TECHETHOS

FUTURE O TECHNOLOGY O ETHICS



Enhancing EU law on climate engineering, neurotechnologies, and digital extended reality

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D6.2 Policy briefs on EU legal frameworks
Draft version submitted to the European Commission for review



D6.2 Policy briefs on enhancing EU legal frameworks for the studied technologies				
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The TechEthos Project

Short project summary

TechEthos is an EU-funded project that deals with the ethics of the new and emerging technologies anticipated to have high socio-economic impact. The project involves ten scientific partners and six science engagement organisations and runs from January 2021 to the end of 2023.

TechEthos aims to facilitate "ethics by design", namely, to bring ethical and societal values into the design and development of new and emerging technologies from the very beginning of the process. Technologies covered are "climate engineering", "neurotechnologies" and "digital extended reality". The project will produce operational ethics guidelines for these technologies for users such as researchers, research ethics committees and policymakers. To reconcile the needs of research and innovation and the concerns of society, the project will explore the awareness, acceptance and aspirations of academia, industry and the general public alike and reflect them in the guidelines.

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Definitions and abbreviations

Table 1: List of Definitions

Term	Explanation
Carbon Dioxide Removal (CDR)	A type of climate engineering technique, also known as "negative emissions techniques", that removes atmospheric CO ₂ and stores it in geological, terrestrial, or oceanic reservoirs.
Climate engineering	Also known as geoengineering, refers to the deliberate large-scale intervention in the Earth's climate system, in order to moderate global warming.
Digital extended reality	Refers to a collection of technologies that are related to each other, with a common functionality to emulate and imitate human traits and social circumstances: language, appearance, lived spaces, objects, experiences, etc. XR is also known as a mix of virtual reality (VR), augmented reality (AR) and mixed reality.
Ethics-by-design	An approach to research and innovation that consider ethical principles and considerations early on in the design and development phase.
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.
Policy brief	Refers to a short document produced by the TechEthos project with recommendations aimed at policymakers. The policy briefs attached to this document are specifically aimed at enhancing EU law and policy related to climate engineering (CDR and SRM), neurotechnologies and digital extended reality.
Solar Radiation Modification (SRM)	A type of climate engineering technique that aims to reflect some sunlight and heat back into space to reduce warming.

Table 2: List of Abbreviations

Term	Explanation
Al	Artificial intelligence
Al Act	Proposal for a Regulation of the European Parliament and of the Council laying down harmonised rules on Artificial Intelligence (Artificial Intelligence Act) and amending certain Union legislative acts (21.4.2021, COM(2021) 206 final)
AR	Augmented reality
BCI	Brain computer interface
CCS	Carbon capture and storage



CDR	Carbon dioxide removal
CFREU	Charter of Fundamental Rights of the European Union
CO ₂	Carbon dioxide
CRCF	European Commission proposal for a Regulation of the European Parliament and of the Council establishing a Union certification framework for carbon removals (30.11.2022 COM(2022) 672 final)
DG	Directorate General
DMA	Digital Markets Act
DoA	Description of Action
DSA	Digital Services Act
ENMOD	United Nations Convention on the Prohibition of Military or Any Other Hostile Use of Environmental Modification Techniques
ETS	Emission Trading Scheme
EU	European Union
GDPR	General Data Protection Regulation
IPCC	Intergovernmental Panel on Climate Change
LULUCF	Land use, land use change and forestry
МВІ	Machine brain interface
MDR	Medical Devices Regulation
MR	Mixed reality
NLP	Natural language processing
SDGs	Sustainable Development Goals
SRM	Solar radiation modification
UN	United Nations
UNCBD	United Nations Convention on Biological Diversity
VR	Virtual reality
XR	Digital extended reality



Policy briefs: Introduction

This section provides an overview of the process followed in the development of the four policy briefs annexed to this document. The recommendations contained in the policy briefs are targeted towards European Union (EU) policymakers and officials involved in the preparation of legislative or policy initiatives.

The policy briefs offer recommendations to policymakers at the EU level to enhance legal frameworks for the governance of climate engineering (CDR and SRM), neurotechnologies and digital extended reality (XR). The recommendations are based on the legal and policy analysis of TechEthos Work Package 4, the findings of which were consulted on and validated through a series of consultation meetings with 14 policymakers at the European Commission. This section outlines the process and methodology, and provides further details on the consultation meetings that were held as part of the process.

