Proposal for THE UNITED KINGDOM NEUROCOGNITIVE RIGHTS AND ADVANCED NEUROTECHNOLOGY ACT 2025

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JUSTIFICATION FOR THE UNITED KINGDOM NEUROCOGNITIVE RIGHTS AND ADVANCED NEUROTECHNOLOGY ACT 2025

NECESSITY AND URGENCY

The United Kingdom stands at a critical technological inflection point that demands immediate legislative action. The Neurocognitive Rights and Advanced Neurotechnology 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.

In the post-Brexit era, the UK has a unique opportunity to establish itself as a global leader in neurotechnology governance, setting distinctive standards that reflect British values while positioning the UK as a hub for responsible innovation in this emerging field. This represents a pivotal moment for the UK to exercise its regulatory sovereignty in shaping the development of transformative technologies.

Recent developments in computational neuroscience, neural signal processing, and brain modulation technologies have progressed at an exponential rate, far outpacing our legal frameworks. British research institutions including the University of Cambridge, University College London, and Imperial College, alongside UK-based technology companies and NHS trusts, 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 United Kingdom already faces concrete challenges requiring urgent regulatory response:

1. British technology corporations and startups have invested over £2 billion in brain-computer interfaces for commercial and medical applications, with minimal oversight regarding privacy and security protocols for neural data.
2. The Medicines and Healthcare products Regulatory Agency (MHRA) 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 £800 million into UK neurotechnology startups in the past five years alone, creating a rapidly expanding market operating in a regulatory vacuum.
4. Early clinical trials within the NHS of cognitive enhancement technologies raise profound questions about equitable access and potential creation of cognitive disparities that could undermine British social cohesion.
5. International competitors, including the United States, China, and the European Union, are rapidly developing their own neurotechnology capabilities, creating geopolitical imperatives for establishing UK leadership in ethical standards and governance.

6. Without a unified UK approach, devolved administrations may develop divergent regulatory frameworks, creating fragmentation that would impede innovation and create regulatory complexity.

BRITISH LEGAL AND VALUES FOUNDATION

The UK Neurocognitive Rights and Advanced Neurotechnology Act builds upon Britain'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 UK legal protections:

- The Human Rights Act 1998, particularly Article 8 (right to respect for private and family life) and Article 9 (freedom of thought, conscience and religion)
- The common law tradition of protecting individual autonomy and bodily integrity
- The Data Protection Act 2018 and UK GDPR, which established robust standards for data protection but require enhancement to address the unique challenges of neural data
- The UK's strong medical ethics framework and informed consent requirements

Distinguished British legal scholars and ethicists, including those from the Nuffield Council on Bioethics and the Royal Society, have articulated the need for specific neurorights protections in UK jurisprudence. Their work demonstrates that traditional privacy doctrines, even those in the UK GDPR, are insufficient to address technologies that can potentially access thoughts, memories, and cognitive processes.

British courts have 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 BRITISH COMPETITIVENESS

Establishing a comprehensive legal framework for neurotechnology is central to the UK's post-Brexit strategic autonomy objectives and digital sovereignty agenda. The United Kingdom must lead in setting ethical standards and regulatory frameworks for neurotechnology development to ensure these technologies advance British values of human dignity, privacy, and fairness.

UK Research and Innovation (UKRI), the Medical Research Council, and numerous British research institutions have invested significantly in neurotechnology research. These investments demonstrate the strategic importance of neurotechnology for British scientific leadership and economic development.

Without a comprehensive UK-wide regulatory framework, the United Kingdom 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 regulatory fragmentation through divergent approaches across the UK
4. Undermining public trust in legitimate and beneficial applications of neurotechnology
5. Failing to protect the fundamental rights of UK citizens in an emerging technological domain

ECONOMIC AND INNOVATION BENEFITS

The neurotechnology sector represents a significant growth opportunity for the British economy. According to market analyses, the global neurotechnology market is projected to reach £25 billion by 2027, with the UK positioned to capture a substantial portion of this growth through its strong research base, world-class universities, innovative healthcare system, and dynamic technology sector.

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 United Kingdom
2. Create harmonized standards that facilitate interoperability and sector growth
3. Build public trust necessary for widespread adoption of beneficial neurotechnologies
4. Establish the United Kingdom as a global leader in ethical neurotechnology development
5. Position British companies advantageously in global markets through first-mover advantages in ethical neurotechnology
6. Create a distinctive post-Brexit regulatory framework that could become a template for other nations

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 British precedents:

- The specialized chambers of the High Court, such as the Technology and Construction Court
- The expertise of the Upper Tribunal in complex regulatory matters
- The specialized jurisdiction of the Intellectual Property Enterprise Court
- The UK's tradition of developing specialization in the judiciary to address novel technical challenges

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 British 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 United Kingdom as a global pioneer in neurocognitive justice—an area that will inevitably become central in coming decades.

GLOBAL LEADERSHIP AND STANDARD-SETTING

The United Kingdom has historically led in establishing regulatory frameworks for emerging technologies, from early legislation on human fertilization and embryology to more recent frameworks for gene editing and artificial intelligence. Neurotechnology represents the next frontier requiring British 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 United Kingdom can establish global standards aligned with British values of human dignity, privacy, and individual liberty. Failure to act would cede leadership to other nations or regions whose frameworks may not prioritize these values to the same degree.

The UK has consistently demonstrated that well-designed regulation can become a global standard. A comprehensive British framework for neurocognitive rights could similarly shape global practices in neurotechnology development and deployment, creating a distinctive "London Effect" in neurotechnology governance.

CROSS-PARTY APPEAL

The UK Neurocognitive Rights and Advanced Neurotechnology Act transcends traditional political divides, offering compelling justifications for support across the political spectrum:

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

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

For security advocates, the Act establishes frameworks essential for maintaining British 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 throughout the United Kingdom.

For devolution advocates, the Act demonstrates the capacity for UK-wide cooperation on complex emerging challenges while respecting the competencies of devolved administrations.

ALIGNMENT WITH EXISTING UK PRIORITIES

The UK Neurocognitive Rights and Advanced Neurotechnology Act aligns perfectly with existing British strategic priorities:

- The UK's Digital Strategy for a technology-driven economy
- The Life Sciences Vision for innovative healthcare technologies
- The NHS Long Term Plan for personalized and innovative care
- The UK's commitment to ethical AI development
- The government's focus on Science Superpower status
- The Industrial Strategy's emphasis on high-tech growth sectors

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

DISTINCTIVE BRITISH APPROACH TO NEUROTECHNOLOGY GOVERNANCE

This legislation offers an opportunity to create a distinctively British approach to neurotechnology governance, drawing on the UK's unique strengths:

- The UK's pragmatic common law tradition that allows for flexibility and adaptability
- The UK's world-leading healthcare system with its strong ethical frameworks
- The British tradition of balanced and proportionate regulation

- The UK's historical leadership in both scientific innovation and ethical governance
- Britain's strong tradition of individual liberty and protections against state overreach

This approach will offer an alternative to both the more prescriptive European regulatory model and the more market-oriented American approach, positioning the UK as an attractive middle ground for global neurotechnology development.

CONCLUSION

The UK Neurocognitive Rights and Advanced Neurotechnology 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, Parliament has the opportunity to establish landmarks in the protection of human dignity for the digital age.

This legislation will position the United Kingdom as the global leader in ethical neurotechnology development and neurocognitive rights protection—upholding Britain'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 Britain's commitment to fundamental rights and human dignity. We urge Parliament to prioritize passage of this vital legislation to secure cognitive liberty for current and future generations of British citizens and to establish the UK as the global leader in responsible neurotechnology innovation.

UNITED KINGDOM NEUROCOGNITIVE RIGHTS AND ADVANCED NEUROTECHNOLOGY ACT 2025

2025 CHAPTER 12

An Act to establish comprehensive protections for neurocognitive rights, regulate advanced neurotechnologies, establish specialised courts for adjudicating cases involving neurocognitive rights, and for other purposes.

[27th April, 2025]

BE IT ENACTED by the King's most Excellent Majesty, by and with the advice and consent of the Lords Spiritual and Temporal, and Commons, in this present Parliament assembled, and by the authority of the same, as follows:—

PART 1

GENERAL PROVISIONS

Section 1: Short Title, Commencement, and Extent

(1) This Act may be cited as the Neurocognitive Rights and Advanced Neurotechnology Act 2025.

(2) This Act shall come into force on such day as the Secretary of State may by order appoint, and different days may be appointed for different purposes.

(3) This Act extends to England and Wales, Scotland, and Northern Ireland.

(4) Her Majesty may by Order in Council direct that any provision of this Act shall extend, with such modifications as appear to Her Majesty to be appropriate, to any of the Channel Islands, the Isle of Man, or any British overseas territory.

Section 2: Purpose and Objectives

(1) The purpose of this Act is to establish a comprehensive legal framework for: (a) protecting neurocognitive rights; (b) regulating the development, deployment, and use of neurotechnology; (c) establishing specialised judicial mechanisms for adjudicating cases involving neurocognitive rights; and (d) ensuring that the United Kingdom is a global leader in responsible neurotechnology governance.

