competent higher federal authority insofar as this is necessary to assess the reliability of the operator, the project manager and the biosafety officer(s) or to assess the expertise of the project manager or the biosafety officer(s).

(4) The type and scope of the data shall be regulated by the Federal Ministry of Food and Agriculture in agreement with the Federal Ministry for Economic Affairs and Energy by ordinance with the consent of the Bundesrat.

§ 30 Enactment of statutory ordinances and administrative regulations

(1) The Federal Government shall, after consultation with the Commission, determine by ordinance with the consent of the Bundesrat the responsibility and the required expertise of the project leader in order to achieve the purposes specified in Section 1 No. 1, in particular with regard to the need for and the extent of knowledge to be demonstrated in classical and molecular genetics, practical experience in handling microorganisms and the required knowledge, including the provisions of occupational health and safety law on working in a genetic engineering facility.

(2) The Federal Government shall be empowered, after hearing the Commission, to determine by ordinance, with the consent of the Bundesrat, for the achievement of the purposes specified in § 1 No. 1,

1. how the workplace, the operating facilities and the technical work equipment at the individual safety levels must be designed, set up and operated so that they comply with the safe

comply with safety-related, occupational medical, hygienic and other occupational science findings which must be observed for the protection of employees and which are necessary for the humane design of work;

2. the necessary operational measures, in particular
   a) how the working procedure must be designed so that workers are not endangered by genetic engineering work or a release,
   b) how work areas must be monitored to detect contamination by genetically modified organisms,
   c) how genetically modified organisms must be stored within the company and what hazards must be pointed out so that employees are not endangered by unsuitable storage and are informed of the hazards posed by these organisms by hazard warnings,
   d) what precautions must be taken to ensure that genetically modified organisms do not fall into the hands of unauthorised persons or otherwise get lost,
   e) which personal protective equipment must be provided and used by workers as intended,
   f) that the number of employees handling genetically modified organisms can be limited and that the duration of such employment can be limited,
   g) how workers must behave so that they do not endanger themselves or others, and what measures must be taken,
   h) under which circumstances access restrictions must be provided for the protection of workers;
3. that and how many biological safety officers shall be appointed by the operator to verify the fulfilment of the project manager's tasks and to advise the operator and the responsible persons in all matters of biological safety, how these tasks are to be performed in detail, what expertise in biological safety is to be demonstrated and how the biological safety officer or officers are to be appointed with the participation of the works council or staff council;
4. what knowledge and skills those involved in genetic engineering work or a release must have and what evidence of this must be provided;
5. how and at what intervals the employees are to be instructed about the hazards and measures to avert them and how the employees are to be made aware of the content of the regulations to be applied in the enterprise in an activity-related operating instruction, taking into account safety advice;
6. what precautions are to be taken to prevent occupational accidents and incidents and to limit their effects on workers, and what measures are to be taken to organise first aid;
7. that and which responsible supervisors must be appointed to supervise genetic engineering work and releases as well as other work in the hazardous area, and which powers must be delegated to them so that the occupational health and safety tasks can be fulfilled;
8. that, with regard to the protection of workers, the operator must carry out a hazard assessment and draw up a hazard prevention plan, which documents must be prepared for this purpose, and that these documents must be kept available for inspection by the competent authority for the purpose of reviewing the hazard assessment as well as the hazard prevention plan;
9. that the employees are to receive occupational health care and that records are to be kept on this and for this purpose
   a) the operator can be obliged to have the employees involved in genetic engineering work or a release medically examined,
   b) the doctor in charge of a preventive medical examination has to fulfil certain obligations in connection with the examination findings, in particular with regard to the content of a certificate to be issued by him and to informing and advising on the result of the examination,

c) the competent authority decides if findings of the doctor are deemed to be incorrect,

d) the data to be included in the record are transmitted to the statutory accident insurance institutions or to a body appointed by them for the purpose of investigating work-related health hazards or occupational diseases;

9a. for which activities employees must be allowed to undergo follow-up examinations;

10. that the employer must inform the works council or staff council of events that the council needs to know in order to fulfil its duties;

11. that the competent authorities are authorised to issue certain orders in individual cases, also against supervisors and other employees, in particular in cases of imminent danger, in order to implement statutory orders;

12. that certain precautions must be taken when terminating a genetic engineering work or a release;

13. that the transport of genetically modified organisms is to be made subject to compliance with certain precautionary measures;