Process (adapted from Description of Action):

- Carry out consultation meetings with stakeholders, especially EU policymakers and officials involved in the preparation of legislative or policy initiatives;
- Assess the need for dedicated legislation at the EU level in relation to the three technologies on the basis of the legal issues identified in TechEthos Deliverables 4.1 and 4.2;
- Prepare four policy briefs (one for neurotechnologies and digital extended reality, two for climate engineering) (3-4 pages).

Methodology

The policy briefs were prepared on the basis of the TechEthos legal and policy analysis (WP4). The recommendations were developed from the legal issues identified in Deliverables 4.1 (analysis of international and EU laws and policies) and 4.2 (comparative analysis of national legal case studies). In addition, TechEthos Deliverable 2.2 (ethical analysis) was considered to incorporate the ethical challenges identified by the TechEthos project in the formulation of recommendations to enhance EU legal frameworks.

The findings from the legal analysis in D4.1 and 4.2 were presented and discussed during a series of policy consultation meetings with relevant EU officials, particularly with those working at relevant Directorate General (DG) units and cabinets of the European Commission and involved in relevant legislative and policy development processes. These consultation meetings were held over the December 2022-February 2023 period, which helped validate the regulatory challenges at the EU level identified by the TechEthos project and formulate regulatory priorities for the EU into policy recommendations. Despite our efforts, we were unable to secure a dedicated meeting with relevant DGs to discuss neurotechnologies for the preparation of these policy briefs. However, we did touch upon some cross-cutting issues between neurotechnologies and XR in the XR-related consultation meetings. Furthermore, we continue to pursue options with relevant stakeholders on the recommendations for enhancing EU legal frameworks on neurotechnologies, including through the TechEthos Advisory and Impact (ADIM) Board.





Technology family	Consultation meetings
Climate engineering	 02/12/2022: meeting with members of DG Climate Action (CLIMA) Unit C.3: Low Carbon Solutions (III) – Land Economy & Carbon Removals 17/02/2023: meeting with members of DG Research & Innovation (RTD) Unit B.3: Healthy Planet Directorate – Climate and Planetary Boundaries
Neurotechnologies	 Some cross-cutting issues between neurotechnologies and XR discussed during the XR-related consultation meetings
Digital extended reality	 11/01/2023: meeting with Cabinet Expert and Member of Cabinet for EU Commissioner Margrethe Vestager 13/01/2023: meeting with members of DG Connect (CNECT) I.4: Market Convergence and Social Media, DG CNECT A.2: AI policy, and DG CNECT G.1: Data Policy and Innovation

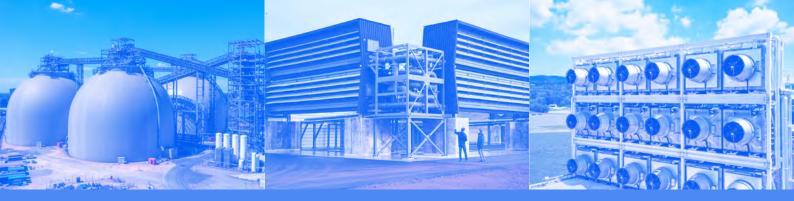
Considering the distinct characteristics and regulatory priorities for CDR and SRM, the decision was made to split the climate engineering policy brief into two separate briefs. The recommendations developed for CDR and SRM are set within the context of EU law and policy, including the European Climate Law, EU environmental law, the Charter of Fundamental Rights of the European Union (CFREU), and the European Commission initiative on a Carbon Removal Certification Framework (CRCF), as well as international environmental law, including international conventions of the UN.

The recommendations developed for neurotechnologies are set within the EU legal and policy context of the CFREU, the Medical Devices Regulation (MDR), the General Data Protection Regulation (GDPR), and the proposed Artificial Intelligence (AI) Act.

The recommendations developed for XR are set within the EU legal and policy context of the CFREU, the GDPR, the proposed AI Act, and the Digital Services Act (DSA).

