

## General Terms and Conditions

Date: March 2019

### 1. Scope

The General Terms and Conditions (GTC) shall form an integral part of any and all assignments or contracts governing sample analysis carried out by Friedrich-Loeffler-Institute, Federal Research Institute for Animal Health (FLI). They include assignments which FLI carries out as part of its official duties and competencies under the Animal Health Act and the Genetic Engineering Act on the one hand and is allowed to accept according to § 1, section 2 of FLI's schedule of fees<sup>1</sup> on the other hand. The GTC shall not apply to sample materials which were submitted for research purposes subject to separate Material Transfer Agreements (MTAs). The GTC shall be accepted by the submitter either explicitly by confirming acknowledgment when completing and sending the sample submission form provided on FLI's template server or they shall be considered accepted when the sender submits samples without completing the sample submission form against better judgment. The GTC shall be valid for the assignment or contract duration. Any conflicting or deviating General Terms and Conditions of the contracting party shall only form an integral part of the contract or assignment, when FLI accepts them in writing.

### 2. Issuing and accepting of assignments

An assignment or contractual relationship shall be deemed to be concluded upon receipt of the sample and the sample submission form and FLI's acceptance thereof, following an evaluation of the assignment. The assignment shall be accepted either explicitly (via FLI's template server) or implicitly by carrying out the assignment.

The submitter shall be considered the customer in a juridical sense, if no other arrangements are in place.

### 3. Remuneration/payment conditions

In case FLI carries out assignments subject to § 27, section 2 or 3, sentence 1, no. 2 of the Animal Health Act in connection with the Veterinary Vaccine Regulation, fees according to the statutory cost regulation relating to vaccines for veterinary use dated November 24<sup>th</sup> 2010 (Federal Law Gazette I page 1637) and the related amendments (last amended by Article 2 of the regulation dated 24<sup>th</sup> September 2014 (Federal Law Gazette I page 1558)) will be charged.

In all other cases, where FLI provides a sample analysis as part of its official duties, according to § 27, section 3 or 6 of the Animal Health Act, it is not entitled to any remuneration. Notwithstanding, the submitter shall be obliged to directly bear shipping costs and possible fees (e.g. customs, import or veterinary fees) or reimburse FLI within 14 days upon issuing an invoice. The announcement of the test results may be deferred until all outstanding claims have been settled.

Assignments outside the official duties of FLI will be charged under FLI's schedule of fees.

Any claims of FLI resulting from an assignment may not be set off against any counterclaims by the submitter.

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<sup>1</sup> Schedule of fees for the levying of charges for tests of FLI on the basis of the frame schedule of fees for the levying of charges for examinations of federal research institutes in the sphere of the Federal Ministry of Food, Agriculture and Forestry dated December 12<sup>th</sup> 1996 (Federal Gazette No. 9 dated January 15<sup>th</sup> 1997, page 305) and the related amendments.

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4. Rights to samples/Handling of samples/Storage of samples

According to § 929 of the German Civil Code, the animal owner who submits a sample, agrees to an unlimited acquisition of possession and property of the sample by FLI by accepting these GTC or by submitting the sample. Thus, FLI shall have all rights in connection with the sample set forth in § 903 of the German Civil Code, such as an exclusive, transferable right of use unrestricted in time, territory and content.

In case the submitter is not the animal owner, the submitter shall guarantee and warrant that the animal owner agrees with FLI's acquisition of not only possession but also property of the sample.

In general, FLI is not obliged to retain samples but it reserves the right to retain samples for its own purposes. In any case, the submitter agrees to the processing and use of the submitted samples for scientific purposes including third-party-funded research.

5. Test results

The submitter shall be entitled to any result of the tests carried out by FLI either as part of or outside its official duties. For the avoidance of misunderstandings, any partial publication or disclosure of the provided results shall always require FLI's explicit written consent. Moreover, FLI and its staff shall be entitled to use, publish and independently analyze any test result from such assignments for scientific purposes in compliance with data protection.

6. Archiving/Data protection/Confidentiality

The test reports along with work documentation will be stored in FLI's archive for a period of 10 years.

The collecting of personal data of the submitter in the sample submission form of FLI's laboratory information management software (inter alia contact data, details on the intended assignment, assignment date and number) as well as their processing by FLI shall only be permissible for the implementation of the contract (conducting tests and drawing up reports) and in compliance with data protection regulations (in particular Article 6 section 1 b) or c) of the General Data Protection Regulation (GDPR) and other applicable legislation. By submitting the sample submission form or the sample material, the submitter agrees to the processing of their personal data. Data protection information in the meaning of the Article 13 et seq. GDPR can be found on the website of the FLI via the following link: <https://www.fli.de/en/data-privacy/>.

The test results shall, in principle, be treated confidentially as well, i.e., they shall not be disclosed to any third party without the submitter's prior approval for a period of 5 years, unless they must be disclosed due to an administrative or court order or they may be included in scientific publications in an anonymized way due to FLI's right of use as defined in no. 5 above.

7. Scope of liability/Standard of due care/Remedy/Damages

It is understood, that the submitter shall be responsible for the sample until receipt by FLI's staff or its authorized representatives and that results contained in the final report only pertain to the submitted sample. Thus, the submitter shall ensure and monitor the accuracy of sampling and make arrangements for safe shipping of the sample. The submitter shall also be responsible for the accuracy of data provided in the sample submission form.

When carrying out the assignments, FLI undertakes to exercise due scientific care and to perform all relevant tasks in line with the latest scientific and technical standards.

If a test result gives rise to objections (assertion of warranty claims), they shall be permissible at any time. If it turns out that the complaint was justified and FLI is responsible, the assignment shall be repeated at FLI's expense.

Claims for damages against FLI - for whatever reason - are excluded, unless they are caused by intent or gross negligence of FLI. This shall also apply for indirect damages. In case of personal injuries, the statutory provisions shall apply.

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8. Final clause

- a. Place of performance shall be the registered office of FLI´s respective testing laboratory.
- b. The contract shall be governed by German law with the exception of international private law and the United Nations Convention on Contracts for the international Sale of Goods (CSIG). Place of jurisdiction for any possibly arising disputes shall be the competent court for Friedrich Loeffler Institute, headquartered at Riems.
- c. If not agreed otherwise, explicitly and in writing, the present GTC shall apply exclusively.
- d. In case any of these GTC turn out to be partially or fully invalid or unenforceable, or should they become invalid or unenforceable, it shall not affect the validity of the remaining provisions. The same shall apply in case of an omission. In order to replace the invalid or unenforceable provision or to close the gap, the parties shall agree upon a provision which, as far as legally possible, represents the original economic intent of the parties or what they would have intended had they thought of it.