Recommendations to the European Commission on

BRAIN–COMPUTER INTERFACES

The need for a comprehensive ethical and legal framework

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EXECUTIVE SUMMARY

Implantable technologies, particularly Brain-Computer Interfaces (BCIs), raise significant ethical and societal concerns, notably regarding the physical and mental integrity of citizens in Europe and beyond.

Current EU fundings[1] for medical research are allocated on BCIs with limited consideration for their ethical implications. Moreover, Brain-Computer Interfaces (BCIs) are currently categorized under EU Regulation 2017/745 of 5th April, 2017, on Medical Devices[2]. This classification remains unchanged since then, despite its renewal in 2022. However, given the rapid pace of technological progress, EU regulators should reassess the adequacy of existing provisions and expand the regulatory framework to address BCIs and neurotechnologies comprehensively from both ethical and legal perspectives. Our recommendations are based on these initial observations:

- Last May 2024, President von der Leyen's political manifesto stated that Europe could capitalise on the upcoming biotech revolution through "*biotechnologies, supported by AI and digital tools, which can help modernise entire parts of our economy, from farming and forestry to energy and health*"[3].

- The BCIs market is a **booming and highly innovative market** estimated to grow at a 9.9% CAGR* and potentially reaching approximately $11 billion in size by 2030.

- EU Regulatory amendments and new EU policy creation (including framework, guidelines and processes) are already under way in the fields of Medical Device. **EU Health Commissioner Olivér Várhelyi** unveiled plans for a 2026 **Biotech Act** aimed at streamlining regulation on biotech innovation rooted in Europe[4]. This upcoming Biotech Act will have implications on the regulation of BCIs, necessitating further legal clarity.

- Many international organisations already gave a preliminary assessment of the BCIs ethical challenges.

Words marked with an asterisk (*) are defined in the glossary at the end of the document.

In this position paper, we propose to the European Commission a comprehensive assessment of the current technological landscape, differentiating between neuroscientific aspirations and the actual, present-day capabilities of neurotechnology. Additionally, we will examine the ethical concept of **Identity Integrity** in the context of emerging Brain-Computer Interface (BCI) technologies and its application to policymaking.

We will recommend the adoption of a regulatory framework integrating a risk-based approach, best practices, and clear EU regulatory guidelines to ensure the ethical and responsible development, deployment, and oversight of Brain-Computer Interfaces (BCIs).

Legal recommendation for an ethical use of BCIs

- Adopt a risk-based approach based on the precautionary principle in the revision of the **Medical Device Regulation including BCIs.**
- Include specific provisions in the upcoming **Biotech Act** regarding BCIs.
- **Discriminate between therapeutic and enhancing techniques** in relevant legislation.
- Reconsider the scope of **EU fundamental rights** to **include the emerging concepts of neurorights and identity integrity** to enshrine the **protection of the human mind** regarding their neural activity.

This paper will solely focus on BCIs and wearable neurotechnological devices with attention to their applications in therapeutic, enhancement, and recreational contexts and exclude **brain-to-brain technologies*** as well as the ethics of warfare applications.

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Chapter I
BCIs' state of development

Brain-computer interfaces (BCIs) establish a direct communication pathway between the brain and an external device, by-passing the peripheral nervous system. These systems aim to enable individuals to execute tasks—such as operating a computer or a robotic limb—through neural activity alone, without physical movement. At this pivotal moment in history and with the rapid and exponential advances in neuroscience humanity faces profound questions about its future. Over the past decades, increasing interest in brain sciences has fuelled numerous multidisciplinary research initiatives. These initiatives aim to deepen our understanding of brain function through the integration of neuroscience with computational and engineering disciplines. Within this landscape, neurotechnologies—both invasive and non-invasive—have emerged as critical tools. As these technologies evolve and become increasingly **miniaturized**, **precise**, and **efficient**, they enable **non-destructive observation of neural processes** and **enhance diagnostic and therapeutic interventions,** making it possible to **modulate brain activity directly** and **repair damaged areas** or **construct alternative neural pathways to compensate for deficits**. In doing so, they provide unprecedented insight into the biological substrates of memory, emotion, intuition, personality, character, and consciousness.

The **convergence of neuroscience with digital technologies** is transforming our understanding of both the physiological, functional, and pathological states of the human brain. This convergence allows for increasingly granular **visualization** and **quantification of brain activity**, revealing the intricate dynamics of neural function and offering **new perspectives on the nature of human identity.**

> **"Act in such a way that you treat humanity, whether in your own person or in the person of another, always at the same time as an end, never merely as a means."**
>
> Emmanuel Kant, Groundwork of the Metaphysics of Morals (1785)

Large-scale international collaborations, including the **European Human Brain Project** which ran from 2013 until 2023[5], the **NIH Brain Initiative**[6] in the United States of America, and the global **International Brain Initiative**[7] aim to create comprehensive repositories of brain data and neural imagery. While they hold great promises, they also demand a critical and multidisciplinary perspective. It is within this context that **neuroethics**, a field formally established in the early 2000s, provides a potential framework for reflection and regulation.

As we move towards the era of the "connected brain," questions arise about **human dignity, bodily and mental integrity, and dealing with vulnerability.**

The first section examines the current state of development of brain-computer interfaces (BCIs). The second section explores the ethical challenges posed by BCIs, focusing on neuroethics, neurorights, and the broader ethics of neuroscience.

Finally, the third section offers legal recommendations to the European Commission, grounded in the Medical Device Directive and the Biotech Act, while reexamining fundamental rights related to neural activity through the lens of Identity Integrity.

I. BRAIN-COMPUTER INTERFACE TECHNOLOGY LANDSCAPE

Neurotechnology operates at the cross section of biological cognition and digital systems, enabling the modulation of neural circuits involved in cognition and behaviour. Based on neuroimaging techniques, they encompass invasive methods, and non-invasive methods. Their development occurs in both research and industrial settings, for both therapeutic and commercial cognitive enhancement purposes.

Neuroimaging encompasses a range of medical imaging techniques that allow for the observation of brain activity during the execution of cognitive tasks. These technologies have significantly transformed our understanding of the brain's structure and function, offering enhanced diagnostic precision for neurological and psychiatric disorders.

The ultimate concern in neurotechnology lies in the qualitative shift from interfacing with machines via sensory-motor outputs to bypassing these systems entirely. The vision of directly linking the brain to AI systems—bypassing speech, sight, and movement—evokes scenarios in which human cognition becomes entangled with digital architectures with possible direct decoding of cognitive functions such as **intention, attention, and emotion**. This paradigm shift challenges existing conceptions of human agency and identity.

a. BCI Technology History

The earliest brain imaging techniques were developed to address the limitations of *postmortem* analyses, which provided static, incomplete views of the brain, incapable of capturing its dynamic processes.

