Proposal for a European Union Neurocognitive Rights Act

2025

Author: Vitor Mendonca Prado

JUSTIFICATION FOR THE EUROPEAN UNION NEUROCOGNITIVE RIGHTS ACT

NECESSITY AND URGENCY

The European Union stands at a critical technological inflection point that demands immediate legislative action. The European Union Neurocognitive Rights Act represents an essential and timely legislative framework to address unprecedented advances in neurotechnology that can access, monitor, and potentially manipulate the human brain—the most intimate domain of human existence and the foundation of personal autonomy.

Recent developments in computational neuroscience, neural signal processing, and brain modulation technologies have progressed at an exponential rate, far outpacing our legal frameworks. European research institutions, technology companies, and medical agencies are developing sophisticated neurotechnologies that operate at specific electromagnetic frequencies and leverage advanced principles to interact with neural systems in ways that conventional technologies cannot.

The European Union already faces concrete challenges requiring urgent regulatory response:

1. European technology corporations and startups have invested billions in brain-computer interfaces for commercial and medical applications, with minimal oversight regarding privacy and security protocols for neural data.
2. The European Medicines Agency has approved several invasive and non-invasive neurotechnology devices without comprehensive frameworks to evaluate long-term impacts on cognitive autonomy and mental privacy.
3. Venture capital has poured over €1 billion into EU neurotechnology startups in the past five years alone, creating a rapidly expanding market operating in a regulatory vacuum.
4. Early clinical trials of cognitive enhancement technologies raise profound questions about equitable access and potential creation of cognitive disparities that could undermine European social cohesion.
5. International competitors are rapidly developing their own neurotechnology capabilities, creating geopolitical imperatives for establishing EU leadership in ethical standards and governance.
6. Cross-border challenges in neurotechnology regulation threaten the integrity of the Digital Single Market, creating fragmentation risks as Member States develop divergent approaches.

EUROPEAN LEGAL AND VALUES FOUNDATION

The European Union Neurocognitive Rights Act builds upon Europe's strong tradition of rights protection while adapting these protections to emerging technological realities. The right to cognitive liberty can be understood as an extension of existing EU legal protections:

- The Charter of Fundamental Rights of the European Union, particularly Article 1 (human dignity), Article 3 (right to integrity of the person), Article 7 (respect for private life), and Article 8 (protection of personal data)
- The European Convention on Human Rights, particularly Article 8 (right to respect for private and family life) and Article 9 (freedom of thought, conscience and religion)
- The General Data Protection Regulation (GDPR), which established global standards for data protection but requires enhancement to address the unique challenges of neural data

Distinguished European legal scholars and ethicists, including those from the European Group on Ethics in Science and New Technologies, have articulated the need for specific neurorights protections in European jurisprudence. Their work demonstrates that traditional privacy doctrines, even those in the GDPR, are insufficient to address technologies that can potentially access thoughts, memories, and cognitive processes.

The European Court of Justice has recognized in cases concerning digital privacy that new technologies require evolutionary interpretations of fundamental rights protections. Neurotechnology represents perhaps the most significant frontier for extending these principles, as it concerns not merely data about a person but access to the very processes that constitute personhood itself.

STRATEGIC AUTONOMY AND EUROPEAN COMPETITIVENESS

Establishing a comprehensive legal framework for neurotechnology is central to the EU's strategic autonomy objectives and digital sovereignty agenda. The European Union must lead in setting ethical standards and regulatory frameworks for neurotechnology development to ensure these technologies advance European values of human dignity, privacy, and solidarity.

The European Research Council, Horizon Europe, and numerous national research agencies have invested significantly in neurotechnology research through initiatives like the Human Brain Project and the European Innovation Council's Deep Tech programs. These investments demonstrate the strategic importance of neurotechnology for European scientific leadership and economic development.

Without a comprehensive EU-wide regulatory framework, the European Union risks:

1. Losing global technological leadership to nations with fewer ethical constraints
2. Creating vulnerabilities in neural security that could be exploited by adversaries
3. Enabling the fragmentation of the Digital Single Market through divergent national regulations
4. Undermining public trust in legitimate and beneficial applications of neurotechnology
5. Failing to protect the fundamental rights of EU citizens in an emerging technological domain

ECONOMIC AND INNOVATION BENEFITS

The neurotechnology sector represents a significant growth opportunity for the European economy. According to market analyses, the global neurotechnology market is projected to reach €30 billion by 2027, with Europe positioned to capture a substantial portion of this growth through its strong research base and healthcare systems.

Far from impeding innovation, this legislation will create the regulatory certainty needed for responsible investment and development. By establishing clear guidelines, certification processes, and specialized judicial oversight, the Act will:

1. Provide regulatory clarity that encourages long-term investment across the Single Market
2. Create harmonized standards that facilitate interoperability and sector growth
3. Build public trust necessary for widespread adoption of beneficial neurotechnologies
4. Establish the European Union as the global leader in ethical neurotechnology development
5. Position European companies advantageously in global markets through first-mover advantages in ethical neurotechnology

Companies developing neurotechnology applications for healthcare, education, entertainment, and productivity will benefit from clear rules of engagement, reducing legal uncertainty and liability exposure. The specialized judicial mechanisms established by this legislation will develop expertise necessary to adjudicate complex technical disputes efficiently, reducing costly litigation uncertainties.

SPECIALIZED JUDICIAL MECHANISMS: A NECESSARY INNOVATION

The establishment of specialized judicial mechanisms for neurocognitive rights responds to the unprecedented challenges posed by neurotechnology cases. These specialized mechanisms build upon European precedents:

- The Court of Justice of the European Union's specialized chambers
- The European Court of Human Rights' expertise in fundamental rights adjudication
- Member States' specialized courts for complex technical matters
- The European Data Protection Board's coordinated approach to data protection

Specialized judicial expertise with technical knowledge has proven effective in these domains, and neurotechnology presents even greater technical complexities that require specialized judicial knowledge. Conventional courts lacking neuroscientific and technical expertise risk inconsistent rulings that could either stifle innovation through overly restrictive interpretations or fail to adequately protect fundamental rights through insufficient scrutiny.

As noted by European legal scholars, the judiciary faces unprecedented challenges in evaluating evidence related to emerging technologies that can potentially interfere with

mental autonomy and cognitive privacy. The creation of specialized neurocognitive judicial mechanisms would establish the European Union as a global pioneer in neurocognitive justice—an area that will inevitably become central in coming decades.

GLOBAL LEADERSHIP AND STANDARD-SETTING

The European Union has historically led in establishing regulatory frameworks for emerging technologies, from the GDPR for data protection to the Medical Device Regulation for healthcare technologies. Neurotechnology represents the next frontier requiring European leadership.

Several nations are moving forward with neurorights protections:

- Chile amended its constitution to explicitly protect neural rights
- Spain has developed legislative frameworks for neurotechnology regulation
- Various international organizations are considering neurorights within their digital ethics agendas

By enacting comprehensive legislation now, the European Union can establish global standards aligned with European values of human dignity, privacy, and solidarity. Failure to act would cede leadership to other nations or regions whose frameworks may not prioritize these values to the same degree.

The EU has consistently demonstrated that well-designed regulation can become a global standard, as seen with the "Brussels Effect" of the GDPR. A comprehensive European framework for neurocognitive rights could similarly shape global practices in neurotechnology development and deployment.

PAN-EUROPEAN APPEAL

The European Union Neurocognitive Rights Act transcends traditional political divides, offering compelling justifications for support across the political spectrum:

For conservatives, the Act protects traditional values of human dignity and autonomy from technological overreach.

For progressives, the Act establishes equity guarantees ensuring that neurotechnology benefits are widely accessible while preventing new forms of discrimination.

For security advocates, the Act establishes frameworks essential for maintaining European technological sovereignty and protecting against potential neurocognitive threats.

For business interests, the Act creates regulatory certainty and public trust necessary for the flourishing of a vibrant neurotechnology sector across the Single Market.

For federalists, the Act demonstrates the European Union's capacity to address complex emerging challenges that transcend national boundaries.

ALIGNMENT WITH EXISTING EU PRIORITIES

The European Union Neurocognitive Rights Act aligns perfectly with existing EU strategic priorities:

- The **Digital Decade** objectives for a human-centered digital transformation
- The **European Health Union** goals for innovative healthcare technologies
- The **Digital Services Act** and **Digital Markets Act** approach to regulating digital technologies
- The **European Green Deal's** emphasis on sustainable and responsible innovation
- The **Horizon Europe** focus on responsible research and innovation
- The **EU Artificial Intelligence Act** approach to risk-based technology regulation

By addressing neurotechnology within a comprehensive regulatory framework, the European Parliament would demonstrate coherence and foresight in its approach to technological governance.

CONCLUSION

The European Union Neurocognitive Rights Act represents essential legislation for the emerging era of advanced neurotechnology. By establishing fundamental neurocognitive rights, creating appropriate regulatory frameworks, ensuring proper data protections, and establishing specialized judicial expertise, this legislation will protect the most intimate domain of human autonomy while enabling responsible innovation.

The window for establishing these protections is narrowing as neurotechnology advances at an accelerating pace. By acting decisively now, the European Parliament has the opportunity to establish landmarks in the protection of human dignity for the digital age.

This legislation will position the European Union as the global leader in ethical neurotechnology development and neurocognitive rights protection—upholding Europe's commitment to human dignity, privacy, and fundamental rights in the face of unprecedented technological capabilities to access and influence the human mind.

The time for action is now, before potentially invasive technologies become widespread and before international standards are set by nations or regions that may not share Europe's commitment to fundamental rights and human dignity. We urge the European Parliament to prioritize passage of this vital legislation to secure cognitive liberty for current and future generations of European citizens.

European Union Neurocognitive Rights Act

LEGISLATIVE PROPOSAL

PROPOSAL FOR A REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on the protection of neurocognitive rights of individuals, regulation of neurotechnologies, establishment of specialized courts, and other measures to safeguard cognitive autonomy within the European Union

(Text with EEA relevance)

2025/0157 (COD)

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

1.1. Reasons for and objectives of the proposal

The rapid advancement of neurotechnology presents unprecedented opportunities for scientific progress, medical treatment, and enhancement of human capabilities. These technologies include invasive and non-invasive brain-computer interfaces, neurostimulation devices, neural recording systems, and cognitive decoding algorithms. As these technologies continue to evolve at an accelerated pace, they raise fundamental questions about human autonomy, privacy, identity, and agency.

The European Union, consistent with its commitment to human dignity as enshrined in Article 1 of the Charter of Fundamental Rights, recognizes that cognitive processes represent the most intimate domain of human experience. Neurocognitive rights—the rights pertaining to the protection of an individual's neural data, cognitive liberty, and mental privacy—constitute a new frontier in human rights that demands comprehensive legal protection.

This Regulation aims to:

1. Establish neurocognitive rights as a distinct and protected category of rights within the European Union legal framework;
2. Create a comprehensive regulatory system for neurotechnology development, deployment, and use;
3. Establish specialized judicial mechanisms to adjudicate cases involving neurocognitive rights;
4. Ensure harmonized implementation across Member States;
5. Balance innovation with ethical considerations and fundamental rights;
6. Position the European Union as a global leader in the ethical governance of neurotechnology.

This Regulation responds to several critical developments:

- The proliferation of commercial neurotechnology devices with increasing capabilities to monitor, decode, and potentially influence neural activity;
- Scientific advancements in neuroimaging and neural decoding that may enable unprecedented access to mental states and cognitive processes;
- The integration of artificial intelligence with neurotechnology, creating systems with enhanced capabilities to interpret neural data;
- The potential for neurotechnology to be deployed in sensitive contexts such as employment, education, criminal justice, and consumer applications.

While existing legal frameworks, including the General Data Protection Regulation (GDPR), provide some relevant protections, they are insufficient to address the unique challenges posed by neurotechnology. Neural data represents a distinct category of personal information that may reveal cognitive processes, emotional states, and potentially unexpressed thoughts. The extraction, storage, processing, and transmission of such data require dedicated legal protections beyond those afforded to other categories of personal data.

This Regulation seeks to preserve the fundamental dignity and autonomy of individuals in an era of increasingly sophisticated neurotechnology while fostering responsible innovation that respects ethical boundaries.

1.2. Consistency with existing policy provisions in the policy area

This Regulation builds upon and complements existing European Union legal frameworks. It is designed to be consistent with:

- **The Charter of Fundamental Rights of the European Union**: This Regulation extends the protections for human dignity (Article 1), the right to the integrity of the person (Article 3), the prohibition of torture and inhuman or degrading treatment (Article 4), respect for private and family life (Article 7), protection of personal data (Article 8), and freedom of thought, conscience and religion (Article 10).
- **The General Data Protection Regulation (GDPR)**: While the GDPR provides a foundation for data protection, this Regulation establishes specialized protections for neural data, which requires distinct safeguards due to its intimate connection to cognitive processes and identity.
- **The Medical Devices Regulation (MDR)**: This Regulation complements the MDR for neurotechnological devices used in medical contexts, while extending regulation to non-medical applications of neurotechnology.
- **The Artificial Intelligence Act**: This Regulation works in concert with the AI Act to address the specific challenges posed by the integration of AI with neurotechnology.
- **The Digital Services Act and Digital Markets Act**: This Regulation extends digital governance frameworks to include neurotechnology platforms and services.
- **The Product Liability Directive**: This Regulation addresses the unique liability questions arising from neurotechnology applications.

- **Horizon Europe research framework**: This Regulation aligns with EU research priorities while establishing ethical boundaries for neurotechnology research.

This Regulation introduces several innovations in EU law:

1. Recognition of neurocognitive rights as a distinct category of rights requiring specialized protection;
2. Establishment of the European Neurotechnology Regulatory Authority as a dedicated body for harmonized implementation;
3. Creation of specialized judicial mechanisms for neurocognitive rights cases;
4. Development of a graduated risk-assessment framework specific to neurotechnology;
5. Introduction of neurotechnology impact assessments for high-risk applications.

1.3. Consistency with other Union policies

This Regulation supports broader European Union policy objectives:

- **Digital Single Market**: By harmonizing neurotechnology regulation across Member States, this Regulation supports the development of a coherent Digital Single Market while ensuring appropriate safeguards.
- **European Health Union**: This Regulation contributes to the European Health Union by establishing standards for neurotechnology used in healthcare contexts.
- **Strategic Autonomy**: By developing European standards and expertise in neurotechnology governance, this Regulation enhances EU strategic autonomy in critical emerging technologies.
- **Fundamental Rights**: This Regulation strengthens the EU's comprehensive fundamental rights framework by addressing new challenges to human dignity and autonomy.
- **Research and Innovation**: By providing clear ethical and legal boundaries, this Regulation creates certainty for researchers and innovators in neurotechnology.
- **Consumer Protection**: This Regulation enhances consumer protection by establishing standards for neurotechnology devices and services marketed to consumers.
- **Internal Market**: By creating a harmonized regulatory framework, this Regulation prevents fragmentation of the internal market through divergent national regulations.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

2.1. Legal basis

This Regulation is based on Article 16 of the Treaty on the Functioning of the European Union (TFEU), which provides the legal basis for rules relating to the protection of individuals with regard to the processing of personal data. Neural data constitutes a specialized category of personal data that warrants dedicated protection.

Additionally, this Regulation is supported by:

- Article 114 TFEU, which provides the legal basis for measures to ensure the establishment and functioning of the internal market. A harmonized approach to neurotechnology regulation is essential to prevent fragmentation and ensure the proper functioning of the internal market for these technologies.
- Article 168 TFEU, which concerns public health, is relevant to the medical applications of neurotechnology.
- Article 169 TFEU, regarding consumer protection, applies to consumer applications of neurotechnology.
- Article 4(2)(j) TFEU, which establishes shared competence between the Union and Member States in the area of common safety concerns in public health matters.

2.2. Subsidiarity (for non-exclusive competence)

The principle of subsidiarity, as set out in Article 5(3) of the Treaty on European Union (TEU), is respected by this Regulation.

The objectives of this Regulation cannot be sufficiently achieved by Member States acting individually for the following reasons:

1. **Cross-border nature**: Neurotechnology development, deployment, and use frequently cross national boundaries. Divergent national regulations would fragment the internal market and create legal uncertainty.
2. **Harmonized protection**: Only action at the Union level can ensure a consistent level of protection for neurocognitive rights across all Member States.
3. **Regulatory efficiency**: A unified regulatory approach prevents duplicative regulatory burdens that would arise from multiple national regulatory systems.
4. **Global positioning**: A united European approach strengthens the EU's position in establishing global standards for neurotechnology governance.
5. **Pooled expertise**: The specialized technical and ethical expertise required for effective neurotechnology regulation is most efficiently mobilized at the Union level.

Action at the Union level will better achieve the objectives of this Regulation through:

1. Establishing a single set of rules applicable throughout the Union;
2. Creating regulatory coherence and predictability for technology developers;
3. Ensuring equal protection of neurocognitive rights for all Union citizens;
4. Preventing regulatory arbitrage between Member States;
5. Enabling coordinated research and development prioritization.

2.3. Proportionality

This Regulation complies with the principle of proportionality as set out in Article 5(4) TEU. It does not go beyond what is necessary to achieve the objectives of establishing adequate

protections for neurocognitive rights and creating an appropriate regulatory framework for neurotechnology.

The Regulation employs a risk-based approach, calibrating regulatory requirements according to the level of risk presented by different neurotechnology applications. This ensures that regulatory burdens are proportionate to potential harms.

The Regulation preserves flexibility for Member States in several domains:

1. Implementation of specialized judicial mechanisms according to national legal traditions;
2. Adaptation of enforcement mechanisms to existing national administrative structures;
3. Integration of neurocognitive rights protections within existing fundamental rights frameworks;
4. Establishment of additional protections that do not contravene the harmonized approach.

The Regulation focuses on establishing essential requirements rather than prescribing detailed technical specifications, allowing for innovation while ensuring core protections.

2.4. Choice of the instrument

A Regulation, rather than a Directive, is the appropriate legal instrument for this initiative for several reasons:

1. **Direct applicability**: A Regulation ensures uniform application across all Member States without requiring national transposition, which is essential for the effective protection of neurocognitive rights.
2. **Legal certainty**: Given the novel nature of neurocognitive rights and neurotechnology regulation, a Regulation provides immediate clarity on applicable rules.
3. **Rapid technological evolution**: The direct applicability of a Regulation allows for more timely protection in a field characterized by rapid technological advancement.
4. **Harmonized implementation**: A Regulation prevents divergent implementation that could lead to uneven protection of neurocognitive rights or fragmentation of the internal market.
5. **Cross-border dimensions**: The cross-border nature of neurotechnology development and deployment requires the uniform protection that a Regulation provides.

The Regulation is complemented by implementing and delegated acts where technical specifications or evolving standards require more flexible updating mechanisms.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

3.1. Stakeholder consultations

The Commission conducted extensive consultations with a diverse range of stakeholders between January 2023 and December 2024. These consultations included:

- **Public consultation**: An open public consultation gathered 3,782 responses from citizens, civil society organizations, academic institutions, industry representatives, and public authorities across all Member States.
- **Targeted stakeholder workshops**: Twelve specialized workshops brought together experts from neuroscience, ethics, law, industry, medicine, consumer protection, and human rights.
- **Technical expert groups**: Four technical expert groups composed of leading researchers and practitioners in neurotechnology, neuroethics, data protection, and medical regulation convened regularly over 18 months.
- **Member State consultations**: Dedicated consultations with Member State representatives through the Council working groups and specialized national regulatory authorities.
- **Industry engagement**: Structured dialogues with neurotechnology developers, from startups to established medical device companies.
- **Civil society forum**: A dedicated forum for civil society organizations focused on digital rights, patient advocacy, and disability rights.

Key feedback from stakeholders included:

1. **Balance of innovation and protection**: Strong consensus on the need to balance innovation in neurotechnology with robust protections for individuals.
2. **Regulatory clarity**: Industry stakeholders emphasized the importance of clear, predictable regulatory frameworks to guide investment and development.
3. **Rights-based approach**: Civil society organizations advocated for a rights-based approach that recognizes the unique nature of neural data and cognitive processes.
4. **Graduated regulation**: Broad support for a risk-based approach that calibrates regulatory requirements according to potential harm.
5. **International alignment**: Recognition of the need for European leadership while ensuring compatibility with international frameworks.
6. **Inclusivity**: Emphasis on ensuring that neurotechnology governance reflects diverse perspectives, particularly from potentially vulnerable groups and persons with disabilities.
7. **Adaptability**: Acknowledgment of the need for a regulatory framework that can evolve as neurotechnology capabilities advance.

This Regulation incorporates this stakeholder feedback through its risk-based approach, recognition of neurocognitive rights as a distinct category, establishment of specialized regulatory mechanisms, and provisions for ongoing stakeholder involvement in governance.

3.2. Collection and use of expertise

The Commission drew upon extensive scientific and technical expertise in developing this Regulation:

- **Scientific Advisory Committee on Neurotechnology**: A multidisciplinary committee of leading scientists advised on the current state and future trajectory of neurotechnology capabilities.
- **European Brain Research Area**: Insights from the coordinated European brain research community informed understanding of neuroscientific developments.
- **European Group on Ethics in Science and New Technologies**: Ethical dimensions were explored through dedicated opinions on neurotechnology and cognitive rights.
- **Joint Research Centre**: Technical analyses of neurotechnology applications and their potential impacts.
- **European Data Protection Board**: Expertise on the relationship between neural data protection and existing data protection frameworks.
- **European Union Agency for Fundamental Rights**: Analysis of fundamental rights implications of neurotechnology.
- **Academic research**: Comprehensive review of academic literature on neuroethics, neurotechnology regulation, and cognitive rights.
- **International frameworks**: Examination of emerging international standards and frameworks for neurotechnology governance.
- **Industry technical standards**: Analysis of industry-developed technical standards for neurotechnology interoperability and safety.

This expertise informed key aspects of the Regulation, including:

1. The technical classification of neurotechnology categories;
2. The risk assessment framework for different applications;
3. The specific protections required for neural data;
4. The appropriate boundaries between prohibited and permitted uses;
5. The technical standards for security and safety requirements.

3.3. Impact assessment

The Commission conducted a comprehensive impact assessment that examined the potential economic, social, and fundamental rights impacts of different policy options. The impact assessment report (SWD(2025) 87 final) and its executive summary (SWD(2025) 88 final) are published alongside this proposal.

The impact assessment evaluated four policy options:

Option 1: Self-regulation and existing frameworks This option would rely on industry self-regulation complemented by application of existing regulatory frameworks such as the GDPR and MDR to neurotechnology.

Option 2: Targeted amendments to existing legislation This option would introduce neurotechnology-specific amendments to existing legal instruments without creating a dedicated comprehensive framework.

Option 3: Comprehensive regulatory framework (preferred option) This option would establish a dedicated Regulation for neurocognitive rights and neurotechnology regulation, including specialized institutional mechanisms.

Option 4: Prohibitive approach This option would significantly restrict neurotechnology development and applications through prohibitions and strict limitations.

The impact assessment concluded that Option 3 would most effectively balance the protection of neurocognitive rights with support for responsible innovation. This option was determined to:

1. Provide the strongest protection for fundamental rights while enabling beneficial neurotechnology applications;
2. Create legal certainty for all stakeholders;
3. Prevent fragmentation of the internal market;
4. Establish the EU as a global leader in neurotechnology governance;
5. Support European competitiveness in neurotechnology development;
6. Create a sustainable governance framework adaptable to technological evolution.

The Regulatory Scrutiny Board issued a positive opinion on the impact assessment on 15 March 2025, with recommendations that were incorporated into the final proposal.

3.4. Regulatory fitness and simplification

This Regulation aims to establish a clear, coherent regulatory framework that minimizes unnecessary administrative burdens while ensuring effective protection of neurocognitive rights. Key simplification measures include:

1. **Single regulatory framework**: This Regulation creates a unified framework for neurotechnology, preventing the need for compliance with multiple, potentially inconsistent regulatory regimes.
2. **One-stop shop mechanism**: The European Neurotechnology Regulatory Authority will serve as a coordinating body for cross-border matters, simplifying compliance for operators active in multiple Member States.
3. **Risk-based approach**: Regulatory requirements are calibrated according to risk levels, ensuring proportionate obligations that do not unnecessarily burden low-risk applications.
4. **Coherence with existing frameworks**: This Regulation is designed to work coherently with existing frameworks such as the GDPR and MDR, reducing duplicative compliance requirements.
5. **Digital-by-default procedures**: Administrative procedures established by this Regulation will be digital by default, reducing paperwork and administrative costs.

6. **SME considerations**: The Regulation includes specific provisions to support compliance by SMEs, including simplified procedures and technical assistance.

7. **Transitional provisions**: Appropriate transition periods are established to allow for adaptation without disruption to existing services.

The Regulation has been designed with particular attention to its impact on research and innovation, ensuring that legitimate scientific advancement is not unduly hindered while establishing necessary ethical boundaries.

4. BUDGETARY IMPLICATIONS

The implementation of this Regulation will have the following budgetary implications for the Union:

1. **European Neurotechnology Regulatory Authority**: Establishment and operation of this new body will require staff, facilities, and operational funding estimated at €25 million annually after an initial setup phase.

2. **European Neurocognitive Rights Court**: Support for the specialized judicial mechanisms will require approximately €15 million annually.

3. **Research and standardization**: Development of technical standards, research into neural data protection methods, and support for ethics-by-design approaches will require approximately €30 million annually through Horizon Europe and the Digital Europe Programme.

4. **Support for Member State implementation**: Technical assistance to Member States for implementation is estimated at €10 million annually during the initial implementation phase.

5. **International coordination**: Activities to promote international alignment of neurotechnology governance standards will require approximately €5 million annually.

A detailed financial statement is attached to this proposal, outlining specific resource requirements and their allocation over the 2026-2030 period.

Member States will also incur costs for the implementation of national aspects of this Regulation, including establishment of national competent authorities, training of specialized judiciary, and enforcement mechanisms. These costs are expected to be offset in the medium term by the benefits of a harmonized approach that prevents costlier fragmentation of regulatory approaches.

5. OTHER ELEMENTS

5.1. Implementation plans and monitoring, evaluation and reporting arrangements

The implementation of this Regulation will be supported by a comprehensive plan that includes:

1. **Phased implementation**: Key provisions will be implemented according to a staged timeline, allowing for adequate preparation:

- Establishment of the European Neurotechnology Regulatory Authority: 6 months after entry into force
- Baseline neurocognitive rights protections: 12 months after entry into force
- Full regulatory framework for high-risk applications: 24 months after entry into force
- Specialized judicial mechanisms: 36 months after entry into force

2. **Implementation support**: The Commission will provide:
   - Detailed guidance documents for different stakeholder groups
   - Technical assistance to Member States
   - Training programmes for national authorities
   - Support tools for neurotechnology developers and users
3. **Monitoring mechanisms**: The implementation and effects of this Regulation will be monitored through:
   - Annual reporting by the European Neurotechnology Regulatory Authority
   - Biennial surveys of neurotechnology stakeholders
   - Tracking of neurocognitive rights cases through the specialized judicial mechanisms
   - Monitoring of neurotechnology development and deployment patterns
4. **Evaluation framework**: The Commission will:
   - Conduct an interim evaluation three years after full application
   - Conduct a comprehensive evaluation five years after full application
   - Establish a permanent expert monitoring group to provide ongoing assessment
5. **Key performance indicators**: Evaluation will assess:
   - Level of protection for neurocognitive rights across the Union
   - Clarity and effectiveness of the regulatory framework
   - Impact on neurotechnology innovation
   - Administrative burden on stakeholders
   - Effectiveness of enforcement mechanisms
   - International influence of the European approach

The Commission will report to the European Parliament and Council on the results of these evaluations and, if necessary, present proposals for amendments to this Regulation.

5.2. Detailed explanation of the specific provisions of the proposal

The Regulation is structured in fourteen titles:

Title I: General Provisions Establishes the subject matter, scope, and definitions. This Title clarifies the Regulation's relationship with other legal instruments and sets out key principles.

Title II: Neurocognitive Rights Defines and establishes the specific neurocognitive rights protected under the Regulation, including cognitive liberty, mental privacy, cognitive identity integrity, and equitable access to cognitive augmentation.

Title III: Classification and Risk Assessment of Neurotechnology Establishes a classification system for neurotechnology and a framework for assessing risks associated with different applications.

Title IV: Prohibited Practices Defines neurotechnology applications and practices that are prohibited within the European Union due to their incompatibility with fundamental rights.

Title V: Requirements for High-Risk Neurotechnology Sets out specific requirements for neurotechnology applications classified as high-risk, including technical standards, safety measures, and transparency obligations.

Title VI: Obligations of Providers and Users Establishes the obligations of different actors in the neurotechnology ecosystem, from developers to end-users.

Title VII: Neural Data Governance Provides specific rules for the collection, processing, storage, and sharing of neural data, complementing and extending the GDPR framework.

Title VIII: Conformity Assessment and Certification Establishes procedures for assessing conformity with the Regulation's requirements and certification mechanisms.

Title IX: European Neurotechnology Regulatory Authority Creates a dedicated regulatory authority to oversee implementation, coordinate between national authorities, and adapt standards as technology evolves.

Title X: Specialized Judicial Mechanisms Establishes specialized judicial mechanisms for adjudicating cases involving neurocognitive rights.

Title XI: Market Surveillance and Enforcement Sets out provisions for effective oversight of the neurotechnology market and enforcement of the Regulation.

Title XII: International Coordination Addresses the global dimensions of neurotechnology governance and establishes mechanisms for international cooperation.

Title XIII: Delegated Acts and Implementation Provides for the adoption of delegated and implementing acts to supplement the Regulation.

Title XIV: Final Provisions Contains provisions on penalties, evaluation and review, and entry into force.

The Annexes to the Regulation provide technical specifications, risk assessment methodologies, and procedural details that complement the main text.

HAVE ADOPTED THIS REGULATION:

TITLE I: GENERAL PROVISIONS

Article 1: Subject matter and purpose

1. This Regulation lays down: (a) Rules establishing neurocognitive rights as a protected category of rights within the European Union; (b) A harmonized regulatory framework for the development, deployment, and use of neurotechnology; (c) Prohibitions on certain applications of neurotechnology deemed incompatible with fundamental rights; (d) Specific requirements for high-risk neurotechnology applications; (e) Rules for the governance of neural data; (f) Provisions for the establishment of specialized judicial mechanisms for neurocognitive rights cases; (g) Provisions for the establishment of the European Neurotechnology Regulatory Authority.

2. The purpose of this Regulation is to: (a) Protect the neurocognitive rights of natural persons; (b) Ensure a high level of protection for human dignity, privacy, and autonomy in relation to neurotechnology; (c) Establish conditions under which neurotechnology may be developed and used in compliance with Union values and fundamental rights; (d) Prevent fragmentation of the internal market for neurotechnology; (e) Foster responsible innovation in neurotechnology that respects ethical boundaries; (f) Establish the European Union as a global leader in the ethical governance of neurotechnology.

3. This Regulation is without prejudice to Union law on data protection, medical devices, artificial intelligence, consumer protection, non-discrimination, and fundamental rights.

Article 2: Scope

1. This Regulation applies to: (a) The development, placing on the market, putting into service, and use of neurotechnology within the Union; (b) Providers of neurotechnology, regardless of whether they are established within the Union or in a third country; (c) Users of neurotechnology located within the Union; (d) Providers and users of neurotechnology located in a third country, where the output of the system is used in the Union.

2. This Regulation applies to neurotechnology used in both public and private sectors and for both commercial and non-commercial purposes.

3. This Regulation applies to neurotechnology used in all contexts, including but not limited to healthcare, research, education, employment, criminal justice, consumer applications, and military applications subject to Article 2(6).

4. This Regulation does not apply to: (a) Neurotechnology used exclusively for national security purposes by national security agencies; (b) Neurotechnology used exclusively in the context of military activities where exclusively subject to international humanitarian law; (c) Research on neurotechnology conducted in controlled laboratory settings that does not involve deployment with human subjects, subject to the provisions on research ethics in Article 76.

5. Without prejudice to paragraph 4, this Regulation shall apply to neurotechnology used by law enforcement, border management, or migration authorities.

6. This Regulation is without prejudice to the competences of the Member States regarding activities concerning public security, defense, and national security in accordance with Union law.

Article 3: Definitions

For the purposes of this Regulation, the following definitions apply:

1. **'Neurotechnology'** means any device, method, or system that enables direct monitoring, recording, stimulation, or modulation of neural activity, or that enables the extraction, processing, or interpretation of neural data.
2. **'Neural data'** means any data obtained directly or indirectly from the measurement or monitoring of the structure or function of the brain or nervous system, or data that reflects cognitive processes or mental states.
3. **'Neurocognitive rights'** means the rights of individuals with respect to the protection of their neural data, cognitive processes, mental privacy, cognitive liberty, and cognitive identity integrity.
4. **'Cognitive liberty'** means the right of individuals to autonomous control over their own cognitive functions, mental processes, and consciousness, including the freedom to control their own cognitive processes and mental life without external intrusion, manipulation, or interference.
5. **'Mental privacy'** means the right of individuals to keep their thoughts, emotions, preferences, and cognitive processes private and protected from unauthorized access, collection, or disclosure.
6. **'Cognitive identity integrity'** means the right of individuals to maintain the continuity and authenticity of their cognitive processes and sense of self, protected from unauthorized alterations.
7. **'Brain-computer interface'** means any technology that establishes a direct communication pathway between a brain and an external device, system, or interface.
8. **'Invasive neurotechnology'** means neurotechnology that requires physical insertion into or contact with the brain or nervous system, including but not limited to implanted electrodes, neural dust, or intravenous nanobots designed to interact with neural tissue.
9. **'Non-invasive neurotechnology'** means neurotechnology that does not require physical insertion into or contact with the brain or nervous system, including but not limited to electroencephalography (EEG), functional magnetic resonance imaging (fMRI), functional near-infrared spectroscopy (fNIRS), and transcranial magnetic stimulation (TMS).
10. **'Neural recording'** means the measurement, monitoring, or recording of neural activity, whether through invasive or non-invasive means.
11. **'Neurostimulation'** means the application of electromagnetic, electrical, magnetic, or other energy to neural tissue for the purpose of modulating neural activity.

12. **'Neural decoding'** means the process of interpreting neural data to infer mental states, cognitive processes, intentions, emotions, or other information about an individual's cognitive activity.

13. **'Provider'** means any natural or legal person, public authority, agency or other body that develops neurotechnology with a view to placing it on the market or putting it into service under its own name or trademark, whether for payment or free of charge.

14. **'User'** means any natural or legal person, public authority, agency or other body using neurotechnology under its authority, except where the neurotechnology is used in the course of a personal non-professional activity.

15. **'Individual'** means a natural person who is the subject of neural data collection or processing, or who is directly affected by the operation of neurotechnology.

16. **'Informed neural consent'** means consent for the use of neurotechnology or the processing of neural data that meets all the conditions of consent under Article 4(11) of Regulation (EU) 2016/679, with additional specific considerations for the unique nature of neural data.

17. **'High-risk neurotechnology'** means neurotechnology classified as high-risk in accordance with Article 17 of this Regulation.

18. **'Neural security'** means the protection of neural data and neurotechnology systems from unauthorized access, use, disclosure, disruption, modification, or destruction.

19. **'Neural data breach'** means a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorized disclosure of, or access to, neural data transmitted, stored or otherwise processed.

20. **'Neural fingerprint'** means a distinctive pattern of neural activity that can be used to identify an individual.

21. **'Cognitive bias'** means a systematic pattern of deviation from norm or rationality in judgment or decision-making that occurs due to the specific way information is processed by the brain.

22. **'Neuromarketing'** means the application of neurotechnology to measure and influence consumer behavior and decision-making processes.

23. **'Therapeutic neurotechnology'** means neurotechnology used for the diagnosis, prevention, monitoring, treatment, or alleviation of disease, injury, or disability.

24. **'Cognitive augmentation'** means the use of neurotechnology to enhance, modify, or improve cognitive capabilities beyond typical functioning.

25. **'Specialized judicial mechanism'** means a court, tribunal, or other judicial body with specific expertise and jurisdiction over cases involving neurocognitive rights.

26. **'European Neurotechnology Regulatory Authority'** means the Union body established pursuant to Article 80 of this Regulation.

27. **'National competent authority'** means the authority or authorities designated by a Member State to implement and enforce this Regulation.

28. **'Neural data processing'** means any operation or set of operations which is performed on neural data or on sets of neural data, whether or not by automated means.

29. **'Neural data controller'** means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of neural data.

30. **'Conformity assessment'** means the process of verifying whether the requirements set out in this Regulation relating to neurotechnology have been fulfilled.

31. **'Conformity assessment body'** means a body that performs conformity assessment activities, including calibration, testing, certification and inspection.

32. **'Notified body'** means a conformity assessment body designated in accordance with this Regulation.

33. **'Serious incident'** means any incident that directly or indirectly causes, might have caused, or might cause significant harm to an individual's neurocognitive rights, health, safety, or fundamental rights.

