

99045001006000

Construction and operation of genetic engineering facilities Approval

Heruntergeladen am 28.06.2025

<https://fimportal.de/xzufi-services/S1000020010000004990/S100002>

Modul	Sachverhalt
Leistungsschlüssel	99045001006000
Leistungsbezeichnung I	Construction and operation of genetic engineering facilities Approval
Leistungsbezeichnung II	Apply for a permit to build and operate genetic engineering facilities
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Hamburg
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	<div lang="en-x-mtfrom-de">Genetic engineering law</div> , <div lang="en-x-mtfrom-de">Genetic engineering</div> , <div lang="en-x-mtfrom-de">Plant genetic engineering work</div> , <div lang="en-x-mtfrom-de">Security level 3</div> , <div lang="en-x-mtfrom-de">Security level 4 genetic engineering</div>

Modul	Sachverhalt
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	08.08.2024
Fachlich freigegen durch	
Handlungsgrundlage	§ 8 Law on the Regulation of Genetic Engineering (GenTG) https://www.gesetze-im-internet.de/gentg/_8.html § 10 Law on the Regulation of Genetic Engineering (GenTG) https://www.gesetze-im-internet.de/gentg/_10.html § 11 Law on the Regulation of Genetic Engineering (GenTG) https://www.gesetze-im-internet.de/gentg/_11.html Genetic Engineering Safety Ordinance (GenTSV) https://www.gesetze-im-internet.de/gentsv_2021/index.html Genetic Engineering Procedure Ordinance (GenTVfV) https://www.gesetze-im-internet.de/gentvfv/index.html
Teaser	
Volltext	Significant changes include changes to the scope or mode of operation of a genetic engineering facility. For these changes for genetic engineering facilities at safety levels 3 and 4, you also need approval from the competent authority.
Erforderliche Unterlagen	written or electronic application other documents required for the project to check the requirements, such as 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 of the greenhouse/climate chamber of the animal rooms and, if applicable, description of the

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shielding of the animal facility Copy of the operating instructions according to § 17 paragraph 2 GenTSV Copy of the hygiene plan according to § 17 paragraph 3 GenTSV Copy of the skin protection plan according to Annexes 2 to 4 GenTSV if applicable, flow chart according to EN ISO 10628 where applicable, a programme for the successful control of plant diseases, weeds, arthropods and rodents pursuant to Section 15 in conjunction with Annex 3, Section I b, No. 3; Section II b, No. 5 GenTSV if necessary, proof of effectiveness of autoclave procedure where appropriate, proof of effectiveness of inactivation by chemical processes Documents proving the expertise and reliability of the project manager and the person responsible for biological safety Documents that prove the expertise and reliability of your relevant employees If applicable, proof of the non-profit status of the operator

Voraussetzungen

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Kosten

Fees are charged in accordance with the environmental fee regulations. The amount may depend on the value of the genetic engineering facility. You can find out the exact amount in advance from the responsible authority.

Verfahrensablauf
Bearbeitungsdauer

The processing time varies depending on the type of procedure. If all the required documents and the safety classification by the Central Commission for Biological Safety are available, the responsible body will decide on your application for approval within 90 days.

Frist

You need the permit before you can start constructing or operating the genetic engineering facilities.

weiterführende Informationen

<https://www.hamburg.de/betriebe-umwelt/>
<https://www.hamburg.de/betriebe-umwelt/>
<https://www.hamburg.de/politik-und-verwaltung/behoerden/bukea/themen/betrieblicher-umweltschutz/ansprechpartner-start-160502>
<https://www.hamburg.de/betriebe-umwelt/start-ansprechpartner/>

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	https://www.hamburg.de/gentechnik/ https://www.hamburg.de/gentechnik/
Hinweise	There are no special features to note.
Rechtsbehelf	Objection within one month after receiving the decision
Kurztext	The construction and operation of genetic engineering facilities, significant changes to these facilities and initial genetic engineering work must be reported, registered or approved by the competent authority. Facilities for genetic engineering work at safety levels 3 and 4 require approval Facilities for genetic engineering work at safety level 2 can be approved upon application Security level 2 systems must be registered Security level 1 facilities must be reported written or electronic application
Ansprechpunkt	
Zuständige Stelle	Authority for the Environment, Climate, Energy and Agriculture
Formulare	
Ursprungsportal	Hamburg Service, Hamburg Service (Currently this link is only available in german)