BIOBANKING FOR A HEALTHIER WORLD

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LEGAL HELPDESK

Q&A NO. 030

What environmental laws in Austrian and the European Union are or can become relevant for biobanks?

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1. Introduction

COMMENT

Sustainability of biobanks very often not only pertains to environmental sustainability, but rather refers to financial and resource allocation over time[1]. This is apparent in guidelines and recommendations regarding biobank sustainability, such as the Organisation for Economic Co-operation and Development's (OECD) Recommendation of the Council on Human Biobanks and Genetic Research Databases, which specifically mentions termination of funding as a key consideration that should guide the establishment of a biobank (§2.C) regarding its sustainability.

Environmental sustainability is, however, of increasing relevance, as biobanks will only survive over time if measures are taken to guarantee their long-term resilience[2], and they are a well-articulated part of the naturally balancing environmental machinery. It is argued that they should remain an asset in the health and biomedical research context and not an intergenerational liability for the future.

2. Biobanks: Environmental Impact

Biobanks have a significant environmental impact, which can be especially damaging if not appropriately managed. As detailed by fellow BBMRI.at Project Partner Biobank Graz, there are numerous examples of the environmental impact of biobanks and the biobanking activity, for which their team has devised strategies to mitigate, as systematised in the table below:

Sector	Measures
Freezers and cryogenic storage systems	• Use energy efficient freezers and storage systems; • Perform regular maintenance (de-icing); • Optimize loading (avoid empty spaces in boxes and shelfs); • Use space-saving techniques (e.g. condense sample tubes on plates); • Refrain from storing primary tubes, such as PAXgene tubes and store e.g. isolated DNA or RNA in smaller tubes instead; • In case of round cryotanks, use slim towers that can host smaller boxes to use the empty space between the regular towers; • Temperature optimization (raising temperature from -80 °C to -70 °C saves up to 33 % of energy); • Minimize door opening times and frequency.

[1] SAMUEL, G., LUCIVERO, F., & LUCASSEN, A. M. (2022). Sustainable biobanks: a case study for a green global bioethics. *Global Bioethics*, *33*(1), pp. 50-64, p. 51.
[2] SAMUEL, G., HARDCASTLE, F., & LUCASSEN, A. M. (2022). Environmental sustainability and biobanking: a pilot study of the field. *New Genetics and Society*, *41*(2), pp. 157-175.

Refrigerants and LN2	• Choose environmentally friendly refrigerants and invest in CO2 neutrally produced liquid nitrogen (LN2).
Electricity and Alternative Storage	• Integrate renewable energy sources and explore storage solutions that require less cooling, such as desiccation and lyophilization.
Sample Management and Transport	• Assess and minimize sample volumes, disposing of unnecessary samples, and choose carbon-neutral transport options while consolidating shipments.
Instruments and equipment	• Promote the reuse of materials and equipment, prioritize repairs, and assess the necessity of existing infrastructure.
Consumables	• Purchase recycled or biodegradable lab ware (e.g. tips, gloves, bags, boxes, lids, etc.); • Use high density racks and trays in freezers and storage systems; • Reuse e.g. boxes and lids for sample shipment;
IT and data storage	• Use energy efficient IT solutions and data centers; • Remove redundant or outdated data files; • Use waste heat of servers.
Buildings	• Install renewable energy sources in buildings and encourage remote work and sustainable transport options for commuting.
Staff Training	• Train staff on sustainability practices, focusing on efficient resource use, recycling, and process optimization.

Table 1 - Strategies to mitigate the environmental impact of biobanking (by Biobank Graz)

3. Strategies for the pursuit of green biobanking

Considering the previously described measures, the strategies for the pursuit of green biobanking can be summarised as follows:

- Following **recommendations** proposed by the scientific community as best practices for biobanks to reduce carbon emissions. These are available as biobank internal policies or detailed in specialised literature;
- 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**;
- Guiding and educating policy-making stakeholders into the benefits of **exploring other regulatory opportunities.**

3.1 Current Regulatory Framework

International Soft Law:

- 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**

International Standards and Certificates:

- **ISO 14001:2015**: creates a framework for organizations to design and implement an environmental management system (EMS).

European Union Soft Law:

- 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: **The European Green Deal**.

The pursuit of climate neutrality is likewise set out by a binding legal instrument, the **Regulation (EU) 2021/1119**[3], also known as the **European Climate Law.**

European Union Hard Law:
The following are selected examples of Regulations and Directives that may affect, to different extents, the operation of biobanks and their activity.