Annexes

- TechEthos Policy Brief #1: Enhancing EU legal frameworks for Carbon Dioxide Removal
- o **TechEthos Policy Brief #2:** Enhancing EU legal frameworks for Solar Radiation Modification
- o TechEthos Policy Brief #3: Enhancing EU legal frameworks for Neurotechnologies
- TechEthos Policy Brief #4: Enhancing EU legal frameworks for Digital Extended Reality



Policy Brief

Enhancing EU legal frameworks for Carbon Dioxide Removal

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February 2023

Highlights



This policy brief provides legal and policy recommendations at the European Union (EU) level on the governance of Carbon Dioxide Removal (CDR). Together with Solar Radiation Modification (SRM), CDR can be understood to fall within the category of 'climate engineering', or 'geoengineering'. To protect and uphold ethical, fundamental rights and sustainability considerations in the research, development and deployment of CDR, the Horizon 2020-funded <u>TechEthos</u> project encourages EU policymakers to:

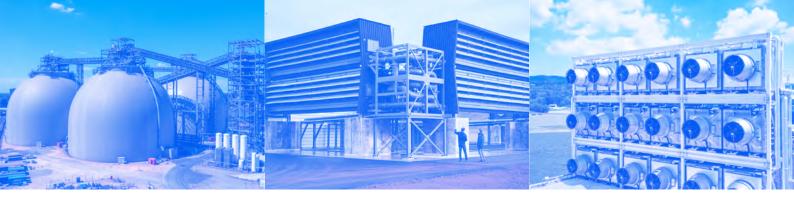
- Clarify the EU's terminology and rationale for the use of terms, including climate engineering, geoengineering, carbon removal and CDR, and pursue the harmonisation of terms to bring them in line with the terminology of the Intergovernmental Panel on Climate Change (IPCC);
- Clarify what role if any CDR has to play in meeting the EU's legally binding target of net-zero by 2050;
- Explicitly incorporate EU fundamental rights into policies and decision-making processes governing CDR techniques in the EU;

- Clarify the legal status of carbon removals and recognise them as distinct from emission reductions;
- Define the sustainability requirements for CDR, particularly those in the context of the Sustainable Development Goals (SDGs), the EU Taxonomy Regulation, and the Carbon Removal Certification Framework (CRCF) initiative;
- Pursue greater international collaboration in relation to CDR to promote the standardisation of removal accounting to avoid double counting, and the enforcement of such standards;
- Review the adequacy of environmental liability regimes in relation to CDR activities in the EU, including research and deployment.

Who is this for?

This brief is primarily aimed at EU institutions, including the European Commission, the European Parliament, the Council of the European Union, and the European Council. The brief seeks to inform EU policymakers and officials involved in the preparation of legislative or policy initiatives related to climate action, climate technologies, climate engineering, geoengineering, carbon removal, and CDR.





Introduction

CDR is a type of climate engineering technique, also known as "negative emissions techniques", that removes atmospheric CO2 and stores it in geological, terrestrial, or oceanic reservoirs. Whilst the objective of CDR is to alleviate impacts of climate change, CDR techniques also present certain risks and regulatory challenges. This policy brief sets out recommendations based on the regulatory challenges related to CDR identified through an analysis of EU laws and policies as part of the TechEthos project. In particular, these recommendations are considered in the context of the European Climate Law, the CCS Directive, the European Green Deal, and the European Commission's recent CRCF initiative.

Recommendations



Clarify the EU's terminology and rationale for the use of terms related to CDR, and pursue the harmonisation of terms

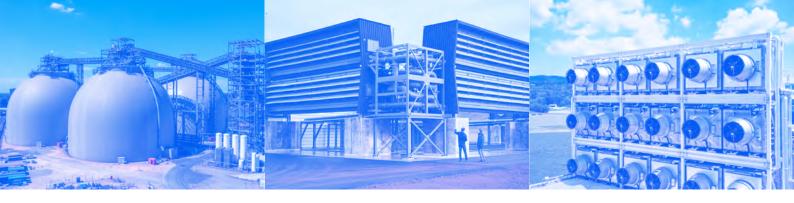
- The EU should clarify its terminology and rationale for the use of terms related to CDR, including climate engineering, geoengineering, and carbon removal, and define the types of methods that are considered CDR. In doing so, the EU should seek to harmonise with the terminology of the IPCC.
- The EU should recognise the distinction between two types of Carbon Capture and Storage (CCS); CCS capturing CO2 emissions from fossil fuel combustion or cement kilns and therefore constituting emission reductions, on the one hand, and CCS from direct air capture (DAC) or bioenergy processes achieving the removal of CO2 from the atmosphere (CDR),

- on the other. This distinction is particularly relevant in the evaluation of existing EU laws, such as the EU Emission Trading Scheme (ETS), governing CCS.
- Furthermore, the EU should evaluate the applicability of existing EU laws, such as the regulatory frameworks for waste and chemicals, and clarify the definition of geological storage of CO2 in the context of waste disposal and ocean dumping, similar to the 2006 amendment to the London Protocol on ocean dumping.

