

99045001006000, 99045001006000

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

Heruntergeladen am 28.06.2025

<https://fimportal.de/xzufi-services/414188886/L100040>

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	Niedersachsen
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	methodisch freigegeben
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	17.11.2020
Fachlich freigegeben durch	Lower Saxony Ministry for the Environment, Energy, Building and Climate Protection, Department 32
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 https://www.gesetze-im-internet.de/gentg/_8.html https://www.gesetze-im-internet.de/gentg/_9.html#:~:text=%C2%A7%209%20Weitere%20gentechnische%20Arbeiten,beabsichtigten%20Beginn%20der%20Arbeits%20anzuzeigen. https://www.gesetze-im-internet.de/gentg/_10.html https://www.gesetze-im-internet.de/gentg/_12.html https://www.gesetze-im-internet.de/gentg/_9.html#:~:text=%C2%A7%209%20Weitere%20gentechnische%20Arbeiten,beabsichtigten%20Beginn%20der%20Arbeits%20anzuzeigen. https://www.gesetze-im-internet.de/gentg/_10.html https://www.gesetze-im-internet.de/gentg/_12.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.

Modul

Sachverhalt

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 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 intended for 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.

Modul

Sachverhalt

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 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

Modul

Sachverhalt

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
- 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
 - 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 the legal interests are to be expected
 - there are no prohibitions under the War Weapons Control Act to the contrary
 - other public law regulations and occupational health and safety concerns do not preclude 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

Modul	Sachverhalt
	<p>authorities responsible under federal state law.</p> <p>The amount of the fees results from tariff number 37 of Annex 1 to the Lower Saxony Ordinance on Fees and Expenses for Official Acts and Services (General Fee Schedule - AllGO-).</p> <p>The fees depend on the investment costs or the time required for processing. Expenses are to be reimbursed separately.</p>
Verfahrensablauf	<p>Modification of genetic engineering facilities of safety levels 1 to 4 and other genetic engineering work of safety levels 2-4: Depending on the safety level, the construction and operation of a genetic engineering facility or the significant modification of a genetic engineering facility are subject to notification (S1), notification (S2) or approval (S3-4). The performance of further genetic engineering work is subject to notification (S2) or approval (S3-4). When you apply for a permit, you will receive a notification.</p>
Bearbeitungsdauer	<p>Different deadlines depending on the procedure</p>
Frist	<p>Notification Procedure: Once the notification has been received by the authority, you can only start working directly at security level 1. Subsequently, there may be additional claims, in which you may be asked to submit further documents and information. You will then receive an acknowledgement of receipt with the following possible statuses: Application in order, with additional request for documents or with reasons for failure. Application procedure: The operator may commence the construction and operation of the genetic engineering facility and the execution of the initial genetic engineering work 45 days after receipt of the notification by the competent authority or, with its approval, earlier. The expiry of the deadline shall be deemed to be consent to the construction and operation of the genetic engineering facility and to the performance of the genetic engineering work. Approval procedure: A decision on an application for authorisation must be made in writing within a period of 45 or 90 days. The time limits shall be suspended as long as the Authority waits for the dossier to be</p>

Modul	Sachverhalt
	completed or until the Commission has received the necessary opinion on the safety classification of the planned genetic engineering work and on the necessary safety measures.
weiterführende Informationen	
Hinweise	https://www.gewerbeaufsicht.niedersachsen.de/startseite/gefahrschutz/gentechnik/gentechnik-52082.html https://www.gewerbeaufsicht.niedersachsen.de/startseite/gefahrschutz/gentechnik/gentechnik-52082.html
Rechtsbehelf	<ul style="list-style-type: none"> • Objection according to § 80 para. 2 sentence 1 no. 4r NJG • Review in preliminary proceedings pursuant to section 68 (1) sentence 1 of the Code of Administrative Procedure https://voris.wolterskluwer-online.de/browse/document/cite/a20628ee-063b-3a4b-9830-255b63a9ee9c https://www.gesetze-im-internet.de/vwgo/_68.html https://voris.wolterskluwer-online.de/browse/document/cite/a20628ee-063b-3a4b-9830-255b63a9ee9c https://www.gesetze-im-internet.de/vwgo/_68.html
Kurztext	<ul style="list-style-type: none"> • 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 <ul style="list-style-type: none"> • In Lower Saxony, the State Trade Inspectorates of Braunschweig, Göttingen and Hanover are responsible for notification, registration and approval procedures in accordance with the GenTG.
Ansprechpunkt	
Zuständige Stelle	In Lower Saxony, the State Trade Inspectorates of Braunschweig, Göttingen and Hanover are responsible for notification, registration and approval procedures

Modul	Sachverhalt
	in accordance with the GenTG.
Formulare	<ul style="list-style-type: none"> • 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