



## Policy Brief

# Enhancing EU legal frameworks for Neurotechnologies

# TECHETHOS

FUTURE ◦ TECHNOLOGY ◦ ETHICS

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## Highlights



To protect and uphold ethical, legal and fundamental rights considerations in the development and deployment of neurotechnologies, the Horizon 2020-funded [TechEthos](#) project encourages European Union (EU) policymakers to:

- Recognise and define **neurorights** within the EU's existing fundamental rights frameworks;
- Clarify the legal status of **brain and other neural data** under the General Data Protection Regulation (GDPR);
- Address **justice, equality & discrimination gaps** in neurotechnology applications and use cases;
- Monitor and evaluate the adequacy of existing regulatory frameworks governing emerging use cases of neurotechnologies, such as **consumer and dual-use applications**;
- Consider the appropriate types of **legal or policy instruments** for the regulation of neurotechnologies in the EU;
- Clarify the regulation of **Artificial Intelligence (AI)-based neurotechnologies** and consider specific **use cases** in the classification of neurotechnologies under the proposed AI Act.

## Who is this for?

This brief is primarily aimed at EU institutions, such as the European Commission, European Parliament, the Council of the European Union, and the European Council. In particular, this brief seeks to inform EU policymakers and officials involved in the preparation of legislative or policy initiatives related to **neurotechnologies, medical devices, dual use items, privacy and data protection, and AI systems**.

## Introduction

Neurotechnologies refers to devices and procedures used to access, monitor, investigate, assess, manipulate, and/or emulate the structure and function of the neural systems of natural persons. Whilst neurotechnologies have the potential to improve healthcare provision and the quality of life, emerging applications of such technologies present certain risks and regulatory challenges. This policy brief sets out the regulatory priorities identified through an analysis of EU laws and policies as part of the TechEthos project.

In particular, these regulatory priorities are considered in the context of the Charter of Fundamental Rights of the European Union (CFREU), the GDPR, the Medical Devices Regulation (MDR), the dual-use regulation, and the proposed AI Act.





## Recommendations



### Recognise and define neurorights within the EU's existing fundamental rights frameworks

- The EU should recognise and define putative neurorights, such as the right to cognitive liberty, prospectively through the adoption of a **Declaration on Neurorights and Principles**, similar to the European Declaration on Digital Rights and Principles. Recognition through a soft law mechanism such as this would serve as guidance for policymakers in the development of EU law and policy.
- In addition, the EU should ensure the adequate protection and effective enforcement of existing rights under the CFREU. The **right to mental integrity** under Article 3, for instance, should be extended to protect against instances of unlawful, neurotechnology-enabled interference with and/or manipulation of the brain and other neural activity.
- The EU should encourage the adoption of **ethics-by-design** approaches to mitigate against the possible risks associated with the development of neurotechnologies. This could include mandatory requirements to involve ethics committees and conduct ethical and human rights impact assessments in EU regulatory frameworks with application to neurotechnologies, such as the **proposed AI Act**.

### Clarify the legal status of brain and other neural data under the GDPR

- The EU should explicitly recognise and protect **brain and other neural data** as special category

personal data within the meaning of **Article 9 of the GDPR**. This would ensure more robust and effective protection of brain and other neural data that does not fit into existing categories under Article 9, such as genetic or health data, whilst not prohibiting the lawful processing of such data in the context of, inter alia, potentially beneficial scientific and biomedical research and therapeutic applications.

### Address justice, equality & discrimination gaps in applications and use cases of neurotechnologies

- **Discrimination:** The EU should expand the types of 'ground' covered by the right to non-discrimination under Article 21 CFREU to include brain and other neural data and associated statuses. This would protect against the misuse of brain and other neural data to discriminate on the basis of mental health status or cognitive performance in various socio-economic contexts, such as employment, insurance, and the administration of justice.
- **Neuroenhancement:** Building upon the commitment to the protection of equality in the CFREU and to avoid potential negative implications for the protection of related fundamental rights, such as the right to non-discrimination, the EU should continue to monitor the development of and take steps to establish appropriate and proportionate regulation for emerging applications of "neuroenhancement".
- **Justice:** In accordance with the CFREU and Directive 2016/343, the European Commission should continue to work with Member States to ensure that the growing use of neuroscientific evidence in legal proceedings does not interfere with the protection of fundamental rights, such as the right to a fair trial, the presumption of innocence, and the right not to incriminate oneself.