Clarify what role – if any – CDR has to play in the EU's legally binding target of net-zero by 2050

- In implementing the legally binding objective of net-zero by 2050 set out in the European Climate Law, the EU should clarify what role if any CDR has to play in achieving this target. This should be investigated in light of the IPCC emission pathways compatible with achieving carbon neutrality by 2050, which assume some form of CDR in the future. The EU should investigate and clarify whether, if at all, different forms of CDR are to be considered as part of its mitigation strategy alongside the evaluation of alternative pathways to achieving net-zero.
- In doing so, the EU should carefully evaluate wider socio-economic implications of CDR, including but not limited to fundamental rights, biodiversity, international development, international trade, food production and food security, short- and long-term cost implications, and energy security, and look for forms of CDR that benefit multiple, wider policy goals.
- Furthermore, the EU should evaluate potential resource competitions, such as competing uses of biomass, land, water, low-carbon power and heat, emerging within and between ensembles of CDR and other mitigation measures in pathways to net-zero emissions.





Explicitly incorporate EU fundamental rights into policies and decision-making processes governing CDR techniques in the EU

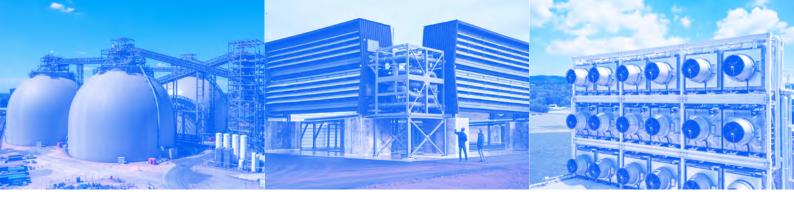
- In governing and facilitating CDR activities and research, the EU should adopt a holistic approach to protect fundamental rights and the environment. The EU should incorporate fundamental rights in the development of sustainability requirements for the assessment and approval of CDR projects, such as through existing EU law related to environmental risk and impact assessments, and the European Commission's Carbon Removal Certification Framework (CRCF) initiative.
- In facilitating and funding further research into CDR, the EU should evaluate the effective governance of CDR research in respect of rights related to scientific research, such as the right to freedom of scientific research, the right to enjoy the benefits of scientific progress, moral and material interests resulting from scientific production, and the rights of research participants, stretching beyond the borders of the EU.
- The EU should evaluate the effectiveness and inclusivity of existing processes for public participation for all parties and individuals involved in and/or likely affected by CDR activities. The EU should evaluate and promote the legitimacy, inclusivity and transparency of CDR activities and decision-making processes, facilitate access to information, encourage public and stakeholder consultation, and promote access to environmental justice in line with relevant international environmental agreements such as the Aarhus Convention.

Clarify the legal status of carbon removals and recognise them as distinct from emission reductions

 In clarifying what constitutes carbon removals, the EU should also clarify the legal status of such removals, taking into account the extent

- to which the legal status of carbon removals may give rise to any monetary value, and any rights or obligations.
- Considering the asymmetric climate impacts
 of carbon removals and emission reductions,
 the EU should recognise carbon removals
 as distinct from emission reductions in
 relevant laws and policies. Failure to recognise
 their distinct characteristics by awarding an
 equivalent legal status may create a moral
 hazard and unduly legitimise a delay in emission
 reductions, which would impede the EU's ability
 to achieve net-zero.
- In considering the possible integration of CDR governance into existing EU laws and policies, such as the EU ETS, the EU should recognise and incorporate the distinct characteristics of carbon removals and emission reductions and prevent risks of double counting. Existing and emerging governance frameworks of CDR must be capable of accommodating the temporal element of carbon removals and take into account the intermediate climate risk. In other words, account for the climate impact of CO2 emissions before their removal through CDR.
- In negotiating the European Commission's CRCF initiative, the EU institutions should consider the varying permanency and quality of carbon removals and explore the need for a tiered approach to certification of such removals based on their durability and as a function of the foreseen usage of the resulting certificates.
- The regulation of carbon removals requires a clear and robust definition to help create a standard and guarantee the quality of carbon removals. The EU should explore the best ways to develop, assess and enforce the QU.A.L.ITY (QUantification, Additionality and baselines, Long-term storage and sustainabilITY) criteria as proposed by the European Commission's CRCF initiative, to enable effective and highquality certification and accounting of carbon removals, avoid risks of double counting, and the reversal of stored removals.