In the late 19th century, Italian physician and physiologist Angelo Mosso observed changes in cerebral blood flow during mental activity by measuring cortical pulsations in neurosurgical patients with skull defects[8]. He concluded that cognitive engagement increases blood supply to the brain. This led to the development of the "Human Circulation Balance"[9], one of the earliest non-invasive neuroimaging techniques which enabled measurement of blood redistribution during emotional and intellectual activity.

By the early 21st century, neuroimaging had evolved into sophisticated methodologies enabling researchers to localize brain regions involved in specific cognitive functions. Such developments have been instrumental in the rise of cybernetics since the 1950s, the maturation of cognitive science and neuroscience laying the groundwork for modern neurotechnologies.

b. Various Brain-Computer Interfaces (BCIs) methods

BCIs were first conceptualized in the early 1970s, with the initial human trials emerging in the mid-1990s. **Additionally, robotic exoskeletons controlled by Brain-Computer Interfaces are under development**[10].

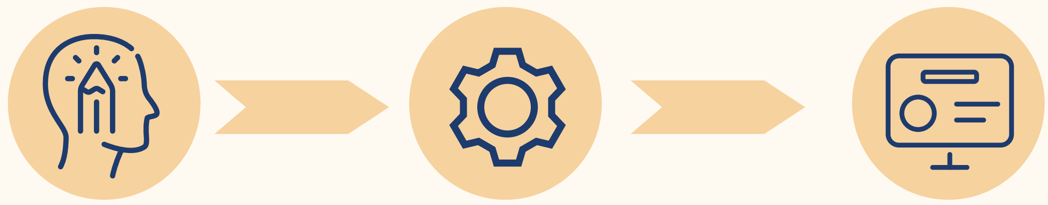
Interpretating neuroimaging and BCI data is complex and context dependent. Brain images, often presented in vivid colours, may give an illusion of objectivity and comprehensive insight into cognition, but they remain indirect, temporal representations of a single signal amid the vast complexity of neural activity. **The risk of reducing the person to their neural correlates would overlook the individual's lived experience, history, and social context.**

All BCI systems share a fundamental structure

1
Acquisition of brain signals

2
Signal processing and classification

3
Translation of neural activity into commands to an external BCI device



The user typically focuses on a mental task or stimulus, generating characteristic brain activity captured by electroencephalography* (EEG) or implanted electrodes. The data are transmitted to a computer, processed via machine-learning algorithms, and used to control the device in real time. Many BCIs operate in a closed-loop or neurofeedback mode, allowing users to refine their control over time.

BCI systems can be categorized based on the degree of invasiveness: invasive, semi-invasive, and non-invasive.

Invasive BCIs

Invasive techs involve the implantation of microelectrode arrays directly into the cerebral cortex, enabling high-resolution recording of neuronal activity. Although this approach provides superior spatio-temporal precision, it is associated with risks such as inflammation, infection, and signal degradation over time. Current applications remain limited to a small cohort of volunteers, such as patients with severe motor impairments. Examples of BCIs include implants such as **N1** developed by **Neuralink** in a clinical trial for quadriplegic patients[11], as well as **NeuroPace**[12] developed by the **Stanford Medical Comprehensive Epilepsy Program** for epileptic patients with US Food and Drug Administration clearance since 2013. Invasive technologies include neural implants developed by companies undergoing clinical training like **Synchron**[13] on patients suffering severe chronic bilateral upper-limb paralysis unresponsive to therapy devices, even though Synchron places implants through the patient's bloodstream, circumventing the cost and risks of physically penetrating the human skull. **Deep Brain Stimulation*** is an invasive method used in the treatment of certain neurological disorders. It works by sending low-intensity electrical signals to brain circuits via electrodes implanted deep within the brain. This treatment can be used to manage neurological conditions such as

Parkinson's disease, tremors, or dystonia, and more rarely, treatment-resistant psychiatric disorders such as severe forms of an obsessive-compulsive disorder or depression.

Although Deep Brain Stimulation devices are primarily employed for therapeutic purposes, the use of Deep Brain Stimulation for cognitive enhancement in healthy individuals, aiming to improve concentration, memory, creativity, situational awareness, stress resistance etc., and remain largely experimental, they are tested for specific cognitive enhancements in individuals without clinical disorders. The convergence of AI and enhanced cognition with BCIs like Neuralink, ***Kernel***[14] would allow us to think a question and get the answer instantly, enhance our brain capacities or move a device by imagining a movement. **Military applications** are already being tested with soldiers potentially enhancing their situational awareness or stress resistance by **monitoring and interpreting neural activity related to attention, fatigue, and threat detection**, feeding this data into augmented reality (AR) or command systems to enhance rapid decision-making and enabling "neuro-adaptive" interfaces which adjust visual or auditory input based on the soldier's cognitive load or awareness level, among other features[15].

Semi-invasive BCIs

Semi-invasive methods such as **electrocorticography*** utilize electrode grids placed beneath the *dura mater,* the thick, strong membrane layer located directly under the skull and vertebral spine. While offering less spatial resolution than fully invasive systems, they present fewer medical risks and are showing promising clinical applications. The Swedish company, **Cochlear Bone Anchored Solutions**, proposes **BAHA**[16]**,** for bone-anchored hearing aid, a semi-implantable device that transfers sound to the inner ear through the bone. In 2024, the **Wimagine** device, created by the **Clinatec/CEA research centre** in Grenoble, France, comprises of two wireless grids of 64 electrodes each, enabling a paraplegic individual to walk using thought-controlled neural[17].

Non-invasive BCIs

Non-invasive BCIs are the most commercially widespread and raise the most significant ethical concerns. These systems, including electroencephalography (EEG) **headsets, EEG-enabled earphones, headsets or eyeglasses,** are marketed not only for clinical use but increasingly for non-medical applications, targeting healthy users seeking to enhance their concentration, intellectual abilities, emotions, and physical strength[18]. Non-invasive implants include the Mendi[19] headband that captures precise brain activity measurements to reduce stress and improve brain focus.

Layer 7 Cortical Interface by **Precision Neuroscience**, not yet for sale though, which used a cranial micro-slit technique, the insertion of which is designed to be fast and minimally invasive. The array will conform to the surface of the brain and is engineered to be reversible[20].

c. Focus on non-medical, recreational and enhancement BCI use

Although such systems hold tremendous therapeutic promise, they also raise profound ethical issues. While clinical applications aim to restore lost functions such as mobility or communication in paralyzed individuals, non-medical uses raise concerns regarding cognitive enhancement, mental privacy, and potential dual use in civilian and military contexts or neuromarketing[21].

Electro-Encephalogram headsets, EEG-enabled earphones, glasses, cameras or antennae increase vision, emotions, concentration, etc. and provide live data on the person's surroundings, people and environment. For example, BCI systems are already capable of interpreting basic mental states (e.g. attention or fatigue) and intentions. Smart glasses include **OCO**[22] by **Emteq Labs** which measure emotional responses, through facial **muscle activity and biometric responses for behavioural analytics in business environments** or for well-being applications, with a grant from EU Horizon 2020.