(2) The objectives of this Act are to: (a) protect the neurocognitive rights of individuals throughout the United Kingdom; (b) establish conditions under which neurotechnology may be developed and used in compliance with United Kingdom values and fundamental rights; (c) prevent potential harms arising from the misuse or unregulated use of neurotechnology; (d) foster responsible innovation in neurotechnology; (e) provide legal certainty for neurotechnology developers, providers, and users; and (f) strengthen the United Kingdom's position as a global leader in ethical neurotechnology development and governance.

Section 3: Interpretation

(1) In this Act, unless the context otherwise requires:

"artificial intelligence system" means software that is developed with one or more techniques that enable the system to generate outputs such as content, predictions, recommendations, or decisions influencing the environments they interact with;

"brain-computer interface" means any technology that establishes a direct communication pathway between a brain and an external device, system, or interface;

"cognitive identity integrity" means the right of individuals to maintain the continuity and authenticity of their cognitive processes and sense of self, protected from unauthorised alterations;

"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;

"competent authority" means any authority designated by a relevant national authority as having responsibility for the enforcement of this Act;

"distributor" means any natural or legal person in the supply chain, other than the provider or the importer, that makes neurotechnology available on the market;

"high-risk neurotechnology" means neurotechnology classified as high-risk in accordance with Section 20 of this Act;

"importer" means any natural or legal person established in the United Kingdom that places on the market neurotechnology bearing the name or trademark of a natural or legal person established outside the United Kingdom;

"informed neural consent" means consent for the use of neurotechnology or the processing of neural data that meets all the conditions specified in Section 34 of this Act;

"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;

"market surveillance" means the activities carried out and measures taken by public authorities to ensure that neurotechnology complies with the requirements set out in this Act and does not endanger health, safety, neurocognitive rights, or other aspects of public interest protection;

"mental privacy" means the right of individuals to keep their thoughts, emotions, preferences, and cognitive processes private and protected from unauthorised access, collection, or disclosure;

"National Centre for Neurotechnology Regulation" or "NCNR" means the body established pursuant to Section 44 of this Act;

"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;

"neural data breach" means a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, neural data transmitted, stored or otherwise processed;

"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;

"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;

"neural recording" means the measurement, monitoring, or recording of neural activity, whether through invasive or non-invasive means;

"neural security" means the protection of neural data and neurotechnology systems from unauthorised access, use, disclosure, disruption, modification, or destruction;

"neural state" means the configuration of brain activity at a given moment, which may correlate with mental states, cognitive processes, or emotional experiences;

"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;

"Neurocognitive Rights Court" means the specialised court established under Section 55 of this Act;

"neurostimulation" means the application of electromagnetic, electrical, magnetic, or other energy to neural tissue for the purpose of modulating neural activity;

"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;

"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);

"provider" means a natural or legal person, public authority, agency or other body that develops neurotechnology or that has neurotechnology developed 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;

"reasonable expectation of privacy" means the objective expectation that an individual's neural data will not be accessed, collected, processed, or disclosed without their knowledge and consent, under circumstances where society would recognise such an expectation as reasonable;

"relevant national authority" means: (a) in relation to England, the Secretary of State; (b) in relation to Wales, the Welsh Ministers; (c) in relation to Scotland, the Scottish Ministers; and (d) in relation to Northern Ireland, the Department of Health;

"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;

"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.

(2) For the purposes of this Act, placing on the market means the first making available of neurotechnology on the United Kingdom market.

(3) For the purposes of this Act, putting into service means the supply of neurotechnology for first use directly to the user or for own use on the United Kingdom market for its intended purpose.

(4) For the purposes of this Act, making available on the market means any supply of neurotechnology for distribution or use on the United Kingdom market in the course of a commercial activity, whether in return for payment or free of charge.

Section 4: Relationship with Other Acts

(1) The provisions of this Act are without prejudice to the Data Protection Act 2018, but shall be considered as supplementing and extending the protections specifically applicable to neural data.

(2) Where neurotechnology qualifies as a medical device under the Medical Devices Regulations 2002 (S.I. 2002/618) or any subsequent legislation, it shall comply with both those Regulations and this Act. Where the requirements of this Act conflict with the requirements of those Regulations, the requirements of those Regulations shall prevail in relation to safety and performance, but the provisions of this Act shall prevail in relation to neurocognitive rights protections.

(3) Where neurotechnology incorporates artificial intelligence systems that fall within the scope of any future artificial intelligence legislation, it shall comply with both that legislation and this Act. In the event of conflict, the provisions providing the higher level of protection for neurocognitive rights shall prevail.

(4) This Act does not affect the application of competition law.

(5) This Act does not affect the powers and responsibilities of the security and intelligence services under the Intelligence Services Act 1994, the Regulation of Investigatory Powers Act 2000, or the Investigatory Powers Act 2016, but those agencies shall have regard to the principles of this Act in carrying out their functions.

Section 5: Basic Principles

(1) The development, deployment, and use of neurotechnology within the United Kingdom shall be guided by the following principles:

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

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

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

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

(e) **Non-discrimination**: Neurotechnology shall not be developed or used in ways that discriminate against individuals or groups based on protected characteristics under the Equality Act 2010.

(f) **Benefit to humanity**: The development of neurotechnology should prioritise applications that benefit human health, well-being, and flourishing.

(g) **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.

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

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

(j) **Security**: Neurotechnology shall be developed and deployed with robust security measures to prevent unauthorised access, influence, or control.

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

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

(2) All provisions of this Act shall be interpreted and applied in a manner consistent with these principles.

PART 2

NEUROCOGNITIVE RIGHTS

Section 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 authorised law enforcement purposes, subject to judicial oversight, solely in cases of serious criminal offences and in accordance with Section 31.

(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 authorisation 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 Section 41. (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 Section 30.

Section 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 unauthorised 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 Act, supplementing and extending the protections provided by the Data Protection Act 2018.

(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 Section 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 anonymised 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) The relevant national authorities may provide for derogations to the right to mental privacy only when strictly necessary and proportionate for the purposes specified in Section 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 characterise an individual's cognitive processes.

Section 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 unauthorised 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.

Section 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 recognised 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) The relevant national authorities shall develop policies to promote: (a) Equitable access to therapeutic neurotechnology through the National Health Service and other 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 realisation of equitable access.

Section 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 favourably 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) Relevant national authorities 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) The Equality and Human Rights Commission shall be competent to address cases of neurodiscrimination and shall receive appropriate training on neurotechnology and neurocognitive rights.

Section 11: Right to Neural Security

(1) Every person has the right to neural security, which includes: (a) The right to protection from unauthorised 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, unauthorised neurostimulation, or other forms of brain-targeted cyberattacks.

(2) Providers of neurotechnology shall implement appropriate technical and organisational 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 unauthorised 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 regulations made by the Secretary of State under Section 74.

(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 Section 50.

(6) Relevant national authorities shall establish specialised capacity within their cybersecurity agencies to address neural security threats and shall cooperate through the National Cyber Security Centre to develop harmonised approaches to neural security.

Section 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 analyse 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 Act; (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 personalisation, 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 subsection (5), basic information about the presence and general purpose of neurotechnology must still be provided, and complete information must be available to oversight bodies.

Section 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 Section 20, 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 jeopardise 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 subsection (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.

Section 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 Secretary of State shall support the development of standardised formats and protocols for neural data portability through appropriate British Standards.

(7) The right to neural data portability complements and extends the right to data portability under the Data Protection Act 2018 in its application to neural data.

Section 15: Relationship with Other Rights

(1) The neurocognitive rights established in this Part shall: (a) Complement and extend existing fundamental rights and freedoms recognised in United Kingdom and international law; (b) Be interpreted in harmony with the Human Rights Act 1998; (c) Not be construed as restricting or adversely affecting rights recognised in United Kingdom or international law.

(2) In case of overlap between neurocognitive rights and other recognised 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 Act, but have obligations to respect the neurocognitive rights of natural persons.

Section 16: Implementation of Neurocognitive Rights

(1) The relevant national authorities shall take all necessary measures to ensure the effective implementation of the neurocognitive rights established in this Part, 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 Secretary of State shall support implementation through: (a) Developing guidance documents on the practical application of neurocognitive rights; (b) Facilitating exchange of best practices; (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 National Centre for Neurotechnology Regulation 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 analysing data on implementation; (d) Issuing recommendations to address emerging issues; (e) Facilitating coordination between national authorities.

(4) Civil society organisations, 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; (b) Collection of data on reported violations and remedial actions; (c) Stakeholder consultations; (d) Independent research on implementation effectiveness; (e) Peer review among competent authorities.

PART 3

CLASSIFICATION AND REGULATION OF NEUROTECHNOLOGY

Section 17: Risk-based Approach

(1) This Act establishes a risk-based approach to the regulation of neurotechnology, recognising 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 Section 19; (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 Part 4; (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 Act.

(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 Secretary of State may by regulations made by statutory instrument: (a) Update the list of prohibited neurotechnology in Section 19 to reflect technological developments and emerging risks; (b) Update the list of high-risk neurotechnology applications in Section 20 to reflect technological developments and emerging risks; (c) Establish detailed criteria for the classification of neurotechnology into appropriate risk categories; (d) Establish a methodology for neurotechnology risk assessment.