Devise robust sustainability requirements for CDR, particularly those in the context of the SDGs, the EU Taxonomy Regulation, and emerging climate laws and policies including the European Commission's CRCF initiative

- In negotiating a regulatory framework for the certification of carbon removals such as the Commission's CRCF initiative, the EU should take a holistic approach to the development of sustainability requirements beyond the borders of the EU to ward against the offshoring of rights impacts and biodiversity harms. The EU should also expand the sustainability requirement of the QU.A.L.ITY criteria of the CRCF initiative to include the consideration of fundamental rights impacts.
- Furthermore, the EU should define the additionality requirement in the QU.A.L.ITY criteria of the CRCF initiative and consider the extent to which certain carbon removals occur naturally or as part of ongoing activities, particularly in the context of the land use, land use change and forestry (LULUCF) sector.
- The EU should work closely with international trade partners and governments to promote and enforce the EU's sustainability requirements and avoid double counting of carbon removals.
- The EU should pay particular attention to the risk of greenwashing and adapt its policies to mitigate the **risk of greenwashing** in the context of various possible use cases of CDR certificates and carbon removal accounting. In doing so, the EU should evaluate the role of the fossil fuel industry engaging in CDR.

Pursue greater international collaboration in relation to CDR to promote the standardisation of removal accounting and the enforcement of such standards

- Considering possible international trade aspects of CDR activities, the EU should collaborate internationally to develop and promote the standards for the certification of carbon removals and associated criteria under the CRCF initiative, the requirements for effective and inclusive public participation, and the accounting of carbon removals.
- Furthermore, the EU should encourage the monitoring and communication of environmental harms or risks of harm at the international level, promote access to information related to CDR research and deployment, and facilitate wide-ranging and inclusive public participation.

Review the adequacy of environmental liability regimes in relation to CDR activities in the EU, including research and deployment

 In governing CDR activities in the EU, the EU should review the adequacy of environmental liability frameworks related to CDR to provide legal certainty to researchers, developers, investors and operators, and allow for adequate redress in the event of environmental harm.

























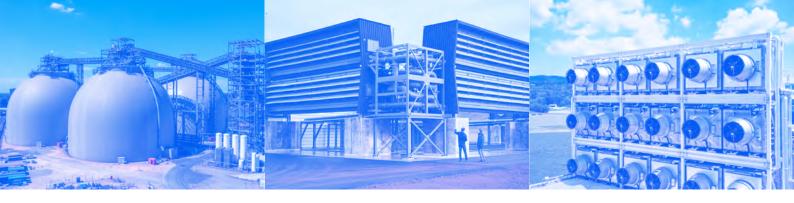












Final take-aways



A key takeaway is the need to clarify key terms and the role CDR will play in the EU's climate strategies and legally binding net-zero target. In particular, the EU should **recognise** carbon removals as distinct from emission reductions, to avoid creating a moral hazard that would legitimise delayed emission reductions.

The following actions would further strengthen the existing and emerging legal and policy frameworks applicable to the governance of CDR:

- Harmonise the EU's terminology with the IPCC and clarify what role – if any – CDR has to play in meeting the EU's net-zero by 2050 climate target;
- Recognise CDR activities as distinct from activities involving emission reductions in existing legal frameworks, such as the EU ETS;
- Explicitly incorporate fundamental rights in CDR policies and decision-making processes and identify and implement more effective means of public participation;
- Develop clear and robust sustainability requirements for CDR, such as in negotiation of the Commission's CRCF initiative;
- Increase international collaboration on CDR to promote standardisation in removal accounting and prevent double counting;
- Review the adequacy of existing EU legal frameworks, including environmental liability regimes, to provide legal certainty and enhance access to environmental justice.

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: <u>www.techethos.eu</u>; and <a href="https://doi.org/10.5281/zenodo.7619852.
- Bernstein M.J. and Mehnert E.W. (2022)
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- Santiago, N., et al. (2022). TechEthos D4.1: Analysis of international and EU law and policy. TechEthos Project Deliverable. Available at: www.techethos.eu; and https://doi.org/10.5281/zenodo.7650731
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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.

