

99003021005000, 99003021005000

Activities with pathogen permission

Heruntergeladen am 08.07.2025

<https://fimportal.de/xzufi-services/9317182/L100040>

Modul	Sachverhalt
Leistungsschlüssel	99003021005000, 99003021005000
Leistungsbezeichnung I	Activities with pathogen permission
Leistungsbezeichnung II	
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Niedersachsen
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	Leistungsobjekt mit Verrichtung
Leistungsgruppierung	Gesundheit (003)
Verrichtungskennung	Erlaubnis (005)
SDG-Informationsbereich	Erlangung von Lizenzen, Genehmigungen oder Zulassungen im Hinblick auf die Gründung und Führung eines Unternehmens
Lagen Portalverbund	Anmeldepflichten (2010100), Erlaubnisse und Genehmigungen (2010400)

Modul	Sachverhalt
Einheitlicher Ansprechpartner	Nein
Fachlich freigegeben am	13.09.2018
Fachlich freigegeben durch	Lower Saxony Ministry of Social Affairs, Health and Equality
Handlungsgrundlage	https://www.gesetze-im-internet.de/ifsg/_44.html https://www.gesetze-im-internet.de/ifsg/_44.html
Teaser	
Volltext	<p>In Germany, there is a general permit requirement for activities involving pathogens. Anyone who wants to bring pathogens into Germany as a responsible person, export them, store them, hand them over or work with them needs a permit.</p> <p>The term pathogens refers to pathogens capable of reproducing (viruses, bacteria, fungi, parasites) or other biological transmissible pathogens that can cause infection or a communicable disease in humans.</p> <p>In particular, activities involving pathogens include:</p> <ul style="list-style-type: none"> • experiments with pathogens capable of reproducing, • microbiological and serological tests for the detection of notifiable pathogens, • targeted enrichment or multiplication of pathogens. <p>Exceptions to the permit requirement exist for the following groups of persons or activities:</p> <ul style="list-style-type: none"> • Doctors, dentists and veterinarians who carry out microbiological tests for diagnostics in their own patients, • Persons who carry out microbiological quality assurance work and have the necessary expertise and who are exempted from the permit requirement by the competent authority upon request, • Employees who work under the supervision of a person who has a permit or is exempt from the permit requirement • certain procedures (e.g. sterility tests).

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	<p>Further information on the topic of "Activities with pathogens" can be found in the following services:</p> <ul style="list-style-type: none"> • Pathogens: Indication of changes in activities with pathogens • Pathogens: Indication - of the commencement of activities with pathogens
Erforderliche Unterlagen	<ul style="list-style-type: none"> • Certified copies of educational and study certificates • Certificate of at least two years of full-time activity with pathogens under supervision • Certificate of good conduct
Voraussetzungen	<ul style="list-style-type: none"> • natural person possesses the necessary expertise, and has so far proved to be reliable in relation to the activity with pathogens for which it is applying for authorisation. • The requisite expertise is demonstrated by: the completion of a degree in human, dental or veterinary medicine, pharmacy or the completion of a scientific course of study at a university of applied sciences or university with microbiological content, and at least two years of full-time work with pathogens under the supervision of a person who is in possession of a permit to work with pathogens. <p>Another full-time activity of at least two years in the field of bacteriology, mycology, parasitology or virology is also recognised as proof of expertise if equivalent expertise has been acquired.</p> <p>If the requirements are not fully met, a limited permit may be granted.</p>
Kosten	<p>Fees are charged in accordance with Appendix 1 to Section 1 (1) of the General Schedule of Fees of the State of Lower Saxony (AllGO) in accordance with No. 49.1.18.1.</p>
Verfahrensablauf	
Bearbeitungsdauer	<p>3 Monat(e)</p> <p>Section 53a (2) sentence 1 of the Infection Protection Act (IfSG)</p>

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Frist	Permission from the competent authority is required as early as possible so that the start of activity with pathogens can be reported at least 30 days before the scheduled date.
weiterführende Informationen	
Hinweise	<p>Regardless of whether the activity requires a permit or not, there is an obligation to report. The activity may only be commenced when the notification is complete and the activity is not prohibited after examination of the documents and the premises. Any significant change in the premises, activity, disposal or spectrum of pathogens must be reported to the competent authority.</p> <p>Anyone who carries out an activity in accordance with §§ 44 et seq. of the Infection Protection Act (IfSG) is subject to official supervision in accordance with § 51 IfSG. Additional fees may apply for site inspections and inspections that may be required.</p> <p>https://www.gesetze-im-internet.de/ifsg/BJNR104510000.html#BJNR104510000BJNG000900310 https://www.gesetze-im-internet.de/ifsg/_51.html https://www.gesetze-im-internet.de/ifsg/BJNR104510000.html#BJNR104510000BJNG000900310 https://www.gesetze-im-internet.de/ifsg/_51.html</p>
Rechtsbehelf	If the competent authority refuses to grant the permit, an appeal against this decision may be brought before the administrative court.
Kurztext	Anyone who wants to bring pathogens into Germany as a responsible person, export them, store them, hand them over or work with them needs a permit.
Ansprechpunkt	<p>The responsibility lies with the district and the independent city in whose district the activity is to be carried out.</p> <p>This procedure can also be carried out through a "Point of Single Contact". The "Point of Single Contact" is a special service offered by the municipalities and the state for service providers.</p>

Modul	Sachverhalt
	https://service.niedersachsen.de/dlp/ea https://service.niedersachsen.de/dlp/ea
Zuständige Stelle	
Formulare	The application must be submitted informally.
Ursprungsportal	Tätigkeiten mit Krankheitserregern Erlaubnis, Activities with pathogen permission