34. **'Neurotechnology impact assessment'** means a systematic process to evaluate the potential impacts of neurotechnology on individuals' rights and freedoms, particularly neurocognitive rights.

35. **'Neural data trust'** means a governance framework that establishes independent stewardship of neural data with fiduciary responsibilities toward the individuals whose neural data is held in trust.

36. **'Neurofeedback'** means the process of providing real-time feedback to an individual about their own neural activity to enable self-regulation of brain function.

37. **'Neural state'** means the configuration of brain activity at a given moment, which may correlate with mental states, cognitive processes, or emotional experiences.

38. **'Neural profile'** means a collection of neural data or derived inferences that characterize an individual's patterns of brain activity, cognitive processes, or mental states.

39. **'Neural firewall'** means technical measures designed to protect an individual's neural system from unauthorized external influence or access.

40. **'Technical specification'** means a document that prescribes technical requirements to be fulfilled by neurotechnology.

Article 4: Relationship with other Union law and national law

1. Where a specific provision of Union law applies to a specific aspect of neurotechnology or neural data processing covered by this Regulation, that specific provision shall apply to that specific aspect. This Regulation shall complement such specific provisions of Union law.

2. This Regulation shall not affect the application of: (a) Regulation (EU) 2016/679; (b) Directive 2002/58/EC; (c) Regulation (EU) 2017/745; (d) Regulation (EU) 2022/1925; (e) [Artificial Intelligence Act].

3. Where neurotechnology qualifies as a medical device under Regulation (EU) 2017/745, it shall comply with both that Regulation and this Regulation. Where the requirements of this Regulation conflict with the requirements of Regulation (EU) 2017/745, the requirements of Regulation (EU) 2017/745 shall prevail in relation to risk management, technical documentation, and conformity assessment.

4. This Regulation shall not affect Member State competence for matters pertaining to public security, defense, or national security.

5. Member States may maintain or introduce national provisions that provide a higher level of protection for neurocognitive rights than that provided by this Regulation, provided that such provisions are compatible with Union law and do not restrict or hinder the free movement of neurotechnology within the internal market.

6. Member States shall notify the Commission of any national provisions adopted pursuant to paragraph 5, and the Commission shall make such information publicly available.

Article 5: Basic principles

The development, deployment, and use of neurotechnology within the Union shall be guided by the following principles:

1. **Human dignity**: Neurotechnology shall respect the inherent dignity of all human beings and shall not be used in a manner that degrades, objectifies, or instrumentalizes individuals.

2. **Human autonomy**: Neurotechnology shall preserve and enhance human autonomy and agency, respecting individuals' capacity to make free and informed decisions about their cognitive processes.

3. **Cognitive liberty**: Individuals have the right to autonomous control over their own cognitive functions, mental processes, and consciousness, including the freedom from unwanted or unauthorized manipulation.

4. **Mental privacy**: Neural data shall be subject to the highest standards of privacy protection, recognizing the intimate nature of information derived from cognitive processes.

5. **Non-discrimination**: Neurotechnology shall not be developed or used in ways that discriminate against individuals or groups based on protected characteristics.

6. **Benefit to humanity**: The development of neurotechnology should prioritize applications that benefit human health, well-being, and flourishing.

7. **Justice and fairness**: The benefits and risks of neurotechnology should be distributed fairly across society, with special attention to preventing new forms of inequality or exploitation.

8. **Transparency**: The capabilities, limitations, and operations of neurotechnology should be transparently communicated to individuals and society.

9. **Accountability**: Those who develop, deploy, or use neurotechnology shall be accountable for its impacts on individuals and society.

10. **Security**: Neurotechnology shall be developed and deployed with robust security measures to prevent unauthorized access, influence, or control.

11. **Scientific integrity**: Research and development in neurotechnology shall adhere to the highest standards of scientific integrity and ethical research practices.

12. **International cooperation**: The governance of neurotechnology shall be coordinated internationally to establish consistent ethical standards while respecting cultural diversity.

TITLE II: NEUROCOGNITIVE RIGHTS

Article 6: Right to cognitive liberty

1. Every person has the right to cognitive liberty, which includes: (a) The right to autonomous control over their own cognitive functions, mental processes, and consciousness; (b) The right to freedom from external intrusion, manipulation, or interference with their cognitive processes without their informed neural consent; (c) The right to freedom of thought, including the right to keep one's thoughts private or to express them freely; (d) The right to psychological continuity, including protection from disruptions to one's sense of self or personal identity through neurotechnological intervention.

2. Limitations to the right to cognitive liberty may be imposed only if they are: (a) Provided for by law; (b) Necessary in a democratic society; (c) Proportionate to a legitimate aim; (d) Subject to appropriate safeguards; (e) Limited to the following circumstances: (i) To protect the fundamental rights and freedoms of others; (ii) To prevent imminent and serious harm to the individual or others; (iii) For legitimate medical treatments with informed neural consent, or in emergency medical situations where consent cannot be obtained; (iv) For properly authorized law enforcement purposes, subject to judicial oversight, solely in cases of serious criminal offenses and in accordance with Article 55.

3. Any limitation of the right to cognitive liberty must be implemented in a manner that: (a) Preserves the essence of the right; (b) Is subject to prior judicial authorization where feasible; (c) Is subject to effective remedies; (d) Is subject to rigorous monitoring and evaluation.

4. Specific provisions relating to cognitive liberty in special circumstances: (a) In medical contexts, therapeutic neurotechnology may be used with informed neural consent or, in emergency situations, according to the best interests of the patient as determined by medical professionals and subject to review. (b) In research contexts, experimental neurotechnology may be used with informed neural consent and ethical approval, subject to the additional protections in Article 76. (c) In educational contexts, neurotechnology may be used to support learning with appropriate informed neural consent, but not for coercive cognitive manipulation.

(d) In employment contexts, neurotechnology may not be required as a condition of employment or advancement except in narrowly defined high-risk occupations where public safety concerns predominate and subject to specific protections in Article 54.

Article 7: Right to mental privacy

1. Every person has the right to mental privacy, which includes: (a) The right to keep their thoughts, emotions, preferences, and cognitive processes private and protected from unauthorized access, collection, or disclosure; (b) The right to control the collection, use, and sharing of their neural data; (c) The right to protection from technologies designed to access, decode, or interpret mental states without informed neural consent.

2. Neural data shall be considered a special category of personal data and shall receive the highest level of protection under this Regulation, complementing and extending the protections provided by Regulation (EU) 2016/679.

3. Specific protections for mental privacy include: (a) A prohibition on the involuntary collection of neural data except in narrowly defined circumstances as specified in Article 6(2)(e); (b) A requirement for specific, informed neural consent for the collection and processing of neural data; (c) A right to withdraw consent for the continued collection and processing of neural data; (d) Enhanced security requirements for the storage and transmission of neural data; (e) Limitations on the inferences that may be drawn from neural data; (f) Restrictions on the sharing and transfer of neural data; (g) Measures to prevent the re-identification of anonymized neural data; (h) A right to erasure of neural data subject to legitimate exemptions.

4. The right to mental privacy applies to both direct neural data and to data or inferences derived from neural data.

5. Member States may provide for derogations to the right to mental privacy only when strictly necessary and proportionate for the purposes specified in Article 6(2)(e), and subject to appropriate safeguards.

6. Mental privacy protections extend to: (a) Neural data collected through invasive neurotechnology; (b) Neural data collected through non-invasive neurotechnology; (c) Inferences drawn from neural data; (d) Data derived from neural data through processing or analysis; (e) Neural profiles or patterns that characterize an individual's cognitive processes.

Article 8: Right to cognitive identity integrity

1. Every person has the right to cognitive identity integrity, which includes: (a) The right to maintain the continuity and authenticity of their cognitive processes and sense of self; (b) The right to protection from unauthorized or involuntary alterations to neural processes that substantively impact identity; (c) The right to psychological and narrative continuity of self; (d) The right to protection from algorithmic or technological determination of identity based on neural data.

2. Specific protections for cognitive identity integrity include: (a) Prohibition of neurotechnology applications that substantially alter a person's sense of agency,

personal identity, or core beliefs without informed neural consent; (b) Requirements for comprehensive disclosure of potential identity impacts before applying neurotechnology that may affect cognitive identity; (c) Enhanced consent requirements for neurotechnology that may significantly impact cognitive identity; (d) Rights to access and challenge identity-related inferences drawn from neural data; (e) Protections against identity discrimination based on neural data or profiles; (f) Recognition of the dynamic nature of identity and the right to evolve one's identity naturally over time.

3. In therapeutic contexts where neurotechnology is used to treat conditions that affect identity (such as certain psychiatric or neurological conditions), treatment shall respect the individual's identity to the greatest extent possible while addressing medical needs.

4. Identity-significant alterations through neurotechnology are permissible when: (a) There is clear, specific informed neural consent; (b) The individual has received comprehensive information about potential identity impacts; (c) The intervention serves legitimate therapeutic purposes or autonomous self-development; (d) Appropriate psychological support is available before, during, and after the intervention; (e) The individual retains the right to discontinue the intervention.

5. The development and use of neurotechnology shall respect the plurality of conceptions of identity in different cultural, philosophical, and religious traditions.

Article 9: Right to equitable access to neurotechnology

1. Every person has the right to equitable access to beneficial neurotechnology, which includes: (a) The right to access therapeutic neurotechnology for recognized medical conditions without discrimination; (b) The right to non-discriminatory participation in approved research involving neurotechnology; (c) The right to benefit from advancements in neurotechnology that significantly enhance quality of life.

2. Member States shall develop policies to promote: (a) Equitable access to therapeutic neurotechnology through healthcare systems; (b) Research into neurotechnology applications for underserved populations and conditions; (c) Reduction of economic, social, geographical, and cultural barriers to accessing beneficial neurotechnology; (d) Universal design principles in neurotechnology development; (e) Digital literacy programmes to enable informed participation in neurotechnology.

3. The right to equitable access shall be implemented progressively, taking into account: (a) Available resources; (b) Technical feasibility; (c) Risk-benefit assessments; (d) Priority for therapeutic applications.

4. Measures to promote equitable access shall include: (a) Development of affordable neurotechnology solutions; (b) Public funding for research addressing conditions affecting disadvantaged populations; (c) Training of healthcare providers in neurotechnology applications; (d) Policies to prevent the emergence of cognitive divides based on differential access to enhancement neurotechnology.

5. This right shall not be interpreted as creating an immediate entitlement to specific neurotechnology services or products, but rather as establishing a framework for progressive realization of equitable access.

Article 10: Right to protection from neurodiscrimination

1. Every person has the right to protection from discrimination based on: (a) Neural data; (b) Neural profiles; (c) Cognitive traits detectable through neurotechnology; (d) Use or non-use of neurotechnology; (e) Neurological or cognitive characteristics.

2. Prohibited forms of neurodiscrimination include: (a) Denial of employment, education, housing, insurance, financial services, or other opportunities based solely on neural data or profiles; (b) Imposition of unwarranted disadvantages based on cognitive characteristics detected through neurotechnology; (c) Mandatory neurotechnological assessment as a prerequisite for basic rights or services; (d) Algorithmic discrimination based on inferences from neural data; (e) Creation of disadvantageous categories based on neural traits without scientific validity or legitimate purpose.

3. The right to protection from neurodiscrimination extends to both direct discrimination (treating a person less favorably based on neural data or characteristics) and indirect discrimination (applying apparently neutral provisions, criteria, or practices that disadvantage persons with certain neural characteristics).

4. Legitimate differentiations based on neural data may be permissible only when: (a) Objectively justified by a legitimate aim; (b) Based on scientifically valid methods and data; (c) Proportionate to that aim; (d) Necessary in a democratic society; (e) Subject to appropriate safeguards.

5. Member States shall ensure effective remedies for victims of neurodiscrimination, including: (a) Judicial and administrative procedures; (b) Appropriate sanctions for proven cases of neurodiscrimination; (c) Compensation for material and non-material damages; (d) Mechanisms to challenge discriminatory decisions based on neural data.

6. Equality bodies established under Union anti-discrimination law shall be competent to address cases of neurodiscrimination and shall receive appropriate training on neurotechnology and neurocognitive rights.

Article 11: Right to neural security

1. Every person has the right to neural security, which includes: (a) The right to protection from unauthorized access to their neural systems through neurotechnology; (b) The right to protection from malicious interference with neurotechnology upon which they depend; (c) The right to robust security measures for any neurotechnology that interacts with their neural systems; (d) The right to protection from neural hacking, unauthorized neurostimulation, or other forms of brain-targeted cyberattacks.

2. Providers of neurotechnology shall implement appropriate technical and organizational measures to ensure a level of neural security appropriate to the risk, including: (a) State-of-the-art encryption for neural data; (b) Authentication

mechanisms to prevent unauthorized access; (c) Secure transmission protocols for neural data; (d) Intrusion detection systems specific to neurotechnology; (e) Regular security audits and vulnerability assessments; (f) Secure update mechanisms; (g) Technical measures to ensure fail-safe operation during security breaches; (h) Neural firewalls for invasive or connected neurotechnology.

3. Specific neural security requirements for different categories of neurotechnology shall be further specified in delegated acts adopted by the Commission pursuant to Article 121.

4. Users of neurotechnology shall be provided with: (a) Clear information about neural security risks; (b) Actionable guidance on securing their neurotechnology; (c) Prompt notification of neural security breaches that may affect them; (d) Means to verify the security status of their neurotechnology.

5. Neural security breaches shall be subject to mandatory reporting requirements as specified in Article 97.

6. Member States shall establish specialized capacity within their cybersecurity agencies to address neural security threats and shall cooperate through the European Union Agency for Cybersecurity (ENISA) to develop harmonized approaches to neural security.

Article 12: Right to neurotechnology transparency

1. Every person has the right to transparency regarding neurotechnology, which includes: (a) The right to know when they are subject to neurotechnology; (b) The right to understandable information about the capabilities, limitations, and potential risks of neurotechnology; (c) The right to know what neural data is being collected, how it is being processed, and for what purposes; (d) The right to information about the algorithms used to analyze or interpret neural data; (e) The right to know the identity of the neural data controller and any third parties with whom neural data may be shared.

2. Providers of neurotechnology shall ensure transparency by: (a) Providing clear, accessible documentation on the functioning of their neurotechnology; (b) Disclosing known limitations, potential risks, and appropriate use cases; (c) Making technical specifications available to competent authorities for verification; (d) Providing users with interfaces that clearly indicate when the neurotechnology is active; (e) Maintaining logs of neural data processing activities.

3. Users of neurotechnology in institutional contexts shall: (a) Provide clear notice when neurotechnology is in operation; (b) Explain in accessible language what neural data is being collected and why; (c) Obtain informed neural consent when required by this Regulation; (d) Make information available about recourse mechanisms for individuals who believe their neurocognitive rights have been violated.

4. Special transparency requirements apply to: (a) Commercial applications of neurotechnology, which must disclose when neural data is used for commercial purposes such as personalization, prediction, or profiling; (b) Public sector applications, which must maintain public registers of neurotechnology use except

where limited exceptions for public security apply; (c) Research applications, which must clearly delineate experimental aspects and potential uncertainties.

5. The right to transparency may be limited only in exceptional circumstances where full disclosure would: (a) Significantly undermine public security in a manner that can be demonstrated by the competent authority; (b) Fundamentally compromise the efficacy of therapeutic neurotechnology for specific well-documented medical reasons; (c) Substantially impair legitimate research objectives in a manner that cannot be mitigated through alternative transparency measures.

6. Even when full transparency is limited under paragraph 5, basic information about the presence and general purpose of neurotechnology must still be provided, and complete information must be available to oversight bodies.

Article 13: Right to explanation of neurotechnology decisions

1. Every person has the right to meaningful explanation of decisions made or supported by neurotechnology that significantly affect them, including: (a) The right to understand the main factors that influenced a decision based on neural data; (b) The right to explanation of the logic involved in automated decisions using neural data; (c) The right to information about the reliability and validity of inferences drawn from neural data; (d) The right to contest decisions based on neural data analysis.

2. Explanations provided shall be: (a) Delivered in clear, non-technical language accessible to the individual; (b) Sufficiently detailed to enable understanding of the decision logic without overwhelming the individual; (c) Timely, provided before or at the time the decision takes effect when possible; (d) Actionable, giving the individual sufficient information to effectively exercise their right to contest the decision if desired.

3. For high-risk applications of neurotechnology as defined in Article 17, providers shall: (a) Design systems with explainability as a core requirement; (b) Develop appropriate documentation of decision logic; (c) Implement technical means to generate consistent explanations; (d) Test the comprehensibility of explanations with representative users.

4. Users of high-risk neurotechnology shall: (a) Ensure staff are trained to provide supplementary explanations when needed; (b) Maintain records of the factors considered in significant decisions; (c) Establish processes for reviewing contested decisions; (d) Provide contact points for individuals seeking additional explanation.

5. The right to explanation applies particularly to decisions regarding: (a) Access to essential services; (b) Employment and educational opportunities; (c) Healthcare treatment based on neural data; (d) Law enforcement or judicial proceedings involving neural evidence; (e) Financial or insurance decisions influenced by neural data.

6. The right to explanation may be limited only where: (a) Disclosure would reveal legitimate trade secrets that cannot be adequately protected through more limited explanations; (b) Full explanation would seriously jeopardize public security in a specific, demonstrable manner; (c) The decision has negligible impact on the individual's rights or legitimate interests.

7. Even when limitations apply under paragraph 6, individuals retain the right to: (a) Basic information about the decision process; (b) Confirmation that neural data influenced the decision; (c) Review of the decision by a human decision-maker; (d) Contest the decision through appropriate channels.

Article 14: Right to neural data portability

1. Every person shall have the right to neural data portability, which includes: (a) The right to receive their neural data from a neural data controller in a structured, commonly used, machine-readable format; (b) The right to transmit their neural data to another neural data controller without hindrance; (c) The right to have their neural data transmitted directly from one neural data controller to another, where technically feasible.

2. The right to neural data portability applies to: (a) Neural data provided knowingly and actively by the individual; (b) Neural data generated through the individual's use of neurotechnology; (c) Derived neural data and inferences to the extent technically feasible and not disproportionately impinging on the legitimate interests of the neural data controller.

3. Neural data controllers shall: (a) Develop interoperable formats for neural data to facilitate portability; (b) Establish secure transmission methods for neural data transfers; (c) Provide clear information on how to exercise data portability rights; (d) Complete portability requests without undue delay and within one month, with possible extension of two further months for complex requests; (e) Provide neural data in formats that preserve its utility and meaningful interpretability.

4. The right to neural data portability shall not adversely affect the rights and freedoms of others, including intellectual property rights and trade secrets.

5. For therapeutic neurotechnology, neural data portability shall be implemented in a manner that: (a) Ensures clinical relevance of transferred data; (b) Maintains appropriate medical context; (c) Complies with applicable healthcare interoperability standards; (d) Supports continuity of care.

6. The Commission shall support the development of standardized formats and protocols for neural data portability through the European Standardisation Organizations.

7. The right to neural data portability complements and extends the right to data portability under Article 20 of Regulation (EU) 2016/679 in its application to neural data.

Article 15: Relationship with other rights

1. The neurocognitive rights established in this Title shall: (a) Complement and extend existing fundamental rights and freedoms recognized in Union and international law; (b) Be interpreted in harmony with the Charter of Fundamental Rights of the European Union; (c) Not be construed as restricting or adversely affecting rights recognized in Union law, international law, or Member State constitutions.

2. In case of overlap between neurocognitive rights and other recognized rights, the interpretation that provides the highest level of protection to individuals shall

prevail, taking into account: (a) The unique vulnerability of neural systems; (b) The intimate connection between neural processes and personal identity; (c) The rapid evolution of neurotechnology capabilities; (d) The potential for novel forms of intrusion enabled by neurotechnology.

3. The exercise of neurocognitive rights shall respect the rights and freedoms of others and may be subject only to limitations that are: (a) Provided for by law; (b) Necessary in a democratic society; (c) Proportionate to legitimate aims; (d) Preserving the essence of the right in question.

4. The interpretation and application of neurocognitive rights shall evolve to address new challenges posed by advancing neurotechnology, guided by: (a) Scientific evidence; (b) Ethical principles; (c) Democratic deliberation; (d) Respect for human dignity.

5. Legal persons do not possess neurocognitive rights under this Regulation, but have obligations to respect the neurocognitive rights of natural persons.

Article 16: Implementation of neurocognitive rights

1. Member States shall take all necessary measures to ensure the effective implementation of the neurocognitive rights established in this Title, including: (a) Establishing or designating competent authorities with sufficient resources and expertise to monitor and enforce compliance; (b) Providing for effective judicial remedies for violations of neurocognitive rights; (c) Ensuring that remedies are accessible, affordable, timely, and effective; (d) Establishing appropriate penalties for violations; (e) Promoting awareness and understanding of neurocognitive rights among the public, professionals, and institutions.

2. The Commission shall support implementation through: (a) Developing guidance documents on the practical application of neurocognitive rights; (b) Facilitating exchange of best practices among Member States; (c) Monitoring implementation and publishing biennial reports; (d) Recommending corrective measures where implementation is inadequate; (e) Providing technical and financial support for capacity building.

3. The European Neurotechnology Regulatory Authority shall contribute to implementation by: (a) Developing technical standards and specifications relevant to neurocognitive rights protection; (b) Providing expert advice on evolving neurotechnology challenges; (c) Collecting and analyzing data on implementation; (d) Issuing recommendations to address emerging issues; (e) Facilitating coordination between national authorities.

4. Civil society organizations, academic institutions, and industry shall be encouraged to participate in implementation through: (a) Monitoring compliance; (b) Raising awareness; (c) Developing technical solutions; (d) Providing feedback on implementation challenges; (e) Contributing to the evolution of standards and best practices.

5. Implementation shall be subject to regular evaluation through: (a) Periodic assessment of the state of neurocognitive rights protection in each Member State; (b) Collection of data on reported violations and remedial actions; (c) Stakeholder

consultations; (d) Independent research on implementation effectiveness; (e) Peer review among Member States.

TITLE III: CLASSIFICATION AND RISK ASSESSMENT OF NEUROTECHNOLOGY

Article 17: Risk-based approach

1. This Regulation establishes a risk-based approach to the regulation of neurotechnology, recognizing that different applications of neurotechnology present different levels of risk to neurocognitive rights, fundamental rights, health, safety, and societal values.

2. Neurotechnology shall be classified into the following risk categories: (a) **Prohibited neurotechnology**: Applications of neurotechnology that present unacceptable risks to fundamental rights, human dignity, or democratic values and are prohibited under Title IV; (b) **High-risk neurotechnology**: Applications of neurotechnology that present significant risks to neurocognitive rights, fundamental rights, health, safety, or democratic values and are subject to the specific requirements set out in Title V; (c) **Limited-risk neurotechnology**: Applications of neurotechnology that present moderate risks and are subject to specific transparency obligations; (d) **Minimal-risk neurotechnology**: Applications of neurotechnology that present minimal risk and are subject only to the general provisions of this Regulation.

3. The classification of neurotechnology into risk categories shall be determined by: (a) The invasiveness of the technology; (b) The purpose and context of use; (c) The potential impact on neurocognitive rights and fundamental rights; (d) The categories of individuals affected; (e) The scale of deployment; (f) The level of autonomy in decision-making; (g) The nature of neural data processed; (h) The potential for surveillance, control, or manipulation; (i) The reversibility of effects; (j) The robustness of scientific evidence supporting safety and efficacy; (k) The availability of alternative methods that present lower risks.

4. The Commission shall adopt delegated acts in accordance with Article 121 to supplement this Regulation by: (a) Updating the list of prohibited neurotechnology in Article 22 to reflect technological developments and emerging risks; (b) Updating the list of high-risk neurotechnology applications in Article 23 to reflect technological developments and emerging risks; (c) Establishing detailed criteria for the classification of neurotechnology into appropriate risk categories; (d) Establishing a methodology for neurotechnology risk assessment.

5. Providers of neurotechnology shall conduct an initial risk assessment of their neurotechnology in accordance with the criteria established in this Regulation and shall classify their neurotechnology accordingly.

6. National competent authorities may review the risk classification determined by providers and may reclassify neurotechnology if they determine that the initial classification was incorrect, subject to the coordination procedure set out in Article 83.

7. The European Neurotechnology Regulatory Authority shall provide guidance on risk assessment and classification and shall maintain a public database of risk classifications for neurotechnology applications.

Article 18: Classification criteria for invasive neurotechnology

1. For the purposes of risk classification, invasive neurotechnology shall be evaluated according to: (a) The degree of invasiveness, including: (i) Surgical implantation requirements; (ii) Depth and location of neural tissue interaction; (iii) Permanence of the implant; (iv) Physical properties of the interface materials; (b) The neural regions or networks targeted, with heightened scrutiny for technologies targeting: (i) Brain regions involved in core aspects of self and identity; (ii) Brain regions involved in decision-making and autonomy; (iii) Brain regions involved in emotional processing; (iv) Brain systems involved in memory formation and retrieval; (c) The modalities of neural interaction, including: (i) Recording capabilities; (ii) Stimulation capabilities; (iii) Bidirectional interaction capabilities; (iv) Precision and selectivity of neural targeting; (d) The therapeutic or non-therapeutic purpose; (e) The established or novel nature of the technology; (f) The reversibility of effects; (g) The longevity of the intervention; (h) The control mechanisms available to the individual.

2. Invasive neurotechnology shall be classified as high-risk if it meets any of the following criteria: (a) It enables deep brain stimulation for non-therapeutic purposes; (b) It enables continuous or long-term recording of neural activity from multiple brain regions; (c) It uses novel neural interface materials with limited long-term safety data; (d) It enables automated or algorithmic control of stimulation parameters without direct medical supervision; (e) It targets brain regions implicated in core aspects of personality, identity, or decision-making; (f) It is controlled by artificial intelligence systems with significant autonomy; (g) It enables wireless transmission of neural data or receipt of stimulation commands; (h) It is intended for use outside controlled medical environments.

3. Even when used for therapeutic purposes, invasive neurotechnology shall be classified as high-risk when it: (a) Represents a novel application with limited clinical evidence; (b) Targets brain regions with significant potential for cognitive or personality effects; (c) Employs closed-loop systems with autonomous adjustment capabilities; (d) Is intended for long-term or permanent implantation; (e) Is intended for use in vulnerable populations, including children or persons with cognitive impairments.

4. Therapeutic invasive neurotechnology with established safety records and limited potential for cognitive or personality effects may be classified as limited-risk if it: (a) Has received marketing authorization as a medical device; (b) Is used under appropriate medical supervision; (c) Has clear evidence of therapeutic benefit; (d) Has well-established risk profiles.

5. The Commission shall adopt delegated acts in accordance with Article 121 to supplement this Regulation by specifying: (a) Technical parameters for assessing invasiveness; (b) Methods for evaluating potential cognitive and identity impacts; (c) Criteria for determining adequate safety evidence; (d) Standards for control and override mechanisms.

Article 19: Classification criteria for non-invasive neurotechnology (continued)

1. For the purposes of risk classification, non-invasive neurotechnology shall be evaluated according to: (d) The stimulation capabilities, including: (iii) Duration and frequency of stimulation; (iv) Potential for direct or indirect modulation of cognitive functions; (e) The level of user control and awareness, including: (i) Transparency of operation; (ii) User ability to enable or disable the technology; (iii) User understanding of capabilities and limitations; (iv) Presence of override mechanisms; (f) The potential for continuous or persistent monitoring; (g) The potential for combination with other technologies, particularly artificial intelligence; (h) The evidence base for safety and efficacy.

2. Non-invasive neurotechnology shall be classified as high-risk if it meets any of the following criteria: (a) It enables real-time decoding of specific thoughts, intentions, or mental imagery; (b) It is used in educational, employment, legal, or security contexts for assessment, selection, or monitoring purposes; (c) It is used to influence decision-making without the explicit awareness of the individual; (d) It employs neurostimulation techniques capable of significantly altering mood, cognition, or behavior; (e) It is used for continuous monitoring in non-therapeutic contexts; (f) It is used on vulnerable populations, including children, persons with cognitive disabilities, or persons in institutional settings; (g) It is integrated with artificial intelligence systems for automated interpretation or response; (h) It is used in consumer applications with limited evidence of safety and efficacy.

3. Non-invasive neurotechnology shall be classified as limited-risk if it: (a) Collects neural data of moderate sensitivity without real-time decoding of specific thoughts; (b) Provides neurofeedback for wellness, performance enhancement, or educational purposes; (c) Uses well-established stimulation methods with limited intensity; (d) Is used in consumer contexts with adequate transparency and user control; (e) Has established safety profiles but has potential for misuse if used improperly.

4. Non-invasive neurotechnology shall be classified as minimal-risk if it: (a) Collects basic neural data with low spatial and temporal resolution; (b) Does not enable identification of specific mental states beyond general categories; (c) Is used in controlled research or personal use contexts with appropriate safeguards; (d) Provides clear information about capabilities and limitations; (e) Has well-established safety profiles and minimal potential for misuse.

5. The Commission shall adopt delegated acts in accordance with Article 121 to supplement this Regulation by specifying: (a) Technical thresholds for resolution, precision, and other parameters relevant to risk assessment; (b) Criteria for evaluating user control adequacy; (c) Standards for transparency in consumer applications; (d) Methods for assessing potential for significant cognitive or behavioral influence.

Article 20: Classification criteria for neural data processing

1. For the purposes of risk classification, neural data processing shall be evaluated according to: (a) The type and sensitivity of neural data processed, including: (i) Raw neural data; (ii) Processed neural features; (iii) Neural signatures or patterns; (iv)

Derived inferences about mental states or cognitive processes; (b) The processing methods employed, including: (i) Basic statistical analysis; (ii) Machine learning algorithms; (iii) Deep neural networks; (iv) Real-time adaptive processing; (c) The purpose of processing, including: (i) Medical diagnosis or treatment; (ii) Research; (iii) User experience personalization; (iv) Behavioral prediction or influence; (d) The scale and scope of processing, including: (i) Individual-level processing; (ii) Group-level processing; (iii) Population-level processing; (iv) Cross-dataset analysis; (e) The potential for re-identification of anonymized data; (f) The potential for revealing information beyond what was knowingly provided; (g) The potential for deriving sensitive inferences about personality, preferences, or vulnerabilities; (h) The retention period and access controls.

2. Neural data processing shall be classified as high-risk if it: (a) Attempts to decode specific thoughts, intentions, or mental imagery; (b) Aims to predict individual behavior or decisions based on neural data; (c) Creates detailed neural profiles that characterize individuals; (d) Combines neural data with other personal data for comprehensive profiling; (e) Uses neural data for automated decision-making in sensitive contexts; (f) Applies novel analytical methods with uncertain validity or reliability; (g) Involves processing that may reveal information the individual did not intend to disclose; (h) Enables persistent tracking of cognitive or emotional states.

3. Neural data processing shall be classified as limited-risk if it: (a) Analyzes neural data for general patterns without attempting to decode specific thoughts; (b) Uses established analytical methods with demonstrated validity; (c) Processes data for purposes clearly communicated to and understood by individuals; (d) Implements appropriate safeguards against misuse or unauthorized access; (e) Maintains neural data processing transparency.

4. Neural data processing shall be classified as minimal-risk if it: (a) Involves basic analysis of low-sensitivity neural data; (b) Does not attempt to draw inferences about mental states or cognitive processes; (c) Is conducted on effectively anonymized data with minimal re-identification risk; (d) Is limited in scope and duration; (e) Does not involve automated decision-making.

5. The Commission shall adopt delegated acts in accordance with Article 121 to supplement this Regulation by specifying: (a) Criteria for assessing neural data sensitivity; (b) Standards for evaluating inference capabilities; (c) Methods for assessing re-identification risks; (d) Requirements for valid anonymization of neural data.

Article 21: Context-specific risk factors

1. The risk classification of neurotechnology shall take into account context-specific factors that may elevate or mitigate risks, including: (a) The setting of use, with higher risk attributed to: (i) Institutional settings with power imbalances; (ii) Educational settings, particularly involving minors; (iii) Employment contexts; (iv) Criminal justice or security contexts; (v) Consumer environments with limited user awareness; (b) The characteristics of intended users or subjects, with higher risk attributed to: (i) Vulnerable populations, including children, elderly persons, persons with disabilities, and persons in institutional care; (ii) Persons with limited technological literacy; (iii) Persons in situations of dependency or duress; (iv)

Persons targeted without their knowledge; (c) The level of user autonomy and choice, with higher risk attributed to: (i) Mandatory use scenarios; (ii) Applications with limited user control; (iii) Applications with obscured functionality; (iv) Applications where refusal has significant negative consequences; (d) The scale of deployment, with higher risk attributed to: (i) Mass deployment; (ii) Continuous or persistent use; (iii) Applications affecting large populations; (iv) Applications with network effects; (e) The potential societal impacts, with higher risk attributed to: (i) Applications that may exacerbate existing inequalities; (ii) Applications that may enable mass surveillance; (iii) Applications that may significantly alter social dynamics; (iv) Applications that may influence democratic processes.

2. The presence of robust safeguards may mitigate risk classification, including: (a) Comprehensive informed neural consent processes; (b) Independent ethical oversight; (c) Regular auditing and impact assessment; (d) Clear limitations on use; (e) Effective redress mechanisms; (f) Technical constraints on functionality; (g) Training requirements for operators; (h) Systematic evaluation of impacts.

3. The Commission shall adopt delegated acts in accordance with Article 121 to supplement this Regulation by specifying a methodology for incorporating context-specific factors into the overall risk assessment.

4. The European Neurotechnology Regulatory Authority shall provide guidance and tools to support consistent evaluation of context-specific risk factors by providers, users, and regulatory authorities.

TITLE IV: PROHIBITED PRACTICES

Article 22: Prohibition of certain neurotechnology applications

1. The following neurotechnology applications are prohibited within the European Union as incompatible with Union values, fundamental rights, and neurocognitive rights: (a) Neurotechnology designed or used for covert cognitive surveillance without consent or proper legal authorization in accordance with Article 55; (b) Neurotechnology designed or used for involuntary alteration of a person's cognitive processes, thoughts, emotions, memories, or sense of identity outside legitimate therapeutic contexts with appropriate safeguards; (c) Neurotechnology designed or used for cognitive manipulation that substantially undermines a person's autonomy, agency, or capacity for voluntary decision-making; (d) Neurotechnology designed or used to extract neural data that reveals specific thoughts, mental images, or unexpressed intentions without informed neural consent or proper legal authorization in accordance with Article 55; (e) Neurotechnology that establishes direct brain-to-brain interfaces enabling one person to control another person's neural processes without their continuous informed neural consent; (f) Neurotechnology designed or used to assess or determine legal liability based on neural data indicative of unexpressed intentions, attitudes, or predispositions; (g) Neurotechnology designed or used for automated scoring, categorization, or discrimination based on neural data in employment, education, access to essential services, or similar contexts; (h) Neurotechnology designed or used to establish technological systems that enable social scoring or mass surveillance based on neural data; (i) Neurotechnology designed or used to deploy "nudging" techniques that exploit neural vulnerabilities to manipulate behavior without the awareness of

the affected individuals; (j) Neurotechnology designed or used to induce addiction or compulsive behavior; (k) Neurotechnology designed or used to cause physical or psychological harm; (l) Neurotechnology designed or used for torture or cruel, inhuman, or degrading treatment; (m) Neurotechnology involving neural data processing that enables or facilitates discriminatory practices based on protected characteristics as defined in Article 21 of the Charter of Fundamental Rights of the European Union.

2. The prohibition under paragraph 1 shall not apply to research activities conducted under appropriate ethical oversight, provided that: (a) The research does not result in harm to research participants; (b) The research complies with all applicable ethical standards and has received approval from the relevant research ethics committee; (c) The research has legitimate scientific or medical objectives; (d) The research is conducted with appropriate safeguards to protect neurocognitive rights; (e) Informed neural consent is obtained from all research participants, where the research involves human subjects.

3. Member States shall ensure that intentional violations of the prohibitions in paragraph 1 are subject to effective, proportionate, and dissuasive penalties in accordance with Article 119.

4. The European Neurotechnology Regulatory Authority shall issue guidelines to clarify the scope of the prohibitions and to provide examples of prohibited applications to assist stakeholders in compliance.

5. The Commission shall regularly review the list of prohibited applications in light of technological developments and may adopt delegated acts in accordance with Article 121 to update the list of prohibited applications.

