

99045004261000, 99045004261000

Notify change regarding the operation of genetic engineering facilities

Heruntergeladen am 10.06.2025

<https://fimportal.de/xzufi-services/411042175/L100008>

Modul	Sachverhalt
Leistungsschlüssel	99045004261000, 99045004261000
Leistungsbezeichnung I	Notify change regarding the operation of genetic engineering facilities
Leistungsbezeichnung II	Notify change regarding the operation of genetic engineering facilities
Typisierung	3 - Bundesaufsichtsverwaltung: Regelung
Quellredaktion	Sachsen-Anhalt
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	fachlich freigegeben (gold)
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	Gentechnik (045)
Verrichtungskennung	Entgegennahme (261)
SDG-Informationsbereich	Erlangung von Lizenzen, Genehmigungen oder

Modul	Sachverhalt
	Zulassungen im Hinblick auf die Gründung und Führung eines Unternehmens
Lagen Portalverbund	Anmeldepflichten (2010100), Abfall, Schadstoffe und Emissionen (2130100), Erlaubnisse und Genehmigungen für Forschungsvorhaben (2100200)
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	05.07.2024
Fachlich freigegeben durch	Federal Ministry of Food and Agriculture (BMEL)
Handlungsgrundlage	https://www.gesetze-im-internet.de/gentg/_9.html https://www.gesetze-im-internet.de/gentg/_9.html
Teaser	Do you wish to carry out genetic engineering work that has already been notified, registered or approved in another genetic engineering facility? Then you must inform the competent authority before starting the work.
Volltext	Genetic engineering work is subject to high safety standards. The aim of these standards is to limit the contact of the organisms used with humans and the environment and thus ensure a high level of safety. Genetic engineering work is divided into different safety levels. The safety levels are differentiated according to the degree of risk to human health and the environment: • Safety level 1: no risk • Safety level 2: low risk • Safety level 3: moderate risk • Safety level 4: high risk You must notify the competent authority if you wish to carry out genetic engineering work of safety levels 2 or 3 in another facility of the same operator. The prerequisite is that both the genetic engineering work and the facility have already been notified, registered

Modul	Sachverhalt
	or approved for the first time. You do not have to notify changes to genetic engineering work at safety level 1. Changes to safety level 4 work must always be notified or approved again. You must notify the competent authority of the change before you start the activity.
Erforderliche Unterlagen	
Voraussetzungen	• The change concerns genetic engineering work of safety levels 1, 2 and 3. • Both the genetic engineering work and the genetic engineering facility have already been notified, registered or approved. • The change only concerns the change of location. The operator must remain the same.
Kosten	Abgabe: Es fallen keine Kosten an There are no costs.
Verfahrensablauf	• You make the informal notification and send it to the competent authority. • You then start the genetic engineering work.
Bearbeitungsdauer	
Frist	You must submit the notification before the start of the genetic engineering work. You are in breach of the regulations if you intentionally or negligently fail to submit a notification or fail to do so correctly or on time. This can be punished with a fine of up to EUR 50,000.
weiterführende Informationen	https://www.bvl.bund.de/DE/Arbeitsbereiche/06_Gentechnik/gentechnik_node.html https://www.bvl.bund.de/DE/Arbeitsbereiche/06_Gentechnik/gentechnik_node.html
Hinweise	
Rechtsbehelf	No legal remedy is provided for.
Kurztext	• Notification on the operation of genetic engineering facilities Acceptance

Modul

Sachverhalt

- The competent authority must be notified of any changes in the operation of genetic engineering facilities
 - Change means: genetic engineering work is to be carried out in another registered or approved facility
 - The operator may not change
 - Modification only possible for genetic engineering work that has already been notified, registered or approved
 - applies to genetic engineering work of safety levels 2 and 3
 - Changes to safety level 1 work do not have to be notified
 - Changes to safety level 4 work must be newly notified or newly approved
 - The competent authority must be notified before work commences
 - Responsible: competent authority

Ansprechpunkt

Zuständige Stelle

Formulare

Ursprungsportal

Änderung bezüglich des Betriebs gentechnischer Anlagen mitteilen, Notify change regarding the operation of genetic engineering facilities