(5) A statutory instrument containing regulations under subsection (4) may not be made unless a draft of the instrument has been laid before and approved by a resolution of each House of Parliament.

(6) Providers of neurotechnology shall conduct an initial risk assessment of their neurotechnology in accordance with the criteria established in this Act and shall classify their neurotechnology accordingly.

(7) 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 Section 49.

(8) The National Centre for Neurotechnology Regulation shall provide guidance on risk assessment and classification and shall maintain a public database of risk classifications for neurotechnology applications.

Section 18: Classification Criteria for 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) For the purposes of risk classification, non-invasive neurotechnology shall be evaluated according to: (a) The recording capabilities, including: (i) Spatial resolution; (ii) Temporal resolution; (iii) Types of neural signals recorded; (iv) Depth of recording; (b) The stimulation capabilities, including: (i) Type of stimulation (electrical, magnetic, ultrasonic, etc.); (ii) Intensity of stimulation; (iii) Duration and frequency of stimulation; (iv) Potential for direct or indirect modulation of cognitive functions; (c) 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; (d) The potential for continuous or persistent monitoring; (e) The potential for combination with other technologies, particularly artificial intelligence; (f) The evidence base for safety and efficacy.

(3) 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 personalisation; (iv) Behavioural 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 anonymised 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.

(4) The risk classification of neurotechnology shall also 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.

(5) 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.

(6) The Secretary of State may by regulations establish a methodology for incorporating context-specific factors into the overall risk assessment, and such regulations shall be made by statutory instrument subject to approval by resolution of each House of Parliament.

(7) The National Centre for Neurotechnology Regulation shall provide guidance and tools to support consistent evaluation of context-specific risk factors by providers, users, and regulatory authorities.

Section 19: Prohibited Neurotechnology Applications

(1) The following neurotechnology applications are prohibited within the United Kingdom as incompatible with United Kingdom values, fundamental rights, and neurocognitive rights: (a) Neurotechnology designed or used for covert cognitive surveillance without consent or proper legal authorisation in accordance with Section 31; (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 authorisation in accordance with Section 31; (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, categorisation, 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 behaviour without the awareness of the affected individuals; (j) Neurotechnology designed or used to induce addiction or compulsive behaviour; (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 the Equality Act 2010.

(2) The prohibition under subsection (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) Any person who intentionally develops, provides, deploys, or uses prohibited neurotechnology shall be guilty of an offence.

(4) A person guilty of an offence under subsection (3) shall be liable: (a) On summary conviction in England and Wales, to imprisonment for a term not exceeding 12 months or to a fine (or both); (b) On summary conviction in Scotland, to imprisonment for a term not exceeding 12 months or to a fine not exceeding the statutory maximum (or both); (c) On summary conviction in Northern Ireland, to imprisonment for a term not exceeding 6 months or to a fine not exceeding the statutory maximum (or both); (d) On conviction on indictment, to imprisonment for a term not exceeding 5 years or to a fine (or both).

(5) The National Centre for Neurotechnology Regulation shall issue guidelines to clarify the scope of the prohibitions and to provide examples of prohibited applications to assist stakeholders in compliance.

(6) The Secretary of State shall regularly review the list of prohibited applications in light of technological developments and may by regulations made by statutory instrument amend subsection (1) to update the list of prohibited applications.

(7) A statutory instrument containing regulations under subsection (6) may not be made unless a draft of the instrument has been laid before and approved by a resolution of each House of Parliament.

Section 20: 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 Part 4: (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 personalisation 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 behaviour 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 behaviour 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 Secretary of State shall regularly review the list of high-risk applications in light of technological developments and may by regulations made by statutory instrument amend subsection (1) to update the list of high-risk applications.

(3) A statutory instrument containing regulations under subsection (2) may not be made unless a draft of the instrument has been laid before and approved by a resolution of each House of Parliament.

(4) Providers of neurotechnology shall assess whether their neurotechnology falls within the categories listed in subsection (1) and shall comply with the requirements set out in Part 4 if it does.

(5) In case of doubt as to whether a specific neurotechnology application falls within the high-risk categories, providers shall consult with the National Centre for Neurotechnology Regulation, which shall provide a non-binding opinion.

(6) Competent authorities may classify additional neurotechnology applications as high-risk based on the criteria set out in Section 18, subject to the coordination procedure set out in Section 49.

Section 21: Limited-risk and Minimal-risk Neurotechnology

(1) Limited-risk neurotechnology includes: (a) Neurotechnology that collects neural data of moderate sensitivity without real-time decoding of specific thoughts; (b) Neurotechnology that provides neurofeedback for wellness, performance enhancement, or educational purposes; (c) Neurotechnology that uses well-established stimulation methods with limited intensity; (d) Neurotechnology used in consumer contexts with adequate transparency and user control; (e) Neurotechnology with established safety profiles but with potential for misuse if used improperly.

(2) Providers and users of limited-risk neurotechnology shall comply with the following specific transparency obligations: (a) Clear disclosure of neural data collection and processing; (b) Explicit information about potential risks and limitations; (c) Comprehensible explanation of intended functionality; (d) Notification of capability changes through updates; (e) Documentation of safety and performance claims.

(3) Minimal-risk neurotechnology includes: (a) Neurotechnology that collects basic neural data with low spatial and temporal resolution; (b) Neurotechnology that does not enable identification of specific mental states beyond general categories; (c) Neurotechnology used in controlled research or personal use contexts with appropriate safeguards; (d) Neurotechnology that provides clear information about capabilities and limitations; (e) Neurotechnology with well-established safety profiles and minimal potential for misuse.

(4) Providers and users of minimal-risk neurotechnology shall comply with the general provisions of this Act but are not subject to the specific requirements for high-risk or limited-risk neurotechnology.

(5) The Secretary of State may by regulations made by statutory instrument: (a) Modify the categories of limited-risk and minimal-risk neurotechnology; (b) Specify additional transparency obligations for limited-risk neurotechnology; (c) Establish simplified compliance procedures for minimal-risk neurotechnology.

(6) A statutory instrument containing regulations under subsection (5) may not be made unless a draft of the instrument has been laid before and approved by a resolution of each House of Parliament.

PART 4

REQUIREMENTS FOR HIGH-RISK NEUROTECHNOLOGY

Section 22: Compliance with Requirements for High-risk Neurotechnology

(1) High-risk neurotechnology shall comply with the requirements set out in this Part.

(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 Section 23 and shall demonstrate compliance with the requirements through the conformity assessment procedures set out in Part 6.

(4) Providers of high-risk neurotechnology shall draw up the technical documentation referred to in Section 28 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 Part.

(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 Section 43.

(8) The requirements of this Part are without prejudice to other applicable requirements under United Kingdom law, including those relating to medical devices, data protection, non-discrimination, and consumer protection.

Section 23: Risk Management System

(1) Providers of high-risk neurotechnology shall establish, implement, document, and maintain a risk management system that shall: (a) Identify and analyse 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 Section 38; (d) Adopt suitable risk management measures in accordance with subsection (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 unauthorised 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 Section 28 and shall regularly update it throughout the lifecycle of the high-risk neurotechnology.

(5) The Secretary of State may by regulations made by statutory instrument specify: (a) Methodologies for identifying, analysing, 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.

(6) A statutory instrument containing regulations under subsection (5) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 24: 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 Act; (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 artefacts 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 organisational measures that prevent unauthorised use.

(5) Providers shall document the neural data governance framework in the technical documentation referred to in Section 28 and shall regularly review and update it to reflect evolving best practices and regulatory requirements.

(6) The Secretary of State may by regulations made by statutory instrument specify: (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.

(7) A statutory instrument containing regulations under subsection (6) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 25: 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 unauthorised 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 unauthorised 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 Secretary of State may by regulations made by statutory instrument specify: (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.

(8) A statutory instrument containing regulations under subsection (7) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 26: 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) Artefact 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 characterised; (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 Secretary of State may by regulations made by statutory instrument specify: (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.

(8) A statutory instrument containing regulations under subsection (7) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 27: 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 Secretary of State may by regulations made by statutory instrument specify: (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.

(7) A statutory instrument containing regulations under subsection (6) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 28: 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 Part and shall provide 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 Schedule 1 to this Act.

(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 Section 23, 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 Section 38; (g) The instructions for use in accordance with Section 29; (h) The UK declaration of conformity referred to in Section 39.

(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 Secretary of State may by regulations made by statutory instrument specify the detailed content and structure of the technical documentation required under this Section.

(8) A statutory instrument containing regulations under subsection (7) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 29: 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 authorised 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 clear and plain English and, where applicable, in the other official languages of the United Kingdom, 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 Secretary of State may by regulations made by statutory instrument specify the detailed content and format of the instructions for use required under this Section for different categories of high-risk neurotechnology.

(6) A statutory instrument containing regulations under subsection (5) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 30: 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 minimise 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 organisational 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 Secretary of State may by regulations made by statutory instrument specify: (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.