EU's contributions to the development of BCI wearables appear to be focused on cognitive enhancement for medical use such as brain trauma therapy and seizure tracking. However, a Spanish company, **Elovvo**[23], with its wearable Brain-Computer Interface that enables self-management of cognitive welfare, received **Cordis** funds in 2017 in order to offer technologies and procedures that **enhance working memory, processing speed, and sustained attention**[24].

The headsets **Insight** from Australian company **Emotiv**[25] can detect the electrical activity of the user's brain to control video games and other applications through thought. Companies such as **Meta** with its **magnetoencephalographic* (MEG)** wearable prototypes **Brain2Qwerty**[26] are investing in neuro-adaptive interfaces capable of detecting, interpreting, and responding to brain signals. These devices capture and process brain data using embedded EEG or MEG sensors, often combined with Machine Learning algorithms to provide real-time neurofeedback or cognitive state estimation and are solely marketed for **enhancement, entertainment, or productivity**.

In the **European Union**, **users' brain data** — such as data derived from neurotechnology (e.g. EEG, fMRI, brain-computer interfaces) — **does not yet**

benefit from specific legal protection tailored to neural data despite the existence of the **General Data Protection Regulation (GDPR)**. The prospect of commercial entities gaining access to analysing and potentially manipulating mental states through neurotechnological interfaces presents unprecedented risks to **autonomy, privacy, and cognitive freedom**. Optimising and augmenting mental performance in healthy individuals opens doors to **discrimination** between enhanced persons and non-implanted persons and to malevolent capture of electrical signal repository data for **surveillance** or **manipulation of neural activity purposes**.

II. BCIS' MARKET SIZE

Neurotechnologies offer transformative potential in medicine, and beyond, with rapid II. BCIs' market size growth generating a dynamic worldwide market. In fact, the global brain implants' market, driven by technological advancements and an increasing prevalence of neurological disorders, varies in market size among sources and market studies. For instance, Grand View Research estimated the market at approximately **$ 6,38 billion in 2024**, projecting a **compound annual growth rate (CAGR) of 9.9% from 2025 to 2030** that is approximately **$10.78 billion by 2030**[27].

The market leaders are American companies **Medtronic**, **Boston Scientific Corporation**, **Abbott** and **NeuroPace**; the Swiss **Aleva Neurotherapeutics**; the Italian American **LivaNova**, and the Chinese **SceneRay.** Solely in Europe, even though these companies are still small and medium-sized enterprises (SMEs), the German **Brain Products**, **CorTec Neuro,** and the French, **Fonds Clinatec,** seem to be well poised for future innovative developments.

III. BCIS' EXISTING POLICIES

The **Medical Device Directive defines its scope of application in Chapter III of Annex XVI**, where brain-computer interfaces (BCIs) are listed as **equipment intended for brain stimulation through electrical currents or magnetic/ electromagnetic fields that penetrate the cranium to alter neuronal activity**. This classification indicates that the EU has established a minimal legal framework under this regulation that primarily governs the market access conditions for BCIs, without addressing the potential risks or harms associated with their use.

In 2021, the Chilean constitution was amended to include Neuronal data[28]. A wide array of rather consensual statements from international bodies or member states underlines the necessary neurotechnological ethical and legal oversight.

Among them:

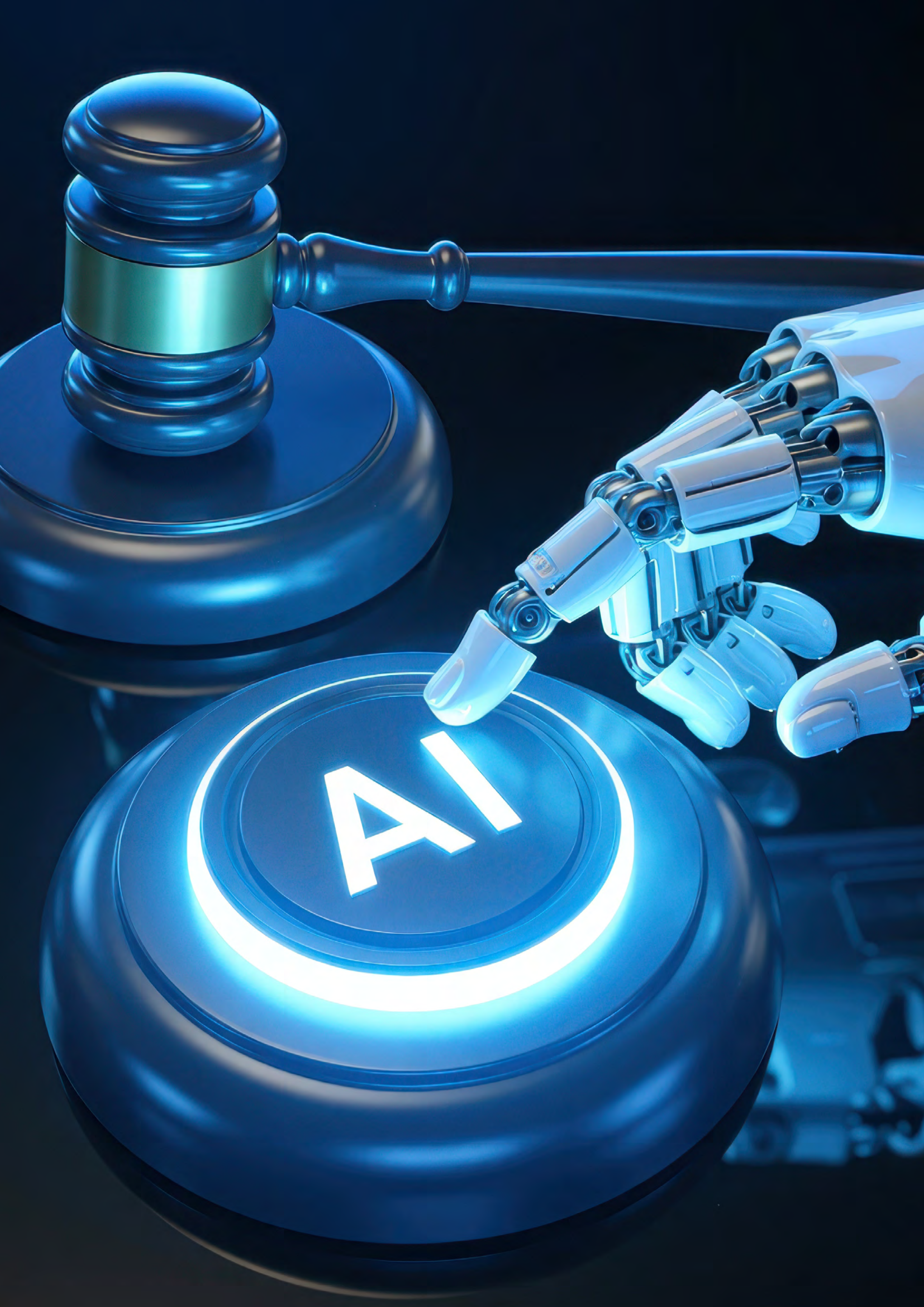
- **Council of the European Union** Analysis and Research Team "*From vision to reality Promises and risks of Brain-Computer Interfaces*" December 2024[29]
- **European Brain Council** *European Charter for the Responsible Development of Neurotechnologies* April 2025[30]
- **UNESCO'**s work (2021–2025) emphasizes global ethics in neurotechnology[31]
- **OECD** Recommendation No. 0457 (2019) promotes responsible innovation in neurotechnologies in 2023[32]
- **China's ethical guidelines** for BCI research[33]
- **IEEE** White paper "*Neurotechnologies: The Next Technology Frontier"* in 2020[34]
- France's 2021 **Bioethics Law** and 2022 **Charter for Responsible Neurotechnologies** aim to regulate national developments[35]

