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Applying for the construction and operation of genetic engineering facilities

Heruntergeladen am 16.06.2025

<https://fimportal.de/xzufi-services/9890248/L100001>

Modul	Sachverhalt
Leistungsschlüssel	99045001006000, 99045001006000
Leistungsbezeichnung I	Applying for the construction and operation of genetic engineering facilities
Leistungsbezeichnung II	
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Hessen
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	methodisch freigegeben
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	Gentechnik (045)
Verrichtungskennung	Genehmigung (006)
SDG-Informationsbereich	Erlangung von Lizenzen, Genehmigungen oder

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	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	12.05.2023
Fachlich freigegeben durch	Hessian Ministry for the Environment, Climate Protection, Agriculture and Consumer Protection (HMUKLV), Department II
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/gentsv_2021/GenTSV.pdf https://www.gesetze-im-internet.de/gentvfv/index.html
Teaser	You may only carry out genetic engineering work in genetic engineering facilities. You must apply for the construction and operation of such a facility.
Volltext	<p>Genetic engineering installations 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 potential hazard.</p> <p>You may only carry out genetic engineering work in genetic engineering facilities. As the operator of a genetic engineering facility, you must notify, register or have approved the construction and operation of the facility as well as other genetic engineering work with the competent authority, depending on the safety level. The competent authority will immediately acknowledge receipt of the application.</p> <p>Whether the procedure is notified, notified or approved depends on the level of safety under which</p>

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the planned genetic engineering work falls.

In this context, the construction of genetic engineering plants,

- in which work of security level 1 is carried out, a notification procedure
- in which work of security level 2 is carried out, a notification procedure (by way of derogation, a permit can also be applied for)
- in which work of safety level 3 and 4 is carried out, a permit procedure.
- The classification of genetic engineering work into safety levels is based on the evaluation of the properties
 - of the donor organism and the nucleic acid section intended for transformation,
 - of the recipient organism,
 - vectors (a tool of genetic engineering that is used to introduce foreign DNA into a cell. These can be viruses, phages or plasmids.),
 - genetically modified organism (GMO).

The overall assessment of risk is based on the combination of all these factors.

In addition to the construction of a genetic engineering facility, any significant modification of the facility is also subject to an official procedure corresponding to the safety level. The most significant changes usually include a change in the size or operation of a genetic engineering facility.

Erforderliche Unterlagen

****Indication of a facility for genetic engineering work of safety level 1:****

- If applicable, proof of the operator's non-profit status
- Expertise: Project manager and biosafety officer (e.g. degree certificate, degree and proof of professional experience in the form of an employment reference)
- if the project manager is not part of the company, then proof of a written agreement with the project

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manager, the operator and the third party according to § 28 para. 6 GenTSV

- Copy of the operating instructions according to § 17 para. 2 GenTSV
- Copy of the hygiene plan according to § 17 para. 3 GenTSV
- Copy of the skin protection plan according to Appendices 2 to 4 GenTSV
- Site plan, construction drawings and furnishing or layout plan showing the location of the laboratory area and the social rooms
- If applicable, proof of efficacy of the autoclaving process
- If necessary, proof of efficacy, inactivation by chemical processes

****Notification/registration/approval according to the Genetic Engineering Act in security levels 2 to 4****

- If applicable, proof of the operator's non-profit status
- Expertise: Project manager and biosafety officer (e.g. degree certificate, degree and proof of professional experience in the form of an employment reference)
- site plan, construction drawings and furnishing or floor plan, from which the location of the social rooms and
 - of the laboratory area and/or
 - of the production area and/or
 - of the greenhouse/climatic chamber
 - of the animal rooms and, if applicable, description of the shielding of the animal enclosure
- Copy of the operating instructions according to § 17 para. 2 GenTSV
- Copy of the hygiene plan according to § 17 para. 3 GenTSV
- Copy of the skin protection plan in accordance with Appendices 2 to 4 of the GenTSV (
 - If necessary, flow diagram according to EN ISO 10628
 - if applicable, programme for the successful control of plant diseases, weeds, arthropods and rodents in accordance with § 15 in conjunction with Annex 3 Sect.

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I b No. 3; Sect. II b No. 5 GenTSV

- If applicable, proof of efficacy of the autoclaving process
- If necessary, proof of efficacy, inactivation by chemical processes

Voraussetzungen

- Reliability of the operator and other responsible persons (project manager and biosafety officer)
 - Expertise of the above-mentioned persons
 - Fulfilment of duties
 - Safety classification and appropriate precautions to ensure that no harmful effects on the legal interests of the GenTG are to be expected
 - Prohibitions under the War Weapons Control Act do not preclude
 - other public law regulations and occupational health and safety concerns do not preclude the construction and operation of the genetic engineering plant

https://www.gesetze-im-internet.de/gentg/_11.html
https://www.gesetze-im-internet.de/gentg/_12.html
https://www.gesetze-im-internet.de/gentg/_11.html
https://www.gesetze-im-internet.de/gentg/_12.html

Kosten

Gebühr: 300€ - 15.000.000€
<https://www.rv.hessenrecht.hessen.de/bshe/document/jlr-UmwMinVwKostOHE2009V17Anlage>
 An administrative fee must be paid in accordance with the State Ordinance on Administrative Fees. The obligation to pay fees also includes the rejection of requested official acts. Detailed information on this can be obtained from the competent authority.

Verfahrensablauf

****Notification/notification/approval of the construction and operation or significant modifications of genetic engineering facilities S1-S4:****
 As an operator, you show or register the planned initial genetic engineering work and the construction or operation or significant modifications of a genetic engineering facility S1 – S4 or submit an application for its approval. 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 have to pay for additional claims. be asked to provide further documents and information at a later date. You will then receive an

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	acknowledgement of receipt with this possible status: application in order, with additional request, with reasons for failure. In the further course of the process, there is an opportunity for you to be heard with a draft decision and finally the decision, including a fee notice if necessary.
Bearbeitungsdauer	The processing time varies depending on the type of procedure.
Frist	<p>Prior to the construction and operation of the genetic engineering facility, the operator must notify, register or have it approved by the competent authority.</p> <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.</p> <p>**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.</p>
weiterführende Informationen	https://rp-giessen.hessen.de/umwelt/gentechnik https://www.lag-gentechnik.de/Fuer-Antragsteller.html https://rp-giessen.hessen.de/umwelt/gentechnik https://www.lag-gentechnik.de/Fuer-Antragsteller.html
Hinweise	There are no hints or specifics.
Rechtsbehelf	If the authority rejects your request, it will send you a rejection notice. In this case, you can file a complaint with the administrative court.
Kurztext	<ul style="list-style-type: none"> • Construction and operation of genetic engineering plants Approval • The construction and operation of genetic engineering facilities and initial genetic engineering

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	<p>work, significant modifications to these facilities and other genetic engineering work must be notified, notified or approved by the competent authority</p> <ul style="list-style-type: none"> • Responsible authority: Regional Council of Giessen, Dec. 44.2 – Genetic engineering
Ansprechpunkt	Please contact the Regional Council of Giessen, Department 44.2 – Genetic Engineering.
Zuständige Stelle	The responsible authority is the Regional Council of Giessen, Department 44.2 – Genetic Engineering.
Formulare	<ul style="list-style-type: none"> • Forms available: Yes • Written form required: Yes • Informal application possible: No • Personal appearance required: No • Online services available: No
Ursprungsportal	Applying for the construction and operation of genetic engineering facilities, Errichtung und Betrieb von gentechnischen Anlagen beantragen