

99031003022000

Heruntergeladen am 08.06.2025

<https://fimportal.de/xzufi-services/28211/L100042>

Modul	Sachverhalt
Leistungsschlüssel	99031003022000
Leistungsbezeichnung I	
Leistungsbezeichnung II	Chemicals Act; application for certification of compliance with the principles of good laboratory practice
Typisierung	2/3 - Bund: Regelung (2 oder 3), Land/Kommune: Vollzug
Quellredaktion	Bayern
Freigabestatus Katalog	unbestimmter Freigabestatus
Freigabestatus Bibliothek	unbestimmter Freigabestatus
Begriffe im Kontext	
Leistungstyp	
Leistungsgruppierung	
Verrichtungskennung	
SDG-Informationsbereich	
Lagen Portalverbund	
Einheitlicher	

Modul	Sachverhalt
Ansprechpartner	
Fachlich freigegeben am	04.03.2025
Fachlich freigegeben durch	Bayerisches Staatsministerium für Umwelt und Verbraucherschutz (Bavarian State Ministry of the Environment and Consumer Protection)
Handlungsgrundlage	http://bundesrecht.juris.de/chemg/BJNR017180980.html#BJNR017180980BJNG000604308 http://bundesrecht.juris.de/chemg/BJNR017180980.html#BJNR017180980BJNG000604308 http://bundesrecht.juris.de/chemg/anhang_1.html http://bundesrecht.juris.de/chemg/anhang_1.html
Teaser	You can apply for a certificate of compliance with the principles of good laboratory practice (GLP) for facilities that carry out tests in accordance with Section 19a (1) ChemG.
Volltext	Laboratories (testing facilities) that carry out non-clinical health and environmental safety tests on substances or mixtures must do so in compliance with the principles of good laboratory practice (GLP) if the results of the safety tests are intended to enable an assessment of the potential hazards of the substances or mixtures for humans and the environment in an authorization, approval, registration, notification or notification procedure (Section 19a (1) of the German Chemicals Act (ChemG)).
Erforderliche Unterlagen	
Voraussetzungen	Anyone who demonstrably intends to carry out tests subject to GLP in accordance with Section 19a (1) (e.g. order request) is entitled to submit an application. An application for a GLP certificate may also be submitted by anyone who is not obliged to carry out GLP-compliant tests but who can demonstrate a legitimate interest (Section 19b (1) sentence 2 ChemG). A legitimate interest is regularly recognized if a government agency in the importing country requests proof from the Bavarian exporter that the tests on its products have been carried out in accordance with GLP principles, although these tests are not subject to GLP under German law.

Modul

Sachverhalt

The GLP certificate is issued to authorized applicants who can prove that they comply with the principles of good laboratory practice (GLP) in Annex 1 (to Section 19a (1) (II) ChemG.

Kosten

The fees in connection with GLP certificates are set out in the Ordinance on the Enactment of the Schedule of Costs under the Bavarian Costs Act (KG):

- Issue of a GLP certificate: EUR 1,500 to EUR 15,000
- Amendment or supplementation of a GLP certificate: EUR 125 to EUR 10,000

The fees are set on a case-by-case basis. The main factor here is the size of the company and the scope of the various inspections, which are used to determine the duration of the inspection and the number of inspectors.

Expenses are added to the fees, e.g. for the inspectors' travel costs.

An advance payment of 90% of the expected costs is due after the application has been submitted. The final payment must be made before the certificate is delivered.

Verfahrensablauf

In Bavaria, applications are accepted by the Bavarian State Office for Health and Food Safety.

An application form in German is available on the website of the Bavarian State Office for Health and Food Safety (LGL).

Upon receipt of the complete application, the Bavarian State Office for Health and Food Safety will notify the test facility of an inspection by members of the Bavarian GLP Inspection Commission. The inspectors arrange an inspection date with the test facility.

If the inspection shows that the test facility or the test site and the tests or phases of tests conducted there

Modul	Sachverhalt
	comply with the GLP principles, the LGL issues the GLP certificate and the corresponding notification. The GLP certificate specifies the test categories and the date of the inspection.
Bearbeitungsdauer	
Frist	none
weiterführende Informationen	http://www.lgl.bayern.de/das_lgl/aufgaben_zustaendigkeiten/zqm_aufgaben/glp_informationen.htm http://www.lgl.bayern.de/das_lgl/aufgaben_zustaendigkeiten/zqm_aufgaben/glp_informationen.htm https://www.vis.bayern.de/produkte_energie/marktueberwachung/glp.htm https://www.vis.bayern.de/produkte_energie/marktueberwachung/glp.htm https://www.lgl.bayern.de/das_lgl/aufgaben_zustaendigkeiten/zqm_aufgaben/glp_informationen.htm https://www.lgl.bayern.de/das_lgl/aufgaben_zustaendigkeiten/zqm_aufgaben/glp_informationen.htm
Hinweise	
Rechtsbehelf	Administrative court action
Kurztext	
Ansprechpunkt	
Zuständige Stelle	
Formulare	
Ursprungsportal	BayernPortal, BayernPortal