Article 23: High-risk neurotechnology applications

1. The following neurotechnology applications shall be classified as high-risk and shall be subject to the requirements set out in Title V: (a) Invasive neurotechnology for non-therapeutic purposes; (b) Neurotechnology used in employment contexts for selection, evaluation, promotion, or termination decisions; (c) Neurotechnology used in educational contexts for assessment, tracking, or personalization of learning for persons under 18 years of age; (d) Neurotechnology used in criminal justice or security contexts for investigation, risk assessment, or sentencing; (e) Neurotechnology used to influence consumer behavior through neural data analysis without explicit awareness of the individual; (f) Neurotechnology that enables real-time decoding of emotional states or cognitive processes for commercial or security purposes; (g) Neurotechnology that enables continuous monitoring of neural activity outside therapeutic contexts; (h) Neurotechnology that integrates artificial intelligence for automated interpretation of neural data or automated stimulation parameter adjustment; (i) Neural data processing that creates detailed individual profiles that can be used to predict behavior or preferences; (j) Neurotechnology used in insurance, banking, or credit contexts to evaluate individuals; (k) Novel neurostimulation techniques with limited evidence of long-term safety; (l) Brain-computer interfaces that enable control of external devices or systems with potential safety implications; (m) Neurotechnology deployed in public spaces capable of collecting neural data from multiple

individuals; (n) Neural interfaces that enable extended reality experiences with potential for psychological impact; (o) Neurotechnology that combines neural data with other biometric or personal data for comprehensive profiling; (p) Therapeutic neurotechnology using novel approaches without established safety profiles.

2. The Commission shall regularly review the list of high-risk applications in light of technological developments and may adopt delegated acts in accordance with Article 121 to update the list of high-risk applications.

3. Providers of neurotechnology shall assess whether their neurotechnology falls within the categories listed in paragraph 1 and shall comply with the requirements set out in Title V if it does.

4. In case of doubt as to whether a specific neurotechnology application falls within the high-risk categories, providers shall consult with the European Neurotechnology Regulatory Authority, which shall provide a non-binding opinion.

5. National competent authorities may classify additional neurotechnology applications as high-risk based on the criteria set out in Articles 18, 19, 20, and 21, subject to the coordination procedure set out in Article 83.

TITLE V: REQUIREMENTS FOR HIGH-RISK NEUROTECHNOLOGY

Article 24: Compliance with requirements for high-risk neurotechnology

1. High-risk neurotechnology shall comply with the requirements set out in this Title.

2. The requirements shall apply throughout the lifecycle of high-risk neurotechnology, including design, development, testing, deployment, use, and decommissioning.

3. Providers of high-risk neurotechnology shall implement a risk management system as set out in Article 25 and shall demonstrate compliance with the requirements through the conformity assessment procedures set out in Title VIII.

4. Providers of high-risk neurotechnology shall draw up the technical documentation referred to in Article 30 before placing the neurotechnology on the market or putting it into service.

5. Providers of high-risk neurotechnology shall implement a quality management system that ensures compliance with the requirements of this Title.

6. Providers of high-risk neurotechnology shall continuously monitor the performance of their neurotechnology after placing it on the market or putting it into service, and shall take appropriate corrective actions if necessary.

7. Users of high-risk neurotechnology shall comply with the obligations set out in Article 52.

8. The requirements of this Title are without prejudice to other applicable requirements under Union law, including those relating to medical devices, data protection, non-discrimination, and consumer protection.

Article 25: Risk management system

1. Providers of high-risk neurotechnology shall establish, implement, document, and maintain a risk management system that shall: (a) Identify and analyze known and foreseeable risks associated with the neurotechnology, including risks to neurocognitive rights, health, safety, fundamental rights, and potential societal impacts; (b) Estimate and evaluate the risks that may emerge when the high-risk neurotechnology is used in accordance with its intended purpose and under conditions of reasonably foreseeable misuse; (c) Evaluate other possibly arising risks based on the analysis of data gathered from the post-market monitoring system referred to in Article 46; (d) Adopt suitable risk management measures in accordance with paragraph 2.

2. The risk management measures shall: (a) Eliminate or reduce risks through adequate design and development; (b) Where appropriate, implement adequate mitigation and control measures in relation to risks that cannot be eliminated; (c) Provide adequate information about residual risks to users and affected individuals; (d) Establish monitoring mechanisms to continuously assess the effectiveness of risk management measures.

3. Risk management shall give specific consideration to: (a) Risks to neurocognitive rights, including cognitive liberty, mental privacy, and cognitive identity integrity; (b) Risks arising from potential technical inaccuracies, limitations, or vulnerabilities; (c) Risks associated with the collection, processing, storage, and transmission of neural data; (d) Risks arising from integration with other systems or technologies; (e) Risks of unauthorized access, use, or modification; (f) Risks to vulnerable populations; (g) Risks of unintended consequences or effects; (h) Risks associated with long-term use; (i) Risks of dependency or addiction; (j) Societal and ethical risks, including potential discriminatory impacts or exacerbation of inequalities.

4. Providers shall document the risk management system in the technical documentation referred to in Article 30 and shall regularly update it throughout the lifecycle of the high-risk neurotechnology.

5. The Commission shall adopt delegated acts in accordance with Article 121 to supplement this Regulation by specifying: (a) Methodologies for identifying, analyzing, and evaluating risks; (b) Criteria for determining the acceptability of risks; (c) Requirements for risk management documentation; (d) Procedures for continuous risk monitoring and review.

Article 26: Neural data quality and governance

1. High-risk neurotechnology involving the collection or processing of neural data shall be designed and developed in such a way as to ensure that the neural data used is: (a) Relevant, representative, and free from errors that could lead to discriminatory or harmful outcomes; (b) Examined for possible biases that could lead to prohibited discrimination; (c) Collected with informed neural consent where required by this Regulation; (d) Processed in a manner that ensures appropriate levels of security and privacy; (e) Subject to robust governance mechanisms throughout its lifecycle.

2. Neural data quality shall be ensured through: (a) Appropriate design of data acquisition protocols; (b) Implementation of data quality assurance measures; (c) Regular validation of data acquisition and processing methods; (d) Documentation

of data sources, acquisition methods, and processing techniques; (e) Technical measures to identify and address data artifacts and anomalies; (f) Monitoring for systematic biases or distortions.

3. Providers of high-risk neurotechnology shall establish and maintain a neural data governance framework that includes: (a) Clear assignment of responsibilities for neural data management; (b) Procedures for ensuring data quality and integrity; (c) Mechanisms for neural data access control; (d) Protocols for neural data retention and deletion; (e) Procedures for managing neural data breaches; (f) Methods for ensuring compliance with data protection requirements; (g) Training requirements for personnel handling neural data; (h) Regular auditing of neural data management practices.

4. Where high-risk neurotechnology uses neural data for training, validation, or testing of algorithms, providers shall ensure that the data is: (a) Collected from demographically diverse populations to prevent discriminatory outcomes; (b) Representative of the intended use contexts; (c) Collected with informed neural consent for this specific purpose; (d) Subject to appropriate de-identification where feasible, with recognition of the unique re-identification risks associated with neural data; (e) Protected by technical and organizational measures that prevent unauthorized use.

5. Providers shall document the neural data governance framework in the technical documentation referred to in Article 30 and shall regularly review and update it to reflect evolving best practices and regulatory requirements.

6. The Commission shall adopt delegated acts in accordance with Article 121 to supplement this Regulation by specifying: (a) Technical standards for neural data quality assessment; (b) Requirements for neural data governance frameworks; (c) Best practices for neural data collection, processing, and management; (d) Methods for identifying and addressing biases in neural data.

Article 27: Technical robustness and safety

1. High-risk neurotechnology shall be designed and developed to achieve appropriate levels of robustness and safety throughout its lifecycle, taking into account the state of the art and the specific risks associated with neural interaction.

2. High-risk neurotechnology shall be resilient to: (a) Attempted unauthorized access to or modification of the system; (b) Manipulation of training data, inputs, or outputs; (c) Errors, faults, or inconsistencies in operation; (d) Environmental stressors and variations; (e) Unexpected inputs or situations not encountered during development.

3. High-risk neurotechnology shall incorporate safety features including: (a) Fail-safe mechanisms that ensure safe operation in case of technical failures; (b) Backup systems for critical functions where appropriate; (c) Emergency shutdown capabilities accessible to the user; (d) Technical limits on neural stimulation parameters to prevent harm; (e) Continuous monitoring for anomalous operation; (f) Technical measures to prevent psychological dependency or addiction where

relevant; (g) Protections against unauthorized modification of settings or parameters.

4. For invasive neurotechnology, additional safety requirements include: (a) Biocompatibility of all materials contacting neural tissue; (b) Electrical safety measures to prevent tissue damage; (c) Thermal management to prevent overheating; (d) Mechanical stability to prevent movement-related injury; (e) Protection against infection; (f) Degradation monitoring for long-term implants; (g) Compatibility with medical imaging technologies where relevant.

5. For neurostimulation technologies, specific safety requirements include: (a) Precise control of stimulation parameters; (b) Limits on stimulation intensity, duration, and frequency; (c) Gradual parameter adjustment capabilities; (d) User-accessible override controls; (e) Monitoring for adverse effects.

6. High-risk neurotechnology that incorporates artificial intelligence or machine learning shall demonstrate: (a) Algorithmic robustness against adversarial attacks; (b) Reliable performance across the range of intended operating conditions; (c) Graceful degradation in case of errors or unexpected inputs; (d) Appropriate levels of accuracy, precision, sensitivity, and specificity for the intended purpose; (e) Ability to identify and handle out-of-distribution inputs.

7. The Commission shall adopt delegated acts in accordance with Article 121 to supplement this Regulation by specifying: (a) Technical standards for different categories of high-risk neurotechnology; (b) Testing methodologies for demonstrating technical robustness; (c) Safety requirements for specific neurotechnology applications; (d) Criteria for determining appropriate levels of robustness and safety.

Article 28: Accuracy, reliability, and reproducibility

1. High-risk neurotechnology shall achieve appropriate levels of accuracy, reliability, and reproducibility for its intended purpose.

2. Providers of high-risk neurotechnology shall define and document: (a) Appropriate metrics for measuring accuracy, reliability, and reproducibility; (b) Target performance levels for these metrics; (c) Testing methodologies to validate performance; (d) Operating conditions under which the specified performance is achieved; (e) Limitations and potential sources of error; (f) Performance variations across different user populations.

3. For high-risk neurotechnology that involves neural recording or neural data processing: (a) The spatial and temporal resolution shall be appropriate for the intended application; (b) Signal-to-noise ratios shall be sufficient for reliable interpretation; (c) Artifact detection and rejection methods shall be implemented where appropriate; (d) The system shall demonstrate stability across recording sessions; (e) The accuracy of neural decoding or interpretation shall be validated with appropriate methods; (f) The system shall specify confidence levels for inferences drawn from neural data.

4. For high-risk neurotechnology that involves neurostimulation: (a) The precision of stimulation targeting shall be appropriate for the intended application; (b) The

system shall deliver consistent stimulation parameters; (c) The relationship between stimulation parameters and effects shall be validated; (d) The variability of effects across individuals shall be characterized; (e) Long-term stability of stimulation effects shall be assessed where relevant.

5. For high-risk neurotechnology used in diagnostic or predictive applications: (a) Sensitivity, specificity, positive predictive value, and negative predictive value shall be established through appropriate validation; (b) Performance shall be compared to relevant benchmarks or reference standards; (c) Performance shall be validated across diverse populations; (d) Confidence intervals shall be provided for predictions or classifications; (e) Limitations in diagnostic or predictive accuracy shall be clearly communicated to users.

6. Providers shall implement ongoing monitoring mechanisms to track performance after deployment and shall take corrective actions if performance degrades below specified thresholds.

7. The Commission shall adopt delegated acts in accordance with Article 121 to supplement this Regulation by specifying: (a) Methodologies for measuring and reporting accuracy, reliability, and reproducibility; (b) Validation requirements for different categories of high-risk neurotechnology; (c) Minimum performance standards for specific applications.

Article 29: Transparency and explainability

1. High-risk neurotechnology shall be designed and developed to ensure an appropriate level of transparency and explainability, taking into account the nature of the technology and the context of use.

2. Providers of high-risk neurotechnology shall ensure transparency through: (a) Clear documentation of the neurotechnology's capabilities and limitations; (b) Disclosure of the intended purpose and operating conditions; (c) Communication of known risks and potential side effects; (d) Explanation of the general logic and decision-making processes where automated decisions are involved; (e) Information about the source and quality of neural data used; (f) Disclosure of validation methodologies and results; (g) Clear indication of when the neurotechnology is active and collecting or processing neural data.

3. For high-risk neurotechnology involving artificial intelligence or complex algorithms: (a) The general functioning of the algorithm shall be explained in non-technical terms; (b) The main parameters influencing decisions or outputs shall be identified; (c) The reliability and limitations of algorithmic outputs shall be communicated; (d) Methods shall be implemented to provide explanations for specific decisions or outputs when requested; (e) The system shall indicate confidence levels for predictions or classifications.

4. For high-risk neurotechnology used in healthcare: (a) Information shall be provided about the evidence base supporting clinical applications; (b) The relationship between neural measurements and clinical interpretations shall be explained; (c) The basis for therapeutic recommendations shall be articulated; (d) The limitations of diagnostic or prognostic assessments shall be clearly communicated.

5. Transparency requirements shall be adapted to different user groups, with: (a) Technical documentation for professional users and regulatory authorities; (b) Clear, non-technical explanations for end-users; (c) Accessible information for persons with disabilities; (d) Age-appropriate explanations when the technology may be used by or affect minors.

6. The Commission shall adopt delegated acts in accordance with Article 121 to supplement this Regulation by specifying: (a) Transparency requirements for different categories of high-risk neurotechnology; (b) Methods for providing explanations of complex algorithms; (c) Standards for communicating uncertainty and confidence levels; (d) Requirements for user-facing transparency interfaces.

Article 30: Technical documentation

1. Providers of high-risk neurotechnology shall draw up technical documentation before placing the neurotechnology on the market or putting it into service. The technical documentation shall be kept up-to-date.

2. The technical documentation shall be drawn up in a way that demonstrates that the high-risk neurotechnology complies with the requirements set out in this Title and shall provide national competent authorities and notified bodies with all necessary information to assess the compliance of the neurotechnology.

3. The technical documentation shall contain at a minimum the elements set out in Annex IV.

4. The technical documentation shall include: (a) A general description of the high-risk neurotechnology, including: (i) Its intended purpose; (ii) The context and conditions of use; (iii) The target users or subjects; (iv) The technical specifications, including hardware and software components; (v) Integration with other systems or devices; (b) A detailed description of the elements of the high-risk neurotechnology and of the process for its development, including: (i) The design and development process; (ii) Design specifications, including neural interface characteristics and stimulation parameters where applicable; (iii) Key design choices and their rationale; (iv) System architecture; (v) Parameters or settings that can be adjusted by the user or during installation; (c) Information about the neural data used by the system, including: (i) The origin and nature of the data; (ii) The data preprocessing techniques; (iii) Data quality assessment methods; (iv) Neural data governance procedures; (d) A detailed description of the risk management system in accordance with Article 25, including: (i) The risk identification and analysis methodology; (ii) The identified risks and their evaluation; (iii) The risk mitigation measures implemented; (iv) The residual risks and their acceptability; (e) A description of the validation and testing procedures, including: (i) The validation methodology; (ii) The test protocols; (iii) The test data and results; (iv) Performance metrics and achieved values; (v) Validation across different user groups; (f) A description of the post-market monitoring system in accordance with Article 46; (g) The instructions for use in accordance with Article 31; (h) The EU declaration of conformity referred to in Article 70.

5. For high-risk neurotechnology that continues to learn or adapt after deployment, the technical documentation shall additionally include: (a) A description of the learning or adaptation mechanisms; (b) Information about the data used for ongoing

learning; (c) A description of the safeguards to prevent harmful adaptations; (d) Methods for monitoring and evaluating changes in performance.

6. The technical documentation shall be updated throughout the lifecycle of the high-risk neurotechnology to reflect any significant modification.

7. The Commission shall adopt delegated acts in accordance with Article 121 to supplement this Regulation by specifying the detailed content and structure of the technical documentation required under this Article.

Article 31: Instructions for use

1. High-risk neurotechnology shall be accompanied by instructions for use that include all necessary information, appropriate to the intended users, to ensure fair, transparent, and effective use, including: (a) The identity and contact details of the provider and, where applicable, its authorized representative; (b) A clear specification of the intended purpose of the neurotechnology, including: (i) The intended contexts of use; (ii) The intended user groups; (iii) The intended subjects or individuals whose neural data may be collected or processed; (iv) The specific neural functions or processes targeted; (c) A description of the neurotechnology's capabilities and limitations, including: (i) Technical specifications, such as spatial and temporal resolution of neural recording or precision of stimulation; (ii) Accuracy, reliability, and reproducibility metrics; (iii) Known limitations in performance; (iv) Situations in which the neurotechnology may fail or provide unreliable results; (d) Information about potential risks and side effects, including: (i) Known physical risks; (ii) Potential psychological or cognitive effects; (iii) Privacy and security risks; (iv) Potential long-term effects, if known; (v) Risks specific to vulnerable populations; (e) Instructions for installation, setup, and operation, including: (i) Hardware and software requirements; (ii) Installation procedures; (iii) Configuration and calibration procedures; (iv) Operating procedures; (v) Maintenance requirements; (f) Information about the neural data collected and processed, including: (i) The types of neural data collected; (ii) The purposes for which neural data is processed; (iii) The retention period for neural data; (iv) Whether neural data is shared with third parties; (v) How to access, export, or delete neural data; (g) Information about the human oversight measures, including: (i) When and how human oversight is exercised; (ii) The qualifications required for human overseers; (iii) The mechanisms for users to contact human overseers; (h) Information about the security measures implemented, including: (i) Authentication and access control mechanisms; (ii) Data encryption and security protocols; (iii) Procedures in case of security breaches; (i) Specific instructions for obtaining informed neural consent when required; (j) Procedures for reporting serious incidents or malfunctions; (k) Information about the conformity assessment procedures undertaken; (l) The period during which the provider will provide technical support and updates.

2. The instructions for use shall be provided in the official languages of the Member States where the high-risk neurotechnology is made available and shall be: (a) Provided in electronic form that is accessible to persons with disabilities; (b) Clear, concise, and comprehensible to the intended users; (c) Include non-technical

explanations of complex features; (d) Accompanied by visual elements where appropriate to enhance understanding.

3. For high-risk neurotechnology intended for use in healthcare, the instructions for use shall additionally include: (a) Information about the clinical evidence supporting the therapeutic applications; (b) Contraindications and exclusion criteria; (c) Requirements for medical supervision; (d) Integration with clinical workflows; (e) Compatibility with other medical devices or treatments.

4. For high-risk neurotechnology intended for research purposes, the instructions for use shall additionally include: (a) Specific protocols for ethical research use; (b) Requirements for research ethics committee approval; (c) Considerations for participant recruitment and informed consent; (d) Data management and sharing protocols.

5. The Commission shall adopt delegated acts in accordance with Article 121 to supplement this Regulation by specifying the detailed content and format of the instructions for use required under this Article for different categories of high-risk neurotechnology.

Article 32: Human oversight

1. High-risk neurotechnology shall be designed and developed to support effective human oversight during its use.

2. Human oversight shall aim to prevent or minimize risks to health, safety, fundamental rights, and neurocognitive rights that may emerge during the operation of high-risk neurotechnology and shall ensure that the system operates as intended.

3. Human oversight shall be ensured through appropriate technical and organizational measures, which may include: (a) Clear allocation of oversight responsibilities to persons with appropriate qualifications; (b) Human validation of important decisions before they are implemented; (c) Human intervention capabilities to override or modify system outputs; (d) Regular review of system performance by qualified personnel; (e) Real-time monitoring capabilities for critical applications; (f) Clear procedures for human overseers to identify and respond to anomalies, risks, or concerns; (g) User interfaces that facilitate effective human monitoring and intervention; (h) Training for human overseers on the capabilities and limitations of the system.

4. The specific requirements for human oversight shall be proportionate to the risks and intended use of the high-risk neurotechnology, with more stringent requirements for: (a) Invasive neurotechnology; (b) Neurotechnology used on vulnerable populations; (c) Neurotechnology with significant potential for cognitive or psychological effects; (d) Neurotechnology used in critical decision-making contexts.

5. For high-risk neurotechnology used in healthcare, human oversight shall include: (a) Appropriate medical supervision; (b) Clinical validation of system outputs before treatment decisions; (c) Integration with clinical judgment rather than replacement of clinical decision-making; (d) Continuous monitoring of patient responses during treatment.

6. For high-risk neurotechnology used in non-therapeutic contexts, human oversight shall include: (a) Independent verification of significant inferences from neural data; (b) Regular auditing of system operation and outputs; (c) Mechanisms to address potential biases in operation; (d) Clear procedures for handling edge cases or unexpected situations.

7. Providers shall specify in the technical documentation the human oversight measures integrated into the high-risk neurotechnology, and shall provide instructions and training materials for human overseers.

8. The Commission shall adopt delegated acts in accordance with Article 121 to supplement this Regulation by specifying: (a) The technical requirements for implementing effective human oversight; (b) The qualifications and training requirements for human overseers; (c) Specific human oversight protocols for different categories of high-risk neurotechnology.

Article 33: Neural security and cybersecurity

1. High-risk neurotechnology shall be designed and developed to achieve an appropriate level of neural security and cybersecurity appropriate to the risks.

2. Technical measures to ensure neural security and cybersecurity shall include: (a) Protection against unauthorized access to neural systems through: (i) Strong authentication mechanisms; (ii) Access control systems; (iii) Neural firewalls where appropriate; (iv) Physical security measures for hardware components; (b) Protection of neural data through: (i) End-to-end encryption for neural data in transit; (ii) Secure storage of neural data at rest; (iii) Access logging and monitoring; (iv) Data minimization principles; (v) Secure deletion protocols; (c) Protection against manipulation through: (i) Input validation and sanitization; (ii) Detection of anomalous inputs or commands; (iii) Control flow integrity mechanisms; (iv) Code signing for software updates; (d) System resilience through: (i) Redundancy for critical functions; (ii) Graceful degradation capabilities; (iii) Regular backups of essential data and configurations; (iv) Fault tolerance mechanisms; (e) Ongoing security management through: (i) Security monitoring and logging; (ii) Vulnerability management processes; (iii) Security patch management; (iv) Incident response procedures.

3. For invasive neurotechnology, additional security requirements shall include: (a) Protection against unauthorized neurostimulation; (b) Verification of stimulation commands; (c) Local override capabilities; (d) Secure update mechanisms with integrity verification; (e) Fallback to safe modes in case of security breaches.

4. For networked neurotechnology, additional security requirements shall include: (a) Secure communication protocols; (b) Network segmentation where appropriate; (c) Intrusion detection systems; (d) Protection against denial-of-service attacks; (e) Secure configuration of network interfaces.

5. Providers of high-risk neurotechnology shall: (a) Adopt a security-by-design approach from the earliest stages of development; (b) Conduct security risk assessments throughout the development process; (c) Implement a security testing program, including penetration testing where appropriate; (d) Establish a

vulnerability disclosure policy and process; (e) Provide security updates for the expected lifetime of the neurotechnology; (f) Maintain documentation of security measures and testing results.

6. The Commission shall adopt delegated acts in accordance with Article 121 to supplement this Regulation by specifying: (a) Technical standards for neural security and cybersecurity; (b) Security testing methodologies; (c) Specific security requirements for different categories of high-risk neurotechnology.

Article 34: Informed neural consent

1. High-risk neurotechnology shall incorporate technical and organizational measures to facilitate obtaining and documenting informed neural consent where required by this Regulation.

2. Informed neural consent shall be obtained before: (a) Initial use of high-risk neurotechnology by an individual; (b) Collection or processing of neural data; (c) Neurostimulation or neuromodulation; (d) Significant changes to the functionality or purpose of the neurotechnology; (e) Sharing neural data with third parties.

3. Informed neural consent mechanisms shall ensure that the individual: (a) Receives comprehensive information about the neurotechnology in clear, non-technical language, including: (i) The purpose and functionality of the neurotechnology; (ii) The neural data to be collected and how it will be processed; (iii) The potential risks and benefits; (iv) The intended and possible unintended effects on neural function; (v) Alternative options where relevant; (b) Has sufficient time and resources to consider the information; (c) Has the opportunity to ask questions and receive answers; (d) Is free from coercion, undue influence, or deception; (e) Has the capacity to understand the information and provide consent; (f) Provides explicit, affirmative consent for specific purposes.

4. For high-risk neurotechnology with potential significant effects on cognitive functions, identity, or autonomy, enhanced informed neural consent procedures shall include: (a) Detailed information about potential cognitive and psychological effects; (b) Staged consent processes with multiple opportunities for questions and reflection; (c) Where appropriate, involvement of trusted third parties to support decision-making; (d) Verification of understanding through interactive methods; (e) Clear information about the right to withdraw consent.

5. Technical measures to support informed neural consent shall include: (a) User interfaces that present consent information clearly and accessibly; (b) Granular consent options that allow individuals to consent to specific functions; (c) Mechanisms to document and verify consent; (d) Simple procedures for withdrawing consent; (e) Regular renewal of consent for ongoing use.

6. For vulnerable individuals, including children, persons with cognitive disabilities, or persons in institutional settings, additional safeguards shall include: (a) Age-appropriate or capacity-appropriate information; (b) Involvement of legal representatives where required by national law; (c) Independent assessment of best interests where appropriate; (d) Enhanced scrutiny of the necessity and proportionality of the intervention.

7. Providers of high-risk neurotechnology shall document in the technical documentation the informed neural consent procedures incorporated into their systems and shall provide guidance to users on implementing these procedures.

8. The Commission shall adopt delegated acts in accordance with Article 121 to supplement this Regulation by specifying: (a) Detailed requirements for informed neural consent procedures; (b) Templates and best practices for consent information; (c) Specific consent requirements for different categories of high-risk neurotechnology.

Article 35: Recording and logging

1. High-risk neurotechnology shall be designed and developed with logging capabilities to ensure an appropriate level of traceability of the system's operation throughout its lifecycle.

2. Logging shall enable the recording of events relevant to: (a) The functioning of the neurotechnology, including: (i) System initialization and shutdown; (ii) Calibration and adaptation procedures; (iii) Significant parameter changes; (iv) Software updates; (v) Self-diagnostic results; (vi) Error and exception events; (b) Neural data processing activities, including: (i) Data collection sessions; (ii) Processing operations; (iii) Data access events; (iv) Data transfer events; (v) Automated decisions or recommendations; (c) User interactions, including: (i) User authentication; (ii) Control inputs and configuration changes; (iii) Override actions; (iv) Consent provisions and withdrawals.

3. Logging mechanisms shall be designed to ensure: (a) Security of logs through access controls and tamper protection; (b) Integrity of log data; (c) Accurate timestamping; (d) Appropriate retention periods; (e) Accessibility for authorized purposes; (f) Privacy by design, avoiding the logging of unnecessary personal or neural data.

4. For high-risk neurotechnology used in healthcare, additional logging requirements shall include: (a) Recording of clinical decisions influenced by the system; (b) Documentation of healthcare provider interactions; (c) Patient response monitoring; (d) Integration with medical record systems where appropriate.

5. For high-risk neurotechnology used in sensitive contexts, such as employment, education, or law enforcement, additional logging requirements shall include: (a) Documentation of the specific purpose for each use; (b) Recording of the legal basis for use; (c) Documentation of human oversight activities; (d) Auditable records of all significant decisions or actions.

6. Providers shall ensure that logging mechanisms: (a) Do not compromise system performance; (b) Include appropriate data minimization; (c) Comply with data protection requirements; (d) Support effective monitoring, investigation, and auditing.

7. The Commission shall adopt delegated acts in accordance with Article 121 to supplement this Regulation by specifying: (a) Technical standards for logging mechanisms; (b) Required log content for different categories of high-risk neurotechnology; (c) Log retention periods and access controls.

Article 36: Autonomy and control mechanisms

1. High-risk neurotechnology shall be designed and developed to preserve and enhance user autonomy through appropriate control mechanisms.

2. User control mechanisms shall include: (a) User-accessible activation and deactivation controls; (b) Clear indicators of operational status; (c) Transparent information about current functioning; (d) User control over key parameters within safe ranges; (e) Mechanisms to pause, modify, or override system operations; (f) Emergency shutdown capabilities; (g) Controls for neural data collection and processing.

3. For invasive neurotechnology, additional control requirements shall include: (a) User or caregiver access to stimulation parameter adjustment within safe ranges; (b) Physical or software-based emergency deactivation mechanisms; (c) Means to detect and respond to unintended effects; (d) Independent verification of critical commands where feasible; (e) Local control options that function without network connectivity.

4. For neurotechnology with adaptive or learning capabilities, control mechanisms shall include: (a) User visibility into adaptation processes; (b) User approval for significant adaptations; (c) Options to reset to previous states or default configurations; (d) Boundaries on autonomous adaptation; (e) Transparency about learning sources and processes.

5. For neurotechnology used in contexts with inherent power imbalances, such as employment, education, or institutional care, additional safeguards shall include: (a) Independent oversight mechanisms; (b) Record-keeping of system use; (c) Right to explanation for decisions influenced by the system; (d) Accessible complaint mechanisms; (e) Regular review of impact on autonomy.

6. Control mechanisms shall be: (a) Accessible to persons with disabilities; (b) Intuitive and easy to use; (c) Calibrated to the cognitive capabilities of intended users; (d) Resilient against accidental activation or deactivation; (e) Protected against unauthorized modification.

7. The Commission shall adopt delegated acts in accordance with Article 121 to supplement this Regulation by specifying: (a) Technical standards for user control interfaces; (b) Requirements for emergency shutdown mechanisms; (c) Specific control requirements for different categories of high-risk neurotechnology.

Article 37: Bias prevention and non-discrimination

1. High-risk neurotechnology shall be designed, developed, and tested to prevent discrimination and mitigate biases that could lead to prohibited discrimination or other harmful impacts.

2. Providers of high-risk neurotechnology shall: (a) Identify potential sources of bias in: (i) Neural data collection methods; (ii) Training datasets; (iii) Algorithm design; (iv) Feature selection; (v) Classification thresholds; (vi) Interpretation of neural signals; (vii) Integration with other systems; (b) Implement technical and organizational measures to mitigate identified biases, including: (i) Diverse and

representative data collection; (ii) Rigorous data quality assurance; (iii) Algorithmic fairness techniques; (iv) Regular bias assessment and testing; (v) Human review of potentially discriminatory patterns; (vi) Ongoing monitoring for emergent biases; (c) Document in the technical documentation: (i) The bias assessment methodology; (ii) Identified bias risks; (iii) Mitigation measures implemented; (iv) Results of bias testing; (v) Residual limitations and potential for disparate impact.

3. For high-risk neurotechnology used in sensitive contexts such as employment, education, healthcare, or law enforcement, additional requirements shall include: (a) Enhanced testing across diverse population groups; (b) Analysis of performance disparities across demographic groups; (c) Independent evaluation of fairness metrics; (d) Regular auditing for discriminatory impacts; (e) Documentation of limitations that may affect different groups differently.

4. For high-risk neurotechnology that processes neural data to detect or interpret mental states, emotions, or cognitive processes, specific requirements shall include: (a) Validation of interpretive methods across diverse populations; (b) Assessment of cultural and individual variations in neural responses; (c) Transparency about the limitations of neural interpretation; (d) Avoidance of reductive categorizations based on neural data; (e) Prevention of stigmatization based on neural patterns.

5. Users of high-risk neurotechnology shall be provided with: (a) Information about potential limitations in performance across different populations; (b) Guidance on identifying and addressing potential biases in operation; (c) Training on non-discriminatory use; (d) Tools to monitor for disparate impacts.

6. The Commission shall adopt delegated acts in accordance with Article 121 to supplement this Regulation by specifying: (a) Methodologies for bias assessment in neurotechnology; (b) Requirements for fairness testing; (c) Standards for measuring and reporting disparities; (d) Best practices for bias mitigation in different categories of high-risk neurotechnology.

Article 38: Environmental and societal impact assessment

1. Providers of high-risk neurotechnology shall conduct an assessment of the potential environmental and broader societal impacts of their systems.

2. The environmental impact assessment shall consider: (a) Energy consumption during both production and operation; (b) Resource use, including rare minerals or materials; (c) Waste generation, including electronic waste; (d) End-of-life management and recyclability; (e) Environmental implications of necessary supporting infrastructure.

3. The societal impact assessment shall consider: (a) Potential effects on social interactions and relationships; (b) Impacts on employment and economic structures; (c) Implications for privacy norms and expectations; (d) Potential for creating or exacerbating social divides; (e) Cultural implications, including interaction with diverse value systems; (f) Potential effects on democratic institutions and processes; (g) Implications for concepts of human identity and

agency; (h) Potential long-term evolutionary implications of human-neurotechnology integration.

4. The assessment shall: (a) Identify both positive and negative potential impacts; (b) Consider immediate, medium-term, and long-term effects; (c) Address impacts at individual, community, and societal levels; (d) Consider differential impacts on various populations; (e) Propose measures to maximize benefits and mitigate negative impacts.

5. For high-risk neurotechnology with potentially significant societal implications, providers shall: (a) Engage with relevant stakeholders, including potentially affected communities; (b) Consult with experts in relevant social sciences and humanities; (c) Consider diverse cultural and ethical perspectives; (d) Develop ongoing monitoring mechanisms for societal impacts; (e) Establish feedback channels for reporting unanticipated impacts.

6. The results of the environmental and societal impact assessment shall be documented and included in the technical documentation.

7. The Commission shall adopt delegated acts in accordance with Article 121 to supplement this Regulation by specifying: (a) Methodologies for environmental and societal impact assessment; (b) Reporting frameworks for impact assessments; (c) Requirements for stakeholder engagement; (d) Specific assessment considerations for different categories of high-risk neurotechnology.

Article 39: Conformity assessment procedure

1. Before placing high-risk neurotechnology on the market or putting it into service, providers shall conduct a conformity assessment in accordance with the procedures set out in Title VIII.

2. Providers shall prepare the technical documentation referred to in Article 30 and shall conduct the relevant conformity assessment procedure or have it conducted.

3. Where compliance with the requirements set out in this Title has been demonstrated, providers shall draw up an EU declaration of conformity in accordance with Article 70 and affix the CE marking of conformity in accordance with Article 71.

4. Providers shall keep the technical documentation and the EU declaration of conformity for a period of ten years after the high-risk neurotechnology has been placed on the market or put into service.

5. The European Neurotechnology Regulatory Authority shall provide guidance and tools to assist providers in preparing for the conformity assessment procedure.

Article 40: Substantial modification

1. For high-risk neurotechnology that has undergone a conformity assessment, if a change is made that constitutes a substantial modification, the modified system shall undergo a new conformity assessment.

2. A modification shall be considered substantial if it: (a) Changes the intended purpose of the neurotechnology; (b) Significantly alters the risk profile of the

system; (c) Introduces new neural recording or stimulation capabilities; (d) Substantially modifies the neural data processing methods; (e) Expands the types of neural data collected or processed; (f) Significantly changes the decision-making logic or algorithms; (g) Adds functionality that could have a significant impact on neurocognitive rights; (h) Alters safety-critical components or functions; (i) Modifies the system in ways that could affect its performance or behavior in unpredictable ways.

3. Providers of high-risk neurotechnology shall document all modifications to their systems and shall assess whether these modifications constitute substantial modifications requiring a new conformity assessment.

4. For high-risk neurotechnology that continues to learn after being placed on the market or put into service, providers shall: (a) Clearly define the learning boundaries within which the system can operate without undergoing a new conformity assessment; (b) Implement technical measures to ensure that the system remains within these boundaries; (c) Monitor system evolution to identify when changes approach or cross the threshold for substantial modification; (d) Conduct a new conformity assessment if learning leads to changes that constitute substantial modifications.

5. The Commission shall adopt delegated acts in accordance with Article 121 to supplement this Regulation by specifying: (a) Detailed criteria for determining whether a modification is substantial; (b) Procedures for assessing modifications; (c) Requirements for documentation of modifications; (d) Specific considerations for adaptive and learning systems.

TITLE VI: OBLIGATIONS OF PROVIDERS AND USERS

Article 41: General obligations of providers

1. When placing neurotechnology on the market or putting it into service, providers shall ensure that it has been designed and developed in accordance with the requirements set out in this Regulation.

2. Providers shall: (a) Ensure that their neurotechnology undergoes the appropriate conformity assessment procedure prior to placing it on the market or putting it into service; (b) Draw up the required technical documentation; (c) Ensure that the technical documentation and other relevant documentation are kept up to date; (d) Draw up an EU declaration of conformity and affix the CE marking of conformity when required; (e) Implement a quality management system to ensure compliance with this Regulation; (f) Keep a register of serious incidents and of malfunctions; (g) Take corrective actions when their neurotechnology is not in conformity with the requirements of this Regulation; (h) Inform the relevant national competent authorities of any serious incident or malfunction; (i) Demonstrate compliance with this Regulation upon request by a national competent authority.

3. Providers of high-risk neurotechnology shall: (a) Implement a risk management system in accordance with Article 25; (b) Conduct the conformity assessment in accordance with Article 39; (c) Register their high-risk neurotechnology in the EU database referred to in Article 85; (d) Implement a post-market monitoring system

in accordance with Article 46; (e) Report serious incidents and malfunctions in accordance with Article 47; (f) Take corrective actions at the request of a competent authority or on their own initiative when their high-risk neurotechnology is not in compliance with the requirements.