However, regulatory frameworks are mostly underdeveloped in areas involving Artificial Intelligence (AI) integration and broader non-medical use cases.

Conversely, commercial applications of non-invasive neurotechnologies—such as EEG-enabled headsets, glasses, or earphones—are not **regulated at all, other than from a safety standpoint**. Similarly, companies selling commercial neurotechnological implants and wearables, proliferating in **neurogaming**, **education, workplace productivity,** and **wellness**, often put the burden-of-proof on the user. Litigation based on AI ACT's Article 5 which strictly prohibits the use of **real-time remote biometric identification systems, such as live facial recognition, in publicly accessible spaces,** will arise.

IV. BCI'S ETHICAL CHALLENGES

As AI-driven neurotechnologies become increasingly integrated into society, thus blurring boundaries between medical, military[36], and commercial uses, they generate vast quantities of personal neural data, a huge market as well as an ethical mayhem. This is why a **unified approach to the ethics of neuroscience** and a **legal framework** would be essential to navigating the socio-political implications of these technologies. At the heart of this discourse is the need to protect the **innermost sanctuary of human life: the brain (and the mind), the *locus* of our privacy, identity, and freedom.**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CHAPTER 2
A new ethical framework

I. BEYOND THE PRECAUTIONARY PRINCIPLE

Beyond security, reversibility, and recyclability of BCIs, guaranteed by the ethical concept of the **precautionary principle*,** the accelerating pace of innovation necessitates a careful, interdisciplinary approach to assessing the societal, ethical, and legal implications of neurotechnology. As such, the **European Commission'**s mission is to ensure **the conformity to European substantive or implicit principles such as dignity**, freedom of thought, informed consent and autonomy.

Although, not explicitly named as a standalone principle in the **Charter of Fundamental Rights of the European Union**, the concept of autonomy is implicitly and substantively protected through several key rights and principles enshrined in the Charter. Given the profound link between brain function and the cognitive attributes that define personhood (the mind), **these technologies challenge our conception of individual agency, moral responsibility, and human singularity.**

On both the commercial and therapeutic fronts, lies the need for the protection of the mind. On the one hand, the interpretation of neural data, the ownership and selling of neural images, and the implications of manipulating consciousness and identity for malevolent usage is key to our ethical perspective. On the other hand, brain interventions may induce long-term changes in brain plasticity—such as long-term potentiation —leading to persistent alterations in mood, personality, emotions, and even identity. Thus, the application of neurotechnologies is far from **benign**. This is how neuroethics, neurorights, and the ethics of neuroscience emerged.

Philosophical traditions have long equated language with thought, and by extension, with intelligence, emotions, and the expression of affective states. Modern artificial intelligence (AI), particularly **machine learning*** and **deep learning***, draws heavily on neurobiological inspiration to model neural computation and emulate aspects of human cognition. These technologies seek to **replicate neuronal information transfer**, enabling machines to mimic, and potentially simulate, elements of human thinking and behaviour. Ever since the 1950s, advances in computational neuroscience have stirred speculation about the possibility of **decoding dreams, extracting thoughts, digitizing consciousness,** and even **"uploading" the mind**.

Despite remarkable advances in neuroscience, the neural correlates of consciousness remain only partially understood, and its fundamental nature continues to elude specific scientific definition.

Nevertheless, the growing precision and scope of neuroscientific tools—such as functional neuroimaging, brain-computer interfaces (BCIs), and neural modulation technologies—opened new frontiers in our understanding of the brain. These innovations are not merely technical milestones; they have also revitalized enduring philosophical inquiries into the nature of consciousness, the self, and the mind-brain relationship.

Crucially, the development and application of neurotechnologies have been guided by specific epistemological assumptions within neuroscience, particularly **reductionist** and **materialist** perspectives that frame consciousness as an emergent property of neural processes. These assumptions are increasingly influential in shaping both scientific inquiry and technological design, often at the expense of more pluralistic or phenomenological conceptions of the mind. As a result, neurotechnological progress is beginning to challenge long-standing philosophical frameworks, including dualistic and non-materialist views of consciousness.

Moreover, recent advances in the ability to map, monitor, and even modulate brain activity have begun to uncover the neural substrates of moral cognition, empathy, and social behaviour. This has profound implications—not only for our theoretical understanding of human nature—but also for ethics, law, and public policy. For instance, if moral reasoning or pro-social behaviour can be linked to specific neural circuits, this raises **complex questions about moral responsibility, free will, and the potential for neuro-intervention in behaviour deemed socially undesirable.**

The implications of this shift are far-reaching. By biologizing dimensions of human subjectivity that were traditionally seen as the domain of philosophy, theology, or the humanities, neurotechnologies risk collapsing the ethical agency into neural determinism. This posture would severely challenge existing moral and legal frameworks, which are largely predicated on autonomous and rational subjectivity, not neurobiological conditioning. Therefore, as neurotechnologies continue to evolve, there is an urgent **need for interdisciplinary reflection that integrates ethical, philosophical, and legal perspectives** into the governance of neuroscience and its applications.

II. HUMAN AND ARTIFICIAL COGNITION: WHAT IS ACCEPTABLE?

The nature of consciousness remains a deeply contested scientific and philosophical question. At the core of this debate lie fundamental inquiries: "*Who am I? What constitutes my interiority?*" While science has made progress, **the essence and origin of consciousness and thought remain matters of speculation and empirical uncertainty**. Human consciousness manifests as a convergence of emotion, cognition, volition, intuition, experience, personal history, and neurobiology.