14. that and how, in order to regulate the circulation and handling of products containing or consisting of genetically modified organisms, the products are to be packaged and labelled, in particular what information is to be provided on the genetic modifications and on the acceptable adverse effects within the meaning of § 16 para. 2, insofar as this is necessary to protect the user;

15. the content and form of the notification, registration and application documents pursuant to § 10 paras. 2 and 3, § 12 paras. 2 and 2a and § 15, in particular the criteria to be applied in the risk assessment
and which criteria are to be observed when drawing up the observation plan, as well as the details of the notification, registration and approval procedure;

16. that, in the event of an accident in a genetic engineering plant

a) the competent authority to draw up off-site emergency plans on the basis of documents to be supplied by the operator, to coordinate their preparation and implementation with the competent authorities of the Member States of the European Union or the other States party to the Agreement on the European Economic Area which may be affected by an accident, and to inform the public about safety measures,

b) the operator shall report the circumstances of the accident and the measures taken by him to the competent authority,

c) the competent authority must report this information to the competent higher federal authority for forwarding to the European Commission, inform the authorities designated by the Member States of the European Union and the other contracting states to the Agreement on the European Economic Area, insofar as these states are potentially affected by the accident, and take all emergency and other necessary measures.

(3) (omitted)

(4) For the requirements according to paragraphs 1 and 2, reference may be made to announcements of expert bodies accessible to the public; in this context, the following shall be taken into account

1. indicate in the statutory instrument the date of publication and specify the source of reference,

2. to file the announcement with the competent higher federal authority in an archived form and to refer to it in the ordinance.

(5) The Federal Government may, after hearing the Commission and with the consent of the Bundesrat, issue general administrative regulations for the implementation of this Act and the statutory orders issued on the basis of this Act.

§ 31 Competent authority and competent higher federal authority

The authorities responsible for implementing this Act shall be determined by the competent authority under Land law or, in the absence of such a determination, by the Land government; the latter may further delegate the authorisation.
The competent higher federal authority is the Federal Office of Consumer Protection and Food Safety.

Part Five Liability Provisions

§ 32 Liability

(1) If, as a result of properties of an organism based on genetic engineering work, someone is killed, their body or health is injured or an object is damaged, the operator is obliged to compensate for the resulting damage.

(2) If several operators are liable to pay compensation for the same damage, they shall be liable as joint and several debtors. In the relationship of the parties liable to pay compensation to each other, the obligation to pay compensation as well as the extent of the compensation to be paid shall depend on the extent to which the damage is
has been caused predominantly by one or the other party; in all other respects sections 421 to 425 and section 426 subs. 1 second sentence and subs. 2 of the Civil Code shall apply.

(3) If fault on the part of the injured party has contributed to the occurrence of the damage, section 254 of the Civil Code shall apply; in the case of damage to property, the fault of the party exercising actual control over the property shall be equivalent to the fault of the injured party. The operator's liability shall not be reduced if the damage was also caused by the action of a third party; paragraph 2 sentence 2 shall apply accordingly.

(4) In the event of death, compensation shall be paid for the costs of the attempted cure and for the pecuniary loss suffered by the deceased as a result of the fact that during the illness his earning capacity was suspended or reduced or his needs were increased. The person liable to pay compensation shall also reimburse the costs of the funeral to the person who has to bear these costs. If, at the time of the injury, the deceased was in a relationship with a third party under which he or she was legally obliged to pay maintenance to the third party, the debtor shall be liable for the costs of the funeral.
If the third party was or could have been dependent on the deceased and if the third party is deprived of the right to maintenance as a result of the death, the person liable to pay compensation shall pay compensation to the third party to the extent that the deceased would have been obliged to provide maintenance during the presumed duration of his or her life. The obligation to pay compensation also applies if the third party was conceived but not yet born at the time of the injury.
The person liable to pay compensation must also pay the survivor, who was in a special personal relationship of proximity to the deceased at the time of the injury, appropriate compensation in money for the emotional suffering caused to the survivor. A special personal relationship of proximity is presumed if the survivor was the spouse, civil partner, parent or child of the deceased.

(5) In the event of bodily injury or damage to health, compensation shall be paid for the costs of healing and for the pecuniary loss suffered by the injured person as a result of the fact that, as a consequence of the injury, his or her
The person's earning capacity has been temporarily or permanently suspended or reduced or his or her needs have been increased. For damage that is not pecuniary damage, equitable compensation in money may also be claimed.

