99045001006000, 99045001006000

Applying for a permit for the construction and operation of genetic engineering facilities

Modul	Sachverhalt
Leistungsschlüssel	99045001006000, 99045001006000
Leistungsbezeichnung I	Applying for a permit for the construction and operation of genetic engineering facilities
Leistungsbezeichnung II	Applying for a permit for the construction and operation of genetic engineering facilities
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Nordrhein-Westfalen
Freigabestatus Katalog	methodisch freigegeben
Freigabestatus Bibliothek	Entwurf
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	Gentechnik (045)
Verrichtungskennung	Genehmigung (006)

Modul	Sachverhalt
SDG-Informationsbereich	Erlangung von Lizenzen, Genehmigungen oder Zulassungen im Hinblick auf die Gründung und Führung eines Unternehmens
Lagen Portalverbund	Erlaubnisse und Genehmigungen (2010400), Anlagenbetrieb und -prüfung (2120100)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	
Fachlich freigegen durch	
Handlungsgrundlage	https://www.gesetze-im-internet.de/gentg/__8.html https://www.gesetze-im-internet.de/gentsv_2021/GenTSV.pdf https://www.gesetze-im-internet.de/gentvfv/index.html
Teaser	As the operator of a genetic engineering facility, you must notify, register or obtain approval from the competent authority for the construction and operation of the facility and other genetic engineering work, depending on the safety level.
Volltext	Genetic engineering facilities of safety levels 1 to 4 are facilities in which genetic engineering work is carried out in a closed system in order 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. Genetic engineering work may only be carried out in genetic engineering facilities. As the operator of a genetic engineering facility, you must notify, register or obtain approval from the competent authority for the construction and operation of the facility as well as other genetic engineering work, depending on the safety level. The competent authority will confirm receipt of the application without delay. Whether the procedure involves notification, registration or approval depends on the safety level to which the intended genetic engineering work falls. The construction of genetic engineering facilities is

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	subject to • in which safety level 1 work is carried out is subject to a notification procedure • in which work of safety level 2 is carried out is subject to a notification procedure (in deviation from this, a permit can also be applied for) • in which work of safety level 3 and 4 is carried out, an authorization procedure. The classification of genetic engineering work into safety levels is based on the assessment of the properties of the donor organism and the • of the donor organism and the nucleic acid segment intendedfor transformation , • the recipient organism, • the vectors (genetic engineering tools used to introduce foreign DNA into a cell. These can be viruses, phages or plasmids), • the genetically modified organism (GMO). The overall risk assessment is based on the interaction of all these factors. In addition to the construction of a genetic engineering facility, every significant change to the facility is also subject to an official procedure corresponding to the safety level. Significant changes generally include changes to the scope or mode of operation of a genetic engineering facility.
Erforderliche Unterlagen	Notification of a facility for genetic engineering work of safety level 1: • Proof of the operator's non-profit status, if applicable • Project manager and biosafety officer expertise (e.g. degree certificate and proof of professional experience in the form of a reference) • If the project manager does not belong to the

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	company, then proof of a written agreement with the project manager, the operator and the third party in accordance with § 28 Para. 6 GenTSV • Copy of the operating instructions in accordance with § 17 Para. 2 GenTSV • Copy of the hygiene plan in accordance with § 17 Para. 3 GenTSV • Copy of the skin protection plan in accordance with Annexes 2 to 4 GenTSV • Site plan, construction drawings and furnishing or layout plan showing the location of the laboratory area and social rooms • Proof of efficacy of the autoclaving process, if applicable • Proof of efficacy of inactivation by chemical processes, if applicable
	Notification/registration/approval in accordance with the Genetic Engineering Act at safety levels 2 to 4 • Proof of non-profit status of the operator, if applicable • Project manager and biosafety officer expertise (e.g. degree certificate and proof of professional experience in the form of a job reference) • Site plan, construction drawings and furnishing or layout plan showing the location of the social rooms and • the laboratory area and/or • the production area and/or • the greenhouse/climate chamber • of the animal rooms and, if applicable, description of the shielding of the animal facility • Copy of the operating instructions in accordance with Section 17 (2) GenTSV • Copy of the hygiene plan in accordance with § 17 Para. 3 GenTSV • Copy of the skin protection plan in accordance with Annexes 2 to 4 GenTSV

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	• Flow diagram according to EN ISO 10628, if applicable • If applicable, program for the successful control of plant diseases, weeds, arthropods and rodents in accordance with § 15 in conjunction with Annex 3 Sect. I b No. 3; Sect. II b No. 5 GenTSV • Proof of efficacy autoclaving method, if applicable • Proof of efficacy inactivation by chemical processes, if applicable
Voraussetzungen	• Reliability of the operator and other responsible persons • Expertise of the above-mentioned persons • Fulfillment of duties • Security levels and appropriate precautions to ensure that no harmful effects on legal interests are to be expected • No conflicting prohibitions under the War Weapons Control Act • Other public law regulations and occupational health and safety occupational health and safety must not conflict with the construction and operation of the genetic engineering facility https://www.gesetze-im-internet.de/gentg/__11.html https://www.gesetze-im-internet.de/gentg/__12.html
Kosten	Is based on the respective administrative fee schedule of the federal state or on the fee statutes of the authorities responsible under federal state law.
Verfahrensablauf	Notification/registration/approval of the construction and operation of or significant changes to genetic engineering facilities S1-S4: As the operator, you must notify or register the planned first-time genetic engineering work and the construction or operation or significant changes to a genetic engineering facility S1 - S4. Once the notification has been received by the authority, you can only start work directly at safety level 1. Subsequent requests may be made and you may be asked to submit further documents and information. You will then receive a confirmation of receipt with these possible statuses:

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	• Application in order, • Application with additional request, • Application with reasons for refusal. You will then have the opportunity to attend a hearing with a draft decision and finally receive the decision, including a fee notice if applicable.
Bearbeitungsdauer	
Frist	Before setting up and operating the genetic engineering facility, the operator must notify the competent authority, register it or have it approved. **Notification procedure:** Once the notification has been received by the authority, you can only start work immediately for safety level 1. Subsequent requests may be made and you may be asked to submit further documents and information. You will then receive a confirmation of receipt with these possible statuses: Application in order, with additional request for documents or with reasons for failure. **Application procedure:** The operator may start setting up and operating the genetic engineering facility and carrying out the initial genetic engineering work 45 days after receipt of the notification by the competent authority or earlier with the latter's consent. The expiry of the deadline is deemed to be consent to the establishment and operation of the genetic engineering facility and to the performance of the genetic engineering work. **Authorization procedure:** A decision on an application for approval must be made in writing within a period of 45 or 90 days. The deadlines are suspended while the authority awaits the completion of the documents or until the required statement from the Commission on the safety classification of the planned genetic engineering work and the necessary safety measures has been received
weiterführende Informationen	https://www.lag-gentechnik.de/Fuer-Antragsteller.html
Hinweise	
Rechtsbehelf	• Appeal (depending on national law, the appeal may

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	be excluded) • Administrative court action
Kurztext	• Construction and operation of genetic engineering facilities Authorization • The establishment and operation of genetic engineering facilities and initial genetic engineering work, significant changes to these facilities and further genetic engineering work must be notified to, registered with or approved by the competent authority. • Competent authority: Depends on the respective state law
Ansprechpunkt	
Zuständige Stelle	
Formulare	• Written form required: yes • Personal appearance required: no
Ursprungsportal	Eine Genehmigung für die Errichtung und Betrieb gentechnischer Anlagen beantragen, Applying for a permit for the construction and operation of genetic engineering facilities