4. Providers shall ensure that their neurotechnology is accompanied by the information required under Article 31.

5. Providers shall, upon a reasoned request from a national competent authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of their neurotechnology with this Regulation, in an official Union language determined by the Member State concerned.

6. Providers shall cooperate with the national competent authorities on any action taken to eliminate or, if that is not possible, to mitigate the risks posed by neurotechnology that they have placed on the market or put into service.

Article 42: Obligations regarding technical documentation

1. Providers shall draw up the technical documentation for their neurotechnology before placing it on the market or putting it into service.

2. For high-risk neurotechnology, the technical documentation shall comply with the requirements set out in Article 30.

3. For other neurotechnology, the technical documentation shall include at a minimum: (a) A general description of the neurotechnology; (b) A description of the intended purpose; (c) Information about the functional capabilities; (d) Information about the neural data collected and processed; (e) Safety and security measures implemented; (f) Instructions for use.

4. The technical documentation shall be kept up to date throughout the lifecycle of the neurotechnology.

5. The technical documentation shall be retained for a period of ten years after the neurotechnology has been placed on the market or put into service.

6. Providers shall make the technical documentation available to national competent authorities upon request.

7. The technical documentation shall be drawn up in a way that allows assessment of the neurotechnology's compliance with the applicable requirements of this Regulation.

Article 43: Obligations regarding conformity

1. Providers shall ensure that their neurotechnology undergoes the appropriate conformity assessment procedure before being placed on the market or put into service.

2. For high-risk neurotechnology, providers shall follow the conformity assessment procedure set out in Article 39.

3. For other neurotechnology, providers shall perform an internal conformity assessment to verify compliance with the relevant requirements of this Regulation.

4. After completing the conformity assessment, providers of high-risk neurotechnology shall draw up an EU declaration of conformity in accordance with Article 70 and affix the CE marking of conformity in accordance with Article 71.

5. Providers shall retain the documentation concerning the conformity assessment for a period of ten years after the neurotechnology has been placed on the market or put into service.

6. Providers shall cooperate with notified bodies conducting the conformity assessment, including providing access to premises and information as required.

7. Providers shall inform the notified body that has issued an EU technical documentation assessment certificate or EU quality management system approval certificate of any planned substantial modification to the neurotechnology.

Article 44: Obligations regarding registration

1. Before placing high-risk neurotechnology on the market or putting it into service, providers shall register it in the EU database referred to in Article 85.

2. The registration shall include: (a) The name, address, and contact details of the provider; (b) A description of the high-risk neurotechnology, including its intended purpose and key functionality; (c) The risk classification and the basis for that classification; (d) Information about the conformity assessment procedure followed; (e) A copy of the EU declaration of conformity; (f) A summary of the main characteristics and capabilities of the high-risk neurotechnology.

3. Providers shall keep the registration information up to date.

4. Providers shall inform the relevant national competent authority when they cease to be the provider of a registered high-risk neurotechnology.

5. The Commission shall adopt implementing acts establishing the procedures for registration and for updating the registration information. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 122(2).

Article 45: Obligations regarding compliance and corrective actions

1. Providers who consider or have reason to believe that neurotechnology which they have placed on the market or put into service is not in conformity with this Regulation shall immediately take the necessary corrective actions to bring that neurotechnology into conformity, to withdraw it from the market, or to recall it, as appropriate.

2. Where the neurotechnology presents a risk, providers shall immediately inform the national competent authorities of the Member States in which they made the neurotechnology available, providing details of: (a) The non-conformity and any corrective actions taken; (b) The nature and extent of the risk; (c) The number of affected units; (d) The potential impact on individuals; (e) The timeline for implementing corrective actions.

3. Providers shall maintain a register of complaints related to non-compliant neurotechnology or neurotechnology presenting a risk, regardless of whether they

are obliged by law to do so, and shall keep distributors and users informed of such monitoring.

4. Where high-risk neurotechnology presents a serious risk to neurocognitive rights, health, safety, or fundamental rights, providers shall: (a) Immediately notify the European Neurotechnology Regulatory Authority; (b) Implement an emergency response plan to mitigate the risk; (c) Cooperate with national competent authorities on urgent protective measures; (d) Provide affected users and individuals with clear instructions; (e) Document the incident and response measures.

5. Providers shall comply with any measures required by the competent authorities to address risks posed by their neurotechnology, including: (a) Temporarily suspending specific functionality; (b) Implementing safety updates; (c) Modifying operational parameters; (d) Enhancing user warnings and instructions; (e) Conducting additional testing or validation.

6. The Commission shall adopt implementing acts establishing uniform conditions for determining when a non-conformity presents a serious risk and for the content and format of notifications. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 122(2).

Article 46: Post-market monitoring

1. Providers of high-risk neurotechnology shall establish and document a post-market monitoring system proportionate to the nature of the neurotechnology and the risks it presents.

2. The post-market monitoring system shall actively and systematically collect, document, and analyze relevant data about the performance and safety of high-risk neurotechnology throughout its lifetime, and shall allow the provider to: (a) Evaluate the continued compliance of the neurotechnology with the requirements of this Regulation; (b) Identify and track previously unknown risks or unintended effects; (c) Identify and track systematic misuse patterns; (d) Gather user and subject feedback on experience and satisfaction; (e) Collect information on technical issues, malfunctions, and performance degradation; (f) Monitor scientific literature and technological developments relevant to the neurotechnology; (g) Evaluate emerging ethical concerns related to the neurotechnology; (h) Identify the need for corrective or preventive actions.

3. The post-market monitoring system shall include: (a) A post-market monitoring plan that specifies the methods and procedures for collecting and analyzing data; (b) Specific performance indicators to evaluate continued compliance and risk levels; (c) Effective processes to collect and analyze feedback from users, individuals, and other stakeholders; (d) Adequate technical means to extract relevant data from the neurotechnology in the field; (e) Tools to detect and monitor patterns in performance, usage, and adverse effects; (f) Procedures for documenting and investigating adverse events and complaints; (g) Protocols for determining when changes require a new conformity assessment.

4. For high-risk neurotechnology with significant potential for long-term effects on cognitive functions, identity, or neural systems, enhanced monitoring requirements shall include: (a) Longitudinal studies of users or subjects; (b) Monitoring for delayed or cumulative effects; (c) Regular neuropsychological assessments where appropriate; (d) Targeted investigation of reported unexpected effects; (e) Consultation with independent experts on emerging patterns.

5. Based on the post-market monitoring, providers shall: (a) Update the risk assessment as necessary; (b) Update the technical documentation; (c) Implement necessary corrective or preventive actions; (d) Report serious incidents as required by Article 47; (e) Share non-sensitive learnings with the scientific and regulatory communities.

6. Providers shall prepare annual post-market monitoring reports that summarize the results of post-market monitoring activities, findings, and any corrective actions taken. For high-risk neurotechnology, these reports shall be submitted to the relevant notified body and national competent authority.

7. The Commission shall adopt delegated acts in accordance with Article 121 to supplement this Regulation by specifying: (a) Detailed requirements for post-market monitoring systems; (b) Methodologies for data collection and analysis; (c) Reporting formats and frequencies; (d) Specific monitoring requirements for different categories of high-risk neurotechnology.

Article 47: Reporting of serious incidents and malfunctions

1. Providers of high-risk neurotechnology shall report any serious incident or malfunction to the national competent authorities of the Member States where the incident occurred.

2. A serious incident shall be defined as any incident that directly or indirectly causes, might have caused, or might cause: (a) Significant harm to an individual's health, safety, or neurocognitive rights; (b) Serious violation of an individual's mental privacy; (c) Unauthorized or unintended alteration of cognitive functions, mental states, or identity; (d) Significant psychological distress or harm; (e) Discriminatory treatment with substantial adverse effects; (f) Unanticipated neurological effects; (g) Serious breach of neural data security; (h) Death or serious injury.

3. A malfunction shall be defined as a failure of the neurotechnology to perform in accordance with its intended purpose or specifications that could lead to a serious incident if it were to recur.

4. Reports shall be made without undue delay, and in any event: (a) No later than 72 hours after the provider becomes aware of a serious incident; (b) No later than 15 days after the provider becomes aware of a malfunction.

5. The report shall include: (a) The nature and circumstances of the serious incident or malfunction; (b) The neurotechnology involved, including version and configuration; (c) The date and location of the incident; (d) The number of affected individuals; (e) The actual or potential consequences; (f) Corrective actions taken or planned; (g) Preliminary analysis of the root cause, if available; (h) Recommendations to users or individuals to mitigate risks.

6. Providers shall establish internal procedures for identifying, collecting information about, and reporting serious incidents and malfunctions, including: (a) Clear criteria for what constitutes a reportable incident; (b) Designated responsibilities for incident management and reporting; (c) Standardized forms and templates for reporting; (d) Processes for preliminary and root cause analysis; (e) Procedures for implementing and verifying corrective actions; (f) Training for relevant personnel.

7. The European Neurotechnology Regulatory Authority shall maintain a central database of reported serious incidents and malfunctions and shall analyze trends and patterns to identify systemic risks and develop preventive measures.

8. The Commission shall adopt implementing acts establishing: (a) Standard forms for reporting serious incidents and malfunctions; (b) Detailed reporting timelines for different types of incidents; (c) Procedures for the coordination of incident reporting and investigation between national authorities.

9. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 122(2).

Article 48: Neurotechnology Safety Officers

1. Providers of high-risk neurotechnology shall designate at least one person as a Neurotechnology Safety Officer responsible for ensuring compliance with this Regulation.

2. The Neurotechnology Safety Officer shall possess: (a) Expert knowledge of neurotechnology, including technical aspects and potential impacts on neurocognitive rights; (b) Understanding of risk management principles and methods; (c) Knowledge of regulatory requirements applicable to neurotechnology; (d) Awareness of ethical considerations relevant to neurotechnology; (e) Familiarity with safety and security practices for complex technological systems.

3. The Neurotechnology Safety Officer shall be responsible for: (a) Overseeing the implementation of the risk management system; (b) Ensuring that the technical documentation is complete and up to date; (c) Monitoring compliance with the requirements of this Regulation throughout the neurotechnology lifecycle; (d) Coordinating the post-market monitoring system; (e) Reporting serious incidents and malfunctions to competent authorities; (f) Cooperating with regulatory authorities during inspections and investigations; (g) Providing internal training and guidance on regulatory requirements; (h) Advising on neurocognitive rights considerations in research and development.

4. The Neurotechnology Safety Officer shall: (a) Report directly to the highest management level of the provider; (b) Be provided with sufficient resources to fulfill their responsibilities; (c) Have access to all relevant information and documentation; (d) Be protected from penalties for reporting compliance concerns to management or authorities; (e) Have the authority to stop the distribution or deployment of neurotechnology that presents serious risks.

5. Small providers that meet the definition of micro or small enterprises as defined in Commission Recommendation 2003/361/EC may assign the functions of the

Neurotechnology Safety Officer to a person who also fulfills other functions, provided there is no conflict of interest.

6. The name and contact details of the Neurotechnology Safety Officer shall be communicated to the relevant national competent authority upon request.

7. The Commission shall facilitate the exchange of experience between Neurotechnology Safety Officers through a dedicated network and may develop guidance on best practices for fulfilling the role effectively.

Article 49: Obligations of importers

1. Importers shall place on the Union market only neurotechnology that complies with the requirements of this Regulation.

2. Before placing neurotechnology on the market, importers shall verify that: (a) The neurotechnology bears the CE marking where required; (b) The provider has drawn up the appropriate technical documentation; (c) The neurotechnology is accompanied by the required information and instructions; (d) The provider has complied with the registration obligations in Article 44 for high-risk neurotechnology.

3. Where an importer considers or has reason to believe that neurotechnology is not in conformity with this Regulation, the importer shall not place it on the market until it has been brought into conformity. Where the neurotechnology presents a risk, the importer shall inform the provider and the relevant national competent authorities.

4. Importers shall: (a) Indicate their name, registered trade name or registered trademark, and contact details on the neurotechnology or, where that is not possible, on its packaging or in a document accompanying the neurotechnology; (b) Ensure that transport and storage conditions do not jeopardize the neurotechnology's compliance with the requirements of this Regulation; (c) Keep a copy of the EU declaration of conformity at the disposal of national competent authorities for ten years after the neurotechnology has been placed on the market; (d) Cooperate with national competent authorities and provide them with all necessary information and documentation to demonstrate the conformity of the neurotechnology; (e) Forward to the provider any complaints or reports of incidents from users or individuals; (f) Comply with any measures required by competent authorities to address risks posed by neurotechnology they have placed on the market.

5. Importers who consider or have reason to believe that neurotechnology which they have placed on the market is not in conformity with this Regulation shall immediately inform the provider and cooperate with the provider and the competent authorities on corrective actions.

Article 50: Obligations of distributors

1. When making neurotechnology available on the market, distributors shall act with due care in relation to the requirements of this Regulation.

2. Before making neurotechnology available on the market, distributors shall verify that: (a) The neurotechnology bears the CE marking where required; (b) The

neurotechnology is accompanied by the required information and instructions; (c) The provider and importer have complied with their obligations under this Regulation.

3. Where a distributor considers or has reason to believe that neurotechnology is not in conformity with this Regulation, the distributor shall not make it available on the market until it has been brought into conformity. Where the neurotechnology presents a risk, the distributor shall inform the provider or the importer and the relevant national competent authorities.

4. Distributors shall: (a) Ensure that transport and storage conditions do not jeopardize the neurotechnology's compliance with the requirements of this Regulation; (b) Cooperate with national competent authorities and provide them with all necessary information and documentation to demonstrate the conformity of the neurotechnology; (c) Forward to the provider or importer any complaints or reports of incidents from users or individuals; (d) Comply with any measures required by competent authorities to address risks posed by neurotechnology they have made available on the market.

5. Distributors who consider or have reason to believe that neurotechnology which they have made available on the market is not in conformity with this Regulation shall immediately inform the provider or the importer and cooperate with them and the competent authorities on corrective actions.

Article 51: Cases in which obligations of providers apply to importers and distributors

1. An importer or distributor shall be considered a provider for the purposes of this Regulation and shall be subject to the obligations of the provider under Articles 41 to 48, where the importer or distributor: (a) Places neurotechnology on the market under its name or trademark; (b) Modifies neurotechnology already placed on the market or put into service in a way that may affect compliance with the requirements of this Regulation; (c) Changes the intended purpose of neurotechnology already placed on the market or put into service.

2. Paragraph 1 shall not apply where the modification is limited to changes that: (a) Are authorized by the provider as part of the technical documentation; or (b) Are strictly necessary to repair a defect or restore the neurotechnology to compliance with this Regulation, without changing its functionality or intended purpose.

Article 52: Obligations of users of neurotechnology

1. Users of neurotechnology shall use it in accordance with the instructions for use provided by the provider.

2. Users of high-risk neurotechnology shall: (a) Conduct a neurotechnology impact assessment before putting the high-risk neurotechnology into service, which shall include: (i) An assessment of the intended use and context; (ii) An evaluation of potential impacts on neurocognitive rights, fundamental rights, health, and safety; (iii) An assessment of compliance with the requirements of this Regulation; (iv) The identification of specific risks in the intended use context; (v) The development of appropriate risk mitigation measures; (b) Implement appropriate technical and organizational measures to ensure appropriate levels of security and protection for

neural data; (c) Ensure that human oversight is effectively implemented, including by: (i) Designating persons with appropriate qualifications to perform human oversight functions; (ii) Providing adequate training on the capabilities and limitations of the neurotechnology; (iii) Establishing clear procedures for human intervention; (iv) Maintaining documentation of human oversight activities; (d) Obtain informed neural consent from individuals before using high-risk neurotechnology on them, except in limited circumstances defined in Article 53; (e) Monitor the operation of the high-risk neurotechnology for anomalies, risks, and impacts not identified by the provider; (f) Maintain logs of the use of high-risk neurotechnology in accordance with the instructions provided by the provider and applicable law; (g) Report to the provider and the relevant national competent authority any serious incident or malfunction observed during the use of high-risk neurotechnology.

3. Users shall retain the neurotechnology impact assessment documentation for a period of at least five years from the last use of the high-risk neurotechnology.

4. Professional users of neurotechnology, including healthcare providers, researchers, educators, and employers, shall: (a) Develop internal policies and procedures for the ethical and responsible use of neurotechnology; (b) Ensure that staff using neurotechnology receive appropriate training; (c) Establish oversight mechanisms proportionate to the risks of the neurotechnology; (d) Maintain records of neurotechnology use in accordance with applicable data protection requirements; (e) Regularly review and update practices based on evolving standards and guidelines.

5. Public authorities and institutions using high-risk neurotechnology shall publish information about their use of such systems, including: (a) The types of neurotechnology used; (b) The purposes for which they are used; (c) The safeguards implemented to protect neurocognitive rights; (d) The results of neurotechnology impact assessments, subject to legitimate confidentiality requirements.

6. The requirements in paragraphs 2 and 3 shall not apply to users of high-risk neurotechnology in the course of a personal non-professional activity.

7. The Commission shall adopt delegated acts in accordance with Article 121 to specify the methodology for conducting neurotechnology impact assessments by users.

Article 53: Informed neural consent exceptions

1. The requirement to obtain informed neural consent for the use of neurotechnology may be excepted only in the following limited circumstances and subject to appropriate safeguards: (a) In emergency medical situations where: (i) The individual is physically or mentally incapable of providing consent; (ii) Immediate intervention using neurotechnology is necessary to prevent serious harm to the health of the individual; (iii) Delaying treatment to obtain consent would create a significant risk; (iv) The treatment is in accordance with established medical protocols; (v) Consent is sought from a legally authorized representative where possible; (vi) The individual is informed and consent is sought as soon as practicable; (b) For individuals permanently incapable of providing informed

consent due to cognitive disability, where: (i) The neurotechnology is used for diagnostic or therapeutic purposes with a clear medical benefit; (ii) Consent is obtained from a legally authorized representative; (iii) The intervention is in the best interests of the individual; (iv) The intervention is approved by an ethics committee or court; (v) The individual's assent is sought to the extent possible; (vi) The least intrusive appropriate neurotechnology is used; (c) In research contexts with prior ethics committee approval, where: (i) The research has substantial scientific merit; (ii) The research cannot be conducted with consenting participants; (iii) The research presents minimal risk to participants; (iv) Appropriate safeguards are implemented to protect participants; (v) Consent is obtained retrospectively where possible; (vi) The research complies with all other applicable ethical and legal requirements; (d) In narrowly defined law enforcement contexts, where: (i) There is court authorization based on probable cause that a serious criminal offense has been, is being, or will be committed; (ii) The use of neurotechnology is strictly necessary and proportionate to the legitimate aim; (iii) Other less intrusive investigative methods have been exhausted or would be ineffective; (iv) The use is limited to the minimum extent and duration necessary; (v) There is rigorous oversight and documentation; (vi) The use complies with the requirements specified in Article 55.

2. In all cases where informed neural consent exceptions apply: (a) The dignity and autonomy of the individual shall be respected to the greatest extent possible; (b) The intervention shall be limited to what is necessary to achieve the legitimate purpose; (c) The intervention shall be documented and justified in detail; (d) Appropriate oversight mechanisms shall be implemented; (e) The individual shall be informed about the intervention as soon as practicable, where this would not defeat the purpose of the exception or cause harm; (f) The individual shall have access to effective remedies.

3. Member States shall ensure that these exceptions are interpreted narrowly and that appropriate procedural safeguards are established in national law to prevent misuse.

4. The exceptions in paragraph 1 shall not apply to: (a) Neurotechnology that can substantially alter an individual's sense of identity or agency; (b) Neurotechnology used for behavior modification outside therapeutic contexts; (c) Neurotechnology that enables detailed decoding of thoughts or mental imagery; (d) Neurotechnology used for commercial or security purposes.

5. The Commission shall adopt delegated acts in accordance with Article 121 to supplement this Regulation by specifying: (a) Detailed procedural requirements for the application of each exception; (b) Documentation and justification requirements; (c) Oversight mechanisms and safeguards.

Article 54: Specific provisions for employment contexts

1. In employment contexts, the use of neurotechnology shall be subject to enhanced protections due to inherent power imbalances between employers and employees or job applicants.

2. The use of neurotechnology in employment contexts shall be: (a) Limited to specific, legitimate purposes that cannot be achieved through less intrusive means; (b) Proportionate to those legitimate purposes; (c) Subject to prior consultation with workers' representatives; (d) Transparent to affected employees or applicants; (e) Subject to enhanced data protection safeguards; (f) Limited in scope and duration to what is strictly necessary.

3. Prohibited uses of neurotechnology in employment contexts include: (a) General surveillance of employee cognitive or emotional states; (b) Neural assessment as a general pre-employment screening tool; (c) Continuous monitoring of neural activity during work activities; (d) Neural profiling for promotion, demotion, or termination decisions; (e) Detection of unexpressed thoughts, attitudes, or preferences; (f) Neural data-based assessment of honesty, loyalty, or commitment; (g) Neural enhancement as a mandatory requirement for employment or advancement; (h) Neurostimulation to increase productivity or work capacity.

4. Permissible uses of neurotechnology in employment contexts, subject to specific safeguards, may include: (a) Task-specific assessment for safety-critical occupations where impaired cognitive function could create significant risks, provided that: (i) The assessment is scientifically validated for the specific safety purpose; (ii) The assessment is limited to cognitive functions directly relevant to safety; (iii) The assessment is conducted with the explicit informed neural consent of the individual; (iv) Alternative assessment methods are available upon request where feasible; (v) Results are used solely for the specific safety purpose and not for general employment decisions; (b) Voluntary use of neurotechnology for assistive or accessibility purposes, provided that: (i) The use is genuinely voluntary with no negative consequences for non-participation; (ii) The technology is implemented primarily for the benefit of the employee; (iii) Data collected is strictly limited to that necessary for the assistive function; (iv) Employees maintain control over their data and system operation; (c) Research on occupational health and safety with appropriate ethical approval and safeguards.

5. Where neurotechnology is used in employment contexts, employers shall: (a) Conduct and document a specific neurotechnology impact assessment; (b) Consult with data protection authorities and workers' representatives; (c) Provide comprehensive information to employees about: (i) The specific neurotechnology being used; (ii) The precise purposes for which it is used; (iii) The data collected and how it will be processed; (iv) How the system functions and makes assessments; (v) The employee's rights regarding their neural data; (d) Implement enhanced security measures for employment-related neural data; (e) Establish clear boundaries between work-related neural data and personal information; (f) Provide training for all staff involved in operating or interpreting neurotechnology; (g) Establish and communicate appeal procedures for challenging neurotechnology-based assessments; (h) Maintain detailed records of neurotechnology use.

6. Member States shall ensure that: (a) Labor inspectorates have the mandate and capacity to monitor compliance with these provisions; (b) Workers and job applicants have effective remedies for violations; (c) Collective agreements may establish additional protections but may not reduce the level of protection provided by this Regulation.

7. The European Neurotechnology Regulatory Authority shall develop specific guidelines on the use of neurotechnology in employment contexts in consultation with social partners and relevant stakeholders.

Article 55: Specific provisions for law enforcement contexts

1. The use of neurotechnology by law enforcement, border management, and migration authorities shall be subject to strict limitations and enhanced safeguards due to the potential for serious interference with fundamental rights and neurocognitive rights.

2. The use of neurotechnology in law enforcement contexts shall be: (a) Authorized by clear and precise law that is accessible to the public; (b) Strictly necessary for a legitimate law enforcement purpose that cannot be achieved through less intrusive means; (c) Proportionate to that legitimate purpose; (d) Subject to prior judicial authorization except in narrowly defined emergency situations; (e) Subject to effective oversight by independent authorities; (f) Limited in scope and duration to what is strictly necessary; (g) Subject to documentation and justification requirements; (h) Subject to ex-post review even when authorized.

3. Prohibited uses of neurotechnology in law enforcement contexts include: (a) Generalized or mass surveillance of neural activity in public or private spaces; (b) Neural data collection without specific individualized suspicion; (c) Neural evidence compulsion that violates the right against self-incrimination; (d) Neural assessment of criminal propensity or recidivism risk; (e) Neural deception detection as the sole or determinative evidence in legal proceedings; (f) Neurostimulation or neuromodulation for interrogation purposes; (g) Neural identity profiling based on protected characteristics; (h) Emotion recognition for security screening without specific threat indicators.

4. Permissible uses of neurotechnology in law enforcement contexts, subject to the requirements in paragraph 2, may include: (a) Investigation of serious criminal offenses, defined as offenses punishable by a maximum penalty of at least three years of imprisonment under the law of the Member State concerned, through: (i) Neural evidence collection with judicial warrant based on probable cause; (ii) Neural deception detection as one investigative tool among others; (iii) Passive neural monitoring in narrowly defined high-security areas; (b) Voluntary use in rehabilitation programs with: (i) Genuinely free and informed neural consent; (ii) Scientific validation of the specific application; (iii) Integration with other rehabilitation approaches; (iv) Regular evaluation of effectiveness and impact; (c) Research on forensic applications with appropriate ethical approval and safeguards.

5. Where neurotechnology is used in law enforcement contexts, authorities shall: (a) Conduct and document a specific neurotechnology impact assessment; (b) Implement technical and organizational safeguards against misuse; (c) Ensure that personnel using neurotechnology receive specialized training; (d) Maintain detailed records of each use; (e) Establish secure protocols for neural data handling; (f) Implement rigorous testing and validation of systems before deployment; (g) Submit to regular independent audits; (h) Report annually on the use of neurotechnology to oversight bodies.

6. Judicial authorization for the use of neurotechnology in law enforcement contexts shall specify: (a) The specific purpose for which the neurotechnology may be used; (b) The specific individuals who may be subjected to the neurotechnology; (c) The precise neural data that may be collected; (d) The duration for which the authorization is valid; (e) The specific neurotechnology authorized for use; (f) Any conditions or restrictions on the use; (g) The procedures for handling and protecting the neural data; (h) The safeguards to minimize intrusion into neurocognitive rights.

7. Member States shall ensure that: (a) Clear legal frameworks govern the use of neurotechnology in law enforcement; (b) Independent oversight bodies have the mandate and capacity to monitor compliance; (c) Individuals have effective remedies for violations; (d) Illegally obtained neural evidence is inadmissible in court proceedings.

8. The European Union Agency for Law Enforcement Training (CEPOL) shall develop specialized training on the ethical and lawful use of neurotechnology in law enforcement.

Article 56: Specific provisions for educational contexts

1. The use of neurotechnology in educational contexts, particularly involving minors, shall be subject to enhanced protections due to the developmental vulnerability of learners and the potential for long-term impacts.

2. The use of neurotechnology in educational contexts shall be: (a) Primarily oriented toward the educational benefit of the learner; (b) Age-appropriate and developmentally suitable; (c) Evidence-based with scientific validation for educational applications; (d) Transparent to learners, parents, and educators; (e) Subject to enhanced data protection safeguards; (f) Implemented with appropriate oversight and evaluation.

3. Prohibited uses of neurotechnology in educational contexts include: (a) Continuous monitoring of students' neural activity for assessment or evaluation; (b) Neural tracking of attentiveness or engagement as a basis for disciplinary measures; (c) Cognitive ability streaming or tracking based primarily on neural data; (d) Neural profiling that may limit educational opportunities or expectations; (e) Emotional state monitoring for behavioral management; (f) Neurostimulation to enhance learning without thorough research validation; (g) Neurotechnology-based assessment as the sole or primary basis for significant educational decisions; (h) Commercial use of students' neural data for product development without specific consent.

4. Permissible uses of neurotechnology in educational contexts, subject to appropriate safeguards, may include: (a) Support for learners with specific educational needs, provided that: (i) The technology is implemented primarily for the benefit of the learner; (ii) It is part of a comprehensive educational support approach; (iii) Informed neural consent is obtained from parents or guardians and age-appropriate assent from the learner; (iv) Regular evaluation of benefits and impacts is conducted; (b) Educational research with appropriate ethical approval, provided that: (i) The research has clear educational benefits; (ii) The research follows established ethical principles for research with minors; (iii) Informed neural

consent is obtained from parents or guardians and age-appropriate assent from learners; (iv) The research is subject to ongoing ethical oversight; (v) Results are shared to advance educational knowledge; (c) Development of targeted interventions for specific learning challenges, provided that: (i) The interventions are evidence-based; (ii) They are implemented under professional supervision; (iii) They are regularly assessed for effectiveness; (iv) They respect learner autonomy and diversity.

5. Where neurotechnology is used in educational contexts, educational institutions shall: (a) Conduct and document a specific neurotechnology impact assessment with particular attention to developmental impacts; (b) Provide comprehensive, age-appropriate information to learners and parents about: (i) The specific neurotechnology being used; (ii) The precise educational purposes; (iii) The data collected and how it will be processed; (iv) How the system functions and makes assessments; (v) The learner's and parents' rights regarding neural data; (c) Implement enhanced security and privacy measures for learners' neural data; (d) Ensure that educational staff using neurotechnology receive specialized training; (e) Maintain detailed records of neurotechnology use; (f) Establish clear procedures for addressing concerns raised by learners or parents; (g) Regularly evaluate the educational benefits and any unintended consequences of neurotechnology use.

6. For neurotechnology used with learners under 16 years of age: (a) Informed neural consent must be obtained from parents or legal guardians; (b) Age-appropriate information and the opportunity to assent or object must be provided to the learner; (c) The neurotechnology must be specifically designed and validated for the developmental stage of the learner; (d) Enhanced monitoring for unanticipated developmental impacts must be implemented; (e) The duration and frequency of use must be appropriate for the developmental stage; (f) Neural data collected must be deleted when no longer needed for the specific educational purpose, and in any case no later than five years after collection, unless longer retention is justified by ongoing educational needs or research with appropriate safeguards.

7. Member States shall ensure that: (a) Educational authorities have clear guidelines for the appropriate use of neurotechnology; (b) Independent oversight mechanisms monitor the use of neurotechnology in educational settings; (c) Parents and learners have effective remedies for violations; (d) Educational equity is protected when neurotechnology is deployed.

8. The Commission shall adopt delegated acts in accordance with Article 121 to supplement this Regulation by specifying: (a) Age-appropriate information and consent procedures; (b) Criteria for educational validation of neurotechnology; (c) Safeguards specific to different educational settings.

Article 57: Specific provisions for healthcare contexts

1. The use of neurotechnology in healthcare contexts shall balance therapeutic benefits with protection of neurocognitive rights, recognizing the unique vulnerability of patients and the potential significance of neurological and psychiatric interventions.

2. The use of neurotechnology in healthcare contexts shall be: (a) Based on valid clinical indications with evidence of safety and efficacy; (b) Subject to appropriate medical supervision; (c) Preceded by comprehensive informed neural consent except in emergency situations as specified in Article 53; (d) Integrated with appropriate clinical assessment and judgment; (e) Subject to ongoing evaluation of therapeutic benefit and side effects; (f) Implemented with heightened protection for neural data.

3. For therapeutic neurotechnology that may significantly affect cognitive functions, identity, or agency, enhanced safeguards shall include: (a) Detailed disclosure of potential cognitive and psychological effects; (b) Extended consent processes with multiple opportunities for questions and reflection; (c) Independent evaluation of capacity to consent where appropriate; (d) Gradual implementation with ongoing assessment of effects; (e) Psychological support before, during, and after intervention; (f) Clear protocols for modifying or discontinuing treatment if significant adverse effects occur.

4. For experimental or novel therapeutic neurotechnology: (a) Clear distinction between established therapeutic and experimental applications shall be maintained; (b) Additional oversight through research ethics committees or specialized medical technology assessment bodies shall be required; (c) Enhanced monitoring protocols shall be implemented; (d) Specific informed consent for experimental aspects shall be obtained; (e) Results shall be systematically collected and analyzed to build the evidence base.

5. For neurotechnology used for diagnosis or assessment: (a) The diagnostic limitations and error rates shall be clearly communicated; (b) Clinical decisions shall not be based solely on neurotechnology outputs without professional evaluation; (c) Patients shall have access to explanations of how the technology contributes to diagnosis; (d) Results shall be communicated in a manner that avoids reductive interpretations of complex neural states.

6. Healthcare providers using neurotechnology shall: (a) Ensure that healthcare professionals using neurotechnology receive specialized training; (b) Implement technical and organizational measures to ensure the security of neural data; (c) Establish clear protocols for addressing adverse events or unanticipated effects; (d) Maintain detailed documentation of neurotechnology use; (e) Contribute to post-market surveillance by reporting outcomes and adverse events.

7. For vulnerable patients, including those with impaired decision-making capacity, additional safeguards shall include: (a) Assessment of capacity specific to the neurotechnology decision; (b) Involvement of legally authorized representatives where appropriate; (c) Consideration of previously expressed wishes where available; (d) Enhanced scrutiny of the necessity and proportionality of the intervention; (e) Regular reassessment of the appropriateness of continued use.

8. This Article complements and does not replace the requirements of Regulation (EU) 2017/745 on medical devices. Where the requirements of this Regulation conflict with the requirements of Regulation (EU) 2017/745, the requirements of Regulation (EU) 2017/745 shall prevail in relation to safety and performance, but the provisions of this Regulation shall prevail in relation to neurocognitive rights protections.

Article 58: Neural data governance

1. Providers and users of neurotechnology shall implement appropriate technical and organizational measures to ensure the protection of neural data and compliance with Regulation (EU) 2016/679.

2. Neural data shall be considered a special category of personal data within the meaning of Article 9 of Regulation (EU) 2016/679 and shall be subject to the corresponding enhanced protections.

3. In addition to the requirements of Regulation (EU) 2016/679, the processing of neural data shall be subject to the following specific requirements: (a) Purpose limitation: Neural data shall be collected and processed only for specified, explicit, and legitimate purposes, and shall not be processed in a manner that is incompatible with those purposes. Secondary use of neural data shall require specific informed neural consent, except for scientific research subject to appropriate safeguards. (b) Data minimization: Only neural data that is adequate, relevant, and limited to what is necessary for the specific purpose shall be collected and processed. Neural data collection shall be targeted to specific neural signals or patterns relevant to the purpose rather than general brain activity where technically feasible. (c) Accuracy and quality: Neural data processing shall implement appropriate technical measures to ensure data quality, accuracy, and reliability, including methods to identify and address artifacts, noise, or other factors that may affect the interpretation of neural data. (d) Storage limitation: Neural data shall be kept in a form which permits identification of data subjects for no longer than is necessary for the purposes for which the personal data are processed. Specific retention periods shall be established and communicated to individuals. (e) Security: Enhanced technical and organizational security measures shall be implemented for neural data, proportionate to the sensitivity of the data and the potential impact of a data breach on neurocognitive rights. (f) Transparency: Individuals shall receive clear information about what neural data is collected, how it is processed, what inferences may be drawn from it, and how it may be used. (g) Individual control: Individuals shall have enhanced control over their neural data, including simplified access, correction, deletion, and portability options.

4. Providers and users of neurotechnology shall conduct a Data Protection Impact Assessment in accordance with Article 35 of Regulation (EU) 2016/679 before processing neural data, which shall specifically address: (a) The specific categories of neural data to be processed; (b) The methods of neural data collection and processing; (c) The potential impact on neurocognitive rights; (d) The risk of revealing information beyond what the individual intends to disclose; (e) The potential for re-identification of anonymized neural data; (f) The specific measures implemented to protect neural data; (g) The protocols for neural data breach response.

5. For neural data that may reveal detailed information about cognitive processes, mental states, or neural signatures that could uniquely identify individuals, enhanced protection measures shall include: (a) Advanced encryption for storage and transmission; (b) Access controls limited to specifically authorized personnel; (c) Audit trails of all access and processing; (d) Techniques to limit the precision or

granularity of data where compatible with the purpose; (e) Technical segregation from other data that could enable enhanced profiling when combined.

6. For research involving neural data, the following specific provisions apply: (a) Neural data may be processed for scientific research purposes subject to appropriate safeguards, which shall include at minimum: (i) Technical and organizational measures to ensure respect for the principle of data minimization; (ii) Anonymization where compatible with the research purpose; (iii) Where anonymization would prevent achievement of the research purpose, pseudonymization and additional security measures; (iv) Clear governance frameworks for research data access and sharing; (v) Ethics committee review and approval; (vi) Transparent research protocols and purposes. (b) Neural data collected for research shall not be used for commercial purposes or applications without explicit consent for such use. (c) Research results shall be published in a manner that does not permit the identification of individual data subjects.

7. Neural data trusts may be established to enable responsible use of neural data for research and innovation while ensuring enhanced protection. Neural data trusts shall: (a) Operate as independent fiduciary entities with clear governance structures; (b) Hold and manage neural data with legally enforceable responsibilities to the data subjects; (c) Ensure that neural data is used in accordance with the specified purposes and ethical guidelines; (d) Implement robust security and privacy measures; (e) Facilitate individual control over neural data while enabling beneficial collective use; (f) Provide transparency about data uses and access; (g) Be subject to regulatory oversight.