One promising line of inquiry regarding our understanding of consciousness involves *brain organoids*—three-dimensional, self-organizing neuronal structures derived from **induced pluripotent stem cells* (IPSCs).** Since their emergence in 2008[37], brain organoids have advanced our understanding of early brain development, and more recently, through integration with AI and EEG monitoring, they exhibit spontaneous neural activity resembling rudimentary brain waves. This raises the provocative and ethically sensitive question: **could these organoids acquire sentience or a form of artificial consciousness?** If so, they may serve as a prototype for synthetic, autonomous cognitive systems. Research into cerebral organoids challenges our understanding of the structures necessary for consciousness, prompting inquiry into whether self-awareness can emerge independently of the human body with Artificial Intelligence[38]. These inquiries bring about even more urgent bioethical concerns.

The development of **humanoid robots** and **cybernetic avatars**, equipped with robotic and digital intelligence, exemplifies attempts to **model and replicate human cognitive and sensorimotor capacities**. These technologies offer valuable applications and experimental platforms, but they also **probe fundamental anthropological questions about the nature and limits of the human being.**

As we advance our understanding of the brain, often referred to as a "black box" due to its complexity, we edge closer to blurring the lines between empirical neuroscience and **transhumanist fantasies.** The concept of the "**enhanced human**" or **"human enhancement"***, already present in certain medical domains, raises difficult questions about the boundary between therapeutic intervention and enhancement. In this context, the convergence of AI, neurotechnologies, and data science fosters visions of a technologically transformed human condition, stimulating both hope and fear. **At this critical juncture, society and policymakers must make informed decisions to define clearly the boundaries of what is acceptable and unacceptable in the realm of human enhancement.**

III. PENETRATING THE HUMAN SANCTUARY

With the convergence between Neuroscience, Computing, and Engineering, the ethical, legal, and societal implications of neurotechnology become even more complex as neurotech **intertwines** more and more digitalisation. Moreover, the **blurring of boundaries between therapeutic and non-therapeutic**, civilian and military, and public and private applications is generating massive datasets of brain activity that demand urgent regulatory scrutiny. At the heart of these developments lies a direct interface with the most intimate aspects of human identity—consciousness and subjectivity. **The brain, and the mind as the seat of thought, memory, and intention, is a private sanctuary.** Neurotechnologies that penetrate this sanctuary pose unprecedented challenges to privacy, autonomy, and freedom of thought. As a result, it is imperative that research and innovation in AI, cerebral organoids, and neuro-interfaces be guided by an unwavering European commitment to the common good and safeguarded from misuse that might infringe upon our **mental sovereignty as it should be enshrined in the EU Charter of Fundamental Rights.**

IV. ARE BRAIN DATA SALEABLE AS COMMODITIES ?

Why has brain data—purportedly a proxy for conscience—become a focal point of such intense interest ? What societal or commercial goals do these data serve ? And how can ethical reflection guide us through the profound challenges that such developments present? Could consciousness and thought be quantifiable, transferable, and saleable? Consciousness and thought being the most intricate and elusive concept in both science and philosophy, we can still assert that selling such data as a trace of our conscience or our thought would fail to **capture the full essence of our individuality**—our subjectivity, life history, and cultural embeddedness. These are questions that continue to resist reductive explanations and remain at the heart of ongoing philosophical, anthropological, theological, and scientific inquiry.

The once-fictional notion of commodifying human "thoughts" has increasingly become a reality, propelled by advances in neurotechnology capable of decoding, interpreting, and even transmitting neural activity. What was once confined to the realm of science fiction is now being realized through brain-computer interfaces and machine learning algorithms that can reconstruct mental states, intentions, and emotional responses from brain data. This technological possibility profoundly challenges longstanding assumptions about privacy, inaccessibility, and singularity of human consciousness.

Traditionally, **thoughts have been regarded as the final domain of personal autonomy, intangible, unobservable, and inherently private**. The ability to externalize and potentially commercialize mental content raises fundamental questions about the nature of subjectivity and the boundaries of the self. If inner cognitive processes can be captured, stored, or traded, it calls into question the **inviolability of mental life**, blurring the line between personhood and data.

Moreover, such developments invite ethical and legal scrutiny regarding cognitive liberty, consent, and mental integrity. The **commercialization of neural data** not only risks reducing human consciousness to a set of exploitable signals but also reconfigures our understanding of identity, agency, and moral responsibility in a world where even thoughts may be surveilled, monetized, or manipulated.

Despite technological advances, **consciousness continues to elude definitive scientific explanation**. Nonetheless, current explorations into its neural correlates rely heavily on both invasive and non-invasive neurotechnologies, such as Electroencephalography (EEG) and **Functional Magnetic Resonance Imaging* (fMRI).** If all mental and emotional phenomena are reducible to patterns of neuronal activity, what, then, makes us uniquely human?

As these evolving neurotechnologies continue to challenge long-standing philosophical conceptions of selfhood, we call on policymakers and global governance bodies to safeguard freedom of thought and conscience.

V. THE LIMITS OF NEURORIGHTS

Neurorights and Digital rights emerged as a possible tool for safeguarding fundamental aspects of human cognition, freedom, and autonomy. They encompass a **set of legal and ethical protective measures aimed at preserving mental privacy, free-will, equal access to mental augmentation, protection of algorithmic bias, and personal identity in the face of neurotechnological interventions**. As BCI and AI-driven cognitive enhancement progresses, the **potential for unauthorized access, manipulation, or exploitation of neural data grows**. These concerns extend beyond privacy into the realm of personal agency, as individuals may be subjected to subconscious influence, behavioural modification, or even direct interference with thought processes.

The current focus on Neurorights such as Digital Rights only provides for the protection of mental capacities. Some scholars have proposed to create **Digital rights**[39] in bodily-embarked AI systems which they believe threaten human rights in the age of neuroscience and neurotechnology. They suggest the creation of **four new fundamental rights**:

- **Right to cognitive freedom** as the right to alter one's mental state by technical means and the right to refuse to do so. It is in fact the right not to be pressured into revealing data.
- **Right to mental privacy** as the right to prevent illegitimate access to our brain information. This is in fact the question of neuromarketing.
- **Right to mental integrity** as the right of individuals to protect their mental dimension from any potential danger, for example, from hacking by a neural device (or hacking of a neuro-device).
- **Right to psychological continuity** as the right to preserve one's personal identity and consistency of individual behaviour against unacceptable changes, even if the changes introduced are not *per se* dangerous.

