BRIEFING
STOA Options Brief

European Parliament

The protection of mental privacy in the area of neuroscience

Societal, legal and ethical challenges

The world of neuroscience is seeing a rapid multidisciplinary convergence between artificial intelligence (AI) and new neurotechnologies that enable the recording or even altering of human neuronal activity. While greatly advancing brain science and neural engineering, this convergence raises concerns about surveillance, subliminal manipulation of preferences, and the collection of information about the brain and mental states. The main study addressed by this options brief assesses the legal, ethical and societal implications of this rapid development of neurotechnologies. It also assesses whether there is a need to develop a new regulatory framework at European Union level to address the emerging concept of 'neurorights'. This briefing summarises policy options for developing and commercialising neurotechnologies while providing guarantees against their possible misuse.

The fast development of new neurotechnologies includes an array of devices, algorithms and methodologies able to record and monitor neural activity. Even though non-invasive neurotechnologies enhance human capabilities, they could also impact (self-)perception, attention, mood, memory and decision-making, which might present a threat to individual and collective autonomy and well-being. As a response to concerns over the possible future impact of neuroenhancement technologies, the new concept of 'neurorights' has emerged, actively promoted by the Neurorights Foundation. Neurorights can be defined as ethical, legal, social or natural principles of freedom or entitlement related to a person's cerebral and mental state. Several countries have started developing regulations that aim to protect their citizens from the potential risks and harm linked to new neurotechnologies.

The study covers neuropsychology, ethics, sociology and law, due to the interdisciplinary nature of neurotechnology applications. It combines different methodological approaches and builds on the strengths of each perspective. It is based on desk research and brings together literature from each discipline to allow policymakers to make a well-rounded assessment of the efficacy, threats and potential of different types of neurotechnology in relation to individuals and certain socio-demographic groups and for specific social domains. Four near-future use cases demonstrating invasive and non-invasive neurotechnologies applied to healthy and clinical populations have been used to analyse neurotechnology development from four perspectives.

Main results of the study

The study identified the following problems with the current use of neurotechnology and the regulations proposed by the Neurorights Foundation:

- 'neuro-enchantment' (i.e. the inherent persuasiveness of the term 'neuro');
- socio-technical 'imaginaries' driven by neuro-enchantment and boundless optimism;
- 'neuro-essentialism', reification and functionalisation;
- high-level legislation proposing new human rights.

Taking all these characteristics into account, the study concludes that the discussion on neurorights as put forward by the Neurorights Foundation should be reframed to meet the interests and rights of

European Union (EU) citizens and to fulfil the democratic expectations of EU Member States and underlying European values. The neurorights proposed by the Neurorights Foundation more or less explicitly assume that an expansion of neurotechnology in all its forms is desirable. However, a more explicit discussion is needed about situations where neurotechnologies are inadmissible and on developing a more human-centred approach to risk management of neurotechnologies, particularly when they are boosted by the transformative and transgressive power of AI.

There is a clear empirical gap between the organisational and everyday embeddedness of neurotechnology. Resource-rich organisations may be able to set a non-transparent agenda and determine the course of neurotechnological deployment in different domains. Further open research should therefore focus on the experience of legal, ethical and sociological experts and reinforce their involvement in the development of new neurotech applications.

Policy option 1: Laissez-faire/non-interference

The field of neurotechnology is growing rapidly and a laissez-faire attitude without any regulations could lead to problems. As predicted in several studies, portable devices like the ones used for neurofeedback will become popular in the next few years, although there is insufficient research on their positive and negative effects. In addition, there is a clear publication bias in scientific literature, where statistically insignificant results are silenced while positive findings are often over-interpreted and overrepresented in the public discourse. Such positive advertising ('neuro-enchantment') can drive the market for neurotechnologies before there has been a critical assessment of potential side-effects that could harm mental and physical health. Another aspect of non-interference in consumer neurotech is the physiological data of European citizens, which could be harvested by non-European companies. Such data is critical for further research and development, but also for preserving privacy and security.

Policy option 2: Blanket prohibition of neurotechnologies in the EU

Prohibiting certain uses of neurotechnology could prevent possible negative side-effects or misuse. However, this would have drastic consequences on the neurotech domain and exclude European science and the European economy from international markets. Progress in neurotech is also needed as part of the treatment arsenal for clinical and vulnerable user groups. Policymakers need to consider in which domains and for which purposes neurotechnology offers significant gains and where potential bans could be necessary. Importantly, much more precise criteria to establish the borders between medical/therapeutical and enhancement neurotech applications must be developed by specialists, stakeholders, civil society and legislators.

Policy option 3: A set of orchestrated steps to change the state of play

The third option is to take a set of orchestrated steps to prevent the EU market from being freely dominated by non-European neurotech agents. These steps must be taken jointly and might not lead to the desired result if applied in isolation.