(6) Compensation for loss or reduction of earning capacity and for increased needs of the injured person as well as compensation to be granted to a third party in accordance with subsection 4, sentences 3 and 4 shall be paid for the future in the form of a cash annuity. § Section 843 subsections 2 to 4 of the Civil Code shall apply accordingly.

(7) If the damage to an object also constitutes an impairment of nature or the landscape, section 251 subsection (2) of the Civil Code shall apply to the extent that the injured party restores the state that would exist if the impairment had not occurred, subject to the proviso that expenses for restoring the previous state are not disproportionate solely because they exceed the value of the object.
of the object considerably. At the request of the person entitled to compensation, the injuring party shall make an advance payment for the necessary expenses.

(8) The provisions of the German Civil Code applicable to tortious acts shall apply mutatis mutandis to the limitation period.

§ 33 Maximum liability amount

If damage has been caused as a result of characteristics of an organism based on genetic engineering work, the operator shall, in the case of § 32, be liable to the injured parties up to a maximum amount of 85 million euros. If the several compensations to be paid on the basis of the same damaging event exceed the maximum amount specified in sentence 1, the individual compensations shall be reduced in the same proportion as their total amount bears to the maximum amount.

§ 34 Presumption of cause

(1) If the damage has been caused by genetically modified organisms, it shall be presumed to have been caused by characteristics of these organisms resulting from genetic engineering work.

(2) The presumption is rebutted if it is likely that the harm is due to other characteristics of these organisms.

§ 35 Claims for information of the injured party

(1) If facts exist which justify the assumption that personal injury or damage to property is due to genetic engineering work carried out by an operator, the operator shall be obliged, at the request of the injured party, to provide information on the nature of the damage.
and the course of the genetic engineering work carried out in the genetic engineering facility or underlying a release, insofar as this is necessary to determine whether a claim exists under section 32. Sections 259 to 261 of the Civil Code shall apply mutatis mutandis.

(2) A right to information shall also exist under the conditions of subsection (1) sentence 1 vis-à-vis the authorities responsible for the registration, the granting of a permit or the supervision.

(3) The claims according to paragraphs 1 and 2 do not exist insofar as the processes are to be kept secret due to legal regulations or the secrecy corresponds to an overriding interest of the operator or a third party.

§ 36 Financial security

(1) The Federal Government shall determine in a statutory instrument, with the consent of the Bundesrat, that the person operating a genetic engineering facility in which genetic engineering work of safety levels 2 to 4 is to be carried out, or who carries out releases, shall be obliged to take precautions to cover damage caused by the properties of an organism resulting from genetic engineering work (financial security). The scope of the financial security for a genetic engineering facility shall take into account the type and scope of the work carried out in the facility; this shall apply to releases
accordingly. The statutory order shall also contain more detailed provisions on the powers to monitor the financial security. After issuing the statutory order in accordance with sentence 1, the Federal Ministry of Justice and Consumer Protection may by statutory order in agreement with the Federal Ministry of
for Economic Affairs and Energy, the Federal Ministry of Food and Agriculture, the Federal Ministry of Education and Research, the Federal Ministry for the Environment, Nature Conservation and Nuclear Safety and the Federal Ministry of Health shall re-determine the amount of the financial security, taking into account the maximum amounts offered on the insurance market.

(2) The financial security can be provided in particular

1. by a liability insurance with an insurance company authorised to do business within the scope of this Act, or
2. by an indemnity or guarantee obligation of the Federal Government or a Land.

The statutory order pursuant to paragraph 1 may also permit other types of financial security, in particular indemnity or guarantee obligations of credit institutions, provided that they offer comparable collateral to a financial security pursuant to sentence 1.

(3) The following are exempt from the obligation to provide cover

1. the Federal Republic of Germany,
2. the countries and
3. legal entities under public law.

§ Section 36a Claims for impairment of use

(1) The transfer of properties of an organism based on genetic engineering work or other entries of genetically modified organisms constitute a substantial impairment within the meaning of section 906 of the Civil Code if, contrary to the intention of the person entitled to use the organism, because of the transfer or other entry products in particular

1. may not be placed on the market, or
2. may only be placed on the market labelled with reference to the genetic modification in accordance with the provisions of this Act or other provisions, or
3. may not be placed on the market with a labelling which would have been possible under the legislation applicable to the production method at the time.

