

LEGAL HELPDESK

Q&A NO. 7

**What needs to be considered
from the legal side
when building/setting up
a biobank?**

By University of Vienna

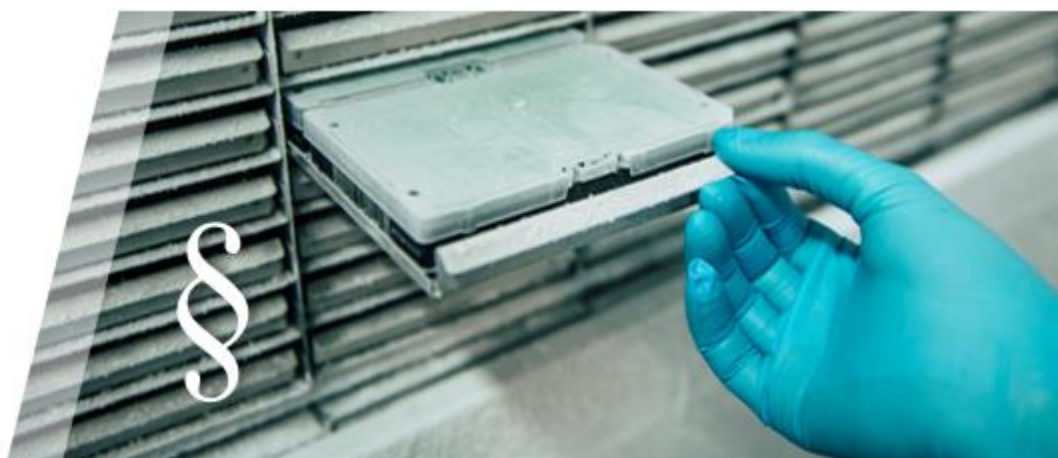


Image provided by Med Uni Graz (Biobank Graz)

Question no. 7

Published: January 2025

Subject: **Biobank, European Union, Legal Acts, Regulations**

1. Overview of relevant laws for biobanks, both at the Austrian and European levels

COMMENT

Currently, there is no single European Union-wide regulation that explicitly regulates biobanks and biobanking, however, the existing European Union (EU) framework addresses some aspects of biobanking, namely the Regulation on personal data protection – which coexists with the EU’s Member States (MS) national regulations on the matter.¹

At a national level, there is legislation in force in different EU MS which specifically address biobanks. Legal requirements to set up a biobank are included in the law as follows:

EU MS	Legislative Act	Requirements for Biobank set up
Belgium	<i>Royal Decree of 28 September 2009 establishing the general conditions which the banks for human substances, the intermediary structures and the production establishments must satisfy to be recognised</i> ²	
Estonia	<i>Inimgeeniuringute seadus (13.12.2000)</i> ³	In particular, Art. 3- Art. 5
Finland	<i>Biopankkilaki - 30.11.2012/688</i> ⁴	In particular Chapter 2, Art. 5 - Art. 10
Hungary	<i>008. évi XXI. törvénya humángenetikai adatok védelméről, a humángenetikai vizsgálatok és kutatások, valamint a biobankok működésének szabályairól</i> ⁵	In particular, Chapter 5, Art. 21- Art. 27
Latvia	<i>Cilvēka genoma izpētes likums (13.06.2002) (only applicable to genome databases)</i> ⁶	In particular, Art.4.

¹ Further information on EU regulation on biobanks can be found in the report/question no. 5 issued by UNIVIE.

² Belgium, *Royal Decree of 28 September 2009 establishing the general conditions which the banks for human substances, the intermediary structures and the production establishments must satisfy to be recognized*. Available at <https://etaamb.openjustice.be/fr/arrete-royal-du-28-septembre-2009_n2009018412.html>

³ Estonia, *Inimgeeniuringute seadus (13.12.2000)*. Available at <<https://www.riigiteataja.ee/akt/72581>>

⁴ Finland, *Biopankkilaki (30.11.2012/688)*. Available at <<https://www.finlex.fi/fi/laki/ajantasa/2012/20120688>>

⁵ Hungary, *008. évi XXI. törvénya humángenetikai adatok védelméről, a humángenetikai vizsgálatok és kutatások, valamint a biobankok működésének szabályairól*. Available at <<https://net.jogtar.hu/jogszabaly?docid=a0800021.tv>>

⁶ Latvia, *Cilvēka genoma izpētes likums (13.06.2002)*. Available at <<https://likumi.lv/ta/en/en/id/64093>>