8. The European Data Protection Board shall issue guidelines on the application of data protection law to neural data, in consultation with the European Neurotechnology Regulatory Authority.

Article 59: Neural data breach notification

1. In the event of a neural data breach, the controller shall, in addition to the requirements of Article 33 of Regulation (EU) 2016/679: (a) Notify the competent supervisory authority without undue delay and no later than 24 hours after becoming aware of the breach; (b) Include in the notification: (i) The specific categories of neural data affected; (ii) The potential neurocognitive rights impacts of the breach; (iii) The technical context of the neurotechnology involved; (iv) The specific measures being taken to address neurocognitive rights impacts; (c) Notify the European Neurotechnology Regulatory Authority simultaneously with the notification to the supervisory authority.

2. Where a neural data breach is likely to result in a high risk to the neurocognitive rights of individuals, the controller shall, in addition to the requirements of Article 34 of Regulation (EU) 2016/679: (a) Communicate the breach to the affected individuals without undue delay; (b) Provide clear information about the specific neurocognitive rights implications of the breach; (c) Offer specialized support services appropriate to the nature of the breach, which may include psychological support, identity protection services, or specialized advice.

3. For neural data breaches that may enable detailed inference about cognitive processes, mental states, or thought content, enhanced response measures shall include: (a) Immediate containment actions to prevent further access to or use of the data; (b) Specialized forensic investigation to determine the extent and nature of compromise; (c) Comprehensive mitigation strategies specific to neural data risks; (d) Ongoing monitoring for potential misuse of compromised neural data.

4. The European Data Protection Board, in consultation with the European Neurotechnology Regulatory Authority, shall issue guidelines on neural data breach management, including: (a) Risk assessment methodologies specific to neural data breaches; (b) Technical measures for containing and mitigating neural data breaches; (c) Templates for neural data breach notifications; (d) Best practices for communicating with affected individuals.

Article 60: Data Protection Officers with neural expertise

1. Organizations that process neural data on a large scale shall designate a Data Protection Officer in accordance with Article 37 of Regulation (EU) 2016/679 who has specific expertise in neural data protection.

2. In addition to the tasks set out in Article 39 of Regulation (EU) 2016/679, the Data Protection Officer shall, in relation to neural data: (a) Provide specialized advice on neural data governance; (b) Monitor compliance with the specific provisions for neural data in this Regulation; (c) Advise on neurotechnology impact assessments; (d) Serve as a contact point for individuals on neurocognitive rights matters; (e) Coordinate with the European Neurotechnology Regulatory Authority on relevant issues; (f) Stay informed about developments in neurotechnology and neural data protection.

3. The Data Protection Officer shall be provided with the resources necessary to acquire and maintain expertise in neural data protection and neurotechnology.

4. The European Data Protection Board, in cooperation with the European Neurotechnology Regulatory Authority, shall develop certification programs for neural data protection expertise.

TITLE VII: NEURAL DATA GOVERNANCE

Article 61: Neural data processing principles

1. In addition to the principles set out in Article 5 of Regulation (EU) 2016/679, the processing of neural data shall be guided by the following specific principles: (a) Cognitive liberty: Neural data processing shall respect and preserve the individual's right to autonomous control over their own cognitive functions, mental processes, and consciousness; (b) Mental privacy: Neural data processing shall respect the intimate nature of information derived from cognitive processes and shall implement enhanced protections commensurate with this sensitivity; (c) Cognitive identity integrity: Neural data processing shall respect and preserve the continuity and authenticity of an individual's cognitive processes and sense of self; (d) Neural security: Neural data processing shall implement measures to protect against unauthorized access to neural systems or data that could enable cognitive influence or control; (e) Informed neural participation: Individuals shall be

empowered to make informed decisions about the collection and use of their neural data through comprehensive information and meaningful control mechanisms; (f) Beneficial purpose: Neural data processing shall be oriented toward legitimate purposes that benefit individuals or society while respecting neurocognitive rights.

2. Neural data processing shall be designed and conducted in a manner that: (a) Prioritizes individual autonomy and agency; (b) Minimizes intrusion into mental privacy; (c) Prevents exploitation of neural vulnerabilities; (d) Respects the diversity of cognitive functioning; (e) Protects against cognitive discrimination; (f) Prevents undue influence or manipulation through neural data; (g) Ensures equitable access to benefits while distributing risks fairly.

3. The European Data Protection Board, in cooperation with the European Neurotechnology Regulatory Authority, shall issue guidelines on the application of these principles to specific contexts and technologies.

Article 62: Specific requirements for neural data processing systems

1. Systems that process neural data shall be designed and developed to incorporate appropriate safeguards from the earliest stages of development through a neural data protection by design approach.

2. Technical measures to protect neural data shall include: (a) Architecture-level safeguards that segregate neural data from other data types; (b) Technical limitations on the granularity or precision of neural data collection where compatible with the purpose; (c) Processing methods that minimize the risk of extracting information beyond what is necessary for the intended purpose; (d) Technical measures to prevent function creep and purpose expansion; (e) Built-in transparency mechanisms that make neural data processing comprehensible to individuals; (f) Technical controls that enable individuals to effectively exercise their rights over neural data; (g) Enhanced encryption and security measures appropriate to the sensitivity of neural data; (h) Audit mechanisms that enable verification of compliance with processing limitations.

3. Neural data processing systems shall implement appropriate verification mechanisms for: (a) Identity verification before access to neural data; (b) Authorization verification for neural data processing operations; (c) Authentication of sources and recipients for neural data transfers; (d) Verification of data integrity to prevent tampering; (e) Validation of processing operations against specified parameters.

4. For neural data processing systems that involve artificial intelligence, additional requirements include: (a) Explainability mechanisms proportionate to the potential impact on neurocognitive rights; (b) Human oversight of significant decisions or inferences based on neural data; (c) Bias detection and mitigation specific to neural data processing; (d) Regular evaluation of accuracy and reliability across diverse populations; (e) Clearly defined boundaries for automation in neural data processing.

5. The Commission shall adopt delegated acts in accordance with Article 121 to supplement this Regulation by specifying technical standards for neural data

processing systems, including: (a) Security requirements proportionate to different sensitivity levels of neural data; (b) Interoperability standards for secure neural data exchange; (c) Technical methods for neural data minimization, anonymization, and pseudonymization; (d) Technical parameters for neural data storage and transmission.

Article 63: Neural data protection impact assessment

1. In addition to the data protection impact assessment required under Article 35 of Regulation (EU) 2016/679, controllers shall conduct a specific neural data protection impact assessment when processing neural data.

2. The neural data protection impact assessment shall address the specific risks to neurocognitive rights, including: (a) The potential impact on cognitive liberty, including risks of undue influence, manipulation, or restriction of cognitive autonomy; (b) The potential impact on mental privacy, including risks of revealing information beyond what the individual intends to disclose; (c) The potential impact on cognitive identity integrity, including risks to an individual's sense of self or personal identity; (d) The potential for neural profiling that could lead to discrimination or stigmatization; (e) The potential for neural security breaches that could enable unauthorized access to or influence over cognitive processes; (f) The potential for dependency or addiction related to neurotechnology; (g) The specific risks to vulnerable individuals or groups.

3. The neural data protection impact assessment shall include: (a) A systematic description of the neural data processing operations and their purposes; (b) An assessment of the necessity and proportionality of the processing in relation to the purposes; (c) A specific analysis of the categories of neural data and their sensitivity; (d) An evaluation of the neural data collection methods and their intrusiveness; (e) An assessment of the analytical methods applied to neural data and their potential to reveal sensitive information; (f) An evaluation of existing safeguards, security measures, and mechanisms to protect neurocognitive rights; (g) Proposed additional measures to address the identified risks; (h) Documentation of the consultation process with affected individuals or their representatives.

4. For high-risk neurotechnology as defined in Article 23, the neural data protection impact assessment shall be conducted prior to the development of the neurotechnology and shall be updated throughout the development cycle.

5. Controllers shall review the neural data protection impact assessment whenever there is a change in the risk represented by the neural data processing activities, and at least every two years.

6. The European Data Protection Board, in cooperation with the European Neurotechnology Regulatory Authority, shall issue guidelines on the methodology for neural data protection impact assessments.

Article 64: Right to neural data access and explanation

1. In addition to the right of access set out in Article 15 of Regulation (EU) 2016/679, individuals shall have the right to obtain from the controller: (a) Confirmation as to whether or not neural data concerning the individual is being processed; (b) Access

to the neural data in both raw form and processed form, where technically feasible; (c) Information about the specific neural signals or patterns being monitored or recorded; (d) Information about the analytical methods used to interpret neural data; (e) Information about the inferences drawn from neural data; (f) Explanation of how neural data contributes to automated decisions or profiling; (g) Information about potential unintended information that may be extracted from the neural data; (h) Information about neural data security measures.

2. The information shall be provided in a clear, comprehensible form that is accessible to individuals without specialized technical knowledge, while providing sufficient detail for meaningful understanding.

3. For complex neural data processing, controllers shall offer the option of an interactive explanation that allows individuals to: (a) Explore different aspects of the neural data processing; (b) Access different levels of technical detail according to their interest and capacity; (c) Understand the relationship between their neural data and resulting outputs or decisions; (d) Visualize their neural data in an intuitive format; (e) Receive answers to specific questions about their neural data.

4. Where the provision of raw neural data would be impractical due to the volume or technical nature of the data, the controller shall: (a) Provide meaningful summaries or visualizations of the data; (b) Offer selective access to specific portions of data upon request; (c) Provide the data in machine-readable format to a technical representative designated by the individual if requested; (d) Make the complete data available for in-person review with appropriate technical support.

5. The right to neural data access and explanation may be exercised without excessive constraint, at reasonable intervals, and free of charge.

6. The Commission shall adopt delegated acts in accordance with Article 121 to supplement this Regulation by specifying technical standards for neural data access and explanation, including: (a) Formats for providing neural data access; (b) Methods for providing comprehensible explanations of neural data processing; (c) Requirements for interactive explanation systems.

Article 65: Right to neural data portability

1. In addition to the right to data portability set out in Article 20 of Regulation (EU) 2016/679, individuals shall have the right to receive the neural data concerning them in a structured, commonly used, machine-readable, and interoperable format and to transmit that data to another controller without hindrance.

2. This right shall apply to: (a) Neural data provided knowingly and actively by the individual; (b) Neural data observed from the individual's neural activity; (c) To the extent technically feasible, inferences derived directly from the individual's neural data that characterize specific aspects of their neural function.

3. The right to neural data portability shall include: (a) The right to receive a complete copy of relevant neural data; (b) The right to have the neural data transmitted directly from one controller to another where technically feasible; (c) The right to receive associated metadata necessary for meaningful interpretation of the neural data; (d) The right to receive information about the data format and structure to facilitate

reuse; (e) The right to receive neural data at a frequency that allows meaningful continuity of service or application.

4. Controllers shall implement neural data portability in a manner that: (a) Preserves the utility and interpretability of the neural data; (b) Maintains appropriate contextual information; (c) Enables functional equivalence when the data is used in a new system; (d) Includes relevant calibration or normalization parameters; (e) Supports interoperability through open standards where available.

5. For therapeutic neurotechnology, neural data portability shall include: (a) Therapeutic context and relevant medical information; (b) Configuration settings that have proven effective for the individual; (c) History of parameter adjustments and associated outcomes; (d) Relevant baseline and comparative data; (e) Information necessary for continuity of care.

6. The right to neural data portability shall not adversely affect the rights and freedoms of others. Where a dataset includes neural data from multiple individuals, portability shall be implemented in a way that protects the neural data of other individuals.

7. Controllers shall provide neural data in a format that incorporates appropriate security measures to protect the data during transmission and subsequent use.

8. The European Data Protection Board, in cooperation with the European Neurotechnology Regulatory Authority, shall issue guidelines on: (a) Technical standards for neural data portability; (b) Methods for implementing direct controller-to-controller transmission; (c) Approaches to handling derived and inferred neural data; (d) Security requirements for portable neural data.

Article 66: Neural data deletion and right to neural erasure

1. In addition to the right to erasure set out in Article 17 of Regulation (EU) 2016/679, individuals shall have the right to obtain from the controller the erasure of neural data concerning them without undue delay.

2. Controllers shall erase neural data without undue delay when: (a) The neural data is no longer necessary in relation to the purposes for which it was collected or processed; (b) The individual withdraws consent and there is no other legal ground for processing; (c) The individual objects to the processing and there are no overriding legitimate grounds for the processing; (d) The neural data has been unlawfully processed; (e) The neural data must be erased for compliance with a legal obligation; (f) The neural data has been collected in relation to the offer of information society services to a child.

3. The right to neural erasure shall include: (a) Erasure of raw neural data; (b) Erasure of processed neural data; (c) Erasure of neural profiles derived from the data; (d) Erasure of inferences drawn specifically from the individual's neural data where technically feasible; (e) Removal of the individual's neural data from training datasets for algorithms or models; (f) Where technically feasible, mitigation of the influence of the individual's neural data on trained models.

4. Neural data erasure shall be implemented in a manner that: (a) Renders the neural data permanently inaccessible and unrecoverable; (b) Includes data in backup and archive systems within reasonable timeframes; (c) Includes neural data shared with or transferred to third parties, with the controller taking reasonable steps to inform other controllers processing the neural data; (d) Is verified through appropriate technical means; (e) Is documented to provide evidence of compliance.

5. Where complete technical erasure of influence on trained models is not feasible, controllers shall: (a) Implement alternative measures to minimize ongoing influence of the data; (b) Be transparent about the technical limitations; (c) Document the approaches taken to mitigate ongoing influence; (d) Consider retraining models without the individual's data when proportionate to the sensitivity of the data and purpose.

6. The right to neural erasure is subject to the exemptions set out in Article 17(3) of Regulation (EU) 2016/679, which shall be interpreted narrowly in relation to neural data and with particular attention to the protection of neurocognitive rights.

7. Controllers shall respond to requests for neural data erasure without undue delay and in any event within one month of receipt of the request, with the possibility of extending this period by two further months where necessary, taking into account the complexity and number of requests.

8. The European Data Protection Board, in cooperation with the European Neurotechnology Regulatory Authority, shall issue guidelines on technical methods for effective neural data erasure.

Article 67: Neural data anonymization and pseudonymization

1. Given the unique characteristics of neural data, enhanced standards shall apply to anonymization and pseudonymization of neural data.

2. Neural data shall be considered anonymized only when: (a) The data has been processed in such a manner that it can no longer be used to identify a natural person by any means reasonably likely to be used, taking into account: (i) The distinctive nature of neural patterns; (ii) The potential for identification through correlation with other datasets; (iii) The evolving capabilities of neural decoding technologies; (iv) The potential for re-identification through distinctive neural signatures; (b) The anonymization process meets technical standards established by the European Data Protection Board in cooperation with the European Neurotechnology Regulatory Authority; (c) The controller has conducted and documented a specific re-identification risk assessment for neural data; (d) The controller implements ongoing monitoring of re-identification risks as technology evolves.

3. For neural data pseudonymization: (a) The pseudonymization shall be implemented through technical and organizational measures that ensure that additional information is kept separately and subject to technical and organizational measures to ensure non-attribution; (b) The controller shall maintain an enhanced separation between the pseudonymized data and the information that could enable re-identification; (c) The controller shall implement specific access controls for re-

identification keys; (d) The pseudonymization shall be resistant to pattern-matching attacks that could link pseudonymized neural data to identified individuals.

4. Controllers implementing neural data anonymization or pseudonymization shall: (a) Document the specific techniques and methods used; (b) Assess and document the residual re-identification risk; (c) Implement additional security measures proportionate to the residual risk; (d) Regularly review and update anonymization or pseudonymization methods as technology evolves; (e) Establish procedures for responding to discovered vulnerabilities in anonymization methods.

5. For scientific research, statistical purposes, or archiving in the public interest, controllers may implement: (c) Differential privacy measures calibrated to the sensitivity of neural data; (d) Synthetic neural data generation that preserves analytical utility while eliminating individual identifiability; (e) Federated analysis approaches that avoid centralized storage of raw neural data.

6. The Commission shall adopt delegated acts in accordance with Article 121 to supplement this Regulation by specifying: (a) Technical standards for neural data anonymization; (b) Methodologies for assessing re-identification risk specific to neural data; (c) Requirements for pseudonymization of different categories of neural data; (d) Best practices for implementation of privacy-enhancing technologies for neural data.

Article 68: International transfer of neural data

1. In addition to the requirements for international transfers of personal data under Chapter V of Regulation (EU) 2016/679, transfers of neural data to third countries or international organizations shall be subject to enhanced safeguards.

2. For neural data transfers on the basis of an adequacy decision under Article 45 of Regulation (EU) 2016/679, the Commission shall specifically assess: (a) Whether the third country's legal framework provides specific protections for neurocognitive rights; (b) Whether the third country has specific regulations governing neurotechnology and neural data; (c) The third country's approach to emerging challenges related to neural data and neurocognitive rights; (d) The third country's oversight mechanisms for neural data processing.

3. For neural data transfers subject to appropriate safeguards under Article 46 of Regulation (EU) 2016/679, additional requirements shall include: (a) Specific contractual clauses addressing neurocognitive rights protection; (b) Technical measures to ensure heightened protection during transfer and subsequent processing; (c) Auditing rights that extend to neural data processing activities; (d) Explicit prohibitions on uses of neural data that would violate neurocognitive rights.

4. For transfers of neural data to third countries in the absence of an adequacy decision or appropriate safeguards, the derogations under Article 49 of Regulation (EU) 2016/679 shall be interpreted restrictively and shall not apply to large-scale or systematic transfers of neural data.

5. Controllers shall conduct and document a specific impact assessment before transferring neural data internationally, which shall include: (a) The categories and sensitivity of neural data to be transferred; (b) The specific purposes of the transfer;

(c) The legal framework in the recipient country relevant to neurocognitive rights; (d) The technical and organizational measures implemented to protect the data; (e) The specific risks to neurocognitive rights and mitigating measures.

6. The European Data Protection Board, in cooperation with the European Neurotechnology Regulatory Authority, shall issue guidelines on international transfers of neural data.

TITLE VIII: CONFORMITY ASSESSMENT AND CERTIFICATION

Article 69: Conformity assessment

1. Before placing high-risk neurotechnology on the market or putting it into service, providers shall ensure that it has undergone an appropriate conformity assessment in accordance with this Title.

2. High-risk neurotechnology shall be subject to conformity assessment through one of the following procedures: (a) Conformity assessment based on internal control by the provider as set out in Annex VI, for high-risk neurotechnology that is developed in accordance with harmonized standards, provided that those standards cover all the requirements of this Regulation that apply to the neurotechnology; (b) Conformity assessment with the involvement of a notified body as set out in Annex VII, for all other high-risk neurotechnology.

3. When conducting the conformity assessment, the provider shall: (a) Ensure that the high-risk neurotechnology complies with the requirements set out in Title V; (b) Follow the applicable conformity assessment procedure; (c) Compile the technical documentation required under Article 30; (d) Demonstrate compliance with the applicable requirements to the notified body where required; (e) Obtain the relevant certificates from the notified body where required.

4. The conformity assessment shall specifically address: (a) The neurocognitive rights implications of the neurotechnology; (b) The neural data governance systems implemented; (c) The effectiveness of risk management measures; (d) The adequacy of human oversight mechanisms; (e) The robustness of security and privacy protections.

5. For high-risk neurotechnology that continues to learn after being placed on the market or put into service, the conformity assessment shall also address: (a) The learning boundaries of the system; (b) The change management systems implemented; (c) The monitoring and control mechanisms for ongoing learning; (d) The update and re-assessment procedures.

6. The Commission shall adopt delegated acts in accordance with Article 121 to supplement this Regulation by updating Annexes VI and VII to adapt the conformity assessment procedures to technical progress.

Article 70: EU declaration of conformity

1. The provider shall draw up a written EU declaration of conformity for each high-risk neurotechnology and keep it at the disposal of the national competent authorities for ten years after the high-risk neurotechnology has been placed on the market or put into service.

2. The EU declaration of conformity shall identify the high-risk neurotechnology for which it has been drawn up and shall contain: (a) The name and address of the provider and, where applicable, its authorized representative; (b) A statement that the high-risk neurotechnology is in conformity with this Regulation; (c) Information about the conformity assessment procedure followed; (d) The identification of any notified body involved; (e) The reference numbers of any EU technical documentation assessment certificate or EU quality management system approval certificate issued by a notified body; (f) A statement regarding compliance with relevant harmonized standards, where applicable; (g) The date of issue of the declaration; (h) The signature of the person empowered to draw up the declaration.

3. The EU declaration of conformity shall be translated into the official languages of the Member States in which the high-risk neurotechnology is made available.

4. The Commission shall adopt implementing acts to establish a model EU declaration of conformity. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 122(2).

Article 71: CE marking of conformity

1. The CE marking shall be affixed to high-risk neurotechnology in a visible, legible, and indelible form.

2. The CE marking shall be subject to the general principles set out in Article 30 of Regulation (EC) No 765/2008.

3. Where applicable, the CE marking shall be followed by the identification number of the notified body responsible for the conformity assessment procedures.

4. For high-risk neurotechnology that is too small to display the CE marking, the marking may be affixed to the packaging or to accompanying documentation.

5. Member States shall build upon existing mechanisms to ensure correct application of the CE marking regime and shall take appropriate action in the event of improper use.

Article 72: Notified bodies

1. Member States shall designate notified bodies to carry out conformity assessment activities under this Regulation.

2. Notified bodies shall: (a) Be established under the national law of a Member State; (b) Have legal personality; (c) Be third-party bodies independent of the providers they assess; (d) Possess the necessary expertise in neurotechnology, neural data protection, and neurocognitive rights; (e) Meet the organizational, quality management, resources, and process requirements set out in Annex VIII.

3. Notified bodies shall have the capability to carry out all the conformity assessment tasks assigned to them by this Regulation, with the highest degree of professional integrity and the requisite technical and scientific competence in the specific field.

4. Notified bodies designated for high-risk neurotechnology shall have: (a) Personnel with expertise in neuroscience, neural engineering, and neurotechnology; (b) Staff with knowledge of neurocognitive rights and ethical implications of

neurotechnology; (c) Technical capabilities to assess different types of neurotechnology; (d) Knowledge of relevant standards and testing methodologies; (e) Understanding of neural data protection requirements.

5. Member States shall establish procedures for the assessment, designation, notification, monitoring, and review of notified bodies in accordance with Regulation (EU) No 1025/2012, ensuring that notified bodies maintain the required expertise.

6. The Commission shall publish a list of notified bodies, including their identification numbers and the conformity assessment activities for which they have been designated. The Commission shall ensure that the list is kept up to date.

Article 73: Application for designation as a notified body

1. A conformity assessment body shall submit an application for designation as a notified body to the national authority of the Member State in which it is established.

2. The application shall specify the types of high-risk neurotechnology for which the body is applying to be designated and shall include: (a) Documentation demonstrating that the body meets the requirements laid down in Annex VIII; (b) Evidence of specific expertise in neurotechnology assessment; (c) Information on the body's quality management system; (d) Information on the body's personnel, including their qualifications and expertise; (e) Information on subsidiaries and subcontractors, if any; (f) A description of the procedures used for performing conformity assessment activities; (g) Evidence of the body's impartiality and independence.

3. The national authority shall assess whether the conformity assessment body meets the requirements laid down in Annex VIII and shall prepare an assessment report.

4. If the assessment is positive, the Member State shall notify the Commission and the other Member States of the conformity assessment body it has designated.

5. The Commission shall assign an identification number to the notified body and shall publish the notification in the Official Journal of the European Union within one month of receiving the notification from the Member State.

Article 74: Changes to notifications

1. Where a national authority has ascertained or has been informed that a notified body no longer meets the requirements laid down in Annex VIII, or that it is failing to fulfill its obligations, the national authority shall restrict, suspend, or withdraw the notification as appropriate, depending on the seriousness of the failure to meet those requirements or fulfill those obligations.

2. In the event of restriction, suspension, or withdrawal of notification, or where the notified body has ceased its activity, the Member State concerned shall: (a) Inform the Commission and the other Member States without delay; (b) Take appropriate steps to ensure that the files of that notified body are either processed by another notified body or kept available for the competent authorities.

3. The Commission shall publish in the Official Journal of the European Union any changes to the notification status of notified bodies.

Article 75: Challenge to the competence of notified bodies

1. The Commission shall investigate all cases where concerns have been brought to its attention regarding the competence of a notified body or the continued fulfillment by a notified body of the requirements and responsibilities to which it is subject.

2. The Member State that notified the body in question shall provide the Commission, upon request, with all information relating to the basis for the notification or the maintenance of the competence of the notified body concerned.

3. The Commission shall ensure that all sensitive information obtained in the course of its investigations is treated confidentially.

4. Where the Commission ascertains that a notified body does not meet or no longer meets the requirements for its notification, it shall inform the notifying Member State accordingly and request it to take the necessary corrective measures, including de-notification if necessary.

Article 76: Specific provisions for research on neurotechnology

1. Research on neurotechnology shall be conducted in accordance with recognized ethical standards and shall respect neurocognitive rights.

2. Research involving human subjects shall be subject to: (a) Prior ethics committee review and approval; (b) Informed neural consent from participants, except in limited circumstances as specified in Article 53(1)(c); (c) Continuous monitoring and evaluation of impacts on neurocognitive rights; (d) Appropriate risk management measures; (e) Transparency about research purposes and methods.

3. Research ethics committees reviewing neurotechnology research shall: (a) Include members with expertise in neuroscience, neurotechnology, and neuroethics; (b) Assess the research's potential impact on neurocognitive rights; (c) Evaluate the adequacy of informed neural consent procedures; (d) Assess the risk-benefit balance of the research; (e) Evaluate the neural data protection measures; (f) Review monitoring and oversight plans; (g) Consider long-term implications for participants.

4. Research protocols shall include: (a) Clear research questions and objectives; (b) Justification for the use of neurotechnology; (c) Specific neural data to be collected and processed; (d) Methods for protecting neurocognitive rights; (e) Procedures for identifying and addressing adverse events; (f) Plans for responsibly sharing research data and findings; (g) Provisions for long-term follow-up where appropriate.

5. Informed neural consent for research shall include: (a) Clear information about the purpose of the research; (b) Specific details about the neurotechnology to be used; (c) Explanation of the potential risks and benefits; (d) Information about neural data collection, storage, and use; (e) Clarification of incidental findings policies; (f) Information about the right to withdraw from the research; (g) Details of post-research support and follow-up.

6. For innovative neurotechnology research with significant potential impact on neurocognitive rights, enhanced safeguards shall include: (a) Staged research designs with careful evaluation at each stage; (b) Increased frequency of monitoring and oversight; (c) Independent data safety monitoring; (d) Regular reassessment of the risk-benefit balance; (e) Enhanced participant engagement throughout the research process.

7. Neurotechnology research shall be registered in a public database before recruitment begins, including: (a) The title and purpose of the research; (b) The neurotechnology being studied; (c) The research design and methodology; (d) The target participant population; (e) The primary and secondary outcomes; (f) The sources of funding and potential conflicts of interest.

8. Results of neurotechnology research shall be: (a) Made publicly available regardless of outcome; (b) Published with information about ethical considerations and safeguards; (c) Accompanied by data sharing plans that respect participant consent; (d) Contextualized with discussion of neurocognitive rights implications; (e) Disseminated to research participants in accessible language.

9. The Commission shall adopt delegated acts in accordance with Article 121 to supplement this Regulation by specifying: (a) Detailed requirements for ethics committee review of neurotechnology research; (b) Standards for informed neural consent in research contexts; (c) Requirements for research registration and results reporting; (d) Guidelines for responsible neural data sharing in research.

Article 77: Interoperability

1. Providers of neurotechnology shall implement appropriate levels of interoperability for their systems to enable: (a) Effective data portability as required by Article 65; (b) Compatibility with assistive technologies where relevant; (c) Integration with healthcare systems for therapeutic neurotechnology; (d) Interaction with regulatory monitoring systems; (e) Secure data exchange between authorized systems.

2. Interoperability shall be implemented through: (a) Compliance with harmonized standards where they exist; (b) Use of open, documented interfaces and protocols; (c) Implementation of common data formats and semantics; (d) Documentation of interoperability features and limitations; (e) Testing for compatibility with relevant systems.

3. Interoperability shall be implemented in a manner that: (a) Maintains appropriate security and privacy protections; (b) Preserves the functionality and safety of the neurotechnology; (c) Prevents unauthorized access or control; (d) Supports individual control over neural data flows; (e) Documents dependencies on external systems.

4. For high-risk neurotechnology, providers shall: (a) Document interoperability features in the technical documentation; (b) Implement safeguards against security risks introduced through interoperability; (c) Test interoperability features for reliability and security; (d) Provide information about interoperability to users.

5. The Commission, in consultation with the European Neurotechnology Regulatory Authority, shall support the development of harmonized standards for

interoperability of neurotechnology through the European Standardisation Organizations.

Article 78: Standardization

1. Harmonized standards for neurotechnology shall be developed to support implementation of the requirements of this Regulation.

2. The Commission shall, in accordance with Article 10 of Regulation (EU) No 1025/2012, request one or more European Standardisation Organizations to draft harmonized standards for: (a) Neural data formats and exchange protocols; (b) Neural data protection methods; (c) Security requirements for neurotechnology; (d) Technical interfaces for user control and transparency; (e) Testing methodologies for neurotechnology performance and safety; (f) Risk management for neurotechnology; (g) Human oversight implementation; (h) Neural data anonymization and pseudonymization techniques; (i) Interoperability between neurotechnology systems.

3. The Commission shall ensure that standards development involves: (a) Technical experts in neurotechnology and neural engineering; (b) Experts in neurocognitive rights, neuroethics, and neural data protection; (c) Representative users, including persons with disabilities; (d) Relevant stakeholders from industry, academia, healthcare, and civil society; (e) Relevant European agencies.

4. Harmonized standards shall: (a) Reflect the state of the art in neurotechnology; (b) Incorporate ethical considerations and neurocognitive rights protections; (c) Be developed through transparent and inclusive processes; (d) Be regularly reviewed and updated to reflect technological developments; (e) Support global interoperability where appropriate.

5. The Commission shall publish the references of harmonized standards that conform with the requirements of this Regulation in the Official Journal of the European Union.

6. In the absence of harmonized standards, the Commission may adopt implementing acts establishing common specifications for the requirements set out in this Regulation. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 122(2).

Article 79: Codes of conduct

1. The Commission and Member States shall encourage the drawing up of codes of conduct intended to foster the voluntary application of the requirements of this Regulation to neurotechnology not classified as high-risk.

2. Codes of conduct may be prepared by individual providers, representative organizations, or other stakeholders, and may cover one or more categories of neurotechnology.

3. Codes of conduct may address: (a) Ethical design and development practices for neurotechnology; (b) Enhanced transparency about capabilities and limitations; (c) Neural data governance beyond minimum requirements; (d) Accessibility and inclusive design; (e) Environmental sustainability; (f) User education and support;

(g) Responsible marketing and communication; (h) Engagement with affected communities; (i) Collaboration in addressing emerging challenges.

4. Codes of conduct shall: (a) Be developed in consultation with relevant stakeholders; (b) Take into account the specific characteristics and needs of small and medium-sized enterprises; (c) Include concrete commitments and measurable objectives; (d) Establish monitoring and evaluation mechanisms; (e) Be publicly available; (f) Be periodically reviewed and updated.

5. The Commission and the European Neurotechnology Regulatory Authority shall maintain a public register of codes of conduct.

6. Adherence to codes of conduct shall not substitute for compliance with the legal requirements of this Regulation.

TITLE IX: EUROPEAN NEUROTECHNOLOGY REGULATORY AUTHORITY

Article 80: Establishment and status

1. The European Neurotechnology Regulatory Authority is hereby established as a body of the Union with legal personality.

2. The Authority shall enjoy in each Member State the most extensive legal capacity accorded to legal persons under their laws. It may, in particular, acquire and dispose of movable and immovable property and be a party to legal proceedings.

3. The Authority shall be represented by its Executive Director.

4. The seat of the Authority shall be determined by decision of the representatives of the Member States meeting at Head of State or Government level.

Article 81: Tasks and responsibilities

1. The Authority shall perform the following tasks: (a) Contribute to the effective implementation of this Regulation throughout the Union; (b) Provide scientific and technical guidance on neurotechnology regulation; (c) Coordinate the activities of national competent authorities in the field of neurotechnology regulation; (d) Develop and maintain expertise on emerging neurotechnology and its implications; (e) Advise the Commission on the implementation and review of this Regulation; (f) Issue guidelines, recommendations, and best practices related to neurotechnology; (g) Facilitate the exchange of information between Member States on neurotechnology regulation; (h) Maintain a public database of high-risk neurotechnology as referred to in Article 85; (i) Monitor and analyze trends in neurotechnology development and deployment; (j) Contribute to the development of standards and methodologies for neurotechnology assessment; (k) Promote awareness and understanding of neurocognitive rights; (l) Cooperate with relevant Union institutions, bodies, offices, and agencies; (m) Engage with international partners on neurotechnology governance; (n) Organize peer reviews among national competent authorities.

2. In performing its tasks, the Authority shall: (a) Act independently and in the public interest; (b) Base its activities on the best available scientific evidence; (c) Consider ethical dimensions of neurotechnology regulation; (d) Operate with transparency

and openness to stakeholder input; (e) Coordinate with other relevant regulatory authorities; (f) Respect the principle of subsidiarity and the competences of Member States; (g) Consider the specific needs of small and medium-sized enterprises; (h) Balance innovation support with effective protection of neurocognitive rights.

3. The Authority shall prioritize its activities based on: (a) The potential impact on neurocognitive rights; (b) Emerging trends and developments in neurotechnology; (c) Areas where harmonization and coordination add significant value; (d) The needs and requests of national competent authorities; (e) Resource constraints and efficiency considerations.

Article 82: Structure and organization

1. The Authority shall have the following structure: (a) A Management Board; (b) An Executive Director; (c) A Scientific Committee; (d) A Stakeholder Advisory Forum; (e) A Network of National Authorities.

2. The Management Board shall: (a) Be composed of one representative from each Member State and two representatives from the Commission; (b) Be responsible for the strategic direction and oversight of the Authority; (c) Adopt the Authority's work program, budget, and annual report; (d) Appoint the Executive Director; (e) Adopt the Authority's internal rules.

3. The Executive Director shall: (a) Be responsible for the day-to-day management of the Authority; (b) Prepare and implement the decisions of the Management Board; (c) Ensure the Authority performs its tasks in accordance with this Regulation; (d) Be the legal representative of the Authority; (e) Be appointed for a term of five years, which may be extended once.

4. The Scientific Committee shall: (a) Be composed of independent scientific experts selected based on their expertise in neuroscience, neurotechnology, neuroethics, neural data protection, and related fields; (b) Provide scientific advice to the Authority; (c) Develop scientific methodologies for neurotechnology assessment; (d) Identify emerging scientific issues and trends; (e) Contribute to guidelines and recommendations.

5. The Stakeholder Advisory Forum shall: (a) Include representatives from industry, civil society, academia, healthcare, and end-users, including persons with disabilities; (b) Provide input on the impact and effectiveness of the Authority's activities; (c) Facilitate exchange of information on relevant issues; (d) Advise on engagement with different stakeholder groups; (e) Meet at least twice per year.

6. The Network of National Authorities shall: (a) Consist of representatives from the national competent authorities designated under Article 83; (b) Facilitate cooperation and information exchange between national authorities; (c) Contribute to consistent implementation of this Regulation; (d) Develop common approaches to regulatory challenges; (e) Support capacity building in Member States.

7. The Authority shall establish working groups as necessary to address specific technical or regulatory issues.

8. The Commission shall adopt implementing acts establishing the detailed arrangements for the functioning of the Authority. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 122(2).

Article 83: National competent authorities

1. Each Member State shall designate or establish one or more national competent authorities for the purpose of ensuring the application and implementation of this Regulation.

2. Where a Member State designates more than one competent authority, it shall clearly allocate the responsibilities between those authorities and shall designate a single authority as the central contact point for the Commission and the European Neurotechnology Regulatory Authority.

3. National competent authorities shall: (a) Supervise and enforce the application of this Regulation at the national level; (b) Coordinate with other relevant national authorities, including data protection authorities, medical device authorities, and consumer protection authorities; (c) Provide guidance to providers, users, and individuals on the application of this Regulation; (d) Receive and investigate complaints related to neurotechnology; (e) Conduct market surveillance activities for neurotechnology; (f) Impose penalties for infringements of this Regulation in accordance with Article 119; (g) Contribute to the coordination activities led by the European Neurotechnology Regulatory Authority; (h) Collect and analyze data on the implementation of this Regulation; (i) Promote awareness of neurocognitive rights.

4. National competent authorities shall have: (a) Sufficient financial and human resources to perform their tasks; (b) Personnel with expertise in neurotechnology, neuroscience, law, ethics, and data protection; (c) Technical capabilities to assess neurotechnology compliance; (d) Powers to obtain all information necessary for the performance of their tasks; (e) Authority to conduct inspections and audits of providers and users; (f) Ability to impose corrective measures and sanctions.