Although these Neurorights offer significant protection against the misuse of neurotechnologies, they also have limitations, particularly in their scope and enforceability as well as their inability to safeguard every aspect of the human condition with a particular attention to the notion of embodiment. The development of neuroscientific knowledge resulted in reducing the characteristics of what make us human to neural and biochemical processes. However, a human being is not simply a mind contained within a body but an **integrated whole in which body and mind are inseparable**. Unlike a purely biological entity, the lived body plays an active role in shaping human experience; it is not a passive vessel but a medium through which individuals engage with the world. Sensory perception, movement, and emotion are not mere outputs of neural activity; they are deeply embedded in one's lived reality. **Furthermore, human beings are not solely defined by their biological characteristics but likewise by their unique identities, shaped through cognition, culture, and lived experience.**

On the one hand, individuals have mental capacities and character traits that enable them to engage with the external world, including communicating with individuals and interacting with objects, to **create meaning in their lives in relation to others** as "*we are never more (and sometimes less) than the co-authors of our own narratives*".[40]

Conversely, our lived experience is deeply rooted in the biological aspects of being human. Our perceptions of space and time are shaped and understood through the sensory faculties of the body: sight, hearing, touch, smell, and taste. It is through these senses that we occupy the world, interact with it, and construct meaning from it. The physical and psychological elements that constitute personal identity are particularly crucial when considering individuals with mental illnesses that involve moral impairments. Philosopher Charles Taylor refers to "qualified horizons"—moral frameworks that anchor our sense of self and agency—as vital components of human identity. Disrupting these structures, especially through coercive means, risks undermining the essence of personhood. This issue becomes especially urgent with the development of neurotechnologies capable of reading or even influencing thought. As these tools potentially link human minds to digital systems and could create **convincing illusions** or **implant false memories**, they raise the possibility of **behavioural manipulation**, presenting profound ethical challenges for the future[41].

VI. BEYOND NEURORIGHTS : IDENTITY INTEGRITY

While neurotechnologies offer promising advancements in medical research and clinical practice, such as treatments for neurological disorders and improved mental health interventions, they also raise concerns about **autonomy, consent, privacy, and the broader impact on what it means to be human.** To a certain extent, **neuroethics** serve as a framework for addressing these concerns. Experts in the field provide ethical guidance tailored to various audiences:

- Neuroscientists who conduct brain research, ensuring responsible experimentation and consideration of long-term effects;
- Healthcare professionals in clinical practice, who must navigate the fine line between treatment and enhancement;
- The broader society, where discussions revolve around regulation, marketing and accessibility of direct-to-consumer neurotechnologies, that is, products and devices directly advertised to end-consumers without requirement of a prescription or professional oversight.

However, with neuroethics, the **deeper philosophical and ethical questions** associated with the implications of these neurotechnologies for what it means to be human, **often remain secondary**, as pragmatic and utilitarian considerations, i.e. **efficiency, economic gain, and technological innovation, take precedence**. This is why, extending beyond neuroethics, we would like to promote the concept of **Identity Integrity** as the basis for legislation.

VII. IDENTITY INTEGRITY : A MORE COMPREHENSIVE ETHICAL FRAMEWORK

What is Identity Integrity? Without clear boundaries for the protection of **brain *and* mind**, there is a growing risk of undermining the integrity of humans not only as individuals but also as a species. The concept of **Identity Integrity** is closely related to the principle of cognitive freedom, defined as "*the right of each individual to think independently and autonomously, to use the full spectrum of his or her mind, and to engage in multiple modes of thought*"[42].

However, the scope of cognitive freedom focuses on the mind whereas Identity Integrity focuses on **the mind AND the brain**. In fact, **Identity Integrity** "*aims at the protection, preservation, and restoration (in the clinical context) of psychological continuity (the mind) and acknowledges the embodied identity of individuals (the brain) as opposed to an identity based only on psychological continuity. It is also committed to* *the view that the body represents an essential repository to make sense of our psychological states*[43, 44]*."* **Identity Integrity** is a concept that represents a fuller and more adequate description of the human condition.

Without clear boundaries for the protection of the brain and mind - which constitute the core concept of **Identity Integrity** - there is a growing risk of undermining the integrity of humans not only as individuals but also as a species. The concept of Identity Integrity is closely related to the principle of cognitive freedom, defined as *"the right of each individual to think independently and autonomously, to use the full spectrum of his or her mind, and to engage in multiple modes of thought*[45]*"*. However, the scope of cognitive freedom is too narrow since its focus is on the mind whereas *Identity Integrity* focuses on the mind *and* the brain.

The growing reliance on neurotechnologies has reinforced the notion that humans are both **malleable** and **enhanceable** through applied science and technology. In this shift, natural sciences increasingly serve as the primary framework for conceptualizing human identity, often at the expense of the humanities. Traditionally, fields such as philosophy, ethics, theology and anthropology have provided critical perspectives on what it means to be human, emphasizing aspects like self-awareness, rationality, purpose, and existential meaning. However, as neuroscientific explanations gain dominance, these characteristics of consciousness, selfhood, personal identity, and agency are increasingly understood in purely biological or mechanistic terms. This neurocentric view, while valuable, risks **reducing the complexity of human experience to mere neural activity, overlooking the social, cultural, and existential dimensions that shape personal identity.**

As a result, there has been a significant shift in the way humans are perceived in Western cultures. The traditional agent-centered view—in which individuals are seen as **autonomous beings** who shape their lives through choices, relationships, aspirations and worldviews—has given way to a **biological framework** that emphasizes humans as organisms **governed by neural and biochemical processes.** This paradigm shift alters the fundamental perspective on personhood, replacing the "I" as a subject with agency and self-determination with an "it", a being defined by its biological functions and physiological mechanisms. Such a perspective is valuable in advancing our scientific understanding of the human but is an understatement of the nature of human existence and the type of "organisms" humans are[46].

A robust ethical framework should be grounded in the following:

- A comprehensive understanding of human dignity arising from a complex **interplay of cognition, emotions, societal influences, meaning and existential purpose**;
- The development of an **Ethics of neuroscience corpus**, anchored in a broad anthropological perspectivethat respects **Human Identity Integrity**;
- The **protection of the mind** explicitly **covering** the protection of the **brain**.

The EU AI Act emphasizes a human-centric approach, affirming a clear separation between artefacts and humans.

It is equally important to recognize and assert that humanhood is defined by more than biological characteristics, namely, their unique corporeal and mental identity.

Legal safeguards should recognize the brain as a sovereign domain, **preventing undue influence from corporations, governments, individuals or other entities** seeking to exploit neural data for profit, control or surveillance. To implement these various types of protection effectively, **the EU, as well as international organizations such as the United Nations and the Council of Europe, should incorporate Identity Integrity into policy development**.

CHAPTER 3
Towards building a new and comprehensive legal framework

I. CURRENT LEGISLATION

The Council of the European Union published a research paper "*From vision to reality: Promises and risks of Brain-Computer Interfaces*" last December 2024[47]. So did the Joint Research Centrein its 2025 report "Emerging applications or neurotechnology and their implications for EU governance. Both the **UNESCO**[48] and the **OECD**[49] equally underlined the need for a comprehensive legal and ethical framework to manage BCIs' usage and evolution. These international bodies underscored the imperative for anticipatory regulatory frameworks to mitigate the potential risks associated with emerging neurotechnologies. While the referenced research papers and declarations are non-binding, they nonetheless reflect a growing consensus on the urgency and criticality of the matter.