1) Evaluating the risks of neurotechnology

Risk evaluation under the AI Act should go beyond the *technology-centred risk classification* of individual technologies. This could be done by adding *human-centred risk evaluation* that is not focused on the impact of single technologies as presently specified in the AI Act, but rather on the ecosystem of technologies as experienced by users in real life. This would help to 1) take better into account the specific needs of vulnerable groups (e.g. children, dementia patients, neurodiverse people) and 2) understand the impact of the whole ecosystem of available technologies, including interactions with single individuals, collectives and societies. Among other things, this would encompass the evaluation of risks associated with the effects of long-term usage. For example, for transcranial electrical stimulation (tES) research mostly recommends treatment lasting a few weeks, but consumer devices suggest regular treatment for over a year. Hence, the duration of neurotechnology usage could play a role in user safety and should be considered as part of risk evaluation. Moreover, the combination

of such neurotechnology with other AI-based systems could have a different impact to that determined by a single technology-centred risk evaluation system.

2) Public communication and neurotechnology literacy

Public communication on neurotechnologies should be tracked, and neurotechnology literacy should be improved not only among the general public but also practitioners and experts who often themselves amplify the effects of neuro-enchantment. Neurotech's public image is dominated by an overoptimistic attitude towards its positive aspects while neglecting negative ones. This is known to be a thriving factor for the development of neuro-enchantment and makes consumers vulnerable. This should be regulated by developing means to promote fair communication on limitations, risks and hype associated with neurotechnologies, including recommendations on daily exposure and safety instructions based on state-of-the-art knowledge ('open-label').

3) Neurotechnology and secondary legislation

Neurorights should no longer be formulated and claimed as human and fundamental rights. For example, as there is already a 'right to physical and mental integrity' in Article 3 of The Charter of Fundamental Rights of the European Union, a specific 'right to mental integrity' will raise questions as to how it differs and its limits. Thus, new human and fundamental rights may cause damage if broadly defined human and fundamental rights are split into specific new human/fundamental rights.

EU legislation already contains consumer, competition and general product safety laws, the Medical Device Regulation (MDR), the AI Act, and the General Data Protection Regulation (GDPR). Adaptations could be considered, such as the explicit inclusion of *neuro data* in Article 9 GDPR or the adaptation of the MDR, in particular Annex XVI(6) MDR, which only contains specific neurotechnologies. Neurotechnologies could also be explicitly included in the AI Act, as Article 8(1) already refers to AI-related technologies as high-risk technologies, which may entail specific AI-related neurotechnologies. As an example of best practice for a new technology regulation, the AI Act should be taken into account and could serve as a role model for a Neurotechnologies Act. Similar to AI, neurotechnologies could be classified based on the risk they pose, with different levels of regulatory scrutiny for non-invasive versus invasive technologies, or consumer-use versus medical-use technologies.

4) Funding neurotechnology research

Research studies investigating possible side-effects and neuropsychological, ethical, legal and societal implications should be supported and funded. Scientific literature differs concerning neurotechnology and the outcomes of associated treatments, with knowledge gaps related to efficacy and possible side-effects. There are hints in the literature that cognitive training in one domain could lead to decreases in another cognitive domain. This has also been shown in EEG (electroencephalography)-based neurofeedback training, but such side-effects are often missed as only a few researchers have the resources to include an extensive battery of tests in their studies. Neurotech devices are used for therapy, but are also increasingly used by lay persons without supervision and without taking into account individual aspects. Unfortunately, standardised double-blind controlled trials, long-term studies and their follow-up are rare in the field of neurofeedback training due to the associated costs.

Furthermore, technologies are never only just 'tools' (e.g. for medical purposes), but also have a socio-political and socio-cultural dimension. The everyday use of neurotechnology creates different conceptions of a social problem, a societal domain and their actors. By making certain mental states 'visible' and claiming to be a source of objective knowledge, neurotechnologies may enforce 'reductionism', including the risks of pathologising individuals and stigmatisation. This can contribute to the medicalisation of neurodivergence and sets of behaviour seen as 'not normal'. All aspects mentioned above require coordinated research at EU level.

5) European neurodata space

As most neurotechnology providers are situated outside the EU, the data of European citizens will mostly be processed outside the EU, which is problematic insofar as non-EU countries have different data security policies. Therefore, EU-based providers of neurotechnology should be supported by implementing a solid legal basis for a European neurodata space. Its design could follow the example of the European Health Data Space (EHDS), the regulation for which is currently being adopted. For neurotechnologies, the aim of such a data space would be to prevent the loss of valuable information on both neurotechnologies and European citizens. A possible alternative is the European Open Science Cloud (EOSC) portal or EU Node. This goal could also be achieved by actively promoting the development and use of EU neurotechnologies in science, research and industry.

6) Standardisation of neurotechnology devices

It should be made clear whether 1) the existing general level of standardisation for neurotechnology devices is sufficient to guarantee reliable and valid usage, 2) existing standards should be adapted, or 3) new standards should be created. Consumer-grade devices are very prone to signal artifacts corrupting the signal and falsifying results. There is a consensus in the scientific community that neurotech devices often record more muscle artifacts than brain activation. Furthermore, artifacts and noise are often not properly filtered out and used for additional software applications, which makes the recorded data rather unreliable. This is especially relevant for the usage of consumer devices that promise the treatment of, for example, symptoms of depression or attention-deficit/hyperactivity disorder (ADHD).

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http://epthinktank.eu (blog)

stoa@ep.europa.eu (contact)

http://www.europarl.europa.eu/stoa/ (STOA website)

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