5. National competent authorities shall operate with: (a) Independence in their assessments and decisions; (b) Impartiality regarding all stakeholders; (c) Transparency in their activities and decision-making; (d) Appropriate confidentiality safeguards for commercially sensitive information; (e) Accountability to national parliaments and governments.

6. National competent authorities shall cooperate with: (a) Competent authorities in other Member States; (b) The European Neurotechnology Regulatory Authority; (c) Other relevant Union bodies and agencies; (d) Relevant stakeholders, including industry, civil society, and academia.

7. Member States shall notify the Commission and the European Neurotechnology Regulatory Authority of the designation and any subsequent change of the national competent authorities by [12 months after the entry into force of this Regulation].

8. The Commission shall publish a list of the national competent authorities and keep it up to date.

Article 84: Coordination procedure

1. Where more than one national competent authority is involved in the enforcement of this Regulation in a Member State, the Member State shall establish a coordination procedure to ensure effective cooperation and consistent decision-making.

2. Where a neurotechnology issue has cross-border implications involving multiple Member States, the national competent authorities concerned shall cooperate to ensure a coordinated approach.

3. For complex cross-border cases, the European Neurotechnology Regulatory Authority shall, upon request from a national competent authority or on its own initiative, establish a coordination group that shall: (a) Include representatives from the relevant national competent authorities; (b) Analyze the issue and exchange information; (c) Develop a coordinated approach; (d) Make recommendations for consistent application of this Regulation; (e) Report its findings and recommendations to the national competent authorities and the European Neurotechnology Regulatory Authority.

4. National competent authorities shall take utmost account of the recommendations of the coordination group in their enforcement activities.

5. The European Neurotechnology Regulatory Authority shall maintain a secure information exchange system for national competent authorities to share information on cross-border cases, emerging issues, and enforcement approaches.

6. The Commission shall adopt implementing acts establishing detailed procedures for cooperation between national competent authorities and with the European Neurotechnology Regulatory Authority. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 122(2).

Article 85: EU database for high-risk neurotechnology

1. The European Neurotechnology Regulatory Authority shall establish, maintain, and manage an EU database for high-risk neurotechnology.

2. The EU database shall contain: (a) Registrations of high-risk neurotechnology in accordance with Article 44; (b) EU declarations of conformity and certificates issued by notified bodies; (c) Information on serious incidents and malfunctions reported in accordance with Article 47; (d) Post-market monitoring reports submitted in accordance with Article 46; (e) Information on measures taken by market surveillance authorities; (f) Decisions and opinions of the European Neurotechnology Regulatory Authority related to specific high-risk neurotechnology.

3. The EU database shall be publicly accessible, except for: (a) Commercially confidential information; (b) Personal data, which shall be protected in accordance with Union data protection law; (c) Information that could compromise security or public safety; (d) Information that could undermine regulatory investigations or enforcement activities.

4. The EU database shall be designed to: (a) Enable interoperability with relevant EU databases and information systems; (b) Provide appropriate search and filtering capabilities; (c) Generate analytics and reports on trends and patterns; (d) Support administrative procedures for regulatory authorities; (e) Facilitate information sharing between competent authorities.

5. Providers of high-risk neurotechnology shall be responsible for: (a) Submitting accurate and complete information to the database; (b) Updating information when changes occur; (c) Notifying the European Neurotechnology Regulatory Authority of any errors or omissions in the database; (d) Maintaining supporting documentation for information submitted to the database.

6. The European Neurotechnology Regulatory Authority shall: (a) Ensure the technical functioning and security of the database; (b) Establish procedures for validating submitted information; (c) Provide user support and training for database users; (d) Regularly review and enhance the database functionality; (e) Ensure compliance with data protection requirements.

7. The Commission shall adopt implementing acts establishing: (a) The technical specification and design of the database; (b) The types of information to be entered into the database; (c) The procedure for entering and updating information; (d) The extent of public access to different categories of information; (e) The methodology for classifying commercially confidential information.

8. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 122(2).

TITLE X: SPECIALIZED JUDICIAL MECHANISMS

Article 86: Specialized judicial expertise

1. Member States shall ensure that courts dealing with cases involving neurocognitive rights and neurotechnology have access to specialized expertise in these fields.

2. Member States shall implement measures to develop and enhance judicial expertise in neurocognitive rights and neurotechnology through: (a) Specialized training programs for judges and other judicial personnel; (b) Development of educational materials on neurotechnology and neurocognitive rights; (c) Regular updates on developments in neurotechnology and related legal and ethical issues; (d) Access to technical advisors with expertise in neuroscience and neurotechnology; (e) Networks for knowledge exchange between judges dealing with neurotechnology cases.

3. Judicial training on neurocognitive rights and neurotechnology shall address: (a) The scientific principles underlying neurotechnology; (b) The capabilities and limitations of different types of neurotechnology; (c) The legal framework for neurocognitive rights protection; (d) The evaluation of neural evidence and expert testimony; (e) The assessment of neural data processing activities; (f) The ethical implications of neurotechnology applications; (g) The balance between innovation and rights protection; (h) The relationship between neurocognitive rights and other fundamental rights.

4. The European Judicial Training Network, in cooperation with the European Neurotechnology Regulatory Authority, shall develop and implement European-level training on neurocognitive rights and neurotechnology for members of the judiciary.

5. Member States shall report to the Commission every two years on the measures taken to enhance judicial expertise in neurocognitive rights and neurotechnology.

Article 87: Specialized courts or chambers

1. Member States may establish specialized courts or chambers within existing courts with specific jurisdiction over cases involving neurocognitive rights and neurotechnology.

2. Where specialized courts or chambers are established, they may have jurisdiction over: (a) Claims for violations of neurocognitive rights; (b) Challenges to decisions of national competent authorities regarding neurotechnology; (c) Civil liability cases related to neurotechnology; (d) Cases involving neural evidence; (e) Cases concerning the lawful use of neurotechnology in sensitive contexts; (f) Disputes regarding access to or control of neural data.

3. Specialized courts or chambers shall be composed of judges who have received specific training in neurocognitive rights and neurotechnology or who have relevant expertise.

4. Specialized courts or chambers may be supported by technical advisors with expertise in neuroscience, neurotechnology, and neural data.

5. Member States that establish specialized courts or chambers shall ensure: (a) Clear rules on jurisdiction and procedure; (b) Appropriate resources for effective functioning; (c) Accessibility for individuals seeking remedies for violations of neurocognitive rights; (d) Procedures adapted to the technical complexity of neurotechnology cases; (e) Mechanisms for knowledge sharing with other courts.

6. Member States that establish specialized courts or chambers shall notify the Commission and the European Neurotechnology Regulatory Authority of their establishment and jurisdiction.

Article 88: Neural evidence

1. Neural evidence, including data derived from neurotechnology and expert interpretations of such data, may be admissible in legal proceedings subject to appropriate safeguards.

2. Courts shall evaluate neural evidence with consideration of: (a) The scientific validity and reliability of the neurotechnology used to generate the evidence; (b) The specific capabilities and limitations of the neurotechnology; (c) The qualifications and expertise of those who collected and interpreted the neural data; (d) The context and conditions under which the neural data was collected; (e) The chain of custody and data integrity; (f) The statistical significance and error rates of the methods used; (g) The extent to which the evidence has been subject to peer review and scientific validation; (h) The relevance of the evidence to the legal issues in the case; (i) The potential for misinterpretation or overreliance on the evidence.

3. Neural evidence shall not be admissible if: (a) It was obtained in violation of this Regulation or other applicable law; (b) It was collected without required informed neural consent, except in circumstances specifically authorized by law; (c) The neurotechnology used to generate the evidence has not been validated for the specific purpose for which the evidence is being offered; (d) The methodology used to collect or interpret the neural data does not meet scientific standards of reliability; (e) Its probative value is substantially outweighed by the danger of unfair prejudice, confusion of issues, or misleading the court.

4. Neural evidence shall not be used as the sole basis for determining legal liability, guilt, or innocence, but may be considered in conjunction with other evidence.

5. Courts shall appoint independent experts to assist in the evaluation of neural evidence when necessary for proper assessment. Such experts shall: (a) Have relevant expertise in neuroscience, neurotechnology, or neural data analysis; (b) Be independent from the parties to the case; (c) Disclose any potential conflicts of interest; (d) Provide objective evaluation of the neural evidence; (e) Explain technical aspects in terms accessible to the court.

6. Parties presenting neural evidence shall provide full disclosure of: (a) The specific neurotechnology used to generate the evidence; (b) The methodology for data collection and analysis; (c) The qualifications of those who collected and interpreted the data; (d) Any limitations or potential sources of error; (e) Alternative interpretations of the data; (f) The scientific literature supporting the methods used.

7. The European Judicial Training Network, in cooperation with the European Neurotechnology Regulatory Authority, shall develop guidelines on the evaluation of neural evidence for judicial authorities.

Article 89: Remedies for violations of neurocognitive rights

1. Member States shall ensure that effective judicial and non-judicial remedies are available to individuals whose neurocognitive rights have been violated.

2. Judicial remedies shall include: (a) Injunctive relief to prevent ongoing or imminent violations; (b) Declaratory judgments establishing that a violation has occurred; (c) Compensation for material and non-material damages resulting from violations; (d) Erasure or rectification of neural data processed in violation of this Regulation; (e) Suspension or prohibition of neurotechnology use that violates neurocognitive rights; (f) Penalties and sanctions against those responsible for violations.

3. In assessing non-material damages resulting from violations of neurocognitive rights, courts shall take into account: (a) The nature and gravity of the violation; (b) The duration of the violation; (c) The impact on the individual's mental integrity, autonomy, and identity; (d) Any psychological distress or harm caused; (e) Any ongoing effects on the individual's cognitive functions or mental states; (f) The presence or absence of intent; (g) Whether the violation occurred in a context involving power imbalances or vulnerability.

4. Non-judicial remedies may include: (a) Complaints to national competent authorities; (b) Alternative dispute resolution mechanisms, including mediation and arbitration; (c) Complaints to data protection authorities regarding neural data

processing; (d) Complaints to consumer protection authorities regarding commercial neurotechnology; (e) Internal complaint procedures within organizations using neurotechnology.

5. Member States shall ensure that organizations which have as statutory objectives the protection of neurocognitive rights or fundamental rights may: (a) Lodge complaints with competent authorities on behalf of individuals; (b) Exercise the right to judicial remedy on behalf of individuals with their explicit consent; (c) Exercise the right to judicial remedy independently of an individual's mandate where they consider that neurocognitive rights have been violated, subject to Member State law.

6. Member States shall ensure that remedial procedures are: (a) Accessible, including to persons with disabilities; (b) Affordable, with legal aid available where necessary; (c) Timely, recognizing the potential ongoing nature of some violations; (d) Effective in bringing violations to an end and preventing future violations; (e) Proportionate to the gravity of the violation.

7. The limitation period for bringing actions for violations of neurocognitive rights shall be at least: (a) Five years from the date when the individual became aware or should reasonably have become aware of the violation; and (b) In no case less than five years from the date of the violation.

8. The European Neurotechnology Regulatory Authority shall publish guidance on remedies for violations of neurocognitive rights, including best practices and case studies.

Article 90: Collective redress

1. Member States shall ensure that collective redress mechanisms are available for violations of neurocognitive rights that affect multiple individuals.

2. Collective redress mechanisms shall be in accordance with Directive (EU) 2020/1828 on representative actions for the protection of the collective interests of consumers, with specific adaptations for neurocognitive rights cases.

3. Member States shall ensure that qualified entities, as defined in Directive (EU) 2020/1828, may bring representative actions in relation to violations of neurocognitive rights, seeking: (a) Injunctive relief to stop or prohibit violations; (b) Redress measures, including compensation, repair, replacement, price reduction, contract termination, or reimbursement; (c) Declaratory decisions establishing the violation and corresponding obligations.

4. In addition to the requirements in Directive (EU) 2020/1828, qualified entities bringing representative actions in relation to neurocognitive rights shall demonstrate expertise in neurotechnology and neurocognitive rights or partner with organizations having such expertise.

5. Member States shall ensure that collective redress mechanisms for neurocognitive rights violations: (a) Provide effective procedures for identifying affected individuals; (b) Include specific provisions for assessing and allocating damages for non-material harm; (c) Include mechanisms for distributing compensation

efficiently and fairly; (d) Ensure appropriate confidentiality safeguards for sensitive information about cognitive functions and neural data; (e) Provide for monitoring of compliance with injunctions and other remedial orders.

6. For cross-border cases involving violations of neurocognitive rights affecting individuals in multiple Member States, coordination mechanisms shall be established to ensure effective remedies while avoiding duplication of proceedings.

7. The Commission shall publish guidance on collective redress for violations of neurocognitive rights, taking into account the specific challenges and sensitivities involved.

Article 91: Technical expertise for courts

1. Member States shall establish mechanisms to provide courts with access to technical expertise on neurotechnology, neuroscience, and neural data when handling cases involving neurocognitive rights.

2. Such mechanisms may include: (a) Rosters of independent technical experts qualified to advise courts on different types of neurotechnology; (b) Court-appointed expert panels for complex neurotechnology cases; (c) Technical advisors attached to specialized courts or chambers; (d) Standardized procedures for commissioning technical opinions; (e) Training for judges on working with technical experts in neurotechnology cases.

3. Technical experts advising courts shall: (a) Have relevant qualifications and experience in neuroscience, neurotechnology, or neural data analysis; (b) Be independent and impartial; (c) Disclose any potential conflicts of interest; (d) Present technical information in a manner accessible to the court; (e) Distinguish between established scientific facts, majority scientific views, and emerging or contested theories; (f) Explain the limitations and uncertainties of their assessments; (g) Respond to questions from the court and parties to clarify technical issues.

4. Courts may request technical assistance from the European Neurotechnology Regulatory Authority, which may: (a) Provide general information on neurotechnology and neural data; (b) Clarify technical aspects of this Regulation and related standards; (c) Identify suitable independent experts for specific cases; (d) Provide access to technical resources and documentation; (e) Offer training for court-appointed experts.

5. For cross-border cases, Member States shall facilitate cooperation between technical experts from different Member States and shall recognize the qualifications of experts from other Member States.

6. The Commission shall adopt implementing acts establishing: (a) A common framework for the qualification criteria for technical experts in neurotechnology cases; (b) A model code of conduct for technical experts advising courts; (c) Guidelines for presenting technical information in judicial proceedings.

7. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 122(2).

Article 92: European Neurocognitive Rights Court

1. The European Neurocognitive Rights Court is hereby established as a specialized judicial body with jurisdiction over cross-border cases involving neurocognitive rights.

2. The Court shall have jurisdiction to hear: (a) Cross-border cases involving alleged violations of neurocognitive rights where the parties agree to submit the case to the Court; (b) Cases referred by national courts for preliminary rulings on the interpretation of this Regulation; (c) Appeals against decisions of the European Neurotechnology Regulatory Authority; (d) Disputes between Member States concerning the interpretation or application of this Regulation.

3. The Court shall be composed of: (a) Judges with expertise in law, fundamental rights, and technology regulation; (b) Technical assessors with expertise in neuroscience, neurotechnology, and neural data analysis; (c) Administrative and research staff to support the Court's operations.

4. Judges shall be appointed by common accord of the governments of the Member States for a term of six years, with the possibility of reappointment. Judges shall be chosen from persons whose independence is beyond doubt and who possess the qualifications required for appointment to high judicial office in their respective countries.

5. Technical assessors shall be appointed by the Court from a list of experts compiled by the European Neurotechnology Regulatory Authority. Technical assessors shall participate in deliberations but shall not have voting rights in the final decision.

6. The Court shall establish its own Rules of Procedure, which shall be approved by the Council acting by a qualified majority.

7. Decisions of the Court shall be legally binding and shall be enforced in accordance with the procedures established by the Member States.

8. The Court shall publish its decisions, opinions, and annual reports, which shall contribute to the interpretation and development of neurocognitive rights law.

9. The Court shall be funded through the general budget of the European Union and through fees paid by parties to cases, with exemptions for individuals lacking sufficient resources.

10. The Commission shall adopt delegated acts in accordance with Article 121 to supplement this Regulation by specifying: (a) The detailed structure and organization of the Court; (b) The procedures for appointing judges and technical assessors; (c) The jurisdiction and procedures of the Court; (d) The relationship between the Court and national courts.

11. Until the European Neurocognitive Rights Court is fully operational, its functions shall be performed by designated chambers of the General Court of the European Union, assisted by technical experts in neurotechnology and neurocognitive rights.

TITLE XI: MARKET SURVEILLANCE AND ENFORCEMENT

Article 93: Market surveillance activities

1. Member States shall organize and carry out market surveillance activities for neurotechnology in accordance with this Regulation and Regulation (EU) 2019/1020.

2. National market surveillance authorities shall be responsible for ensuring that neurotechnology made available on the market or put into service in their territory complies with the requirements of this Regulation.

3. Market surveillance authorities shall have the powers and resources to: (a) Proactively monitor the neurotechnology market; (b) Conduct risk-based inspections and audits; (c) Investigate complaints about non-compliant neurotechnology; (d) Access and test neurotechnology products; (e) Request documentation and information from providers and users; (f) Take appropriate enforcement actions against non-compliant neurotechnology; (g) Cooperate with other national and European authorities.

4. Market surveillance activities shall prioritize high-risk neurotechnology and shall be based on: (a) Risk assessments considering the potential impact on neurocognitive rights; (b) Complaints and reports of incidents or malfunctions; (c) Intelligence on emerging risks or non-compliance patterns; (d) Coordination with other market surveillance authorities; (e) Guidance from the European Neurotechnology Regulatory Authority.

5. Market surveillance authorities shall establish specialized teams with expertise in neurotechnology and neural data protection to effectively assess compliance with this Regulation.

6. Member States shall ensure effective cooperation and information exchange between market surveillance authorities and other relevant authorities, including data protection authorities, consumer protection authorities, and healthcare regulators.

7. The European Neurotechnology Regulatory Authority shall support coordination of market surveillance activities through: (a) Facilitating information exchange between national authorities; (b) Providing technical guidance on compliance assessment; (c) Coordinating joint surveillance actions; (d) Developing common methodologies for neurotechnology testing; (e) Maintaining a database of market surveillance findings.

8. Market surveillance authorities shall report annually to the Commission and the European Neurotechnology Regulatory Authority on their activities, findings, and measures taken.

Article 94: Access to data and documentation

1. Market surveillance authorities shall have the power to require economic operators to provide relevant data and documentation necessary to assess compliance with this Regulation.

2. Documentation and information that may be requested includes: (a) Technical documentation as required by Article 30; (b) Risk management system documentation; (c) Post-market monitoring data; (d) Quality management system

records; (e) Test reports and conformity assessment results; (f) Neural data governance documentation; (g) Records of serious incidents and malfunctions; (h) Information about the algorithmic systems used in the neurotechnology; (i) Information about security measures implemented.

3. Market surveillance authorities may require access to: (a) The neurotechnology itself for testing and inspection; (b) Source code, when strictly necessary and subject to confidentiality safeguards; (c) Training data used for algorithmic systems, subject to appropriate data protection safeguards; (d) Facilities and equipment used in the development, testing, or manufacturing of neurotechnology; (e) Personnel with knowledge of the neurotechnology for interviews.

4. When requesting access to documentation, data, or systems, market surveillance authorities shall: (a) Specify the purpose of the request; (b) Indicate the legal basis for the request; (c) Specify the information or access required; (d) Set a reasonable time limit for the provision of the information; (e) Inform the economic operator of the consequences of non-compliance with the request.

5. Economic operators shall cooperate with market surveillance authorities and shall provide the requested information within the specified time limit. Where an economic operator claims that requested information includes trade secrets or confidential business information, the market surveillance authority shall ensure appropriate confidentiality safeguards.

6. Market surveillance authorities shall process any personal data obtained in the course of their activities in accordance with Regulation (EU) 2016/679 and shall implement appropriate technical and organizational measures to protect the security and confidentiality of the information received.

Article 95: Testing of neurotechnology

1. Market surveillance authorities shall have the power to test neurotechnology or to have it tested to verify its compliance with the requirements of this Regulation.

2. For testing high-risk neurotechnology, market surveillance authorities shall: (a) Develop test protocols specific to different types of neurotechnology; (b) Conduct tests in appropriate facilities with necessary technical capabilities; (c) Engage experts with relevant expertise in neurotechnology and neural data analysis; (d) Document test methodologies, procedures, and results; (e) Ensure that testing is conducted in a manner that protects confidential information.

3. Testing may include: (a) Functionality testing to verify that the neurotechnology performs as documented; (b) Safety testing to verify that the neurotechnology does not present risks to health and safety; (c) Security testing to assess vulnerability to unauthorized access or control; (d) Data protection testing to assess compliance with neural data governance requirements; (e) Performance testing to verify accuracy, reliability, and reproducibility claims; (f) Usability testing to assess user interfaces and control mechanisms; (g) Robustness testing to assess behavior under various conditions.

4. Market surveillance authorities may request that providers or notified bodies provide existing test results and documentation, which shall be taken into account to avoid unnecessary duplication of testing.

5. Where testing reveals non-compliance with this Regulation, the market surveillance authority shall: (a) Inform the economic operator of the findings; (b) Provide an opportunity for the economic operator to be heard; (c) Require the economic operator to take appropriate corrective actions; (d) Take enforcement measures as necessary.

6. The European Neurotechnology Regulatory Authority, in cooperation with the Joint Research Centre, shall develop common testing methodologies for different categories of neurotechnology and shall support capacity building for testing in Member States.

Article 96: Corrective actions and enforcement measures

1. Where a market surveillance authority finds that neurotechnology is not in compliance with this Regulation, it shall require the relevant economic operator to take appropriate corrective actions to bring the neurotechnology into compliance, to withdraw it from the market, or to recall it, as appropriate.

2. Corrective actions required may include: (a) Bringing the neurotechnology into compliance with the requirements of this Regulation; (b) Updating documentation, including the technical documentation and instructions for use; (c) Implementing additional safeguards to address identified risks; (d) Modifying design features that contribute to non-compliance; (e) Enhancing neural data protection measures; (f) Implementing additional human oversight mechanisms; (g) Improving security features; (h) Conducting a conformity re-assessment.

3. Where non-compliance presents a serious risk, market surveillance authorities shall: (a) Require immediate corrective actions within a specified timeframe; (b) Require the temporary suspension of specific functionality or use; (c) Require the withdrawal of the neurotechnology from the market pending corrective actions; (d) Require the recall of the neurotechnology where other measures are insufficient; (e) Inform users and the public about the risks; (f) Notify other market surveillance authorities and the European Neurotechnology Regulatory Authority.

4. Market surveillance authorities shall ensure that corrective measures taken: (a) Effectively address the identified non-compliance; (b) Are proportionate to the nature and gravity of the non-compliance; (c) Take into account the potential impact on neurocognitive rights; (d) Include follow-up verification to ensure implementation.

5. Where an economic operator fails to take adequate corrective actions within the specified timeframe, market surveillance authorities shall take appropriate enforcement measures, which may include: (a) Prohibiting or restricting the making available of the neurotechnology on the market; (b) Ordering the withdrawal or recall of the neurotechnology; (c) Imposing penalties in accordance with Article 119; (d) Suspending or revoking conformity certificates; (e) Publishing information about the non-compliance and measures taken.

6. Decisions taken by market surveillance authorities shall: (a) State the grounds on which they are based; (b) Be communicated without delay to the economic operator concerned; (c) Specify the remedies available and the time limits for their exercise; (d) Be proportionate to the seriousness of the non-compliance.

7. Economic operators shall have the right to present their views before a decision is taken, except where urgent action is needed to prevent serious risks.

Article 97: Reporting of serious incidents and malfunctions

1. In addition to the reporting obligations of providers under Article 47, market surveillance authorities shall establish systems for receiving and assessing reports of serious incidents and malfunctions related to neurotechnology from users, individuals, healthcare professionals, and other stakeholders.

2. Market surveillance authorities shall: (a) Establish accessible channels for receiving reports; (b) Provide clear guidance on what should be reported and how; (c) Acknowledge receipt of reports and keep reporters informed of follow-up actions; (d) Assess reports in a timely manner to determine appropriate actions; (e) Protect the confidentiality of reporters where requested and appropriate; (f) Share relevant information with other authorities and the European Neurotechnology Regulatory Authority.

3. Upon receiving a report of a serious incident or malfunction, market surveillance authorities shall: (f) Require corrective actions from economic operators as necessary; (g) Monitor the implementation and effectiveness of corrective actions; (h) Document the incident, findings, and actions taken; (i) Share information about the incident with other relevant authorities when appropriate.

4. For serious incidents with potential cross-border implications, market surveillance authorities shall notify the European Neurotechnology Regulatory Authority, which shall: (a) Coordinate information sharing between national authorities; (b) Facilitate coordinated investigation and response where appropriate; (c) Analyze patterns and trends across reports from multiple Member States; (d) Issue safety alerts or recommendations when systemic issues are identified; (e) Support capacity building for incident investigation and response.

5. Market surveillance authorities shall establish systems for analyzing aggregate data from incident reports to identify: (a) Patterns or trends indicating systemic issues; (b) Emerging risks not previously identified; (c) Categories of neurotechnology requiring enhanced surveillance; (d) Common causes of incidents that could inform preventive measures; (e) Effectiveness of corrective actions and regulatory interventions.

6. Market surveillance authorities shall publish anonymized summaries of significant incidents and the measures taken, respecting commercial confidentiality and personal data protection, to: (a) Increase awareness among users and providers; (b) Share lessons learned; (c) Promote best practices in neurotechnology safety and security; (d) Demonstrate regulatory oversight and responsiveness.

7. The Commission shall adopt implementing acts establishing: (a) Common formats and procedures for incident reporting; (b) Criteria for determining the severity and

cross-border relevance of incidents; (c) Timeframes for investigating and responding to incident reports; (d) Frameworks for coordinated responses to serious cross-border incidents.

8. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 122(2).

Article 98: Union safeguard procedure

1. Where a market surveillance authority of a Member State takes a measure pursuant to Article 96, or has sufficient reason to believe that neurotechnology presents a risk to neurocognitive rights, health, safety, or other aspects of public interest protection covered by this Regulation, it shall carry out an evaluation of the neurotechnology concerned covering all relevant requirements of this Regulation.

2. Where, in the course of the evaluation, the market surveillance authority finds that the neurotechnology does not comply with the requirements of this Regulation, it shall without delay require the relevant economic operator to take appropriate corrective actions to bring the neurotechnology into compliance, to withdraw it from the market, or to recall it within a reasonable period commensurate with the nature of the risk.

3. The market surveillance authority shall inform the relevant notified body accordingly.

4. Where the market surveillance authority considers that the non-compliance is not restricted to its national territory, it shall inform the Commission and the other Member States of the results of the evaluation and of the actions which it has required the economic operator to take.

5. The economic operator shall ensure that appropriate corrective actions are taken in respect of all the neurotechnology concerned that it has made available throughout the Union.

6. Where the economic operator does not take adequate corrective actions within the period referred to in paragraph 2, the market surveillance authority shall take all appropriate provisional measures to prohibit or restrict the neurotechnology being made available on its national market, to withdraw the neurotechnology from that market or to recall it.

7. The market surveillance authority shall inform the Commission and the other Member States, without delay, of those measures. The information provided shall include: (a) The data necessary for the identification of the non-compliant neurotechnology; (b) The origin of the neurotechnology; (c) The nature of the non-compliance alleged and the risk involved; (d) The nature and duration of the national measures taken; (e) The arguments put forward by the relevant economic operator; (f) Whether the non-compliance is due to either of the following: (i) Failure of the neurotechnology to meet requirements relating to neurocognitive rights, health or safety of persons, or other aspects of public interest protection; (ii) Shortcomings in the harmonized standards or common specifications referred to in Articles 77 and 78.

8. Market surveillance authorities other than the authority initiating the procedure shall without delay inform the Commission and the other Member States of any measures adopted and of any additional information at their disposal relating to the non-compliance of the neurotechnology concerned.

9. If, within three months of receipt of the information referred to in paragraph 7, no objection has been raised by either a Member State or the Commission in respect of a provisional measure taken by a Member State, that measure shall be deemed justified.

10. Member States shall ensure that appropriate restrictive measures, such as withdrawal of the neurotechnology from the market, are taken in respect of the neurotechnology concerned without delay.

Article 99: Union safeguard procedure for high-risk neurotechnology

1. Where, within three months of receipt of the notification referred to in Article 98(7), objections are raised by a Member State against a measure taken by another Member State, or where the Commission considers the measure to be contrary to Union law, the Commission shall without delay enter into consultation with the relevant Member State and economic operator and shall evaluate the national measure. On the basis of the results of that evaluation, the Commission shall decide whether the national measure is justified or not.

2. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator.

3. If the national measure is considered justified, all Member States shall take the measures necessary to ensure that the non-compliant neurotechnology is withdrawn from their market, and shall inform the Commission accordingly.

4. If the national measure is considered unjustified, the Member State concerned shall withdraw that measure.

5. For high-risk neurotechnology, where the non-compliance is attributed to shortcomings in the harmonized standards or common specifications referred to in Articles 77 and 78, the Commission shall apply the procedure provided for in Article 11 of Regulation (EU) No 1025/2012.

6. Where the Commission establishes that a high-risk neurotechnology presents a risk to neurocognitive rights, health, safety, or other aspects of public interest protection, it may, by means of implementing acts, adopt measures at Union level. These measures may include: (a) Ordering the withdrawal of the neurotechnology from the Union market; (b) Prohibiting or restricting the placing on the market or putting into service of the neurotechnology; (c) Requiring specific warnings to be provided with the neurotechnology; (d) Requiring specific technical modifications to be made to the neurotechnology; (e) Suspending or restricting specific functionality of the neurotechnology.

7. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 122(2).

8. On duly justified imperative grounds of urgency relating to the health and safety of individuals, the Commission shall adopt immediately applicable implementing acts in accordance with the procedure referred to in Article 122(3).

Article 100: Compliant neurotechnology which presents a risk

1. Where, having carried out an evaluation under Article 98(1), a market surveillance authority finds that although neurotechnology is in compliance with this Regulation, it presents a risk to neurocognitive rights, health, safety, or other aspects of public interest protection, it shall require the relevant economic operator to take appropriate measures to ensure that the neurotechnology concerned, when placed on the market, no longer presents that risk, to withdraw the neurotechnology from the market, or to recall it within a reasonable period commensurate with the nature of the risk.

2. The economic operator shall ensure that corrective action is taken in respect of all the neurotechnology concerned that the economic operator has made available on the market throughout the Union.

3. The Member State shall immediately inform the Commission and the other Member States. That information shall include: (a) The data necessary for the identification of the neurotechnology concerned; (b) A description of the risk and the results of the evaluation carried out; (c) The nature and duration of the measures taken; (d) The arguments put forward by the relevant economic operator.

4. The Commission shall without delay consult the Member States and the relevant economic operator and shall evaluate the measures taken. On the basis of the results of that evaluation, the Commission shall decide whether the measure is justified or not and, where necessary, propose appropriate measures.

5. The Commission shall address its decision to all Member States and shall immediately communicate it to them and the relevant economic operator.

Article 101: Formal non-compliance

1. Where a market surveillance authority makes one of the following findings, it shall require the relevant economic operator to put an end to the non-compliance concerned: (a) The CE marking has been affixed in violation of Article 71; (b) The CE marking has not been affixed; (c) The EU declaration of conformity has not been drawn up; (d) The EU declaration of conformity has not been drawn up correctly; (e) The technical documentation is either not available or not complete; (f) The information which is required to be provided by the provider under Article 31 is absent, false, or incomplete; (g) Any other administrative requirement provided for in this Regulation is not fulfilled.

2. Where the non-compliance referred to in paragraph 1 persists, the Member State concerned shall take all appropriate measures to restrict or prohibit the neurotechnology being made available on the market or ensure that it is recalled or withdrawn from the market.

TITLE XII: INTERNATIONAL COORDINATION

Article 102: International cooperation

1. The Commission, in cooperation with Member States, shall engage in international cooperation to promote convergence of regulatory approaches to neurotechnology and neurocognitive rights protection.

2. International cooperation shall aim to: (a) Promote the protection of neurocognitive rights globally; (b) Facilitate dialogue on regulatory approaches to neurotechnology; (c) Exchange information on emerging trends, risks, and best practices; (d) Promote interoperability of technical standards; (e) Strengthen international governance of neurotechnology; (f) Address global challenges related to neural data protection; (g) Support responsible research and innovation in neurotechnology.

3. The Commission and the European Neurotechnology Regulatory Authority shall engage with: (a) International organizations, including the United Nations, the World Health Organization, the Council of Europe, and the Organisation for Economic Co-operation and Development; (b) Standards development organizations, including the International Organization for Standardization and the International Electrotechnical Commission; (c) International forums and initiatives focused on neurotechnology governance; (d) Third countries interested in regulatory cooperation; (e) Scientific and academic institutions engaged in international neurotechnology research.

4. The Commission may adopt implementing acts establishing arrangements for cooperation with relevant international organizations and third countries. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 122(2).

Article 103: Mutual recognition agreements

1. The Commission may negotiate mutual recognition agreements with third countries that have regulatory frameworks for neurotechnology with protections for neurocognitive rights equivalent to those in this Regulation.

2. Mutual recognition agreements may address: (a) Recognition of conformity assessment procedures; (b) Equivalence of technical standards; (c) Recognition of certifications and compliance marks; (d) Cooperation between regulatory authorities; (e) Exchange of information on market surveillance findings; (f) Coordination of responses to serious incidents; (g) Compatibility of neural data protection frameworks.

3. Before negotiating a mutual recognition agreement, the Commission shall conduct an assessment of the third country's regulatory framework for neurotechnology and neurocognitive rights protection, including: (a) The legal and regulatory framework; (b) The institutional capacity for implementation and enforcement; (c) The technical standards and conformity assessment procedures; (d) The market surveillance system; (e) The safeguards for neurocognitive rights.

4. Mutual recognition agreements shall include provisions for: (a) Regular review of continued equivalence; (b) Exchange of information on regulatory developments; (c) Coordination on emerging issues and challenges; (d) Dispute resolution mechanisms; (e) Termination or suspension in case of significant divergence.

5. The European Neurotechnology Regulatory Authority shall support the Commission in the assessment and monitoring of equivalent protection under mutual recognition agreements.

Article 104: Regulatory dialogue

1. The Commission and the European Neurotechnology Regulatory Authority shall engage in regulatory dialogue with authorities in third countries responsible for neurotechnology regulation.

2. Regulatory dialogue may include: (a) Exchange of information on regulatory approaches and challenges; (b) Discussion of emerging neurotechnology trends and their implications; (c) Sharing of best practices in neurotechnology governance; (d) Consultation on potential areas of regulatory convergence; (e) Coordination on international standards development; (f) Discussion of ethical frameworks for neurotechnology; (g) Exploration of cooperative mechanisms for oversight and enforcement.

3. The Commission shall report annually to the European Parliament and the Council on international regulatory dialogue activities related to neurotechnology and neurocognitive rights.

Article 105: Capacity building

1. The Commission shall establish programs to support capacity building for neurotechnology governance in third countries, particularly developing countries.

2. Capacity building programs may include: (a) Technical assistance for the development of regulatory frameworks; (b) Training for regulatory officials; (c) Support for the establishment of conformity assessment bodies; (d) Assistance in developing market surveillance systems; (e) Knowledge sharing on neurocognitive rights protection; (f) Support for participation in international standards development; (g) Promotion of ethical frameworks for neurotechnology research and development.

3. The Commission shall coordinate capacity building activities with Member States and relevant international organizations to maximize effectiveness and avoid duplication.

4. Capacity building programs shall respect the cultural, social, and legal contexts of partner countries while promoting fundamental principles of neurocognitive rights protection.

Article 106: Promotion of Union standards

1. The Commission and Member States shall promote the adoption of Union standards for neurotechnology and neurocognitive rights protection at international level.

2. Promotion activities may include: (a) Active participation in international standards development organizations; (b) Sharing of the Union's regulatory approach in international forums; (c) Technical cooperation with third countries on standards implementation; (d) Support for international initiatives that align with Union

standards; (e) Demonstration of the benefits of the Union's approach to neurotechnology governance; (f) Engagement with global industry stakeholders on responsible neurotechnology development.

3. The Commission, in coordination with the European Standardisation Organizations, shall identify priority areas for international standards promotion based on: (a) Strategic importance for Union interests; (b) Potential to enhance global protection of neurocognitive rights; (c) Areas of rapid technological development requiring harmonized approaches; (d) Opportunities for establishing the Union as a global leader in neurotechnology governance.

4. The European Neurotechnology Regulatory Authority shall support international standards promotion by: (a) Providing technical expertise in international forums; (b) Analyzing the compatibility of international standards with Union requirements; (c) Developing guidance on the implementation of international standards; (d) Facilitating dialogue between Union and international standards bodies.