(2) Compliance with good professional practice pursuant to section 16b subsections (2) and (3) shall be deemed economically reasonable within the meaning of section 906 of the Civil Code.

(3) For the assessment of local custom within the meaning of § 906 of the Civil Code, it does not matter whether the extraction of products is carried out with or without genetically modified organisms.

(4) If, according to the factual circumstances of the individual case, several neighbours can be considered to have caused the impairment and it cannot be determined which of them has caused the impairment by his or her action, each is responsible for the impairment. This does not apply if each has caused only a part of the impairment and an apportionment of the compensation among the causers is possible pursuant to section 287 of the Code of Civil Procedure.

§ 37 Liability under other legal provisions

(1) If, as a result of the use of a medicinal product which has been supplied to the consumer within the scope of the Medicinal Products Act and which is subject to the obligation to obtain a marketing authorisation or which has been exempted from the requirement to obtain a marketing authorisation by ordinance, someone is killed or injured in body or health, Sections 32 to 36 shall not apply.

(2) The same shall apply if products containing or consisting of genetically modified organisms are placed on the market on the basis of an authorisation pursuant to section 16 subsection 2 or an approval or authorisation pursuant to other legal provisions within the meaning of section 14 subsection 2. In this case, section 1, paragraph 2, no. 5 of the Product Liability Act shall not apply to the liability of the manufacturer to whom the authorisation or permit to place the product on the market has been granted if the product defect is due to genetic engineering work.

(3) Liability based on other regulations remains unaffected.

Part Six
Penalty and fine regulations

§ 38 Rules on fines

(1) A regulatory offence is committed by anyone who intentionally or negligently

1. contrary to section 6, paragraph 1, sentence 1, in conjunction with a statutory instrument pursuant to section 30, paragraph 2, no. 15, fails to carry out a risk assessment for further genetic engineering work of safety level 1, or fails to do so correctly, completely or in good time,

1a. fails to keep records in contravention of § 6 Para. 3 Sentence 1,

2. carries out genetic engineering work contrary to section 8 sub-section 1 sentence 1,

3. establishes a genetic engineering facility without a permit pursuant to section 8 subsection 1 sentence 2,

4. contrary to section 8 subsection (2), first sentence, also in conjunction with subsection (4), second sentence, fails to notify or to notify in good time the construction or operation or a substantial change in the location, nature or operation of a genetic engineering facility or genetic engineering work,

5. significantly alters the location, nature or operation of a genetic engineering facility without authorisation in accordance with section 8 subsection (4) sentence 1,

6. in contravention of section 9 subsection 2, first sentence, fails to make a notification, fails to make a notification correctly or fails to make a notification in good time,

6a. carries out further genetic engineering work without authorisation in accordance with section 9 subsection 3,

6b. carries out further genetic engineering work contrary to section 9 sub-section 4,

7. places on the market products containing or consisting of genetically modified organisms without authorisation under section 14(1), first sentence, nos. 2 or 3,

7a. who, contrary to § 16c par. 1, does not observe a product or does not observe it correctly,

8. contravenes an enforceable requirement under section 16d(3), first sentence, or section 19, second sentence, or an enforceable order under section 26,

9. contrary to § 9 par. 4a or 5, § 16a par. 2 sentence 1 or 3 or par. 3 sentence 1 or 3 or § 21 par. 1 sentence 1
or 2 in conjunction with sentence 1, para. 1b sentence 1, para. 2 in conjunction with para. 1 sentence 1, para. 3, 4 sentence 1 or para. 5 or 5a sentence 1 or 2 does not make a notification, does not make a notification correctly or does not make a notification in time,

10. contrary to section 25 subsection (2), fails to provide information, to provide it in time, to provide it in full or to provide it correctly, or fails to provide an aid,

11. contravenes an obligation referred to in § 16 par. 5a or § 25 par. 3 sentence 3,

11a. fails to submit the risk assessment or fails to submit it in time in contravention of § 25 par. 6, or

12. a statutory order pursuant to § 2 para. 2 sentence 3, also in conjunction with para. 2a sentence 2, § 6 para. 3 sentence
2, section 7 subsection 2 sentence 2 or section 30 subsection 2 nos. 1 to 14, insofar as they refer to this provision on fines for a specific offence.

(2) The administrative offence can be punished with a fine of up to fifty thousand euros.

(3) Insofar as this Act is executed by federal authorities, the administrative authority within the meaning of section 36(1) no. 1 of the Administrative Offences Act shall be the competent authority under Land law.