## Monitor and evaluate the adequacy of existing regulatory frameworks governing emerging use cases of neurotechnologies, such as consumer and dual-use applications

- In accordance with Article 1(2), the groups of products listed in **Annex XVI of the Medical Devices Regulation (MDR)** should be monitored and updated to include any emerging neurotechnologies without an intended medical purpose for which there exists a harmonised standard for analogous devices with an intended medical purpose based on similar technology.
- The EU should evaluate **possible gaps in the MDR** relating to the product safety of non-invasive direct-to-consumer neurotechnologies, which are marketed as collecting and processing brain and other neural data for non-medical but health-related purposes, such as mental wellbeing.
- In preparing its annual updates to **Annex I of Regulation 2021/821** on the control of exports, brokering, technical assistance, transit and transfer of dual-use items, the European Commission should ensure that emerging dual-use applications of neurotechnologies, such as brain computer interfaces (BCIs), are considered and continuously monitored for potential inclusion.

## Consider the appropriate types of legal or policy instruments for the regulation of neurotechnologies in the EU

- The EU should consider the appropriate type of mechanism for the recognition of neurorights. Similar to the EU's Declaration on Digital Rights and Principles, the adoption of a **Declaration on Neurorights** could serve as a policy instrument to acknowledge neurorights within the meaning of the existing EU fundamental rights framework.

- The EU should promote such a declaration in its relations with other international organisations, including by reflecting these rights and principles in its trade relations, with the ambition of guiding other international partners towards the promotion and protection of neurorights. Such an instrument should also serve as a reference point for businesses involved in the development and deployment of neurotechnologies.

## Clarify the regulation of AI-based neurotechnologies and consider specific use cases in the classification of neurotechnologies under the proposed AI Act

- The classification of **neurotechnologies under the AI Act** will impact the ways in which such technologies can be developed and deployed in the EU. The EU should consider different types of use cases, such as medicine, predictive diagnostics, entertainment and education, in assessing the risk classification of AI-enabled neurotechnologies within the proposed AI Act.
- The EU should evaluate the use of neurotechnologies in **potentially high-risk contexts**, such as **neuromarketing, health insurance and healthcare provision**. The protection of fundamental rights, such as the right to privacy, freedom of thought, non-discrimination, dignity and autonomy, should be a central consideration in the risk classification of AI-enabled neurotechnologies.
- The Council should clarify the reference to **Machine-Brain Interfaces (MBIs)** in recital 16 of its General Approach on the proposed AI Act to elaborate whether all types of MBIs are subject to a prohibition under Article 5. Furthermore, in addition to the exception for the use of MBIs for medical treatment, the Council, in negotiation with the European Parliament, should consider whether there are other use cases of MBIs that should be exempt, such as research.





## Final take-aways



A key takeaway is the growing consensus for **the need to recognise and define neurorights** as part of human rights frameworks. The EU should explicitly recognise the existence of neurorights, such as by adopting a **Declaration on Neurorights and Principles**. Rights-based frameworks, such as the CFREU, are designed to adapt to the issues raised by emerging technologies to protect the rights of individuals.

The following would further strengthen the rights-based approach to the regulation of neurotechnologies:

- Recognise brain and other neural data as **special category personal data** under the GDPR;
- Monitor and assess the possible under-regulation of **consumer and dual use neurotechnology**;
- Adjust and promote the more effective enforcement of **existing legal frameworks**;
- Assess the development of AI-enabled **neurotechnologies in relation to the proposed AI Act**;
- Encourage the adoption of **ethics-by-design** approaches to neurotechnology development through **consultation and stakeholder engagement**.

## Further reading



- Adomaitis, L., Grinbaum, A., Lenzi, D. (2022). TechEthos D2.2: Identification and specification of potential ethical issues and impacts and analysis of ethical issues of digital extended reality, neurotechnologies, and climate engineering. TechEthos Project Deliverable. Available at: [www.techethos.eu](http://www.techethos.eu); and <https://doi.org/10.5281/zenodo.7619852>.
- Bernstein M.J. and Mehnert E.W. (2022) Policy note: Analysis of expert scenarios addressing ethical implications of the selected technologies. TechEthos Project Deliverable to the European Commission. Available at [www.techethos.eu](http://www.techethos.eu); and <https://doi.org/10.5281/zenodo.7615250>.
- Santiago, N., et al. (2022). TechEthos D4.1: Analysis of international and EU law and policy. TechEthos Project Deliverable. Available at: [www.techethos.eu](http://www.techethos.eu); and <https://doi.org/10.5281/zenodo.7650731>
- Vinders, J., et al. (2022). TechEthos D4.2: Comparative analysis of national legal case studies. TechEthos Project Deliverable. Available at: <https://www.techethos.eu/national-legal-cases-on-emerging-technologies/>.

This policy brief is based on the results of the legal analysis of the TechEthos project. Further policy briefs on wider ethical project results will be provided at [www.techethos.eu](http://www.techethos.eu).

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