The European Union's current regulatory framework provides a response to several of the ethical and legal challenges raised by BCIs, particularly regarding the medical use of these technologies. However, it still fails to offer a comprehensive or fully satisfactory response to many broader, cross-cutting issues in this area.

Given the complexity and novelty of the ethical and regulatory challenges presented by these technologies, a sectoral regulatory framework—addressing general technological domains rather than BCIs specifically—**remains insufficient** to capture the distinct legal considerations BCIs entail under European law.

a. Medical Device Regulations

Solely focused on safety of go-to-market products, the EU consolidated Regulation 2017/745, (known as the Medical Devices Regulation), classifies BCIs intended for medical purposes as medical devices. BCIs are therefore subject to the rules relating to clinical tests and safety measures set out in the Regulation. BCIs are coined as "*Equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain*[50]". **The regulation solely establishes requirements for ensuring the safety and performance of medical devices throughout their lifecycle.**

However, two difficulties arise here, both linked to the complexity of the distinction between the medical and non-medical dimensions of BCIs.

Firstly, certain BCI technologies, although designed and programmed for medical use, **may in practice be used abusively or unknowingly, for non-medical purposes.**

Secondly, the **design of certain BCIs may itself straddle the boundary between medical and non-medical use**. Indeed, non-medical BCIs used for gaming or productivity such as EEG headsets, smartwatches, **Artificial Reality glasses, subdermal chips, and other wearables, currently considered as consumer electronics, may escape the Medical Device Regulation** but could still pose safety or ethical concerns that are not sufficiently covered by EU law provisions regarding the safety of consumer or industrial products (e.g. EU General Product Safety Regulation 2023/988).

Together, these two factors highlight the necessity of **dedicated regulatory measures** that account for the inherent ambiguity in both the intended use and the design of these technologies, especially regarding the regulatory boundary between medical and non-medical devices

b. Data Protection with the GDPR

The data protection regime established by the General Data Protection Regulation (EU Regulation 2016/679) encompasses neuronal data acquired through brain-computer interfaces (BCIs), classifying it under the broader categories of health-related or biometric data. Nonetheless, the **GDPR does not explicitly recognize neuronal or brain-derived data as a sui generis category**, despite its uniquely sensitive nature. This absence of specific recognition overlooks the need for a multidimensional regulatory approach; one that would integrate protection against neuromarketing practices, safeguard cognitive liberty, and uphold the right to mental integrity as emerging normative imperatives in the context of neurotechnologies.

c. Regulation on Artificial Intelligence with the AI Act

In the context of BCIs, the **EU AI Act adopts a risk-based regulatory approach aimed, inter alia, at safeguarding individual autonomy and preventing manipulation**. Notably, Article 5(a) prohibits "*placing on the market, the putting into service or the use of an AI system that deploys subliminal techniques beyond a person's consciousness or purposefully manipulative or deceptive techniques, with the objective, or the effect of materially distorting the behaviour of a person or* *a group of persons*". AI systems that employ subliminal techniques, are operating below the threshold of consciousness, as well as those which intentionally manipulate or deceive users in a manner likely to cause harm. However, despite these safeguards, AI-powered BCIs may still operate within regulatory grey zones, particularly in scenarios where AI systems infer users' intentions, cognitive states, or emotional conditions, thereby raising unresolved questions about consent, transparency, and user agency[51].

d. EU Cybersecurity Resilience Act

The recent EU Cyber Resilience Act (Regulation 2024/2847, entered into force in December 2024, but effectively, will apply from December 2027) provides for stronger cybersecurity requirements, including for BCI software. It is nonetheless **unclear whether its provisions could prevent manipulation of neural functions or theft of neuronal data**.

e. General Human Rights Law

The European Convention on Human Rights (ECHR) and, more distinctively from an EU perspective, the EU Charter on Fundamental Rights both recognize essential human rights in the context of BCI usage. **Freedom of thought and conscience** (Article 9 of the **ECHR** and Article 10 of the **EU Charter**) is of particular importance in this perspective, as well as the right to private life (Article 8 of the ECHR and Article 7 of the EU Charter). Non-discrimination is also protected under European human rights law (Article 14 of the ECHR and article 21 of the EU Charter).

To date, these general provisions have neither been concretized through supplementary instruments, such as additional protocols in the context of the European Convention on Human Rights (ECHR), nor been subject to clear interpretative guidance concerning their applicability to scenarios involving the use of brain-computer interfaces (BCIs). This gap is particularly salient with respect to the protection of the integrity of human conscience—or what may be termed "Identity Integrity"—as an essential dimension of the right to freedom of thought and conscience.

The EU legal framework for BCIs is insufficient

- The current EU regulatory landscape provides a basic structure for regulating BCIs, particularly when they function as medical devices.
- The rapid convergence of neuroscience, artificial intelligence, and end-user technologies requires a more consistent and future-proof regulatory framework.
- This should include the establishment of a specific legal instrument to safeguard individual human rights in view of the distinct risks posed by BCIs.

II. RECOMMENDED LEGAL INSTRUMENTS AND REGULATORY PATHWAYS

The EU Regulation 2017/745 on Medical Devices should be revised to include newly developed BCIs, with a risk-based approach such as in the AI Act, while considering the lack of data in this young and undefined market and its rapid evolution.

Recommendation #1 : Revisit the Medical Devices Regulation

Revise the Medical Device Directive to explicitly address the ethical challenges posed by certain emerging neurotechnologies. A potential legal-philosophical approach to accommodate ethical considerations would be to classify these devices using a risk-based framework, aligning regulatory oversight with the degree of potential harm or ethical concern.

The key areas of biotechnologies are medical (development of drugs, diagnostics, and gene therapies), agricultural (genetically modified crops, bio-pesticides, livestock improvement), industrial (use of enzymes or microbes in manufacturing, biofuels, and waste treatment), environmental (bioremediation, pollution monitoring using biosensors), and **neurological with Brain-computer interfaces, neural implants, and cognitive enhancement.**

Consequently, BCIs should fall within the scope of biotechnology under the forthcoming European Biotech Act proposed by Health Commissioner Várhelyi, thus playing a pivotal role in advancing brain health innovation.

Recommendation # 2 : Include of BCIs in the Biotech Act

Incorporate BCIs into the Biotech Act to encompass human-machine hybridisation, ensuring that both its biological ramifications and ethical dimensions are adequately addressed within the legislative framework.

The EU legal framework should provide regulatory clarity on the distinction between therapeutic and non-therapeutic applications, while also establishing ethical boundaries to ensure the responsible use of such technologies.

Recommendation # 3 : Discriminate therapeutic and enhancing techniques in relevant legislation

Establish clear criteria differentiating therapeutic devices from recreational and enhancement technologies, thereby allowing the European Commission to firmly delineate the scope of medical devices under its regulatory authority.