§ 39 Penal provisions

(1) A custodial sentence not exceeding one year or a monetary penalty shall be imposed on anyone who contravenes a statutory instrument under section 36(1) sentence 1 insofar as it refers to this penal provision for a specific offence.

(2) A custodial sentence not exceeding three years or a monetary penalty shall be imposed on anyone who

1. releases genetically modified organisms without authorisation according to § 14 para. 1 sentence 1 no. 1 or
2. operates a genetic engineering facility without a permit pursuant to section 8 subsection 1 sentence 2.

(3) A custodial sentence of three months to five years shall be imposed on any person who, by an act described in subsection 2 or in section 38(1)(2), (8), (9) or (12), endangers the life or limb of another person, property of significant value belonging to another person or components of the natural environment of significant ecological importance.

(4) In the cases of paragraphs 2 and 3, the attempt is punishable.

(5) Any person who acts negligently in the cases referred to in paragraph 2 shall be liable to a custodial sentence not exceeding one year or to a monetary penalty.

(6) Any person who negligently causes the danger in the cases referred to in paragraph 3 shall be liable to a custodial sentence not exceeding five years or to a monetary penalty.

(7) Any person who acts negligently in the cases referred to in paragraph 3 and negligently causes the danger shall be liable to a custodial sentence not exceeding three years or to a monetary penalty.

Part Seven

Transitional and final provisions

§ 40

(omitted)

§ 41 Transitional regulation

(1) For genetic engineering work which, at the time of entry into force of the provisions of this Act on notifications and licensing requirements, was permitted to be carried out in a genetic laboratory registered in accordance with the "Guidelines for Protection against Hazards arising from in-vitro Recombinant Nucleic Acids" (Genetic Guidelines) and which, in accordance with the provisions of this Act, may only be carried out, must be notified or require a licence in licensed or notified genetic engineering facilities, the notification shall be deemed to have been made or the licence shall be deemed to have been granted; Section 9 shall apply to genetic engineering work in such facilities.

(2) A permit granted before the entry into force of the provisions of this Act concerning notifications and licensing obligations under the Federal Immission Control Act shall continue to be valid to the previous extent as a notification or permit within the meaning of this Act. § Section 19 shall apply mutatis mutandis.

(3) (omitted)

(4) The provisions of the Second Act Amending the Genetic Engineering Act of 16 August 2002 (Federal Law Gazette I p. 3220) shall not apply to procedures commenced before the entry into force of this Act, provided that complete application documents are available. This shall not apply to the authorisation of further work of safety levels 3 and 4 in accordance with Section 9(3).

(5) (omitted)

(6) Marketing authorisations granted before 17 October 2002 expire on 17 October 2006 unless an extension has been requested by 17 January 2006.

(7) Until the enactment of a statutory instrument under section 14 subsection 4, but not later than 31 December 2008, the provisions of Commission Decision 94/730/EC of 4 November 1994 establishing simplified procedures for the deliberate release into the environment of genetically modified plants pursuant to Article 6(5) of Council Directive 90/220/EEC (OJ EC No. L 292, p. 31) shall apply in its place, including where reference is made in this Act to that statutory instrument, with regard to the procedure and scope of authorisation.

(8) Until the formation of the Commission in accordance with § 4, their respective tasks shall be performed by a special committee which shall

1. shall be constituted in accordance with the Regulations for the Central Biosafety Commission in force on 3 February 2005; and
2. performs the tasks in accordance with the provisions referred to in point 1.

(9) By way of derogation from the other provisions of this Act

1. the Genetic Engineering Procedures Ordinance in the version published on 4 November 1996 (Federal Law Gazette I p. 1657), last amended by Article 2 of the Act of 16 August 2002 (Federal Law Gazette I p. 3220),
2. the Genetic Engineering Participation Ordinance of 17 May 1995 (Federal Law Gazette I p. 734), amended by Article 1 § 2 of the
Act of 22 March 2004 (Federal Law Gazette I p. 454),

be amended once by 1 October 2006 without consulting the Commission under section 4 or a committee under sections 5 and 5a.

§ 41a

(omitted)

§ 42 Applicability of the provisions for the other Contracting States to the Agreement on the European Economic Area

Upon the entry into force of the Agreement on the European Economic Area, the provisions providing for the participation of the Member States of the European Union shall also apply to the participation of the other States party to the Agreement on the European Economic Area as from 1 January 1995.