(9) A statutory instrument containing regulations under subsection (8) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 31: 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 unauthorised 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 minimisation principles; (v) Secure deletion protocols; (c) Protection against manipulation through: (i) Input validation and sanitisation; (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 unauthorised 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 Secretary of State shall by regulations made by statutory instrument specify: (a) Technical standards for neural security and cybersecurity; (b) Security testing methodologies; (c) Specific security requirements for different categories of high-risk neurotechnology.

(7) A statutory instrument containing regulations under subsection (6) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 32: Informed Neural Consent

(1) High-risk neurotechnology shall incorporate technical and organisational measures to facilitate obtaining and documenting informed neural consent where required by this Act.

(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 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 Secretary of State may by regulations made by statutory instrument specify: (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.

(9) A statutory instrument containing regulations under subsection (8) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 33: 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 initialisation 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 authorised 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 minimisation; (c) Comply with data protection requirements; (d) Support effective monitoring, investigation, and auditing.

(7) The Secretary of State may by regulations made by statutory instrument specify: (a) Technical standards for logging mechanisms; (b) Required log content for different categories of high-risk neurotechnology; (c) Log retention periods and access controls.

(8) A statutory instrument containing regulations under subsection (7) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 34: 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 unauthorised modification.

(7) The Secretary of State may by regulations made by statutory instrument specify: (a) Technical standards for user control interfaces; (b) Requirements for emergency shutdown mechanisms; (c) Specific control requirements for different categories of high-risk neurotechnology.

(8) A statutory instrument containing regulations under subsection (7) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 35: 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 organisational 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 categorisations based on neural data; (e) Prevention of stigmatisation 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 Secretary of State may by regulations made by statutory instrument specify: (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.

(7) A statutory instrument containing regulations under subsection (6) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 36: 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 maximise 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 Secretary of State may by regulations made by statutory instrument specify: (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.

(8) A statutory instrument containing regulations under subsection (7) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 37: 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 Part 6.

(2) Providers shall prepare the technical documentation referred to in Section 28 and shall conduct the relevant conformity assessment procedure or have it conducted.

(3) Where compliance with the requirements set out in this Part has been demonstrated, providers shall draw up a UK declaration of conformity in accordance with Section 39 and affix the UKCA marking of conformity in accordance with Section 40.

(4) Providers shall keep the technical documentation and the UK 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 National Centre for Neurotechnology Regulation shall provide guidance and tools to assist providers in preparing for the conformity assessment procedure.

Section 38: 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 analyse 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 Act; (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 analysing data; (b) Specific performance indicators to evaluate continued compliance and risk levels; (c) Effective processes to collect and analyse 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 Section 50; (e) Share non-sensitive learnings with the scientific and regulatory communities.

(6) Providers shall prepare annual post-market monitoring reports that summarise 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 approved body and competent authority.

(7) The Secretary of State may by regulations made by statutory instrument specify: (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.

(8) A statutory instrument containing regulations under subsection (7) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 39: UK Declaration of Conformity

(1) The UK declaration of conformity shall state that the requirements specified in this Part have been satisfied in relation to high-risk neurotechnology.

(2) The UK declaration of conformity shall contain the information set out in Schedule 2 to this Act and shall be continuously updated.

(3) The UK declaration of conformity shall be written in English.

(4) By drawing up the UK declaration of conformity, the provider shall assume responsibility for compliance with the requirements set out in this Part.

(5) The Secretary of State may by regulations made by statutory instrument amend Schedule 2 to modify the information to be included in the UK declaration of conformity.

(6) A statutory instrument containing regulations under subsection (5) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 40: UKCA Marking

(1) The UKCA marking shall be affixed to high-risk neurotechnology in accordance with the requirements set out in the Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019 (S.I. 2019/696).

(2) The UKCA marking shall be affixed visibly, legibly, and indelibly.

(3) Where the neurotechnology is subject to other legislation requiring the UKCA marking, the marking shall indicate that the neurotechnology also meets the requirements of that other legislation.

Section 41: 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 behaviour 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 Secretary of State may by regulations made by statutory instrument specify: (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.

(6) A statutory instrument containing regulations under subsection (5) is subject to annulment in pursuance of a resolution of either House of Parliament.

PART 5

OBLIGATIONS OF PROVIDERS AND USERS

Section 42: 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 Act.

(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 a UK declaration of conformity and affix the UKCA marking of conformity when required; (e) Implement a quality management system to ensure compliance with this Act; (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 Act; (h) Inform the relevant competent authorities of any serious incident or malfunction; (i) Demonstrate compliance with this Act upon request by a competent authority.

(3) Providers of high-risk neurotechnology shall: (a) Implement a risk management system in accordance with Section 23; (b) Conduct the conformity assessment in accordance with

Section 37; (c) Register their high-risk neurotechnology in the UK database referred to in Section 52; (d) Implement a post-market monitoring system in accordance with Section 38; (e) Report serious incidents and malfunctions in accordance with Section 50; (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 Section 29.

(5) Providers shall, upon a reasoned request from a competent authority, provide that authority with all the information and documentation necessary to demonstrate the conformity of their neurotechnology with this Act, in English or, where acceptable to the competent authority concerned, in another official language of the United Kingdom.

(6) Providers shall cooperate with the 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.

Section 43: 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 Act; (iv) The identification of specific risks in the intended use context; (v) The development of appropriate risk mitigation measures; (b) Implement appropriate technical and organisational 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 Section 44; (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 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 subsections (2) and (3) shall not apply to users of high-risk neurotechnology in the course of a personal non-professional activity.

(7) The Secretary of State may by regulations made by statutory instrument specify the methodology for conducting neurotechnology impact assessments by users.

(8) A statutory instrument containing regulations under subsection (7) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 44: 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 authorised 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 authorised 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 authorisation based on reasonable grounds that a serious criminal offence 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 Section 58.

(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) The exceptions in subsection (1) shall be interpreted narrowly and appropriate procedural safeguards shall be established to prevent misuse.

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

(5) The Secretary of State may by regulations made by statutory instrument specify: (a) Detailed procedural requirements for the application of each exception; (b) Documentation and justification requirements; (c) Oversight mechanisms and safeguards.

(6) A statutory instrument containing regulations under subsection (5) may not be made unless a draft of the instrument has been laid before and approved by a resolution of each House of Parliament.

Section 45: 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 Section 28.

(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 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 Act.

Section 46: 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 Section 37.

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

(4) After completing the conformity assessment, providers of high-risk neurotechnology shall draw up a UK declaration of conformity in accordance with Section 39 and affix the UKCA marking of conformity in accordance with Section 40.

(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 approved bodies conducting the conformity assessment, including providing access to premises and information as required.

(7) Providers shall inform the approved body that has issued a technical documentation assessment certificate or quality management system approval certificate of any planned substantial modification to the neurotechnology.

Section 47: Obligations regarding Registration

(1) Before placing high-risk neurotechnology on the market or putting it into service, providers shall register it in the UK database referred to in Section 52.

(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 UK 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 competent authority when they cease to be the provider of a registered high-risk neurotechnology.

(5) The Secretary of State shall by regulations made by statutory instrument establish the procedures for registration and for updating the registration information.

(6) A statutory instrument containing regulations under subsection (5) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 48: 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 Act 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 competent authorities of the relevant national authorities 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 National Centre for Neurotechnology Regulation; (b) Implement an emergency response plan to mitigate the risk; (c) Cooperate with 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 Secretary of State shall by regulations made by statutory instrument establish uniform conditions for determining when a non-conformity presents a serious risk and for the content and format of notifications.

(7) A statutory instrument containing regulations under subsection (6) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 49: Obligations of Importers

(1) Importers shall place on the UK market only neurotechnology that complies with the requirements of this Act.

(2) Before placing neurotechnology on the market, importers shall verify that: (a) The neurotechnology bears the UKCA 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 Section 47 for high-risk neurotechnology.

(3) Where an importer considers or has reason to believe that neurotechnology is not in conformity with this Act, 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 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 jeopardise the neurotechnology's compliance with the requirements of this Act; (c) Keep a copy of the UK declaration of conformity at the disposal of competent authorities for ten years after the neurotechnology has been placed on the market; (d) Cooperate with 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 Act shall immediately inform the provider and cooperate with the provider and the competent authorities on corrective actions.

Section 50: Reporting of Serious Incidents and Malfunctions

(1) Providers of high-risk neurotechnology shall report any serious incident or malfunction to the competent authorities of the relevant national authorities 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) Unauthorised 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) Standardised 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 National Centre for Neurotechnology Regulation shall maintain a central database of reported serious incidents and malfunctions and shall analyse trends and patterns to identify systemic risks and develop preventive measures.

(8) The Secretary of State shall by regulations made by statutory instrument establish: (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) A statutory instrument containing regulations under subsection (8) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 51: Obligations of Distributors

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

(2) Before making neurotechnology available on the market, distributors shall verify that: (a) The neurotechnology bears the UKCA 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 Act.

(3) Where a distributor considers or has reason to believe that neurotechnology is not in conformity with this Act, 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 competent authorities.

(4) Distributors shall: (a) Ensure that transport and storage conditions do not jeopardise the neurotechnology's compliance with the requirements of this Act; (b) Cooperate with 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 Act shall immediately inform the provider or the importer and cooperate with them and the competent authorities on corrective actions.

