



Department of Innovation and Digitalisation in Law





SUSTAINABILITY IN BIOBANKING: LEGAL FRAMEWORK AND PRACTICAL IMPLEMENTATION

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Why?

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 Following recommendations proposed by the scientific community as best practices for biobanks to reduce carbon emissions.

- How?
- 2. Complying with the current regulatory framework for environmental protection at national, international and EU levels

 As of now, this framework is largely not applicable to biobanks

- Key consideration for long-term sustainability of these repositories
- Aligns with the European Commission's aim of making Europe climate-neutral by 2050
- Contributes to the reduction of operating costs
- Biobanks, as key actors of contemporary scientific advancements, should lead by example in adopting measures for environmental protection

	Austrian	International	European Union (EU)
Soft Law	 The Austrian Strategy for Adaptation to Climate Change, <u>Die Österreichische</u> <u>Strategie zur Anpassung an den</u> <u>Klimawandel</u> Strategy and recommendations for action within 14 fields of activity, including the health sector. 	 United Nations 2030 Agenda for Sustainable Development & 17 Sustainable Development Goals World Health Organization (WHO) Operational framework for building climate resilient and low carbon health systems 	 Communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions: <u>The</u> <u>European Green Deal</u>. The pursuit of climate neutrality is likewise set out by a binding legal instrument, the <u>Regulation (EU)</u> 2021/1119, also known as the European Climate Law.
Hard Law			 Regulation (EU) 2024/1735 (Net Zero Industry

* No specific provisions to be mentioned *

<u>Klimaschutzgesetz</u>

Sets maximum levels of greenhouse gas emissions.

Act (NZIA)) Creates measures to ensure the EU's access to a secure and sustainable supply of net-zero technologies, which include some that can be of use to biobanks, such as sustainable energy efficient technologies.

Already applicable; Will affect biobanks.

 <u>Directive (EU) 2024/1275</u> (Energy Performance of Buildings Directive)

Promotes the improvement of the energy performance of buildings, which is especially relevant for biobanks. To be transposed until May 2026; Will affect biobanks.

 <u>Regulation (EU) 2024/573</u> (New F-gas Regulation)

Governs fluorinated greenhouse gases (including their use and recycling) and prohibits the intentional release of these gases whenever the release is not technically necessary for the intended use. Already applicable: Will affect biobanks.

			Already applicable; Will affect biobanks.	
Standards and Certificates	* No specific provisions to be mentioned *	 <u>ISO 14001:2015</u> Creates a framework for organizations to design and implement an environmental management system (EMS) 	* No specific provisions to be mentioned *	
Table of selected regulatory instruments (simplified) that will guide biobanks in their pursuit for sustainability				

3. Exploring other **regulatory opportunities**

Examples of interaction between regulatory efforts and environmental protection:

- Consent models that allow sample reuse are an example of a potential regulatory pursuit that aligns with environmental protection;
- Ethical and legal guidelines to dispose of unused, surplus samples can further reduce the environmental strain;
- Whilst this is possible in Austria, in other countries, pursuing regulation that permits samples from the deceased being used for research purposes (with informed consent being sought during lifetime) could also be considered more sustainable;
- Policies allowing research on traditionally deemed waste products, such as faecal microbiome samples, are likewise an option.

References:

- Graham, M., Samuel, G., & Farley, M. (2024). Roadmap for low-carbon ultra-low temperature storage in biobanking. Journal of translational medicine, 22(1), 747.
- Samuel, G., & Sims, J. M. (2023). Drivers and constraints to environmental sustainability in UK-based biobanking: balancing resource efficiency and future value. BMC Medical Ethics, 24(1), 36.
- Samuel, G., Hardcastle, F., & Lucassen, A. M. (2022). Environmental sustainability and biobanking: a pilot study of the field. New Genetics and Society, 41(2), 157-175.
- All legal and regulatory sources were linked throughout the poster.

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