- **Regulation (EU) 2024/1735**[4]: 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. The Regulation is already applicable (Article 49(2)) and will affect biobanks, by promoting access and supply to innovative net-zero technologies and other innovative technologies.
- **Directive (EU) 2024/1275**[5]: promotes the improvement of the energy performance of buildings, which is especially relevant for biobanks. The Directive is to be transposed by Member States until May 2026 (Article 35). Although Austria and other Member States will have different regulatory approaches for the transposition and implementation of this Directive, it is relevant to biobanks as they are buildings (or integrated in buildings, such as hospitals) who have high energy consumption, since biobanking is an energy-heavy pursuit, which will be calculatable resorting to the new energy performance calculating methodology, to be adopted under the umbrella of the Directive (Article 4). The Directive will be of relevance to buildings undergoing renovations (Article 8) as well as new buildings, which will have to comply with new provisions regarding solar energy (Article 10).
- **Regulation (EU) 2024/573**[6]: 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 (Article 4). The Regulation has already become applicable in early 2025 (Article 38). It will affect biobanks who operate equipment that contains fluorinated greenhouse gases or use fluorinated greenhouse gases. They will have, *inter alia*, obligations regarding minimisation of leakage of the gases (and quick repair of leakage sites), precautions to limit release of fluorinated greenhouse gases (Article 4) and implementation of leak checks (Article 5).
- **Directive (EU) 2019/904**[7]: the provisions of the Directive "[…] give priority to sustainable and non-toxic re-usable products and re-use systems rather than to single-use products […]" (Recital 2). As consumers of disposable, single-use products, containing plastic, the biobanks – depending on the specific measures adopted during the transposition of the Directive into Member State law – may have to contend with reduced availability of these products (as a general consumption reduction will be pursued) or, for those single-use plastic products for which no suitable and more sustainable alternatives are readily available, be prepared to pay higher prices for them, as producers will be have to absorb the costs of their extended

[3] Regulation (EU) 2021/1119 of the European Parliament and of the Council of 30 June 2021 establishing the framework for achieving climate neutrality and amending Regulations (EC) No 401/2009 and (EU) 2018/1999 ('European Climate Law').
[4] Consolidated text: Regulation (EU) 2024/1735 of the European Parliament and of the Council of 13 June 2024 on establishing a framework of measures for strengthening Europe's net-zero technology manufacturing ecosystem and amending Regulation (EU) 2018/1724 (Text with EEA relevance).
[5] Directive (EU) 2024/1275 of the European Parliament and of the Council of 24 April 2024 on the energy performance of buildings (recast) (Text with EEA relevance).
[6] Regulation (EU) 2024/573 of the European Parliament and of the Council of 7 February 2024 on fluorinated greenhouse gases, amending Directive (EU) 2019/1937 and repealing Regulation (EU) No 517/2014 (Text with EEA relevance).
[7] Directive (EU) 2019/904 of the European Parliament and of the Council of 5 June 2019 on the reduction of the impact of certain plastic products on the environment (Text with EEA relevance).

responsibilities under the polluter-pays principle (Recital 21). The Directive hence presents an impetus for biobanks to reduce and source other non-plastic consumables.

Austrian Soft Law:

- The Austrian Strategy for Adaptation to Climate Change, **Die Österreichische Strategie zur Anpassung an den Klimawandel** presents a strategy and recommendations for action within 14 fields of activity, including the health sector.

Austrian Hard Law:

- Climate Protection Act, the ***Klimaschutzgesetz***, sets maximum levels of greenhouse gas emissions. Within this context, the National Energy and Climate Plan (*Nationale Energie- und Klimaplan* (NEKP)) is pertinent as the description of the measures that will be taken in Austria to achieve the binding targets for energy reduction and climate preservation. The plan has been submitted to the European Commission in accordance with Article 14 of Regulation (EU) 2018/1999, which covers Governance of the Energy Union and Climate Action. Additionally, the Government programme for 2025-2029 (Regierungsprogramm 2025–2029) also places great emphasis on climate and environmental protection.

3.1 Other regulatory opportunities

- Consent models that allow sample reuse[8] are an example of a potential regulatory pursuit that aligns with environmental protection;
- Ethical and legal guidelines to dispose of unused, surplus samples[9] can further reduce the environmental strain;
- Regulations that permit 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.

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.*

[8] GRAHAM, M., SAMUEL, G., & FARLEY, M. (2024). Roadmap for low-carbon ultra-low temperature storage in biobanking. *Journal of translational medicine*, *22*(1), 74, p. 8.
[9] 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.