PART 6

CONFORMITY ASSESSMENT AND CERTIFICATION

Section 52: UK Database for High-risk Neurotechnology

(1) The National Centre for Neurotechnology Regulation shall establish, maintain, and manage a UK database for high-risk neurotechnology.

(2) The UK database shall contain: (a) Registrations of high-risk neurotechnology in accordance with Section 47; (b) UK declarations of conformity and certificates issued by approved bodies; (c) Information on serious incidents and malfunctions reported in accordance with Section 50; (d) Post-market monitoring reports submitted in accordance with Section 38; (e) Information on measures taken by market surveillance authorities; (f) Decisions and opinions of the National Centre for Neurotechnology Regulation related to specific high-risk neurotechnology.

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

(4) The UK database shall be designed to: (a) Enable interoperability with relevant UK 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 National Centre for Neurotechnology Regulation of any errors or omissions in the database; (d) Maintaining supporting documentation for information submitted to the database.

(6) The National Centre for Neurotechnology Regulation 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 Secretary of State shall by regulations made by statutory instrument establish: (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) A statutory instrument containing regulations under subsection (7) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 53: Conformity Assessment

(1) High-risk neurotechnology shall undergo a conformity assessment before being placed on the market or put into service.

(2) The conformity assessment shall verify compliance with the requirements set out in Part 4 of this Act.

(3) The conformity assessment for high-risk neurotechnology shall be conducted through one of the following procedures: (a) Conformity assessment based on internal control (as set out in Schedule 3 to this Act) for high-risk neurotechnology that is developed in accordance with harmonised standards or designated standards, provided that those standards cover all the requirements of this Act that apply to the neurotechnology; (b) Conformity assessment with the involvement of an approved body (as set out in Schedule 4 to this Act) for all other high-risk neurotechnology.

(4) When conducting the conformity assessment, the provider shall: (a) Ensure that the high-risk neurotechnology complies with the requirements set out in Part 4; (b) Follow the applicable conformity assessment procedure; (c) Compile the technical documentation required under Section 28; (d) Demonstrate compliance with the applicable requirements to the approved body where required; (e) Obtain the relevant certificates from the approved body where required.

(5) 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.

(6) 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.

(7) The Secretary of State may by regulations made by statutory instrument amend Schedules 3 and 4 to adapt the conformity assessment procedures to technical progress.

(8) A statutory instrument containing regulations under subsection (7) may not be made unless a draft of the instrument has been laid before and approved by a resolution of each House of Parliament.

Section 54: Approved Bodies

(1) The Secretary of State shall be responsible for designating approved bodies to carry out conformity assessment activities under this Act.

(2) To be designated as an approved body, an organisation shall: (a) Be established under the law of the United Kingdom; (b) Have legal personality; (c) Be a third-party body independent of the providers it assesses; (d) Possess the necessary expertise in neurotechnology, neural data protection, and neurocognitive rights; (e) Meet the organisational, quality management, resources, and process requirements set out in Schedule 5 to this Act.

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

(4) Approved 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) The Secretary of State shall establish procedures for the assessment, designation, notification, monitoring, and review of approved bodies, ensuring that approved bodies maintain the required expertise.

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

(7) The Secretary of State may by regulations made by statutory instrument specify detailed procedures for the designation, operation, and monitoring of approved bodies.

(8) A statutory instrument containing regulations under subsection (7) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 55: 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 Act or other applicable law; (b) It was collected without required informed neural consent, except in circumstances specifically authorised 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 Judicial College, in cooperation with the National Centre for Neurotechnology Regulation, shall develop guidelines on the evaluation of neural evidence for judicial authorities.

PART 7

NATIONAL CENTRE FOR NEUROTECHNOLOGY REGULATION

Section 56: Establishment of the National Centre for Neurotechnology Regulation

(1) There shall be a body corporate known as the National Centre for Neurotechnology Regulation.

(2) The National Centre for Neurotechnology Regulation shall not be regarded as the servant or agent of the Crown or as enjoying any status, immunity or privilege of the Crown.

(3) The property of the National Centre for Neurotechnology Regulation shall not be regarded as property of, or held on behalf of, the Crown.

(4) Schedule 6 to this Act (which makes further provision about the National Centre for Neurotechnology Regulation) has effect.

Section 57: Functions of the National Centre for Neurotechnology Regulation

(1) The National Centre for Neurotechnology Regulation shall have the following functions: (a) Advising the Secretary of State, other Ministers of the Crown, and relevant national authorities on matters relating to neurotechnology regulation and neurocognitive rights; (b) Developing and maintaining technical expertise on neurotechnology and its implications; (c) Coordinating the activities of competent authorities in relation to neurotechnology regulation; (d) Providing guidance on the interpretation and application of this Act; (e) Maintaining the UK database for high-risk neurotechnology as specified in Section 52; (f) Monitoring technological developments in neurotechnology and their regulatory implications; (g) Conducting research on regulatory approaches to neurotechnology; (h) Facilitating cooperation between regulatory authorities, industry, academia, and civil society; (i) Supporting the Secretary of State in developing standards for neurotechnology; (j) Contributing to international cooperation on neurotechnology governance; (k) Promoting awareness and understanding of neurocognitive rights; (l) Providing information and advice to the public about neurotechnology and neurocognitive rights; (m) Such other functions as the Secretary of State may by regulations specify.

(2) In performing its functions, the National Centre for Neurotechnology Regulation 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 relevant national authorities; (g) Consider the specific needs of small and medium-sized enterprises; (h) Balance innovation support with effective protection of neurocognitive rights.

(3) The National Centre for Neurotechnology Regulation shall prioritise its activities based on: (a) The potential impact on neurocognitive rights; (b) Emerging trends and developments in neurotechnology; (c) Areas where harmonisation and coordination add significant value; (d) The needs and requests of competent authorities; (e) Resource constraints and efficiency considerations.

(4) The National Centre for Neurotechnology Regulation shall publish an annual report on its activities, which shall be laid before Parliament by the Secretary of State.

(5) The Secretary of State may by regulations made by statutory instrument specify additional functions for the National Centre for Neurotechnology Regulation.

(6) A statutory instrument containing regulations under subsection (5) may not be made unless a draft of the instrument has been laid before and approved by a resolution of each House of Parliament.

Section 58: Powers of the National Centre for Neurotechnology Regulation

(1) The National Centre for Neurotechnology Regulation shall have the power to: (a) Issue guidance on the interpretation and application of this Act; (b) Issue opinions on the classification of neurotechnology; (c) Develop technical standards and specifications for neurotechnology; (d) Collect and analyse data on neurotechnology development,

deployment, and impacts; (e) Conduct or commission research relevant to its functions; (f) Establish expert groups and advisory committees; (g) Engage with stakeholders, including industry, academia, civil society, and the public; (h) Represent the United Kingdom in international forums on neurotechnology governance; (i) Establish systems for information sharing between competent authorities; (j) Coordinate responses to serious incidents involving neurotechnology; (k) Provide education and training on neurotechnology regulation; (l) Enter into agreements with other organisations to pursue its functions; (m) Exercise such other powers as the Secretary of State may by regulations specify.

(2) The opinions, guidance, and recommendations issued by the National Centre for Neurotechnology Regulation shall: (a) Be published and made publicly available; (b) Be developed through transparent and consultative processes; (c) Be based on scientific evidence and expert input; (d) Take into account diverse stakeholder perspectives; (e) Be regularly reviewed and updated as technology evolves.

(3) While the opinions, guidance, and recommendations issued by the National Centre for Neurotechnology Regulation shall not be legally binding, competent authorities and courts shall take them into account when interpreting and applying this Act.

(4) The Secretary of State may by regulations made by statutory instrument specify additional powers for the National Centre for Neurotechnology Regulation.

(5) A statutory instrument containing regulations under subsection (4) may not be made unless a draft of the instrument has been laid before and approved by a resolution of each House of Parliament.

Section 59: Governance and Structure

(1) The National Centre for Neurotechnology Regulation shall have the following governance structure: (a) A Board; (b) A Chief Executive; (c) A Scientific Advisory Committee; (d) A Stakeholder Forum; (e) Such other committees and working groups as the Board may establish.

(2) The Board shall: (a) Be responsible for the strategic direction and oversight of the National Centre for Neurotechnology Regulation; (b) Consist of a Chair and between 6 and 10 other members appointed by the Secretary of State; (c) Include members with expertise in neuroscience, neurotechnology, neurocognitive rights, ethics, regulation, and data protection; (d) Include at least one member representing each of the following constituencies: (i) Patients or users of neurotechnology; (ii) Industry; (iii) Academia; (iv) Civil society; (e) Adopt rules of procedure for the National Centre for Neurotechnology Regulation; (f) Appoint the Chief Executive, subject to the approval of the Secretary of State.

(3) The Chief Executive shall: (a) Be responsible for the day-to-day management of the National Centre for Neurotechnology Regulation; (b) Implement the decisions of the Board; (c) Prepare and implement the work programme; (d) Prepare the annual report; (e) Manage the staff and resources of the Centre; (f) Represent the Centre externally.

(4) The Scientific Advisory Committee shall: (a) Provide scientific advice to the Board and the Chief Executive; (b) Consist of leading experts in relevant fields appointed by the Board; (c) Monitor scientific developments in neurotechnology and related fields; (d) Contribute to the development of technical standards and guidance; (e) Identify emerging challenges and opportunities for regulation.