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Policy Brief

Enhancing EU legal frameworks for Solar Radiation Modification

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February 2023

Highlights



This policy brief provides recommendations to the European Union (EU) in relation to Solar Radiation Modification (SRM), which together with Carbon Dioxide Removal (CDR) are collectively known as 'climate engineering' or 'geoengineering'. To protect and uphold ethical, fundamental rights and sustainability considerations in the research and development of SRM, the Horizon 2020-funded <u>TechEthos</u> project encourages EU policymakers to:

- Clarify the definition and various types of research activities that constitute SRM research;
- Determine the conditions under which if any

 research into various types of SRM may be conducted:
- Clarify the role if any of various types of SRM in alleviating the impacts of climate change;
- Evaluate the effects of SRM research activities on EU fundamental rights and principles;
- Collaborate internationally and evaluate existing international governance regimes.

Who is this for?

This brief is primarily aimed at EU institutions including the European Commission, European Parliament, the Council of the European Union, and the European Council. This brief seeks to inform EU policymakers and officials involved in the preparation of legislative or policy initiatives related to climate action, climate technologies, climate engineering, geoengineering, and SRM.

Introduction

SRM refers to a type of climate engineering technique that aims to reflect sunlight and heat back into space to reduce warming. Whilst the objective of SRM would be to alleviate some impacts of climate change, such techniques present various risks and are considered controversial. This policy brief sets out recommendations based on the challenges related to SRM identified through an analysis of EU laws and policies as part of the TechEthos project. In particular, these recommendations are considered in the context of EU law and policy, including the European Climate Law and the Green Deal, as well as international environmental agreements to which the EU and/or its Member States are parties to, such as the United Nations Convention on Biological Diversity (UNCBD), the Aarhus Convention, and the UN Convention on the Prohibition of Military or Any Other Hostile Use of Environmental Modification Techniques (ENMOD).



Recommendations



Clarify the definition and various types of research activities that constitute SRM research

- The EU should clarify the definition for and the various types of research activities that constitute SRM research, taking into consideration the distinction between outdoor experimentation and lab-based research, as well as research from deployment. In doing so, the EU should seek to harmonise with the terminology of the Intergovernmental Panel on Climate Change (IPCC).
- The EU should focus not only on large-scale SRM activities with the purpose of moderating the global climate system, but also consider the cumulative effect of small-scale SRM activities conducted for purposes other than the moderation of the global climate system.
- Furthermore, the EU should evaluate the adequacy of existing environmental liability regimes that would apply to different types of SRM research activities, and in relation to the potentially cumulative effect of SRM activities at different scales.

Determine the conditions – if any – under which research into various types of SRM may be conducted

- The EU should investigate whether further research into various types of SRM should be conducted, and determine the conditions, if any, under which SRM research in general, and especially any open-air testing, could be conducted.
- The EU should consider the conditions for SRM research in light of the precautionary principle and the de facto international moratorium on SRM under the UNCBD.
- The EU should evaluate what normative values and ethical principles are at the core of the conditions under which SRM research may be conducted, such as fundamental rights, biodiversity, sustainability, international development and public participation.
- Through its investigation, the EU should

consider the normative framing of research into SRM, particularly in relation to **standards of legitimacy**. This may demand stringent public participation inclusive of representation for both global and intergenerational voices, amongst others.

Clarify the potential role – if any – of various types of SRM in alleviating the impacts of climate change

- The EU should clarify whether SRM could and should play a role – if at all – in alleviating the impacts of climate change. This includes considering whether to facilitate further scientific research into the technical, social and political feasibility of SRM, as well as wider social scientific and humanities-based research into the research ethics and research integrity considerations of SRM, its potential fundamental rights implications, as well as wider socio-economic, environmental and biodiversity considerations.
- The EU should also explore how decisions on the permissibility of SRM research may take various forms of risk and risk-mitigation into account, including SRM's potential for climaterisk-reduction as well as the risks associated with various forms of SRM research or use.

Evaluate the effect of SRM research activities on EU fundamental rights and principles

- The EU should evaluate the implications of SRM research on rights related to scientific research, such as the right to enjoy the benefits from scientific progress, moral and material interests resulting from scientific production, and the rights of research participants. This would inform the conditions – if any – under which research into SRM may be conducted.
- In determining the conditions if any under which SRM research may be conducted, the EU should take a holistic approach to evaluating the effect of SRM on the protection of fundamental rights and the environment, taking into account normative values such as legitimacy and global justice.
- Furthermore, the EU should evaluate effective and inclusive ways of promoting public participation in the context of SRM, which is likely to extend beyond the borders of the EU.