The development of BCIs invites revisiting the scope of fundamental rights considering emerging concepts such as **neurorights** and **identity integrity** to enshrine the **protection of the human mind** regarding **their neural activity**. This includes re-examining the rights to freedom of thought and conscience, particularly in relation to issues of control and surveillance, and reaffirming the inviolability of the *forum internum* as a foundational principle of international and European human rights law. Building on existing ECHR and EU Charter, recent constitutional reforms in Chile, and the Universal Declaration of the Human Mind's Rights, proposed by Prof. Mark Hunyadi, Professor of philosophy at UCLouvain[52], could serve as a foundational framework for further reflection.

Recommendation # 4 : Reconsider the scope of human rights charters

Enshrine Identity Integrity and the protection of the Human Mind into the scope of EU fundamental rights, including the EU Charter.

GLOSSARY

Brain-to-Brain Implant (BtoB)

Brain-to-Brain Implant technology represents the next frontier in neuro-communication, allowing for direct transmission of information between two brains. This is achieved through the implantation of microelectrodes in the brain, which can both record and stimulate neuronal activity. By linking two individuals' brains, BtoB technology aims to facilitate direct exchange of thoughts, sensory experiences, and motor commands. While still largely experimental, BtoB technology holds immense potential for applications in communication, collaborative work, and even therapeutic interventions. For instance, it could enable new forms of telepathy-like communication for people with communication disorders or enhance collaborative problem-solving by synchronizing brain activity. However, significant ethical, technical, and safety challenges remain, including issues of consent, privacy, and the long-term effects of brain implants.

Brain-Computer Interface (BCI)

A Brain-Computer Interface is a system that enables direct communication between the brain and an external device. By interpreting brain signals, BCIs allow users to control computers, prosthetics, and other devices using only their thoughts. This is typically accomplished using EEGi or other neuroimaging techniques to capture brain activity, which is then translated into actionable commands.

BCI technology has made significant strides in recent years, particularly in the field of assistive technology for individuals with disabilities. For example, BCIs can enable people with severe motor impairments to control wheelchairs, communicate through text-to-speech devices, and interact with their environment. In addition to medical applications, BCIs are being explored for use in gaming, virtual reality, and even enhancing cognitive performance.

CAGR

Compound Annual Growth Rate, the mean annual growth rate of an investment over a specified period.

Conscience, Mind and Thought

Although very elusive and difficult human realities, one could say that conscience is the moral faculty that enables individuals to discern right from wrong whereas the mind refers to the broader set of cognitive capacities such as awareness, memory, and reasoning, and thought is a specific mental activity or idea produced by the mind. Thus, conscience is ethical in nature, the mind is the seat of all mental functions, and thought is one of its discrete expressions. Science tends to prove that the conscience arises from brain networks involved in moral judgment, the mind emerges from the brain's overall cognitive activity and thought represents specific mental processes distributed across various neural regions.

Deep Brain Stimulation

A new technique involving personalized deep brain stimulation has shown promise in treating cognitive impairments resulting from moderate to severe traumatic brain injury. This approach tailors stimulation to individual patients, potentially offering a new avenue for cognitive rehabilitation.

Deep Learning

Deep learning is a subset of machine learning that uses multi-layered neural networks to learn, automatically, patterns and representations from large amounts of data. In terms of Machine Learning, Deep Learning has made significant contributions: it automates feature extraction from raw data, greatly improves performance of complex tasks (such as image recognition, natural language processing, and speech), and enables the processing of massive datasets through deep neural network architectures.

ElectroCorticoGraphy or (EcoG)

ElectroCorticoGraphy is used to locate seizure foci, map brain function, and monitor brain activity during neurosurgical procedures. Graphical recording of brain activity using electrodes in direct contact with the cortex. Implanting large area electrocorticography arrays is a highly invasive procedure, requiring a craniotomy.

Electro-Encephalogram (EEG)

The Electro-Encephalogram is a non-invasive method used to record electrical activity of the brain. This is achieved by placing electrodes on the scalp, which detect the electrical signals produced by neuronal activity. The resulting brainwave patterns are then analyzed to provide insights into various brain states, such as sleep, wakefulness, and cognitive processes. EEG has a wide array of applications in both clinical and research settings. Clinically, it is used to diagnose and monitor conditions such as epilepsy, sleep disorders, and brain injuries. In research, EEG aids in the study of cognitive functions, emotional responses and brain-computer interactions. Its real-time monitoring capabilities also make it invaluable in neuro feedback therapy, where individuals learn to regulate their brain activity to alleviate symptoms of conditions such as Attention-deficit with or without hyperactivity disorder (ADHD) and anxiety.

Functional Magnetic Resonance Imaging (fMRI)

fMRI is a brain imaging technique that reveals brain activity by detecting changes in blood flow. It is a non-invasive method that uses MRI technology to measure blood oxygenation levels in different brain areas. When a brain region is active, it requires more oxygen, leading to increased blood flow and a detectable change in the MRI signal. It is non-invasive and allows to visualize brain activity as it shows which areas of the brain are active during different tasks or when thinking about something. Its applications range from research to the study of brain functioning clinical settings, to guide neurosurgery to diagnosis, and the monitoring of various neurological conditions.

Human enhancement

The concept of human enhancement generally refers to the improvement or augmentation of human capabilities, whether physical, cognitive, or emotional, through technology, science, or design. The concept is prominent in fields such as artificial intelligence, bioengineering, neuroscience, and transhumanism. Technologies such as brain–computer interfaces (BCIs), exoskeletons, neural implants, and augmented or virtual reality systems are central to this form of enhancement. However, these developments also raise significant ethical and philosophical questions, particularly regarding the societal implications of enhancing versus protecting human values such as autonomy, dignity, and empathy

Induced pluripotent stem cells (iPSCs)

Induced pluripotent stem cells are cells that are reprogrammed from adult cells to become pluripotent stem cells able to differentiate into any cell type in the body.

Machine Learning Technologies

The use and development of computer systems allow a person to learn and adapt without following explicit instructions, and to do so, by using algorithms and statistical models to analyse and draw patterns in data.

Magnetoencephalogram (MEG)

A magnetoencephalogram is a non-invasive neuroimaging technique that measures the magnetic fields produced by electrical activity in the brain. It is used to map brain function and localize the source of brain activity, often in relation to epilepsy or other neurological conditions.

Precautionary Principle

The precautionary principle can be defined "as the rule that one should never engage in a technological development or application unless it can be shown that this will not lead to large-scale disasters or catastrophe": Engelhardt & Jotterand, The Precautionary Principle: A Dialectical Reconsideration, The Journal of Medicine and Philosophy, 2004, 29, 301-312. Versions of the Precautionary Principle can be found in the Montreal Protocol, the Convention on Biological Diversity, the Helsinki Convention on Marine Protection in the Baltic, the Treaty on The Precautionary Principle by the European Union, the Biosafety Protocol, the Treaty on Persistent Organic Pollutants and Rio Declaration on Environment and Development (1992) for instance

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