Lithuania	<i>Lietuvos Respublikos biomedicininių tyrimų etikos įstatymas</i> ⁷	From the unofficial English translation it seems that the requirements for setting up a biobank are not regulated therein.
Portugal	<i>Lei n.º 12/2005, de 26 de Janeiro – Informação genética pessoal e informação de saúde (last amended by Lei n.º 26/2016, de 22 de Agosto)</i> ⁸	Art.19 (applicable to DNA banks)
Spain	<i>Ley 14/2007, de 3 de julio, de Investigación biomédica</i> ⁹	Chapter 4 – Art. 63-Art. 70
Sweden	<i>Biobankslag (2023:38)</i> ¹⁰	Art. 2-Art. 3, Art. 6

Other national systems do not have a specific mandate on the question at hand, but certain requirements for the establishment of a biobank can be found in the legal system, as in the case of Austria:

EU MS	Legislative Act	Requirements for Biobank set up
Austria	Forschungsorganisationsgesetz (FOG) ¹¹ , Austrian Tissue Safety Act, <i>Ordinance on Human Tissue Banks</i> ¹² , <i>Legal basis for the areas of extraction, processing, storage and distribution of human tissues and cells</i> : <ul style="list-style-type: none"> • Tissue Safety Act (GSG) • Tissue Vigilance Ordinance (GVVO) • Tissue Bank Ordinance (GBVO) • Tissue Procurement Ordinance (GEEVO) 	Art. 2f(1), as for the definition of scientific institution. If tissue samples are handled, the Tissue Safety act and Tissue Bank ordinance are applicable, According to § 29 Abs 1 Gewebesicherheitsgesetz idgF (GSG) the Bundesamt für Sicherheit im Gesundheitswesen (Federal Office for Safety in Health Care) has to keep a register of all certified procurement establishments and approved tissue banks. Tissue banks need to be certified, and included in an European register ¹³ .

In order to illustrate the legal requirements provided by the aforementioned national laws, biobanks need to

- be registered as a legal person¹⁴
- be authorized/ accredited by the respective national (health) authority.¹⁵

⁷ Lithuania, Lietuvos Respublikos biomedicininių tyrimų etikos įstatymas . Available at <<https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/TAIS.101629?ifwid=> >

⁸ Portugal, Lei n.º 12/2005, de 26 de Janeiro – Informação genética pessoal e informação de saúde. Available at <https://www.pgdlisboa.pt/leis/lei_mostra_articulado.php?nid=1660&tabela=leis&so_miolo= >

⁹ Spain, Ley 14/2007, de 3 de julio, de Investigación biomédica. Available at <<https://www.boe.es/buscar/doc.php?id=BOE-A-2007-12945> >

¹⁰ Sweden, Biobankslag (2023:38). Available at < https://www.riksdagen.se/sv/dokument-och-lagar/dokument/svensk-forfattningssamling/biobankslag-202338_sfs-2023-38/#K2 >

¹¹ Austria, Forschungsorganisationsgesetz. Available at <<https://www.ris.bka.gv.at/GeltendeFassung.wxe?Abfrage=Bundesnormen&Gesetzesnummer=10009514> >

¹² BASG - Federal Office for Safety in Health Care / AGES MEA - Austrian Medicines and Medical Devices Agency, *Certification, authorisation, and inspection of tissue establishments*. Available at < <https://www.basg.gv.at/en/healthcare-professionals/tissue-safety/certification-authorisation-and-inspection-of-tissue-establishments#:~:text=According%20to%20the%20Austrian%20Tissue,ordinances%20issued%20on%20its%20basis.> >

¹³ Idem 12

¹⁴ See Estonia, Inimgeeniuringute seadus (13.12.2000 Art.3); Finland Biopankkilaki - 30.11.2012/688 Art. 6; The Biobanks and Health Databanks Act, Art. 4 and 5.

¹⁵ See Estonia, Inimgeeniuringute seadus (13.12.2000 Art.3); Finland Biopankkilaki - 30.11.2012/688 Art. 6; Portugal Lei n.º 12/2005, de 26 de Janeiro – Informação genética pessoal e informação de saúde (last amended by



These national legal requirements could be complemented by standards in the field.¹⁶

- ISO 20387 standard which contains requirements designed to demonstrate the competence of a biobank's operation and the ability to provide biological material and associated data for research and development.¹⁷

Disclaimer: *this commentary aims to provide a summary of the main ethical and legal issues related to the questions put by interested stakeholders and to direct them to the relevant legal provisions that are applicable. It does not, however, preclude from reading the official sources of legislation relating to the subject matters of this document as well as those quoted by the authors and does not constitute legal advice.*

Lei n.º 26/2016, de 22 de Agosto) Article 19 (2); Spain, Ley 14/2007, de 3 de julio, de Investigación biomédica, Art. 64.

¹⁶ WHO, *Biobank and Cohort Building Network, Recommendation to set up a biobank* . Available at <<https://videos.iarc.fr/channels/BCNet/media/MEDIA160331215143240> >

¹⁷ ISO, *ISO 20387 Biotechnology — Biobanking — General requirements for biobanking*. Available at <<https://www.iso.org/standard/67888.html> >