Collaborate internationally and evaluate existing international governance regimes

 The EU should collaborate internationally in defining the conditions – if any – under which SRM research may be conducted. The EU should evaluate the adequacy of existing international governance regimes, including but not limited to, international law on space-related matters, the Aarhus Convention, the UNCBD and the de facto moratorium on SRM, and the ENMOD.

Final take-aways



A key takeaway is the need to clarify the conditions – if any – under which research into SRM may be conducted. The EU should consider the possible wide-ranging implications of SRM research and consider the normative framing of SRM research, particularly in the context of its legitimacy.

The following actions would be beneficial to the EU's consideration of SRM research:

- Clarify the definition of SRM and the various types of research activities that constitute SRM research:
- Evaluate the normative values and ethical principles of SRM research, including but not limited to legitimacy and global justice;
- Adopt a holistic approach to evaluating the effects of SRM on the protection of fundamental rights and the environment;
- Evaluate what role if at all SRM should play in alleviating the effects of climate change;
- Collaborate internationally and evaluate the adequacy of international governance regimes.

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; and <a href="https://doi.org/10.5281/zenodo.7619852.
- Bernstein M.J. and Mehnert E.W. (2022)
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Policy Brief

Enhancing EU legal frameworks for Neurotechnologies

TECHETHOS

FUTURE O TECHNOLOGY O ETHICS

February 2023

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 Al systems.

Introduction

Neurotechnologies refers to devices and procedures used to access, monitor, investigate, assess, manipulate, emulate the structure and function of the neural systems of natural persons. Whilst neurotechnologies have potential the 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 nondiscrimination, 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 noninvasive 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, nondiscrimination, 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 underregulation 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; and <a href="https://doi.org/10.5281/zenodo.7619852.
- Bernstein M.J. and Mehnert E.W. (2022)
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- Santiago, N., et al. (2022). TechEthos D4.1: Analysis of international and EU law and policy. TechEthos Project Deliverable. Available at: <u>www.techethos.eu</u>; and <u>https://doi.org/10.5281/zenodo.7650731</u>
- 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/.

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Policy Brief

Enhancing EU legal frameworks for Digital Extended Reality

February 2023

TECHETHOS

FUTURE O TECHNOLOGY O ETHICS

Highlights



To protect and uphold ethical, legal and fundamental rights considerations in the development and deployment of Digital Extended Reality (XR), the Horizon 2020-funded TechEthos project encourages European Union (EU) policymakers to:

- Promote EU fundamental rights and encourage the adoption of ethics-by-design approaches;
- Broaden the scope of Article 9 General Data Protection Regulation (GDPR) by removing the purpose requirement for biometric data to be classified as special category personal data;
- Develop appropriate instruments to tackle and regulate harmful online content in XR technologies;
- Consider specific use cases in the classification of XR technologies under the proposed Artificial Intelligence (AI) Act;
- Promote the effective enforcement, monitoring and compliance with EU laws related to XR technologies, such as the GDPR, Digital Services Act (DSA), Digital Markets Act (DMA) and 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. This brief seeks to inform EU policymakers and officials involved in the preparation of legislative or policy initiatives related to XR, virtual reality (VR), augmented reality (AR), mixed reality (MR), the metaverse, natural language processing (NLP), privacy and data protection, and AI systems.

Introduction

XR technologies combine advanced computing systems (hardware and software) that can change how people connect with each other and their surroundings and influence or manipulate human actions through interactions with virtual environments. The emergence of this technology family poses certain risks and regulatory challenges, such as those related to privacy and data protection, the regulation of AI and harmful online content, freedom of expression, non-discrimination, and the protection of special categories of persons, especially children.

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 DSA, the DMA and the proposed AI Act.





Recommendations



Promote EU fundamental rights and encourage the adoption of ethics-by-design approaches

- In implementing a rights-based approach to the regulation of digital technologies through appropriate legislative and policy instruments, the EU should more robustly protect and promote the right to disconnect – as described in the European Declaration on Digital Rights and Principles – as a health and safety measure for the protection of workers.
- The EU should encourage the adoption of ethics-by-design approaches to mitigate against the possible risks associated with the development of XR applications, such as by including a requirement for ethical and human rights impact assessments in the proposed AI Act.