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

(6) The Secretary of State may by regulations made by statutory instrument make further provision about the governance and structure of the National Centre for Neurotechnology Regulation.

(7) A statutory instrument containing regulations under subsection (6) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 60: Funding and Resources

(1) The National Centre for Neurotechnology Regulation shall be funded through: (a) Grants from the Secretary of State; (b) Fees charged for services provided; (c) Such other sources as Parliament may approve.

(2) The Secretary of State shall ensure that the National Centre for Neurotechnology Regulation has adequate resources to perform its functions effectively.

(3) The National Centre for Neurotechnology Regulation may charge reasonable fees for: (a) Providing opinions on specific neurotechnology applications; (b) Conducting conformity assessments where authorised; (c) Organising training and educational activities; (d) Publishing specialised reports and analyses; (e) Providing technical assistance to providers of neurotechnology; (f) Such other services as the Secretary of State may by regulations specify.

(4) The level of fees charged shall be set to recover costs and shall not create barriers to compliance, particularly for small and medium-sized enterprises.

(5) The National Centre for Neurotechnology Regulation shall publish a schedule of fees, which shall be reviewed annually.

(6) The accounts of the National Centre for Neurotechnology Regulation shall be: (a) Kept in accordance with directions made by the Secretary of State; (b) Audited by the Comptroller and Auditor General; (c) Laid before Parliament along with the annual report.

(7) The Secretary of State may by regulations made by statutory instrument make further provision about the funding and resources of the National Centre for Neurotechnology Regulation.

(8) A statutory instrument containing regulations under subsection (7) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 61: Competent Authorities

(1) The Secretary of State shall be the competent authority for the purposes of this Act in England.

(2) The Welsh Ministers shall be the competent authority for the purposes of this Act in Wales.

(3) The Scottish Ministers shall be the competent authority for the purposes of this Act in Scotland.

(4) The Department of Health shall be the competent authority for the purposes of this Act in Northern Ireland.

(5) The relevant competent authorities may delegate specific regulatory functions to appropriate regulatory bodies with relevant expertise, including: (a) The Information Commissioner's Office for matters relating to neural data protection; (b) The Medicines and Healthcare products Regulatory Agency for matters relating to neurotechnology used for medical purposes; (c) The Health and Safety Executive for matters relating to neurotechnology used in workplaces; (d) The Office for Communications for matters relating to neurotechnology used in communication services; (e) Such other regulatory bodies as the relevant competent authority considers appropriate.

(6) Where a relevant competent authority delegates functions under subsection (5), it shall: (a) Publish details of the delegation; (b) Ensure that the delegated body has adequate expertise and resources; (c) Establish mechanisms for coordination and information sharing; (d) Maintain oversight of the delegated functions; (e) Review the effectiveness of the delegation periodically.

(7) Competent authorities shall: (a) Monitor and enforce the application of this Act; (b) Coordinate with other relevant 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 Act; (d) Receive and investigate complaints related to neurotechnology; (e) Conduct market surveillance activities for neurotechnology; (f) Impose penalties for infringements of this Act in accordance with Section 72; (g) Contribute to the coordination activities led by the National Centre for Neurotechnology Regulation; (h) Collect and analyse data on the implementation of this Act; (i) Promote awareness of neurocognitive rights.

(8) 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.

(9) 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 the appropriate national parliament or assembly.

(10) The Secretary of State may by regulations made by statutory instrument make further provision about the functions, powers, and duties of competent authorities.

(11) A statutory instrument containing regulations under subsection (10) may not be made unless a draft of the instrument has been laid before and approved by a resolution of each House of Parliament.

Section 62: Coordination Procedure

(1) Where more than one competent authority is involved in the enforcement of this Act, the relevant competent authorities shall establish a coordination procedure to ensure effective cooperation and consistent decision-making.

(2) Where a neurotechnology issue has cross-border implications involving multiple parts of the United Kingdom, the competent authorities concerned shall cooperate to ensure a coordinated approach.

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

(4) Competent authorities shall take utmost account of the recommendations of the coordination group in their enforcement activities.

(5) The National Centre for Neurotechnology Regulation shall maintain a secure information exchange system for competent authorities to share information on cross-border cases, emerging issues, and enforcement approaches.

(6) The Secretary of State may by regulations made by statutory instrument establish detailed procedures for cooperation between competent authorities and with the National Centre for Neurotechnology Regulation.

(7) A statutory instrument containing regulations under subsection (6) is subject to annulment in pursuance of a resolution of either House of Parliament.

PART 8

NEUROCOGNITIVE RIGHTS COURT

Section 63: Establishment of the Neurocognitive Rights Court

(1) There shall be a court known as the Neurocognitive Rights Court.

(2) The Neurocognitive Rights Court shall form part of the Upper Tribunal.

(3) The Neurocognitive Rights Court shall have the authority to hear cases involving alleged violations of neurocognitive rights and disputes arising from the application of this Act.

(4) The Lord Chancellor shall, after consulting the Senior President of Tribunals, make regulations about the composition and procedure of the Neurocognitive Rights Court.

(5) Regulations under subsection (4) shall be made by statutory instrument.

(6) A statutory instrument containing regulations under subsection (4) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 64: Jurisdiction of the Neurocognitive Rights Court

(1) The Neurocognitive Rights Court shall have jurisdiction to hear: (a) Appeals against decisions of competent authorities under this Act; (b) Claims for violations of neurocognitive rights as established in Part 2 of this Act; (c) Disputes between providers and

competent authorities regarding compliance with this Act; (d) Disputes regarding the classification or risk assessment of neurotechnology; (e) Applications for injunctive relief to prevent neurocognitive rights violations; (f) Claims for compensation for harm resulting from neurocognitive rights violations; (g) Applications for judicial review of regulatory decisions affecting neurocognitive rights; (h) Such other matters as may be prescribed by regulations made by the Lord Chancellor.

(2) The Neurocognitive Rights Court shall have jurisdiction throughout the United Kingdom.

(3) The Neurocognitive Rights Court shall have the power to: (a) Make declarations on the interpretation and application of this Act; (b) Issue injunctions to prevent neurocognitive rights violations; (c) Order the cessation of activities that violate this Act; (d) Award compensation for harm resulting from neurocognitive rights violations; (e) Order the deletion or rectification of neural data processed in violation of this Act; (f) Impose appropriate remedies for violations of this Act; (g) Review and overturn decisions of competent authorities; (h) Exercise such other powers as may be prescribed by regulations made by the Lord Chancellor.

(4) The jurisdiction of the Neurocognitive Rights Court is without prejudice to: (a) The jurisdiction of the High Court, Court of Session, or High Court of Northern Ireland to hear judicial review applications; (b) The jurisdiction of other courts to hear claims for damages or other remedies; (c) The jurisdiction of regulatory bodies established under other legislation.

(5) The Lord Chancellor may by regulations made by statutory instrument make further provision about the jurisdiction of the Neurocognitive Rights Court.

(6) A statutory instrument containing regulations under subsection (5) may not be made unless a draft of the instrument has been laid before and approved by a resolution of each House of Parliament.

Section 65: Composition of the Neurocognitive Rights Court

(1) The Neurocognitive Rights Court shall consist of: (a) A President, who shall be a judge of the High Court or Court of Session; (b) Such number of judges as the Lord Chancellor may appoint, who shall be judges of the High Court, Court of Session, or County Court; (c) Such number of other members as the Lord Chancellor may appoint, who shall have expertise in neurotechnology, neuroscience, ethics, data protection, or other relevant fields.

(2) In appointing members under subsection (1)(c), the Lord Chancellor shall ensure that the Neurocognitive Rights Court includes members with expertise in: (a) Neuroscience and neurotechnology; (b) Ethics and philosophy of mind; (c) Data protection and privacy; (d) Human rights law; (e) Such other fields as the Lord Chancellor considers relevant.

(3) For the purpose of hearing a particular case, the Neurocognitive Rights Court shall consist of: (a) At least one judicial member, who shall preside; and (b) At least one, but not more than three, non-judicial members with relevant expertise.

(4) The President of the Neurocognitive Rights Court shall determine the composition of the Court for each case, taking into account the nature of the case and the expertise required.

(5) The Lord Chancellor may by regulations made by statutory instrument make further provision about the appointment, tenure, remuneration, and other terms and conditions of members of the Neurocognitive Rights Court.

(6) A statutory instrument containing regulations under subsection (5) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 66: Procedure and Rules

(1) The Neurocognitive Rights Court shall conduct its proceedings in a fair, efficient, and accessible manner.

(2) The Tribunal Procedure Committee established under section 22 of the Tribunals, Courts and Enforcement Act 2007 shall make Tribunal Procedure Rules for the Neurocognitive Rights Court.

(3) Tribunal Procedure Rules for the Neurocognitive Rights Court may make provision for: (a) The initiation of proceedings; (b) Case management powers; (c) Evidence, including expert evidence; (d) Hearings and decisions; (e) Enforcement of decisions; (f) Appeals; (g) Costs; (h) Such other matters as the Tribunal Procedure Committee considers necessary or desirable.