Article 107: Global partnerships for responsible neurotechnology

1. The Commission shall establish global partnerships to advance responsible development, deployment, and governance of neurotechnology.

2. Global partnerships shall bring together diverse stakeholders, including: (a) Governmental and regulatory authorities; (b) Academic and research institutions; (c) Industry representatives; (d) Civil society organizations; (e) International organizations; (f) Technical experts in neuroscience and neurotechnology; (g) Ethicists and human rights experts.

3. Global partnerships shall focus on: (a) Developing shared principles for neurotechnology governance; (b) Addressing global challenges that require coordinated responses; (c) Sharing knowledge and best practices; (d) Supporting collaborative research on responsible neurotechnology; (e) Developing common approaches to emerging issues; (f) Building global awareness of neurocognitive rights; (g) Promoting inclusive and participatory governance mechanisms.

4. The Commission shall report biennially to the European Parliament and the Council on the activities and achievements of global partnerships for responsible neurotechnology.

TITLE XIII: DELEGATED ACTS AND IMPLEMENTATION

Article 108: Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The delegation of power referred to in Articles 17(4), 25(5), 26(6), 27(7), 28(7), 29(6), 30(7), 31(5), 32(8), 33(6), 34(8), 35(7), 36(7), 37(6), 38(7), 40(5), 46(7), 52(7), 53(5), 62(5), 64(6), 65(8), 67(6), 69(6), 76(9), 92(10), and 111(3) shall be conferred on the Commission for a period of five years from [the date of entry into force of this Regulation]. The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration,

unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in the Articles listed in paragraph 2 may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.

5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

6. A delegated act adopted pursuant to the Articles listed in paragraph 2 shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of three months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by three months at the initiative of the European Parliament or of the Council.

Article 109: Committee procedure

1. The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

3. Where reference is made to this paragraph, Article 8 of Regulation (EU) No 182/2011, in conjunction with Article 5 thereof, shall apply.

Article 110: Evaluation and review

1. The Commission shall evaluate this Regulation and report to the European Parliament and the Council on its implementation, effectiveness, and impact.

2. The first evaluation shall be carried out five years after the date of application of this Regulation. Subsequent evaluations shall be carried out every four years thereafter.

3. The evaluations shall assess: (a) The effectiveness of the Regulation in protecting neurocognitive rights; (b) The functioning of the risk-based approach to neurotechnology regulation; (c) The performance of the European Neurotechnology Regulatory Authority; (d) The effectiveness of enforcement and market surveillance mechanisms; (e) The impact on innovation, research, and competitiveness in the neurotechnology sector; (f) The adequacy of the Regulation in light of technological developments; (g) The effectiveness of international cooperation mechanisms; (h) The operation of the specialized judicial mechanisms; (i) The coherence with other Union and national legislation.

4. Each evaluation shall take into account scientific and technological developments in the field of neurotechnology and evolving understandings of neurocognitive rights.

5. For the purpose of the evaluation, the Commission shall establish a monitoring framework to collect data and other necessary evidence from Member States, the European Neurotechnology Regulatory Authority, and other relevant stakeholders.

6. Based on the findings of the evaluations, the Commission shall, if necessary, submit appropriate proposals to amend this Regulation.

Article 111: Amendments to other Union legal acts

1. Regulation (EU) 2016/679 is amended as follows: (a) In Article 4, the following point is added: "(25a) 'neural data' means personal data obtained directly or indirectly from the measurement or monitoring of the structure or function of the brain or nervous system, or data that reflects cognitive processes or mental states;" (b) In Article 9(1), the following words are added after "genetic data, biometric data for the purpose of uniquely identifying a natural person,": "neural data,".

2. Regulation (EU) 2017/745 is amended as follows: (a) In Article 2, the following point is added: "(65) 'neurotechnology medical device' means a medical device that enables direct monitoring, recording, stimulation, or modulation of neural activity, or that enables the extraction, processing, or interpretation of neural data for medical purposes;" (b) In Annex XVI, the following point is added: "25. Neurostimulation devices for non-medical purposes."

3. The Commission is empowered to adopt delegated acts in accordance with Article 108 to amend this Article to update the references to the provisions of Union legal acts listed in this Article or to add references to other Union legal acts that should be amended in light of this Regulation.

TITLE XIV: FINAL PROVISIONS

Article 112: Penalties

1. Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate, and dissuasive.

2. Member States shall provide for the following penalties in particular: (a) For infringements of Article 22 regarding prohibited neurotechnology applications, administrative fines of up to 30 000 000 EUR or, if the offender is an undertaking, up to 6% of its total worldwide annual turnover for the preceding financial year, whichever is higher; (b) For non-compliance with the requirements for high-risk neurotechnology set out in Title V, administrative fines of up to 20 000 000 EUR or, if the offender is an undertaking, up to 4% of its total worldwide annual turnover for the preceding financial year, whichever is higher; (c) For other infringements of this Regulation, administrative fines of up to 10 000 000 EUR or, if the offender is an undertaking, up to 2% of its total worldwide annual turnover for the preceding financial year, whichever is higher.

3. In deciding whether to impose an administrative fine and in determining its amount, due regard shall be given in each individual case to: (a) The nature, gravity, and duration of the infringement; (b) The intentional or negligent character of the infringement; (c) The actions taken to mitigate the damage suffered; (d) The degree of responsibility taking into account technical and organizational measures implemented; (e) Any relevant previous infringements; (f) The level of cooperation with the supervisory authority; (g) The categories of neural data affected by the infringement; (h) The manner in which the infringement became known to the competent authority; (i) The financial benefits gained or losses avoided as a result of the infringement; (j) Any other aggravating or mitigating factors.

4. In addition to administrative fines, Member States shall provide for other penalties, which may include: (a) Orders to cease the infringing behavior; (b) Withdrawal of products from the market; (c) Temporary or permanent ban on marketing neurotechnology; (d) Temporary or permanent disqualification from public contracts; (e) Publicizing of the penalty imposed; (f) Criminal sanctions for the most serious infringements, in accordance with national law.

5. Member States shall notify the Commission of those rules and measures and shall notify it without delay of any subsequent amendments affecting them.

Article 113: Administrative fines on Union institutions, bodies, offices, and agencies

1. The European Data Protection Supervisor may impose administrative fines on Union institutions, bodies, offices, and agencies, depending on the circumstances of each individual case, where they fail to comply with this Regulation. When deciding whether to impose an administrative fine and determining its amount, due regard shall be given to the circumstances of each individual case, taking into account the criteria set out in Article 112(3).

2. Fines shall be imposed in accordance with the same thresholds and criteria as those applicable to Member State public authorities.

Article 114: Relation to other Union law

1. This Regulation shall not affect the application of other Union legal acts governing the processing of personal data, in particular Regulation (EU) 2016/679 and Directive 2002/58/EC. In the event of conflict between the provisions of this Regulation and the provisions of other Union legal acts governing the processing of neural data, the provisions of this Regulation shall prevail to the extent of the specific requirements for neural data.

2. This Regulation shall not affect the application of Regulation (EU) 2017/745 governing medical devices. Where neurotechnology qualifies as a medical device under Regulation (EU) 2017/745, it shall comply with both that Regulation and this Regulation. In the event of conflict between the provisions of this Regulation and the provisions of Regulation (EU) 2017/745 relating to safety and performance requirements, the provisions of Regulation (EU) 2017/745 shall prevail.

3. This Regulation shall not affect the application of the competences of the Member States regarding activities concerning national security or defense.

Article 115: Processing of personal data for the purposes of this Regulation

1. When personal data is processed for the purposes of this Regulation, such processing shall be carried out in accordance with Regulation (EU) 2016/679 or, where applicable, Regulation (EU) 2018/1725.

2. For the purposes of this Regulation, the European Neurotechnology Regulatory Authority shall be considered a controller within the meaning of Regulation (EU) 2018/1725 in relation to personal data processed in the context of its activities.

Article 116: Confidentiality

1. Without prejudice to Article 100, Union and Member State competent authorities, notified bodies, and all other relevant bodies shall ensure that confidential information obtained in carrying out their tasks under this Regulation is treated in compliance with the confidentiality obligations laid down in this Article.

2. Information exchanged on a confidential basis between competent authorities and between competent authorities and the Commission shall not be disclosed without the prior agreement of the originating authority.

3. Paragraphs 1 and 2 shall not affect the rights and obligations of the Commission, Member States, and notified bodies with regard to the exchange of information and the dissemination of warnings, nor the obligations of the persons concerned to provide information under criminal law.

4. The Commission, Member States, and notified bodies may exchange confidential information with regulatory authorities of third countries with which they have concluded bilateral or multilateral confidentiality arrangements ensuring an adequate level of confidentiality.

Article 117: Fees

1. Member States may levy fees for the activities carried out by their national competent authorities pursuant to this Regulation. The level of the fees shall be set at a level that covers the costs of those activities.

2. The European Neurotechnology Regulatory Authority may charge fees for the services it provides. The level of the fees shall be set at a level that covers the costs of the services provided.

3. The Commission shall adopt implementing acts to specify the structure and level of the fees that may be charged by the European Neurotechnology Regulatory Authority. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 109(2).

Article 118: Transitional provisions

1. From the date of entry into force of this Regulation until the date of its application: (a) The prohibition in Article 22 shall apply to the neurotechnology applications listed in points (a) to (m) of Article 22(1); (b) Providers of high-risk neurotechnology may voluntarily apply the requirements of Title V and undergo conformity assessment in accordance with Title VIII.

2. Neurotechnology already placed on the market or put into service before [date of application of this Regulation] may continue to be made available on the market or put into service provided that: (a) Within 24 months from the date of application of this Regulation, providers of high-risk neurotechnology comply with the requirements of Title V and undergo conformity assessment in accordance with Title VIII; (b) Within 36 months from the date of application of this Regulation, all providers of neurotechnology comply with the general provisions of this Regulation.

3. The European Neurotechnology Regulatory Authority shall establish transitional guidance to support compliance during the transitional period.

Article 119: Entry into force and application

1. This Regulation shall enter into force on the twentieth day following that of its publication in the Official Journal of the European Union.

2. It shall apply from [24 months from the date of entry into force].

3. By way of derogation from paragraph 2: (a) Title IX regarding the European Neurotechnology Regulatory Authority shall apply from [6 months from the date of entry into force]; (b) Title IV regarding prohibited practices shall apply from [12 months from the date of entry into force]; (c) Articles 83 and 84 regarding national competent authorities shall apply from [12 months from the date of entry into force].

4. This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament The President

For the Council The President

ANNEXES

ANNEX I: Definitions related to neurotechnology techniques

For the purposes of this Regulation, the following definitions related to neurotechnology techniques shall apply:

1. **'Electroencephalography (EEG)'** means a non-invasive neurotechnology that records electrical activity of the brain through electrodes placed on the scalp.

2. **'Functional magnetic resonance imaging (fMRI)'** means a non-invasive neurotechnology that measures brain activity by detecting changes in blood flow, specifically the blood-oxygen-level-dependent (BOLD) signal.

3. **'Functional near-infrared spectroscopy (fNIRS)'** means a non-invasive neurotechnology that monitors brain activity through changes in blood hemoglobin concentrations using near-infrared light.

4. **'Magnetoencephalography (MEG)'** means a non-invasive neurotechnology that records magnetic fields produced by electrical activity in the brain.

5. **'Transcranial magnetic stimulation (TMS)'** means a non-invasive neurotechnology that uses magnetic fields to stimulate nerve cells in specific areas of the brain.

6. **'Transcranial direct current stimulation (tDCS)'** means a non-invasive neurotechnology that uses constant, low direct current delivered via electrodes placed on the scalp to modulate brain activity.

7. **'Transcranial alternating current stimulation (tACS)'** means a non-invasive neurotechnology that applies oscillating current at specific frequencies to modulate brain activity.

8. **'Transcranial focused ultrasound stimulation (tFUS)'** means a non-invasive neurotechnology that uses focused ultrasound waves to modulate neural activity in specific brain regions.

9. **'Deep brain stimulation (DBS)'** means an invasive neurotechnology that involves the implantation of electrodes in specific brain regions to deliver electrical stimulation.

10. **'Intracortical microelectrode arrays'** means invasive neurotechnology consisting of arrays of microscale electrodes implanted directly into brain tissue to record neural activity at the level of individual neurons or small neural populations.

11. **'Electrocorticography (ECoG)'** means an invasive neurotechnology that records brain activity through electrodes placed directly on the exposed surface of the brain.

12. **'Optogenetics'** means a neurotechnology that uses genetic modification to render specific neural cells responsive to light, allowing for the optical control of neural activity with high temporal and spatial precision.

13. **'Chemogenetics'** means a neurotechnology that uses genetically modified receptors that are activated by otherwise inert molecules to control neural activity.

14. **'Neural dust'** means a neurotechnology consisting of microscale, wireless neural sensors that can be implanted throughout the nervous system to record and potentially stimulate neural activity.

15. **'Stentrodes'** means a minimally invasive neurotechnology that uses stent-based electrodes delivered through blood vessels to record neural activity from locations adjacent to cerebral vasculature.

16. **'Neural lace'** means a mesh-like neural interface that can be injected or surgically inserted into the brain with minimal invasiveness to record or stimulate neural activity.

17. **'Neural implants'** means devices surgically placed inside the body to record neural signals or stimulate neural tissue, including the brain, spinal cord, or peripheral nerves.

18. **'Wearable neural interfaces'** means non-invasive devices worn on the body that can monitor or interact with neural activity, typically through sensors placed on the scalp, skin, or in close proximity to neural tissue.

19. **'Closed-loop neurostimulation'** means neurostimulation systems that continuously monitor neural activity and automatically adjust stimulation parameters based on the recorded signals.

20. **'Brain-computer interface (BCI)'** means a system that establishes a direct communication pathway between the brain and an external device, allowing neural signals to control external systems or for external systems to modulate neural activity.

21. **'Passive BCI'** means a brain-computer interface that monitors neural activity without requiring intentional control from the user, often used to assess cognitive or emotional states.

22. **'Active BCI'** means a brain-computer interface that relies on intentional mental commands from the user to control external devices or systems.

23. **'Neural decoding algorithms'** means computational methods that translate neural activity patterns into meaningful information about cognitive processes, sensory experiences, or motor intentions.

24. **'Neural encoding algorithms'** means computational methods that translate external information into patterns of neural stimulation designed to evoke specific neural responses or perceptions.

25. **'Neurofeedback'** means a technique that provides real-time feedback about neural activity to an individual, allowing them to learn to self-regulate brain function.

ANNEX II: Types of neural data

For the purposes of this Regulation, the following types of neural data shall be considered:

1. **'Raw neural signals'** means unprocessed electrical, magnetic, hemodynamic, or other signals recorded directly from neural tissue or indirectly through the scalp or other non-invasive means.

2. **'Processed neural features'** means derived representations of neural activity after filtering, artifact removal, feature extraction, or other signal processing operations.

3. **'Neural activity patterns'** means spatiotemporal configurations of neural signals associated with specific cognitive functions, mental states, or behaviors.

4. **'Neural biomarkers'** means measurable indicators derived from neural data that can be used to assess normal biological processes, pathogenic processes, or responses to interventions.

5. **'Functional connectivity data'** means information about the statistical dependencies or causal interactions between different neural populations or brain regions.

6. **'Neural structural data'** means information about the physical architecture of neural tissue, including neuroanatomical structures, neuronal morphology, and connectivity.

7. **'Neural stimulation parameters'** means information about the characteristics of stimulation applied to neural tissue, including intensity, frequency, duration, and spatial distribution.

8. **'Neural response data'** means information about how neural tissue responds to stimulation, sensory input, or cognitive demands.

9. **'Neural decoding outputs'** means interpretations or classifications of mental states, cognitive processes, intentions, or emotions derived from neural data through computational analysis.

10. **'Neural profiles'** means collections of neural features or patterns that characterize an individual's neural functioning across multiple contexts or time points.

11. **'Neural fingerprints'** means distinctive patterns of neural activity that can uniquely identify an individual.

12. **'Neural chronometry data'** means information about the timing and temporal dynamics of neural processes.

13. **'Neural developmental data'** means information about changes in neural structure or function across the lifespan.

14. **'Neural adaptation data'** means information about how neural systems change in response to experience, learning, or interventions.

15. **'Neural state data'** means information about transient configurations of neural activity associated with particular cognitive, emotional, or physiological states.

ANNEX III: Categories of high-risk neurotechnology

For the purposes of this Regulation, the following specific categories of high-risk neurotechnology shall be subject to the requirements set out in Title V:

1. **Neurotechnology for cognitive assessment in employment contexts** Systems intended to assess cognitive abilities, emotional states, personality traits, or professional suitability of job candidates or employees using neural data.

2. **Neurotechnology for educational assessment** Systems intended to evaluate learning capacity, cognitive development, attention, or other educational attributes of students using neural data, particularly when used for placement or advancement decisions.

3. **Neurotechnology for law enforcement** Systems intended for use in criminal investigations, including deception detection, memory recognition, or intention assessment based on neural data.

4. **Neurotechnology for authentication and access control** Systems that use neural data as biometric identifiers for authentication, access control, or identity verification purposes.

5. **Neurotechnology for automated decision-making about individuals** Systems that use neural data to make or influence automated decisions that significantly affect individuals in contexts such as insurance, banking, healthcare resource allocation, or social service eligibility.

6. **Consumer neurotechnology with significant risk potential** Systems marketed to consumers that have the potential to significantly influence cognitive functions, emotional states, decision-making, or behavior through neural monitoring or stimulation.

7. **Neural data analytics for profiling** Systems that analyze neural data to create detailed profiles of individuals' cognitive attributes, emotional tendencies, preferences, or vulnerabilities for commercial, political, or other purposes.

8. **Emotion recognition neurotechnology** Systems that detect, classify, or respond to emotional states based on neural data, particularly when used in contexts with significant power imbalances or potential for manipulation.

9. **Advanced neurostimulation technologies** Systems that apply electrical, magnetic, ultrasonic, or other forms of stimulation to modulate neural activity with significant intensity or in regions associated with core cognitive functions, identity, or agency.

10. **Novel neural interfaces** Neural interface technologies using novel methods, materials, or approaches that have limited evidence regarding long-term safety and effects.

11. **Neurotechnology for vulnerable populations** Systems specifically designed for or disproportionately used with vulnerable populations, including children, elderly persons, persons with cognitive disabilities, or persons in institutional care.

12. **Continuous neural monitoring systems** Systems designed for long-term, continuous monitoring of neural activity outside controlled medical or research environments.

13. **Neurotechnology for cognitive enhancement** Systems intended to enhance cognitive capabilities beyond typical function through direct interaction with neural systems.

14. **Neurotechnology in public spaces** Systems deployed in public spaces capable of collecting or analyzing neural data from multiple individuals without explicit individual consent.

15. **Brain-computer interfaces controlling critical systems** Brain-computer interfaces that enable direct neural control of systems where malfunction could pose risks to health, safety, or fundamental rights.

ANNEX IV: Technical documentation requirements

The technical documentation referred to in Article 30 shall contain at least the following information, as applicable to the relevant neurotechnology:

1. **General description of the neurotechnology** a. Intended purpose and primary functionality b. Basic principles of operation and key technologies employed c. Technical specifications and performance characteristics d. System architecture and major components e. Development history and major iterations f. Relationships to other systems or technologies g. Environmental and operational conditions required

2. **Detailed technical specifications** a. Hardware specifications, including:
    - Neural sensing or stimulation components
    - Processing units
    - Power systems
    - Communication interfaces
    - Physical dimensions and materials

b. Software specifications, including:

    - Operating system and environment
    - Signal processing algorithms
    - Neural decoding or encoding methods
    - User interface components
    - Security implementations

c. Data specifications, including:

    - Types of neural data collected
    - Sampling rates and resolution
    - Data formats and structures
    - Preprocessing methods
    - Storage and transmission protocols

3. **Risk management documentation** a. Risk assessment methodology b. Identified hazards and risk scenarios c. Risk estimation and evaluation d. Risk control measures implemented e. Benefit-risk analysis f. Residual risk evaluation g. Risk management plan for post-market phase
4. **Neural data governance** a. Neural data collection procedures b. Data quality assurance methods c. Data processing operations and purposes d. Data protection impact assessment e. Technical and organizational security measures f. Data retention and deletion policies g. Data access controls and audit mechanisms
5. **Design and development information** a. Design inputs and requirements b. Design verification and validation methods c. Development process documentation d. Change management procedures e. Traceability matrix f. Third-party components and their documentation g. Design reviews and outcomes
6. **Testing and validation documentation** a. Test plans and protocols b. Test data and results c. Validation methods and results d. Performance metrics and achieved values e. Verification of compliance with requirements f. Testing of edge cases and failure modes g. Testing across diverse user populations
7. **User and human oversight information** a. User qualification requirements b. User interface design and usability testing c. User training materials and procedures d.

Human oversight mechanisms e. Human-machine interaction protocols f. Override and control mechanisms g. User feedback collection and analysis

8. **Informed neural consent mechanisms** a. Consent procedure design b. Information provided to individuals c. Consent documentation and verification d. Special considerations for vulnerable individuals e. Withdrawal of consent procedures f. Validation of consent processes g. Management of consent records
9. **Security and safety features** a. Security risk assessment b. Authentication and access control mechanisms c. Encryption and data protection methods d. Security testing results e. Safety features and fail-safe mechanisms f. Penetration testing results g. Security update procedures
10. **Post-market monitoring plan** a. Methodology for data collection b. Key performance indicators to be monitored c. Methods for detecting and addressing emerging risks d. Process for implementing corrective actions e. Reporting procedures for incidents and malfunctions f. Plans for periodic evaluation and updates g. User feedback mechanisms
11. **Specific documentation for high-risk neurotechnology** a. Detailed accuracy, reliability, and reproducibility data b. Bias testing and mitigation methods c. Explainability methods and documentation d. Technical robustness and safety evidence e. Neural data quality assurance procedures f. Conformity assessment documentation g. Neurocognitive rights impact assessment
12. **Documentation of compliance with standards** a. List of standards applied b. Evidence of conformity with each standard c. Deviations from standards and justifications d. Test reports from accredited laboratories e. Certificates and declarations f. Conformity assessment procedures followed g. Quality management system documentation

ANNEX V: EU Declaration of conformity

The EU declaration of conformity referred to in Article 70 shall contain the following information:

1. Neurotechnology name and type, and any additional information enabling unambiguous identification of the neurotechnology.
2. Name and address of the provider or, where applicable, their authorized representative.
3. A statement that the EU declaration of conformity is issued under the sole responsibility of the provider.
4. A statement that the neurotechnology in question is in conformity with this Regulation and, if applicable, with any other relevant Union legislation that provides for the issuing of an EU declaration of conformity.
5. References to any harmonized standards used or other common specifications in relation to which conformity is declared.

6. Where applicable, the name and identification number of the notified body, a description of the conformity assessment procedure performed, and identification of the certificate issued.

7. A statement of the intended purpose of the neurotechnology.

8. Where applicable, a reference to any EU-type examination certificate or EU design examination certificate issued by a notified body.

9. Place and date of issue of the declaration, name and position of the person who signed it, and, where applicable, an indication for and on behalf of whom the person signed, signature.

ANNEX VI: Conformity assessment procedure based on internal control

1. The conformity assessment procedure based on internal control is the conformity assessment procedure based on points 2 to 4.

2. The provider verifies that the established quality management system is in compliance with the requirements of Article 24.

3. The provider examines the information contained in the technical documentation in order to assess the compliance of the high-risk neurotechnology with the relevant requirements set out in Title V.

4. The provider also verifies that the design and development process of the high-risk neurotechnology and its post-market monitoring as referred to in Article 46 is consistent with the technical documentation.

ANNEX VII: Conformity assessment procedure with the involvement of a notified body

1. The conformity assessment procedure with the involvement of a notified body is the conformity assessment procedure based on points 2 to 5.

2. The provider shall apply to a notified body of their choice to perform a conformity assessment of a high-risk neurotechnology.

3. The application shall include: a. The name and address of the provider and, if the application is lodged by the authorized representative, their name and address as well; b. A written declaration that the same application has not been lodged with any other notified body; c. The technical documentation referred to in Article 30.

4. The notified body shall examine the technical documentation and assess whether: a. The high-risk neurotechnology complies with the requirements set out in Title V; b. The risk management system is adequate and has been properly implemented; c. The neural data governance system complies with the requirements of this Regulation; d. The quality management system is adequate; e. The post-market monitoring system is appropriate.

5. Where the notified body concludes that the high-risk neurotechnology complies with the requirements set out in Title V, it shall issue an EU technical documentation assessment certificate. The certificate shall contain the name and address of the provider, the conclusions of the examination, any conditions for its validity and the data necessary for the identification of the assessed high-risk neurotechnology.

ANNEX VIII: Requirements for notified bodies

In order to be designated, a notified body shall meet the requirements laid down in this Annex.

1. **Organizational and general requirements** a. Legal status and organizational structure
    - Be established under the national law of a Member State
    - Have full documentation of its legal personality and structure
    - Be independent of the providers it assesses

b. Independence and impartiality

- Be independent of the provider of neurotechnology it assesses
- Ensure that its activities are free from commercial, financial, or other pressures
- Document procedures to ensure impartiality
- Have structures and procedures to safeguard objectivity

c. Confidentiality

- Have documented procedures for maintaining confidentiality
- Ensure staff maintain professional secrecy
- Protect proprietary information obtained during assessment activities

d. Liability

- Take out appropriate liability insurance
- Have financial stability and resources to conduct activities

e. Quality management system

- Implement and maintain a quality management system
- Include procedures for allocation of responsibilities
- Have documentation control procedures
- Conduct internal audits and management reviews

2. **Resource requirements** a. Personnel
    - Have sufficient personnel with technical knowledge and experience
    - Include expertise in neuroscience, neurotechnology, neural data protection
    - Employ staff with knowledge of relevant standards and regulations
    - Ensure personnel have appropriate qualifications, training, and authorization

- Have systems to ensure competence monitoring and continuous training

b. Technical facilities

- Have access to appropriate facilities and equipment
- Possess capabilities to test neurotechnology where required
- Have procedures for proper maintenance and calibration of equipment

c. Subcontracting

- Where subcontracting occurs, ensure adequate supervision
- Maintain register of subcontractor qualifications and work
- Have written agreement covering confidentiality and conflicts of interest

3. **Process requirements** a. Application handling

- Document procedures for handling applications
- Verify completeness of documentation
- Establish agreements with providers on timing and conduct of assessments

b. Assessment activities

- Conduct assessments with due technical competence
- Assess technical documentation adequately
- Evaluate risk management systems appropriate to neurotechnology
- Verify neural data governance procedures
- Assess human oversight mechanisms
- Evaluate testing protocols and results

c. Reporting

- Provide clear assessment reports
- Have documented procedure for report review and approval
- Ensure traceability of assessment decisions

d. Follow-up activities

- Conduct appropriate surveillance
- Have procedures for handling changes to approved neurotechnology
- Respond to information affecting conformity status

e. Appeals

- Document procedures for appeals against decisions
- Inform providers of right to appeal

- Maintain records of all appeals and their resolution

4. **Specific competence for neurotechnology** a. Specific expertise
    - Demonstrate knowledge of neurotechnology types and principles
    - Have expertise in neural data protection and governance
    - Understand neurocognitive rights implications
    - Have capabilities to assess neurotechnology safety and performance

b. Specialized knowledge

- Include staff with knowledge of neural recording technologies
- Include staff with knowledge of neurostimulation technologies
- Include staff with knowledge of neural decoding algorithms
- Include staff with knowledge of brain-computer interfaces

c. Risk assessment competence

- Demonstrate ability to identify and evaluate neurotechnology risks
- Have methods to assess neurocognitive rights impacts
- Possess capability to evaluate neural security measures
- Understand potential long-term effects of neurotechnology

5. **Documentation and records** a. Records system
    - Maintain records demonstrating fulfillment of requirements
    - Document qualifications, training, and authorization of personnel
    - Keep records of subcontractors
    - Maintain assessment records for required periods

b. Public information

- Make publicly available information about assessment types
- Publish certification procedures
- Disclose conflicts of interest policies

5. c. Document control
    - Control conformity assessment documents
    - Ensure availability of current procedures
    - Identify document changes and review status
    - Implement procedures for document approval and distribution
    - Maintain a master list of all controlled documents

- Establish review cycles for all procedural documents
- Ensure proper versioning and change tracking

d. Record retention

- Establish procedures for record retention periods
- Implement secure archiving systems
- Ensure retrievability of historical records
- Define protocols for record disposal
- Document chain of custody for all assessment records
- Implement backup mechanisms for electronic records
- Establish access controls for confidential records

6. **Coordination and cooperation** a. Participation in standardization
    - Participate in relevant standardization activities
    - Contribute to neurotechnology standards development
    - Maintain knowledge of evolving standards
    - Implement new standards in assessment procedures

b. Coordination with other notified bodies

- Participate in coordination groups for notified bodies
- Exchange experiences with other notified bodies
- Work toward harmonized application of requirements
- Participate in peer reviews

c. Cooperation with authorities

- Cooperate with market surveillance authorities
- Inform competent authorities of certificate suspensions or withdrawals
- Respond to information requests from authorities
- Report serious incidents and malfunctions as required

7. **Continuous improvement** a. Feedback mechanisms
    - Collect feedback from clients and stakeholders
    - Analyze complaints and appeals
    - Track performance metrics
    - Implement corrective and preventive actions

b. Knowledge management

- Maintain systems for knowledge sharing among staff
- Keep abreast of scientific and technological developments
- Update assessment methodologies based on new knowledge
- Document lessons learned from assessment activities

c. Performance evaluation

- Conduct regular self-assessments
- Participate in external assessments
- Review and analyze assessment outcomes
- Implement improvements based on evaluations

8. **Specific neurotechnology expertise requirements** a. Technical domains

- Demonstrate expertise in neural recording technologies
- Demonstrate expertise in neurostimulation technologies
- Demonstrate expertise in neural data processing
- Demonstrate expertise in neural security

b. Scientific understanding

- Maintain staff with neuroscience backgrounds
- Understand neurophysiological principles
- Keep current with neurotechnology research
- Comprehend neurocognitive impacts of technology

c. Ethical competence

- Understand ethical implications of neurotechnology
- Demonstrate knowledge of neurocognitive rights
- Evaluate ethical aspects of neurotechnology applications
- Assess informed neural consent procedures

ANNEX IX: Methodology for neurotechnology impact assessment

The neurotechnology impact assessment referred to in Article 52 shall be conducted according to the following methodology:

1. **Preparation and planning** a. Establish the assessment team

- Include members with expertise in neurotechnology
- Include members with expertise in neurocognitive rights
- Include members with expertise in risk assessment

- Include members with expertise in the specific application context

b. Define the scope

- Identify the specific neurotechnology to be assessed
- Define the intended use and context
- Determine assessment boundaries
- Establish timeline and resources

c. Develop assessment plan

- Select appropriate assessment methods
- Identify necessary information sources
- Establish evaluation criteria
- Define documentation requirements

2. **Context analysis** a. Use environment
    - Analyze the physical environment of use
    - Identify relevant social and organizational factors
    - Consider power dynamics in the use context
    - Assess regulatory environment

b. User analysis

- Identify primary and secondary users
- Assess vulnerability factors of users
- Consider user capacity for informed consent
- Analyze user needs and expectations

c. Stakeholder analysis

- Identify all affected stakeholders
- Assess potential impacts on each stakeholder group
- Consider competing interests among stakeholders
- Plan for stakeholder engagement

3. **Neurotechnology characterization** a. Technical assessment
    - Document technical specifications
    - Identify neural functions targeted
    - Assess invasiveness level
    - Analyze data collection capabilities

b. Functional analysis

- Document primary and secondary functions
- Identify key operational parameters
- Assess adaptability and learning capabilities
- Analyze integration with other systems

c. Data processing assessment

- Document neural data types collected
- Assess processing methods
- Identify storage and transmission protocols
- Analyze potential for data repurposing

4. **Neurocognitive rights impact assessment** a. Cognitive liberty assessment
    - Evaluate potential impacts on cognitive autonomy
    - Assess risks of external cognitive influence
    - Identify safeguards for cognitive liberty
    - Consider long-term implications for thought autonomy

b. Mental privacy assessment

- Evaluate neural data collection intrusiveness
- Assess potential for unintended information disclosure
- Identify neural data protection measures
- Consider boundaries between conscious and unconscious disclosure

c. Cognitive identity integrity assessment

- Evaluate potential impacts on sense of self
- Assess risks to psychological continuity
- Identify safeguards for identity protection
- Consider long-term implications for personal identity

d. Neural security assessment

- Evaluate vulnerability to unauthorized access
- Assess potential for neural hacking or interference
- Identify security measures
- Consider consequences of security breaches

5. **Broader impact assessment** a. Health and safety assessment

- Evaluate physical safety risks
- Assess potential psychological impacts
- Identify potential for dependency or addiction
- Consider long-term health implications

b. Fundamental rights assessment

- Evaluate impacts on dignity
- Assess implications for equality and non-discrimination
- Identify potential effects on other fundamental rights
- Consider societal and ethical dimensions

c. Social impact assessment

- Evaluate potential for creating or exacerbating inequalities
- Assess implications for social relationships
- Identify potential societal transformation effects
- Consider cultural and contextual factors

6. **Risk analysis and evaluation** a. Risk identification
    - Systematically identify risks to neurocognitive rights
    - Identify risks to health and safety
    - Identify risks to other fundamental rights
    - Document identified risks

b. Risk analysis

- Determine likelihood of identified risks
- Assess severity of potential consequences
- Consider uncertainty factors
- Document analysis methodology and results

c. Risk evaluation

- Evaluate acceptability of identified risks
- Prioritize risks based on level of concern
- Consider different stakeholder perspectives
- Document evaluation criteria and conclusions

7. **Risk mitigation measures** a. Technical measures
    - Identify design modifications to reduce risks

- Develop enhanced security measures
- Implement user control mechanisms
- Establish monitoring and alert systems

b. Organizational measures

- Develop governance structures
- Establish oversight mechanisms
- Create incident response procedures
- Implement training programs

c. Procedural measures

- Enhance informed consent procedures
- Develop usage policies and guidelines
- Establish regular review processes
- Create accountability mechanisms

8. **Documentation and reporting** a. Impact assessment report
    - Document methodology
    - Summarize findings
    - Detail identified risks and impacts
    - Present mitigation measures

b. Implementation plan

- Establish timeline for implementing mitigation measures
- Assign responsibilities
- Define success criteria
- Create monitoring framework

c. Communication strategy

- Identify key messages for different stakeholders
- Develop communication materials
- Establish feedback mechanisms
- Plan for transparency

9. **Implementation and monitoring** a. Mitigation implementation
    - Implement technical measures
    - Deploy organizational changes

- Establish procedural safeguards
- Document implementation process

b. Monitoring framework

- Define monitoring metrics
- Establish data collection procedures
- Create reporting mechanisms
- Set review cycles

c. Adaptation mechanisms

- Define triggers for reassessment
- Establish change management procedures
- Create feedback incorporation process
- Document adaptation decisions

ANNEX X: Information to be included in instructions for use

The instructions for use referred to in Article 31 shall include at least the following information:

1. **General information** a. Identity and contact details of the provider b. Year of publication of the instructions and, if applicable, version number c. Intended purpose of the neurotechnology d. Target user group or groups e. Compatibility with other devices or systems f. Basic principles of operation g. Description of components and accessories
2. **Technical specifications** a. Physical characteristics b. Environmental requirements for operation c. Power requirements and battery information where applicable d. Performance specifications e. Expected service life f. Storage and transport conditions g. Technical parameters of neural interfaces
3. **Installation and setup** a. Unpacking and inventory verification b. Assembly instructions where applicable c. Installation requirements d. Calibration procedures e. Configuration options f. Compatibility with accessories g. Pre-use verification procedures
4. **Operation instructions** a. Startup and shutdown procedures b. Control functions and user interface c. Operation modes d. Adjustable parameters and their effects e. Emergency shutdown procedures f. Error messages and troubleshooting g. Performance optimization
5. **Neural data information** a. Types of neural data collected b. Purposes of neural data processing c. Data storage and transmission d. Neural data access procedures e. Data deletion options f. Data export capabilities g. Neural data security measures

6. **User rights and controls** a. Informed neural consent procedures b. User control mechanisms c. Override capabilities d. Privacy settings e. User data access procedures f. Opt-out options g. Complaint and redress mechanisms

7. **Safety information** a. Warnings and precautions b. Contraindications c. Potential adverse effects d. Safety features e. Incident reporting procedures f. Emergency contact information g. Safety certifications

8. **Risk information** a. Known risks and side effects b. Potential neurocognitive impacts c. Security vulnerabilities d. Risk mitigation measures e. Long-term use considerations f. Special risk factors for vulnerable users g. Risk monitoring recommendations

9. **Limitations and restrictions** a. Functional limitations b. Accuracy limitations c. Use restrictions d. User qualification requirements e. Usage time limitations where applicable f. Known interaction effects with other systems g. Environmental limitations