Broaden the scope of Article 9 General Data Protection Regulation (GDPR) by removing the purpose requirement for biometric data to be classified as special category personal data

• XR technologies are capable of collecting a large volume and type of biometric data that may be used for a variety of purposes. For that reason, the EU should remove the requirement under Article 9 GDPR for biometric data to be used "for the purpose of uniquely identifying a natural person". Doing so expands the scope of the biometric data category to include other purposes, such as inferring user preferences or tracking workplace performance, and brings it in line with the more context-based approach to defining special category personal data.

Develop appropriate instruments to tackle and regulate harmful online content in XR technologies

- The EU should evaluate appropriate and effective ways to protect special category groups, in particular, from the effects of harmful online content, including online violence, (sexual) harassment, hate speech, and the spread of mis- and disinformation. Possible interventions to improve the protection of fundamental rights in the development and use of XR technologies may involve measures to verify user and/or machine identity, promote user empowerment through self-reporting measures, and extend the responsibility of providers to monitor and moderate online content, such as through the provisions of the DSA.
- In placing an obligation on online platform providers to moderate harmful online content through the provisions of the DSA, the EU should develop and provide guidance to online platform providers to identify and assess harmful online content, particularly in the context of hate speech, and the spread of misand disinformation.
- In addition to the Code of Practice on Disinformation, the EU should encourage the adoption of similar industry-led selfregulatory codes addressing issues associated with harm to XR users, including hate speech, online violence, (sexual) harassment, and misand disinformation.
- The EU should recognise that the immersive and increasingly realistic nature of XR technologies may exacerbate the risks and impacts of harmful online content consumed through XR, particularly by special category groups such as children.





Consider specific use cases in the classification of XR technologies under the proposed AI Act

- The classification of XR technologies under the AI Act will impact the ways in which such technologies may be developed and deployed in the EU. In determining the general purpose of an AI system, EU should consider different types of use cases to enable the appropriate risk classification of AI-enabled XR and NLP technologies in the proposed AI Act, including non-manipulation, education, workplaces, use by children, healthcare provision, and use in the administration of justice.
- The inclusion of measures to support innovation in the proposed AI Act, such as regulatory sandboxes, can help identify and assess possible harms and potential biases in a controlled testing environment. Furthermore, measures such as watermarks, can help identify AI-generated online content, including avatars, voice, text and video.
- The protection of fundamental rights, such as the right to dignity, the right to autonomy, the right to non-discrimination, the right to privacy, and the right to freedom of expression, should be a central consideration in assessing the risk factor of AI-enabled XR technologies.
- The EU should recognise that the immersive nature of XR technologies may exacerbate the risk of harms experienced by victims and ensure this is taken into account in the risk classification of AI systems in XR technologies.
- The Council should clarify the reference to VR in recital 16 of its General Approach on the proposed AI Act to elaborate whether all 'cases' of VR are subject to a prohibition under Article
- In addition to the exception for the use of VR in the context of medical treatment, the Council,

in negotiation with the European Parliament, should consider whether there are other use cases of VR that should be exempt, such as research.

Promote the effective enforcement, monitoring and compliance with EU laws related to XR technologies, such as the GDPR, DSA, DMA and the proposed AI Act

- In promoting the proper functioning of the internal market and in encouraging EUwide compliance with the regulation of XR technologies, AI systems and harmful online content, the EU should work towards the harmonisation of EU rules and standards as far as possible within the EU's competencies.
- The EU should collaborate closely with Member States to support the enforcement and monitoring of compliance in line with EU values and principles.







Final take-aways



A key takeaway is that the proposed AI Act will significantly impact the development and deployment of XR and NLP technologies in the EU. The **immersive nature of XR technologies** should be considered in the risk classification of such technologies. In identifying and assessing XR and NLP use cases and determining the appropriate risk classification, the **protection of fundamental rights** should be a central consideration.

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

- Expand the scope of the biometric data category under the GDPR;
- Adjust and promote the more effective enforcement of existing legal frameworks;
- Assess different types of XR and NLP use cases in relation to the AI Act;
- Encourage the adoption of ethics-by-design approaches to XR development through consultation and stakeholder engagement;
- Provide appropriate guidance to better regulate and moderate potentially harmful online content.

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; and <a href="https://doi.org/10.5281/zenodo.7619852.
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