(4) Tribunal Procedure Rules for the Neurocognitive Rights Court shall ensure that: (a) Proceedings are accessible to persons without legal representation; (b) Proceedings are conducted without unnecessary formality; (c) The Court has the flexibility to adapt its procedures to the needs of the case; (d) Technical and scientific evidence is presented in a manner that can be understood by the Court; (e) Sensitive neural data is protected during proceedings; (f) Proceedings are conducted efficiently and at proportionate cost; (g) The Court can use alternative dispute resolution where appropriate.

(5) The Neurocognitive Rights Court may appoint independent experts to assist it in understanding complex technical or scientific issues.

(6) The Neurocognitive Rights Court shall publish its decisions in anonymised form, unless the Court considers that publication would not be in the public interest.

(7) The Lord Chancellor may by regulations made by statutory instrument make further provision about the procedure of the Neurocognitive Rights Court.

(8) A statutory instrument containing regulations under subsection (7) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 67: Appeals

(1) An appeal lies from a decision of the Neurocognitive Rights Court on a point of law to: (a) In England and Wales, the Court of Appeal; (b) In Scotland, the Court of Session; (c) In Northern Ireland, the Court of Appeal in Northern Ireland.

(2) An appeal under subsection (1) may be brought only with the permission of: (a) The Neurocognitive Rights Court; or (b) The court to which the appeal would be made.

(3) The court to which an appeal is made may: (a) Affirm the decision of the Neurocognitive Rights Court; (b) Set aside the decision of the Neurocognitive Rights Court; (c) Remit the case to the Neurocognitive Rights Court with directions for its reconsideration; (d) Make any

decision which the Neurocognitive Rights Court could have made; (e) Make such incidental or consequential orders as it considers appropriate.

(4) The Lord Chancellor may by regulations made by statutory instrument make further provision about appeals from the Neurocognitive Rights Court.

(5) A statutory instrument containing regulations under subsection (4) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 68: Remedies for Violations of Neurocognitive Rights

(1) The Neurocognitive Rights Court may grant the following remedies for violations of neurocognitive rights: (a) Declarations that a violation has occurred; (b) Injunctions to prevent ongoing or imminent violations; (c) Orders for the cessation of activities that violate neurocognitive rights; (d) Compensation for material and non-material damages resulting from violations; (e) Orders for the erasure or rectification of neural data processed in violation of this Act; (f) Orders for the suspension or prohibition of neurotechnology use that violates neurocognitive rights; (g) Recommendations for systemic changes to prevent future violations; (h) Such other remedies as the Court considers appropriate.

(2) In assessing non-material damages resulting from violations of neurocognitive rights, the Court 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.

(3) Where a violation affects multiple individuals in a similar way, the Court may: (a) Hear representative proceedings brought on behalf of affected individuals; (b) Order collective remedies for the benefit of all affected individuals; (c) Establish a framework for the assessment of individual damages; (d) Make recommendations for systemic changes to prevent future violations; (e) Order the establishment of a compensation scheme.

(4) In determining appropriate remedies, the Court shall: (a) Consider the principle of effective remedy; (b) Ensure that remedies are proportionate to the violation; (c) Take into account the need to deter future violations; (d) Consider the impact of remedies on innovation and beneficial uses of neurotechnology; (e) Ensure that remedies are implementable and enforceable.

(5) The Court may make interim orders to: (a) Prevent irreparable harm pending the final determination of a case; (b) Preserve evidence; (c) Prevent the continuation of apparent violations; (d) Protect vulnerable individuals; (e) Serve the interests of justice.

(6) The Lord Chancellor may by regulations made by statutory instrument make further provision about remedies for violations of neurocognitive rights.

(7) A statutory instrument containing regulations under subsection (6) may not be made unless a draft of the instrument has been laid before and approved by a resolution of each House of Parliament.

Section 69: Technical Expertise for the Court

(1) The Neurocognitive Rights Court shall have access to technical expertise to assist in understanding neurotechnology, neuroscience, and neural data.

(2) The Court may: (a) Appoint technical advisers to assist the Court; (b) Require parties to provide expert evidence; (c) Commission independent expert reports; (d) Request information from the National Centre for Neurotechnology Regulation; (e) Conduct site visits or demonstrations where appropriate.

(3) Technical advisers appointed by the Court 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) Assist the Court in understanding technical issues; (e) Not participate in the Court's decision-making.

(4) The Court shall establish and maintain a register of technical experts who may be called upon to assist the Court.

(5) The Court shall develop procedures for: (a) The selection and appointment of technical advisers; (b) The role of technical advisers in proceedings; (c) The interaction between technical advisers and the Court; (d) The publication of technical advice provided to the Court; (e) The remuneration of technical advisers.

(6) The Lord Chancellor shall ensure that the Neurocognitive Rights Court has adequate resources to access the technical expertise it requires.

(7) The Lord Chancellor may by regulations made by statutory instrument make further provision about technical expertise for the Neurocognitive Rights Court.

(8) A statutory instrument containing regulations under subsection (7) is subject to annulment in pursuance of a resolution of either House of Parliament.

PART 9

ENFORCEMENT AND PENALTIES

Section 70: Market Surveillance

(1) Competent authorities shall organise and carry out market surveillance activities for neurotechnology in accordance with this Act.

(2) 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 Act.

(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 UK authorities.

(4) Market surveillance activities shall prioritise 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 National Centre for Neurotechnology Regulation.

(5) Market surveillance authorities shall establish specialised teams with expertise in neurotechnology and neural data protection to effectively assess compliance with this Act.

(6) The relevant national authorities 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 National Centre for Neurotechnology Regulation 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 relevant national authority and the National Centre for Neurotechnology Regulation on their activities, findings, and measures taken.

(9) The Secretary of State may by regulations made by statutory instrument make further provision about market surveillance for neurotechnology.

(10) A statutory instrument containing regulations under subsection (9) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 71: 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 Act.

(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 unauthorised 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 behaviour under various conditions.

(4) Market surveillance authorities may request that providers or approved 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 Act, 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 National Centre for Neurotechnology Regulation shall develop common testing methodologies for different categories of neurotechnology and shall support capacity building for testing.

(7) The Secretary of State may by regulations made by statutory instrument make further provision about testing of neurotechnology.

(8) A statutory instrument containing regulations under subsection (7) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 72: Penalties

(1) Competent authorities shall have the power to impose penalties for infringements of this Act.

(2) Penalties shall be effective, proportionate, and dissuasive.

(3) In determining penalties, competent authorities shall take into account: (a) The nature, gravity, and duration of the infringement; (b) The intentional or negligent character of the infringement; (c) The actions taken to mitigate damage; (d) The degree of responsibility taking into account technical and organisational measures implemented; (e) Any relevant previous infringements; (f) The level of cooperation with the authority; (g) The categories of neural data affected by the infringement; (h) The manner in which the infringement became known to the authority; (i) The financial benefits gained or losses avoided as a result of the infringement; (j) Any other aggravating or mitigating factors.

(4) Infringements of this Act shall be subject to administrative fines of up to the higher of the following: (a) For infringements of the provisions regarding prohibited neurotechnology applications in Section 19, £17,500,000 or, in the case of an undertaking, 4% of its total worldwide annual turnover for the preceding financial year, whichever is higher; (b) For infringements of the requirements for high-risk neurotechnology set out in Part 4, £8,700,000 or, in the case of an undertaking, 2% of its total worldwide annual turnover for the preceding financial year, whichever is higher; (c) For other infringements of this Act, £4,350,000 or, in the case of an undertaking, 1% of its total worldwide annual turnover for the preceding financial year, whichever is higher.

(5) In addition to or instead of administrative fines, competent authorities may impose other penalties, including: (a) Orders to cease the infringing behaviour; (b) Withdrawal of products from the market; (c) Temporary or permanent ban on marketing neurotechnology; (d) Temporary or permanent disqualification from public contracts; (e) Publicising of the penalty imposed; (f) Requiring specific corrective actions.

(6) Each competent authority shall establish procedures for imposing penalties that respect the right to due process and other procedural rights, including the right to an effective judicial remedy.

(7) The Secretary of State may by regulations made by statutory instrument adjust the amounts specified in subsection (4) to take account of inflation or to ensure consistency with penalties under other legislation.

(8) A statutory instrument containing regulations under subsection (7) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 73: Corrective Actions and Enforcement Measures

(1) Where a market surveillance authority finds that neurotechnology is not in compliance with this Act, 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 Act; (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 National Centre for Neurotechnology Regulation.

(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 Section 72; (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.

(8) The Secretary of State may by regulations made by statutory instrument make further provision about corrective actions and enforcement measures.

(9) A statutory instrument containing regulations under subsection (8) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 74: Secretary of State's Powers to Make Regulations

(1) The Secretary of State may by regulations make provision for the purposes of implementing this Act, including provision: (a) Amending or supplementing the provisions of this Act; (b) Implementing the provisions of this Act; (c) Specifying technical standards for neurotechnology; (d) Establishing procedures and methodologies for conformity assessment; (e) Specifying the requirements for neural data governance; (f) Establishing the framework for market surveillance; (g) Making transitional or saving provision in connection with this Act.