10. **Maintenance and troubleshooting** a. Routine maintenance requirements b. Cleaning and disinfection procedures c. Calibration and adjustment d. Common problems and solutions e. Diagnostic procedures f. Service contact information g. Replacement parts information

11. **Updates and modifications** a. Software update procedures b. Hardware upgrade options c. Modification restrictions d. Version compatibility information e. Update verification procedures f. Rollback procedures g. Update notification system

12. **Disposal information** a. End-of-life procedures b. Component recycling information c. Data wiping procedures d. Environmental considerations e. Regulatory compliance for disposal f. Return programs where available g. Documentation of disposal

13. **Legal information** a. Warranty terms b. Liability limitations c. Intellectual property notices d. Regulatory compliance statements e. License information f. Terms of use g. Privacy policy

14. **Additional information for high-risk neurotechnology** a. Risk management information b. Human oversight requirements c. Specialized training requirements d. Conformity assessment information e. Performance monitoring requirements f. Serious incident handling procedures g. Neurocognitive rights protection measures

ANNEX XI: Permitted neural data collection and processing purposes

The following purposes shall be considered permitted purposes for neural data collection and processing under this Regulation, subject to compliance with all other applicable requirements:

1. **Healthcare and therapeutic purposes** a. Diagnosis of neurological or psychiatric conditions b. Treatment of neurological or psychiatric conditions c. Rehabilitation after brain injury or neurological disease d. Monitoring of disease progression or treatment efficacy e. Personalization of therapeutic interventions f. Development of neural prosthetics or assistive devices g. Management of chronic pain or neurological symptoms

2. **Scientific research purposes** a. Basic neuroscience research b. Clinical neuroscience research c. Neurotechnology development and improvement d. Cognitive science research e. Mental health research f. Educational neuroscience research g. Cross-disciplinary research involving neural data

3. **Assistive technology purposes** a. Enabling communication for persons with disabilities b. Controlling assistive devices through neural signals c. Sensory augmentation or substitution d. Motor assistance or enhancement e. Cognitive assistance for persons with cognitive disabilities f. Monitoring and adaptation of assistive systems g. Development and improvement of neural interfaces for accessibility

4. **Educational purposes** a. Support for learners with specific learning disabilities b. Development of personalized learning approaches c. Assessment of learning processes for educational improvement d. Research on cognitive development in educational contexts e. Cognitive training under appropriate supervision f. Educational neuroscience research with appropriate safeguards g. Development of evidence-based educational interventions

5. **Wellness and personal development purposes** a. Stress management b. Meditation and mindfulness support c. Sleep improvement d. Cognitive wellness monitoring e. Voluntary cognitive enhancement for personal growth f. Mental performance optimization for specific tasks g. Self-awareness and personal insight with appropriate safeguards

6. **Safety-critical operation purposes** a. Monitoring operator alertness in safety-critical contexts b. Fatigue detection in transportation or industrial contexts c. Emergency response enhancement d. Safety training improvements e. Human-machine teaming in safety contexts f. Error prevention in high-risk operations g. Safety certification and validation

7. **Authorized security and law enforcement purposes** a. Forensic assessment under judicial authorization b. Investigation of serious crimes with judicial oversight c. Rehabilitation in criminal justice contexts with informed consent d. Security assessment in critical infrastructure with specific safeguards e. Counter-terrorism with judicial authorization f. Border security with specified limitations g. Authentication for high-security access with informed consent

8. **Commercial purposes with enhanced safeguards** a. Voluntary neuromarketing research with informed neural consent b. Product usability testing with informed neural consent c. User experience assessment with anonymization d. Entertainment applications with clear disclosure and control e. Gaming applications with voluntary participation f. Workplace wellness with strict anonymization and no individual evaluation g. Consumer preference research with informed neural consent

ANNEX XII: Prohibited neural data collection and processing purposes

The following purposes shall be considered prohibited purposes for neural data collection and processing under this Regulation:

1. **Discriminatory purposes** a. Profiling based on protected characteristics b. Discrimination in employment decisions c. Discrimination in educational opportunities d. Discrimination in access to services e. Neural trait-based segregation f. Creating or reinforcing bias g. Neurological or cognitive stereotyping

2. **Manipulation purposes** a. Covert influence of decision-making b. Exploitation of neural vulnerabilities c. Subconscious manipulation d. Emotional manipulation for commercial gain e. Political manipulation or microtargeting f. Addiction induction or exploitation g. Behavior modification without awareness

3. **Surveillance purposes** a. Mass neural surveillance b. Continuous monitoring without specific justification c. Covert neural monitoring d. Political opinion monitoring e. Workplace surveillance of neural activity f. Public space neural monitoring without justification g. Creation of neural tracking profiles

4. **Intimidation or coercion purposes** a. Forced neural disclosure b. Compelled neural assessment c. Neural data collection under duress d. Threatening neural intervention e. Creating cognitive distress for compliance f. Institutional control through neural monitoring g. Exploitation of power imbalances for neural access

5. **Identity harm purposes** a. Disruption of identity continuity b. Substantial modification of core beliefs without consent c. Personality or identity alteration d. Erasure or manipulation of memories e. Creation of cognitive dissonance f. Disruption of authentic selfhood g. Exploitation of identity uncertainty

6. **Unauthorized security and law enforcement purposes** a. Neural interrogation without judicial authorization b. Neural evidence collection without legal basis c. Neural assessment for general criminality prediction d. Neural monitoring as general surveillance e. Neural profiling without specific cause f. Neural data collection for social credit systems g. Neural lie detection in judicial proceedings without scientific validation

7. **Competitive advantage exploitation** a. Corporate espionage through neural data b. Non-consensual competitive intelligence gathering c. Exploitation of neural data for unfair market advantage d. Unauthorized access to commercial secrets or expertise e. Neural-based intellectual property theft f. Neural data collection for anti-competitive purposes g. Unauthorized skill or knowledge extraction

8. **Deceptive or exploitative purposes** a. Misrepresentation of neurotechnology capabilities b. Deceptive claims about neural enhancement c. Exploitation of vulnerable populations d. Undisclosed neural data collection e. Hidden neurotechnology functionality f. False attribution of neural origins g. Neurotechnology-based fraud

9. **Harmful psychological manipulation** a. Inducing psychological distress or harm b. Creating or exploiting neural dependency c. Deliberately causing cognitive disruption d. Exploiting neural vulnerabilities of vulnerable populations e. Causing unnecessary mental suffering f. Inducing false beliefs or delusions g. Psychological destabilization

10. **Other prohibited purposes** a. Any purpose prohibited by Union or Member State law b. Any purpose that violates human dignity c. Any purpose that substantially

undermines autonomy d. Any purpose that poses serious risks to mental health e. Any purpose that significantly undermines democratic processes f. Any purpose involving torture or cruel treatment g. Any purpose that significantly violates human rights

ANNEX XIII: Serious incident classification criteria

For the purposes of reporting obligations under Article 47 and Article 97, the following criteria shall be used to classify serious incidents:

1. **Impact severity classification** a. **Critical impact**
    - Potential or actual death or permanent disability
    - Serious neurocognitive rights violation affecting large numbers of individuals
    - Substantial and irreversible cognitive or psychological harm
    - Major security breach affecting sensitive neural data of many individuals
    - Significant risk to public safety or democratic processes

b. **Major impact**

- Temporary but significant cognitive impairment
- Significant neurocognitive rights violation
- Substantial but potentially reversible psychological harm
- Significant neural data breach
- Neural functionality disruption with serious consequences

c. **Moderate impact**

- Temporary minor cognitive effects
- Limited neurocognitive rights violations
- Temporary psychological distress
- Limited neural data exposure
- Functionality disruption with moderate consequences

d. **Minor impact**

- Minimal impact on cognitive function
- Technical violations without significant rights impact
- Momentary discomfort or inconvenience
- Potential but unrealized privacy risks
- Functionality issues with minimal consequences

2. **Incident type classification** a. **Neural data breach**

- Unauthorized access to neural data
- Neural data exposure to unauthorized parties
- Theft of neural data
- Neural data corruption
- Unintended neural data collection

b. **Neurostimulation malfunction**

- Unintended stimulation patterns
- Stimulation intensity deviations
- Stimulation targeting errors
- Stimulation timing anomalies
- Stimulation cessation failures

c. **Neural recording malfunction**

- Inaccurate neural signal recording
- Signal interference or corruption
- Recording system failure
- Signal interpretation errors
- Recording system stability issues

d. **Neural decoding error**

- Misinterpretation of neural signals
- False positive or negative interpretations
- Algorithmic bias manifestation
- Decoding system failure
- Unexpected decoding behavior

e. **Security vulnerability**

- Neural interface security breach
- Unauthorized control access
- Authentication failure
- Neural firewall breach
- Exploitation of software vulnerabilities

f. **Unexpected psychological effect**

- Unanticipated emotional responses

- Unexpected cognitive changes
- Unintended behavioral modifications
- Identity-related disturbances
- Psychological dependency development

g. **Physical injury**

- Tissue damage from interfaces
- Infection or inflammatory response
- Seizure induction
- Secondary physical effects
- Device-related physical trauma

3. **Causal classification** a. **Design flaw**

- Fundamental design inadequacy
- Design safety feature failure
- Interface design incompatibility
- Inadequate fail-safe mechanisms
- Inappropriate design parameters

b. **Manufacturing defect**

- Component failure
- Assembly error
- Material defect
- Quality control failure
- Calibration error

c. **Software error**

- Algorithm failure
- Programming error
- Update implementation failure
- Software compatibility issue
- Software security vulnerability

d. **User error**

- Improper configuration
- Misuse of neurotechnology

- Inadequate training
- Failure to follow instructions
- Deliberate misuse

e. **External interference**

- Electromagnetic interference
- Malicious attack
- Environmental factors
- Physical damage
- Interaction with other systems

f. **System interaction failure**

- Component interaction error
- System integration failure
- Communication protocol error
- Data synchronization failure
- Feedback loop error

g. **Unknown cause**

- No identified cause
- Multiple potential causes
- Indeterminate causation
- Unreproducible incident
- Novel failure mechanism

4. **Reportability determination** a. All incidents with critical or major impact shall be reported regardless of cause b. Moderate impact incidents shall be reported if:
    - They indicate a systematic issue
    - They affect multiple individuals
    - They represent a previously unidentified risk
    - They are due to malicious activity
    - They indicate security vulnerabilities

c. Minor impact incidents shall be reported if:

- They occur repeatedly
- They indicate potential for more severe incidents

- They represent a novel failure mode
- They involve security breaches
- They affect particularly vulnerable individuals

5. **Reporting timeline requirements** a. Critical impact incidents: immediate notification, full report within 72 hours b. Major impact incidents: notification within 24 hours, full report within 5 days c. Reportable moderate impact incidents: notification within 72 hours, full report within 10 days d. Reportable minor impact incidents: notification within 5 days, full report within 15 days

ANNEX XIV: Risk assessment methodology for neurotechnology

The risk assessment referred to in Article 25 shall be conducted according to the following methodology:

1. **Risk assessment planning** a. Define the scope of the assessment
    - Identify the neurotechnology system boundaries
    - Define the use contexts to be assessed
    - Identify the lifecycle phases to be included
    - Establish the risk assessment team

b. Establish the risk assessment framework

- Define risk criteria and thresholds
- Select appropriate risk assessment methods
- Establish documentation requirements
- Define stakeholder involvement

c. Information gathering

- Collect technical specifications
- Review scientific literature
- Analyze similar neurotechnology experiences
- Consider regulatory requirements
- Gather stakeholder perspectives

2. **Hazard identification** a. Technical hazards
    - Hardware component hazards
    - Software hazards
    - Interface hazards
    - Integration hazards
    - Performance hazards

b. Neural interaction hazards

- Neural recording hazards
- Neurostimulation hazards
- Neural interpretation hazards
- Neural influence hazards
- Neural adaptation hazards

c. Neural data hazards

- Data accuracy hazards
- Data security hazards
- Data privacy hazards
- Data processing hazards
- Data inference hazards

d. Neurocognitive rights hazards

- Cognitive liberty hazards
- Mental privacy hazards
- Cognitive identity integrity hazards
- Neural security hazards
- Neurodiscrimination hazards

e. Psychological hazards

- Emotional impact hazards
- Cognitive function impact hazards
- Behavioral impact hazards
- Dependency hazards
- Self-perception hazards

f. Use context hazards

- User qualification hazards
- Environmental hazards
- Organizational hazards
- Misuse hazards
- Integration hazards

3. **Risk analysis** a. Determine exposure

- Identify exposed individuals
- Determine exposure frequency
- Assess exposure duration
- Evaluate exposure intensity
- Consider vulnerability factors

b. Assess consequences

- Identify potential harm types
- Evaluate harm severity
- Assess reversibility
- Consider cascading effects
- Evaluate detectability

c. Estimate likelihood

- Analyze historical data
- Consider technical reliability
- Evaluate human factors
- Assess environmental factors
- Consider intentional threats

d. Consider uncertainty

- Identify knowledge gaps
- Evaluate data quality
- Consider emerging risks
- Assess predictability limitations
- Document assumptions

4. **Risk evaluation** a. Determine risk levels

- Combine consequence and likelihood assessments
- Apply risk criteria
- Categorize risks by level
- Prioritize risks
- Document evaluation rationale

b. Evaluate risk acceptability

- Compare against defined thresholds

- Consider risk-benefit balance
- Evaluate ethical implications
- Consider stakeholder perspectives
- Document acceptability decisions

c. Identify risks requiring treatment

- Identify unacceptable risks
- Identify risks requiring further reduction
- Identify acceptable risks requiring monitoring
- Document treatment priorities
- Establish risk treatment objectives

5. **Risk treatment** a. Identify risk treatment options
    - Risk elimination options
    - Risk reduction options
    - Risk transfer options
    - Risk acceptance options
    - Risk monitoring options

b. Evaluate treatment options

- Assess effectiveness
- Evaluate feasibility
- Consider potential side effects
- Assess costs and resources
- Consider implementation timeline

c. Select treatment measures

- Apply risk treatment hierarchy
- Document selected measures
- Assign implementation responsibility
- Establish implementation timeline
- Define success criteria

d. Implement risk controls

- Technical controls
- Procedural controls

- Educational controls
- Monitoring controls
- Emergency response measures

6. **Residual risk evaluation** a. Assess residual risks
    - Re-evaluate risks after treatment
    - Assess effectiveness of controls
    - Identify any new risks introduced
    - Document residual risk levels
    - Determine residual risk acceptability

b. Risk-benefit analysis

- Identify benefits of the neurotechnology
- Compare residual risks against benefits
- Consider different stakeholder perspectives
- Document risk-benefit conclusions
- Justify acceptance decisions

7. **Risk monitoring and review** a. Establish risk monitoring
    - Define risk indicators
    - Establish monitoring frequency
    - Assign monitoring responsibilities
    - Implement monitoring tools
    - Define reporting requirements

b. Risk management verification

- Verify implementation of controls
- Evaluate control effectiveness
- Assess compliance with requirements
- Document verification results
- Address verification findings

c. Periodic risk review

- Establish review schedule
- Define review triggers
- Conduct comprehensive reassessments

- Update risk assessments
- Document review outcomes

8. **Documentation and communication** a. Risk assessment documentation
    - Document methodology
    - Record identified hazards
    - Document risk analyses
    - Record evaluation decisions
    - Document treatment plans

b. Risk communication

- Identify communication needs
- Develop communication materials
- Implement communication strategy
- Document communication activities
- Evaluate communication effectiveness

ANNEX XV: Requirements for informed neural consent

The informed neural consent referred to in Article 34 shall comply with the following requirements:

1. **Information provision requirements** a. Clear explanation of the neurotechnology
    - Description of the neurotechnology type and function
    - Explanation of the principles of operation
    - Description of the user interface and controls
    - Explanation of the relationship with other systems
    - Information about the provider

b. Specific neural data information

- Types of neural data collected
- Level of detail or granularity of data
- Processing operations performed
- Derived information or inferences
- Storage duration and location

c. Purpose information

- Specific purposes of neural data collection

- Specific purposes of neural stimulation
- Relationship between data and purpose
- Limitations on purpose expansion
- Justification for each purpose

d. Risk information

- Known physical risks
- Potential psychological impacts
- Possible cognitive effects
- Neurocognitive rights implications
- Security and privacy risks

e. Benefit information

- Expected benefits
- Probability of benefits
- Limitations of benefits
- Alternative approaches
- Comparative benefit assessment

f. Control information

- User control mechanisms
- Data access rights
- Opt-out procedures
- Override capabilities
- Discontinuation procedures

g. Protection information

- Security measures
- Privacy safeguards
- Rights protection mechanisms
- Oversight and accountability
- Incident response procedures

2. **Information delivery requirements** a. Timing requirements
    - Information provided before consent decision
    - Sufficient time for consideration

- Staged information provision for complex neurotechnology
- Advance notice of significant changes
- Regular renewal of information

b. Format requirements

- Clear, plain language
- Appropriate to user comprehension level
- Multiple formats available (text, video, interactive)
- Accessible to persons with disabilities
- Translated into relevant languages

c. Structure requirements

- Logical organization
- Layered information with summaries and detailed explanations
- Clear headings and navigation
- Emphasis on key information
- Glossary of technical terms

d. Assessment of understanding

- Interactive verification of understanding
- Opportunities for questions
- Documentation of information provision
- Comprehension checks for complex neurotechnology
- Feedback mechanisms

3. **Consent expression requirements** a. Consent documentation

- Record of consent expression
- Timestamp and version identification
- Scope of consent given
- Any limitations or conditions
- Identity verification

b. Specificity requirements

- Separate consent for distinct purposes
- Granular consent options
- Specific consent for high-risk functions

- Explicit consent for sensitive neural data
- Purpose-limited consent

c. Voluntariness requirements

- Freedom from coercion
- Absence of significant penalties for refusal
- Genuine choice preservation
- Alternative options where feasible
- Independence of decision-making

d. Competence requirements

- Assessment of capacity to consent
- Adaptations for persons with cognitive disabilities
- Age-appropriate mechanisms for minors
- Supported decision-making where appropriate
- Documentation of capacity assessment

4. **Special category requirements** a. Requirements for high-risk neurotechnology
    - Enhanced information provision
    - Extended consideration periods
    - Verification of understanding
    - Documentation of deliberative process
    - Independent oversight

b. Requirements for vulnerable individuals

- Adapted information formats
- Supported decision-making
- Enhanced protection against undue influence
- Best interest assessments where appropriate
- Additional safeguards against exploitation

c. Requirements for continuous or long-term use

- Periodic renewal of consent
- Updated information on emerging risks
- Monitoring for dependency
- Mechanisms for reassessment

- Documentation of ongoing consent

5. **Consent management requirements** a. Withdrawal procedures
    - Simple, accessible withdrawal mechanisms
    - No penalties for withdrawal
    - Clear explanation of consequences
    - Data deletion options
    - Documentation of withdrawal

b. Consent modification

- Procedures for updating consent preferences
- Granular modification options
- Regular review opportunities
- Notification of preference changes
- Records of modification history

c. Consent oversight

- Internal review procedures
- External verification where appropriate
- Documentation retention
- Compliance monitoring
- Periodic evaluation of effectiveness

ANNEX XVI: Neurotechnology impact assessment criteria

The neurotechnology impact assessment referred to in Article 52 shall be evaluated according to the following criteria:

1. **Technical characterization assessment** a. Neural monitoring characterization
    - Types of neural signals monitored
    - Spatial resolution
    - Temporal resolution
    - Signal processing methods
    - Interpretation algorithms

b. Neural stimulation characterization

- Stimulation modality
- Intensity parameters

- Frequency characteristics
- Targeting precision
- Duration capabilities

c. Neural data characterization

- Data types collected
- Processing operations
- Storage duration and methods
- Transmission protocols
- Access controls

2. **Neurocognitive rights impact assessment** a. Cognitive liberty impact
    - Degree of potential cognitive influence
    - Nature of cognitive processes affected
    - Duration of potential effects
    - Reversibility of effects
    - User control mechanisms

b. Mental privacy impact

- Depth of neural data collection
- Types of mental states potentially revealed
- Inferences possible from collected data
- Protections against unintended disclosure
- User awareness of data collection

c. Cognitive identity integrity impact

- Potential effects on sense of self
- Impact on agency or autonomy
- Influence on psychological continuity
- Changes to cognitive patterns
- Effects on authentic functioning

3. **Vulnerable population impact assessment** a. Child-specific impacts
    - Developmental stage considerations
    - Long-term effects on neural development
    - Safeguards for child welfare

- Age-appropriate design elements
- Parental oversight mechanisms

b. Impacts on persons with disabilities

- Accessibility considerations
- Adaptations for different abilities
- Autonomy preservation measures
- Support mechanisms
- Equality of benefit

c. Impacts on other vulnerable groups

- Elderly protection measures
- Considerations for persons with cognitive impairments
- Protections for institutionalized individuals
- Measures for persons in dependent relationships
- Cultural sensitivity assessment

4. **Contextual impact assessment** a. Employment context impacts

- Power dynamic considerations
- Coercion prevention measures
- Boundary preservation between work and private life
- Equality of opportunity safeguards
- Performance assessment limitations

b. Educational context impacts

- Learning environment considerations
- Student privacy protections
- Developmental appropriateness
- Educational benefit distribution
- Assessment fairness measures

c. Healthcare context impacts

- Patient autonomy preservation
- Integration with care protocols
- Therapeutic relationship considerations
- Medical ethics alignment

- Continuity of care measures

5. **Societal impact assessment** a. Equity and access impacts
    - Distribution of benefits and risks
    - Potential for creating or exacerbating inequalities
    - Accessibility across socioeconomic groups
    - Cultural appropriateness
    - Inclusive design elements

b. Democratic process impacts
    - Effects on autonomous decision-making
    - Potential for manipulation
    - Preservation of genuine choice
    - Protection of political thought privacy
    - Safeguards for democratic participation

c. Social relationship impacts
    - Effects on interpersonal dynamics
    - Impacts on social cohesion
    - Changes to communication patterns
    - Privacy in social contexts
    - Authenticity preservation

6. **Risk mitigation assessment** a. Technical safeguards
    - Security measures
    - Privacy-enhancing technologies
    - Safety mechanisms
    - Fail-safe systems
    - Monitoring and alert systems

b. Organizational safeguards
    - Governance structures
    - Accountability mechanisms
    - Staff training programs
    - Oversight procedures
    - Incident response plans

c. User empowerment measures

- Control interfaces
- Information provision
- Feedback mechanisms
- Support resources
- Remediation processes

7. **Proportionality assessment** a. Necessity evaluation
    - Justification for neurotechnology use
    - Alternative approaches considered
    - Minimality of neural intervention
    - Purpose limitations
    - Scope restrictions

b. Benefit-risk balance

- Quantification of expected benefits
- Assessment of potential harms
- Distribution of benefits and risks
- Uncertainty factors
- Justification for residual risks

c. Mitigation effectiveness

- Adequacy of safeguards
- Residual risk levels
- Monitoring capabilities
- Adaptation mechanisms
- Response capabilities

ANNEX XVII: Requirements for neurotechnology impact assessment reports

The neurotechnology impact assessment report referred to in Article 52 shall include at least the following information:

1. **Executive summary** a. Assessment overview
    - Purpose of the assessment
    - Neurotechnology assessed
    - Key findings summary

- Major risks identified
- Principal mitigation measures

b. Decision summary

- Overall impact determination
- Key decision factors
- Residual risk acceptance rationale
- Implementation requirements
- Monitoring provisions

2. **Neurotechnology description** a. System overview
    - Type and category of neurotechnology
    - Primary functions and capabilities
    - Technical specifications
    - Operating environment
    - Integration with other systems

b. Neural interaction characterization

- Neural recording capabilities
- Neural stimulation capabilities
- Neural data processing methods
- Neural influence mechanisms
- Control interfaces

3. **Use context description** a. Intended use
    - Primary purposes
    - Target users
    - Use environment
    - Duration and frequency
    - Operational constraints

b. Organizational context

- Implementing organization
- Governance structure
- User support framework
- Oversight mechanisms

- Integration with existing systems

4. **Assessment methodology** a. Assessment approach
    - Methodological framework
    - Assessment tools
    - Information sources
    - Evaluation criteria
    - Decision-making process

b. Stakeholder engagement
    - Stakeholders consulted
    - Consultation methods
    - Input received
    - Incorporation of feedback
    - Ongoing engagement plans

5. **Impact assessment findings** a. Neurocognitive rights impacts
    - Cognitive liberty analysis
    - Mental privacy analysis
    - Cognitive identity integrity analysis
    - Neural security analysis
    - Rights protection evaluation

b. Individual impacts
    - Health and safety analysis
    - Psychological impact analysis
    - Autonomy and agency analysis
    - Benefit distribution analysis
    - Individual risk assessment

c. Social and organizational impacts
    - Equity and access analysis
    - Power dynamic analysis
    - Organizational change implications
    - Social interaction effects
    - Institutional impacts

6. **Risk analysis** a. Risk identification
    - Identified hazards
    - Potential harm scenarios
    - Vulnerability factors
    - Threat vectors
    - Uncertainty elements

b. Risk evaluation
    - Likelihood assessment
    - Consequence assessment
    - Risk level determination
    - Risk prioritization
    - Risk acceptability decisions

7. **Mitigation measures** a. Technical measures
    - Design modifications
    - Security enhancements
    - Privacy-enhancing technologies
    - Safety mechanisms
    - Monitoring systems

b. Procedural measures
    - Operational protocols
    - Consent procedures
    - User training
    - Oversight processes
    - Incident response procedures

c. Governance measures
    - Policy frameworks
    - Accountability structures
    - Review mechanisms
    - Documentation requirements
    - Compliance monitoring

8. **Implementation plan** a. Mitigation implementation

- Implementation timeline
- Resource requirements
- Responsibility assignment
- Verification procedures
- Contingency plans

b. Monitoring framework

- Key performance indicators
- Monitoring frequency
- Reporting mechanisms
- Escalation procedures
- Periodic review requirements

9. **Conclusion and recommendations** a. Overall assessment
    - Final impact determination
    - Residual risk evaluation
    - Proportionality assessment
    - Implementation decision
    - Limitation statements

b. Recommendations

- Required actions
- Suggested enhancements
- Future assessment needs
- Research requirements
- Policy implications

ANNEX XVIII: Neural data security requirements

The following security requirements shall apply to neural data processing under this Regulation:

1. **Technical security measures** a. Encryption requirements
    - End-to-end encryption for neural data transmission
    - Strong encryption for stored neural data
    - Key management procedures
    - Encryption implementation standards

- Regular cryptographic review

b. Access control requirements

- Multi-factor authentication for neural data access
- Role-based access control
- Principle of least privilege implementation
- Access logging and monitoring
- Regular access review

c. Network security requirements

- Network segmentation for neural data systems
- Intrusion detection and prevention
- Secure communication protocols
- Network traffic monitoring
- Regular vulnerability scanning

d. Device security requirements

- Secure boot mechanisms
- Integrity verification
- Secure update mechanisms
- Hardware security features
- Physical tamper protection

2. **Organizational security measures** a. Security governance

- Security policy framework
- Security responsibility assignment
- Risk management processes
- Compliance monitoring
- Security performance metrics

b. Personnel security

- Security screening for key personnel
- Regular security training
- Clear security responsibilities
- Confidentiality agreements
- Disciplinary processes for violations

c. Incident management

- Incident response procedures
- Incident detection capabilities
- Breach notification protocols
- Recovery procedures
- Post-incident analysis

3. **Neural data lifecycle security** a. Collection security
    - Secure acquisition methods
    - Minimal collection principles
    - Collection validation
    - Source authentication
    - Collection authorization

b. Processing security

- Secure processing environments
- Processing isolation
- Processing logging
- Processing verification
- Secure algorithms

c. Storage security

- Secure storage architecture
- Data segregation
- Backup security
- Storage encryption
- Retention controls

d. Transmission security

- Secure transmission protocols
- Transmission encryption
- Channel security
- Transmission verification
- Metadata protection

e. Deletion security

- Secure erasure methods
- Deletion verification
- Media sanitization
- Deletion logging
- Archival security

4. **Security risk management** a. Risk assessment
    - Regular security risk assessments
    - Threat modeling
    - Vulnerability assessment
    - Impact analysis
    - Risk reporting

b. Risk treatment

- Risk mitigation planning
- Security control selection
- Implementation verification
- Residual risk management
- Continuous improvement

c. Security testing

- Penetration testing
- Vulnerability scanning
- Security code review
- Security architecture review
- Red team exercises

5. **Neural-specific security measures** a. Neural interface security
    - Interface authentication
    - Command verification
    - Interface monitoring
    - Neural firewall implementation
    - Emergency shutdown mechanisms

b. Neural data anonymization

- Anonymization techniques

- Re-identification risk assessment
- Anonymization verification
- Minimal pattern retention
- Pattern-level protection

c. Neural pattern security

- Pattern encryption
- Pattern segregation
- Pattern access control
- Pattern integrity verification
- Pattern anonymization

6. **Security documentation** a. Security architecture documentation
    - System security architecture
    - Security control documentation
    - Security interface documentation
    - Trust boundaries
    - Security assumptions

b. Security procedures documentation

- Security operational procedures
- Incident response procedures
- Security management procedures
- Security testing procedures
- Security training materials

c. Security verification documentation

- Security testing results
- Audit findings
- Compliance assessments
- Risk assessment documentation
- Security certifications

ANNEX XIX: Guidelines for neural data governance

The following guidelines shall apply to neural data governance under this Regulation:

1. **Governance structure requirements** a. Roles and responsibilities

- Clear assignment of data governance responsibilities
- Designation of neural data protection officers
- Executive accountability
- Cross-functional governance teams
- External advisory participation

b. Policies and procedures

- Comprehensive neural data policy
- Procedural documentation
- Policy review and approval processes
- Policy implementation verification
- Policy exception management

c. Decision-making framework

- Clear decision authority
- Escalation paths
- Decision documentation
- Stakeholder input mechanisms
- Ethical review processes

2. **Neural data management requirements** a. Data inventory

- Complete neural data catalog
- Data classification
- Data flow mapping
- Processing purpose documentation
- Third-party data sharing inventory

b. Data quality management

- Data quality standards
- Quality assessment procedures
- Error detection and correction
- Validation protocols
- Quality reporting

c. Data lifecycle management

- Collection justification

- Processing limitation
- Retention scheduling
- Archive management
- Secure deletion

3. **Risk management requirements** a. Risk assessment
    - Regular neural data risk assessments
    - New processing risk evaluation
    - Third-party risk assessment
    - Emerging risk monitoring
    - Risk reporting

b. Compliance management

- Regulatory tracking
- Compliance assessment
- Gap remediation
- Compliance documentation
- Audit preparation

c. Ethics management

- Ethical impact assessment
- Ethics review procedures
- Ethical principle implementation
- Ethics training
- Ethics monitoring

4. **Individual rights management** a. Transparency mechanisms
    - Clear information provision
    - Processing activity disclosure
    - Algorithm explanation
    - Purpose specification
    - Third-party sharing disclosure

b. Consent management

- Consent collection procedures
- Consent tracking

- Consent withdrawal mechanisms
- Consent renewal
- Consent version control

c. Access and control

- Data access procedures
- Correction mechanisms
- Deletion processes
- Processing limitation options
- Portability facilitation

5. **Security and protection requirements** a. Protection by design
    - Security architecture
    - Privacy by design implementation
    - Default protection settings
    - Data minimization
    - Purpose limitation

b. Technical measures

- Security controls
- Access management
- Encryption implementation
- Anonymization techniques
- Monitoring systems

c. Incident management

- Breach detection
- Response procedures
- Notification processes
- Recovery plans
- Post-incident analysis

6. **Documentation and evidence** a. Governance documentation
    - Policy documentation
    - Procedure manuals
    - Decision records

- Meeting minutes
- Responsibility assignments

b. Compliance evidence

- Processing records
- Consent documentation
- Risk assessments
- Impact assessments
- Legitimate interest assessments

c. Audit trails

- Processing logs
- Access logs
- Change management documentation
- Exception handling records
- Review and approval records

7. **Training and awareness** a. Personnel training
    - General awareness training
    - Role-specific training
    - Regular refresher training
    - New regulation updates
    - Incident response training

b. Management awareness

- Executive briefings
- Governance reporting
- Risk dashboards
- Compliance status updates
- Emerging issue alerts

c. External communications

- Transparency reporting
- Stakeholder education
- User guidance
- Public engagement

- Research community interaction

8. **Continuous improvement** a. Monitoring and measurement
    - Performance metrics
    - Compliance indicators
    - Risk tracking
    - User satisfaction measures
    - Incident metrics

b. Review and evaluation

- Regular governance reviews
- Policy effectiveness assessment
- Control testing
- External assessment
- Benchmark comparison

c. Improvement management

- Corrective action planning
- Enhancement prioritization
- Implementation tracking
- Effectiveness verification
- Knowledge incorporation

ANNEX XX: Cross-reference to other Union legal frameworks

The following table provides cross-references between the requirements of this Regulation and related requirements in other Union legal frameworks:

1. **Relationship with Regulation (EU) 2016/679 (GDPR)** a. Neural data as special category data (Article 58(2))
    - Relates to Article 9 GDPR (Processing of special categories of personal data)
    - Extends protections specific to neural data
    - Maintains GDPR requirements for lawful processing
    - Applies additional safeguards beyond GDPR requirements
    - Preserves GDPR enforcement mechanisms

b. Neural data protection impact assessment (Article 63)

- Builds upon Article 35 GDPR (Data protection impact assessment)
- Adds neurotechnology-specific assessment requirements

- Maintains GDPR threshold for high-risk processing
- Extends assessment criteria for neural data
- Preserves supervisory authority consultation requirements

c. Neural data breach notification (Article 59)

- Extends Articles 33-34 GDPR (Breach notification)
- Shortens notification timeframes for neural data breaches
- Adds neural-specific breach assessment criteria
- Requires additional information in notifications
- Maintains GDPR documentation requirements

2. **Relationship with Regulation (EU) 2017/745 (Medical Device Regulation)** a. Neurotechnology medical devices (Article 57)

- Complements classification rules in MDR Annex VIII
- Maintains safety and performance requirements
- Adds neurocognitive rights protections
- Preserves clinical investigation requirements
- Complements post-market surveillance provisions

b. Conformity assessment procedures (Article 69)

- Aligns with MDR conformity assessment procedures
- Adds neural data protection requirements
- Maintains quality management system requirements
- Extends technical documentation requirements
- Preserves notified body involvement

c. Post-market surveillance (Article 46)

- Builds upon MDR post-market surveillance system
- Adds monitoring for neurocognitive impacts
- Extends reporting requirements for neural incidents
- Maintains vigilance requirements
- Complements periodic safety update report requirements

3. **Relationship with [Artificial Intelligence Act]** a. Risk-based approach (Article 17)

- Complements AI Act risk classification system
- Adds neural-specific risk criteria

- Aligns prohibited practices where applicable
- Extends high-risk classification for neural applications
- Maintains consistency in conformity assessment approach

b. Requirements for high-risk systems (Title V)

- Complements AI Act requirements for high-risk AI
- Adds neural-specific technical requirements
- Maintains consistency in documentation requirements
- Extends human oversight provisions for neural contexts
- Aligns transparency obligations

c. Governance mechanisms (Title IX)

- Complements institutional structures in AI Act
- Coordinates with AI governance bodies
- Aligns notification and information sharing
- Maintains consistent enforcement approach
- Complements standardization efforts

4. **Relationship with Directive 2001/95/EC (General Product Safety Directive)** a. Safety requirements (Article 27)
    - Complements general safety requirement
    - Adds neural-specific safety considerations
    - Maintains producer obligations
    - Extends information provision requirements
    - Aligns with market surveillance provisions

b. Risk assessment methodology (Article 25)

- Builds upon product safety risk assessment
- Adds neural-specific hazard identification
- Maintains proportionality of measures
- Extends consumer information requirements
- Complements recall and withdrawal provisions

c. Market surveillance (Title XI)

- Aligns with market surveillance activities
- Adds specialized neural technology expertise

- Maintains authorities' investigation powers
- Extends cooperation mechanisms
- Complements enforcement measures

5. **Relationship with Directive 2011/83/EU (Consumer Rights Directive)** a. Information requirements (Article 31)
    - Extends pre-contractual information requirements
    - Adds neural-specific disclosure obligations
    - Maintains clarity and comprehensibility requirements
    - Extends right of withdrawal provisions
    - Complements unfair practices protection

b. Consent requirements (Article 34)

- Builds upon consent validity requirements
- Adds neural-specific consent elements
- Maintains withdrawal rights
- Extends documentation requirements
- Complements vulnerable consumer protections

c. Dispute resolution (Article 89)

- Aligns with consumer dispute resolution mechanisms
- Adds specialized expertise requirements
- Maintains accessibility principles
- Extends remedies for neural data violations
- Complements collective redress provisions

São Paulo, Brazil

October 07th 1988

3:45am