(2) Regulations under this section may: (a) Make different provision for different purposes, different cases, or different areas; (b) Confer functions on the Secretary of State, relevant national authorities, or other persons; (c) Provide for the delegation of functions; (d) Create offences for contraventions of the regulations; (e) Provide for civil penalties for contraventions of the regulations; (f) Provide for appeals against decisions made under the regulations; (g) Make provision binding the Crown; (h) Make consequential, supplementary, incidental, transitional or saving provision.

(3) Regulations under this section that create an offence may not provide for the offence to be punishable: (a) On summary conviction in England and Wales, with imprisonment for a term exceeding 12 months or with a fine exceeding the statutory maximum (or both); (b) On summary conviction in Scotland, with imprisonment for a term exceeding 12 months or with a fine exceeding the statutory maximum (or both); (c) On summary conviction in Northern Ireland, with imprisonment for a term exceeding 6 months or with a fine exceeding the statutory maximum (or both); (d) On conviction on indictment, with imprisonment for a term exceeding 2 years or with a fine (or both).

(4) Regulations under this section that create a civil penalty may not provide for the penalty to exceed £17,500,000 or, in the case of an undertaking, 4% of its total worldwide annual turnover for the preceding financial year, whichever is higher.

(5) Before making regulations under this section, the Secretary of State shall consult: (a) The National Centre for Neurotechnology Regulation; (b) Relevant national authorities; (c) Such other persons as the Secretary of State considers appropriate.

(6) A statutory instrument containing regulations under this section that amend or supplement this Act may not be made unless a draft of the instrument has been laid before and approved by a resolution of each House of Parliament.

(7) A statutory instrument containing any other regulations under this section is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 75: International Cooperation

(1) The Secretary of State shall promote international cooperation on neurotechnology governance and neurocognitive rights protection, with the aim of: (a) Developing common approaches to neurotechnology regulation; (b) Facilitating the exchange of information on best practices; (c) Promoting the adoption of international standards for neurotechnology; (d) Supporting capacity building for neurotechnology governance globally; (e) Addressing global challenges in neural data protection.

(2) The Secretary of State may: (a) Enter into agreements with other countries or international organisations on neurotechnology governance; (b) Participate in international forums and initiatives focused on neurotechnology; (c) Support the development of international standards for neurotechnology; (d) Provide technical assistance to other countries in developing regulatory frameworks for neurotechnology; (e) Promote the principles of this Act in international contexts.

(3) The National Centre for Neurotechnology Regulation shall, on behalf of the United Kingdom: (a) Engage with counterpart regulatory authorities in other countries; (b) Participate in international regulatory networks and forums; (c) Share information on regulatory approaches and experiences; (d) Contribute to international research on neurotechnology governance; (e) Represent the United Kingdom in technical discussions on neurotechnology standards.

(4) The Secretary of State shall report annually to Parliament on international cooperation activities related to neurotechnology governance.

(5) The Secretary of State may by regulations made by statutory instrument make provision for: (a) The implementation of international agreements on neurotechnology governance; (b) The recognition of standards, certifications, or conformity assessments from other jurisdictions; (c) The sharing of information with international partners; (d) The coordination of market surveillance activities across jurisdictions; (e) Other aspects of international cooperation on neurotechnology governance.

(6) A statutory instrument containing regulations under subsection (5) may not be made unless a draft of the instrument has been laid before and approved by a resolution of each House of Parliament.

PART 10

GENERAL AND FINAL PROVISIONS

Section 76: Codes of Practice

(1) The Secretary of State may issue codes of practice for the purpose of providing practical guidance in respect of this Act.

(2) Codes of practice may address: (a) The implementation of the neurocognitive rights established in Part 2; (b) Risk assessment methodologies for neurotechnology; (c) Best practices for neural data governance; (d) Standards for informed neural consent; (e) Approaches to human oversight of neurotechnology; (f) Methods for bias detection and mitigation in neurotechnology; (g) Neural security measures; (h) Approaches to post-market monitoring; (i) Such other matters as the Secretary of State considers appropriate.

(3) Before issuing a code of practice, the Secretary of State shall: (a) Consult the National Centre for Neurotechnology Regulation and such other persons as the Secretary of State considers appropriate; (b) Publish a draft of the proposed code; (c) Consider any representations made about the draft; (d) Make such modifications to the draft as the Secretary of State considers appropriate in light of the representations.

(4) The Secretary of State shall publish any code of practice issued under this section.

(5) A failure to comply with a code of practice issued under this section does not of itself make a person liable to civil or criminal proceedings, but a code of practice issued under this section is admissible in evidence in any civil or criminal proceedings.

(6) In determining any question arising in civil or criminal proceedings, a court or tribunal must take into account a relevant provision of a code of practice issued under this section.

(7) The Secretary of State may from time to time revise and re-issue a code of practice issued under this section.

(8) References in this section to a code of practice issued under this section include a code of practice as revised and re-issued under subsection (7).

Section 77: Research and Development

(1) The Secretary of State shall promote research and development in neurotechnology and neurocognitive rights protection, including: (a) Supporting research into privacy-preserving neural data processing techniques; (b) Promoting the development of secure and trustworthy neurotechnology; (c) Supporting research on the ethical and societal implications of neurotechnology; (d) Facilitating the development of technical standards for neurotechnology; (e) Supporting the development of testing methodologies for neurotechnology.

(2) The Secretary of State may: (a) Provide funding for research and development projects; (b) Establish research programmes in collaboration with research councils and other funding bodies; (c) Create incentives for responsible innovation in neurotechnology; (d) Support the development of skills and expertise in neurotechnology regulation; (e) Facilitate collaboration between industry, academia, and civil society on neurotechnology governance.

(3) Research involving neurotechnology shall be conducted in accordance with ethical standards and shall respect neurocognitive rights, including: (a) Obtaining informed neural consent from research participants; (b) Implementing appropriate safeguards for neural data; (c) Ensuring transparency about research objectives and methods; (d) Considering the potential societal implications of the research; (e) Complying with relevant ethical approval requirements.

(4) The National Centre for Neurotechnology Regulation shall: (a) Identify research priorities for neurotechnology governance; (b) Promote the exchange of research findings on neurotechnology regulation; (c) Maintain a repository of research on neurocognitive rights and neurotechnology governance; (d) Engage with the research community on regulatory challenges and solutions; (e) Provide guidance on ethical research practices.

(5) The Secretary of State may by regulations made by statutory instrument make provision for: (a) The establishment of research funds or programmes; (b) The administration of research funding; (c) The coordination of research activities; (d) The dissemination of research findings; (e) Other aspects of supporting research and development in neurotechnology and neurocognitive rights protection.

(6) A statutory instrument containing regulations under subsection (5) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 78: Neural Data Protection Impact Assessment

(1) Where a type of processing of neural data, in particular using new technologies, is likely to result in a high risk to the rights and freedoms of individuals, controllers shall, prior to the processing, carry out an assessment of the impact of the envisaged processing operations on the protection of neural data.

(2) A neural data protection impact assessment shall contain at least: (a) A systematic description of the envisaged processing operations and the purposes of the processing; (b) An assessment of the necessity and proportionality of the processing operations in relation to the purposes; (c) An assessment of the risks to the rights and freedoms of data subjects, specifically addressing neurocognitive rights; (d) The measures envisaged to address the risks, including safeguards, security measures, and mechanisms to ensure the protection of neural data.

(3) A neural data protection impact assessment shall specifically address: (a) The nature and sensitivity of the neural data to be processed; (b) The methods of neural data collection and processing; (c) The potential impact on cognitive liberty, mental privacy, and cognitive identity integrity; (d) The risk of revealing information beyond what the individual intends to disclose; (e) The potential for re-identification of anonymised neural data; (f) The potential for neural profiling and its implications; (g) The security risks specific to neural data and neurotechnology; (h) The measures to ensure informed neural consent where required.

(4) The controller shall seek the advice of the data protection officer, where designated, when carrying out a neural data protection impact assessment.

(5) Where appropriate, the controller shall seek the views of data subjects or their representatives on the intended processing, without prejudice to the protection of commercial or public interests or the security of processing operations.

(6) Compliance with approved codes of practice shall be taken into account in assessing the impact of processing operations.

(7) Where a neural data protection impact assessment indicates that the processing would result in a high risk in the absence of measures taken by the controller to mitigate the risk, the controller shall consult the Information Commissioner prior to processing.

(8) The Secretary of State may by regulations made by statutory instrument specify: (a) The requirements for neural data protection impact assessments; (b) The methodology for conducting such assessments; (c) The circumstances in which a neural data protection impact assessment is required; (d) The format and content of neural data protection impact assessments; (e) Other matters relating to neural data protection impact assessments.

(9) A statutory instrument containing regulations under subsection (8) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 79: Parliamentary Oversight

(1) The Secretary of State shall lay before Parliament an annual report on the implementation of this Act, including: (a) The activities of the National Centre for Neurotechnology Regulation; (b) The activities of competent authorities in enforcing this Act; (c) The cases heard by the Neurocognitive Rights Court; (d) The development and deployment of neurotechnology in the United Kingdom; (e) Emerging challenges and

opportunities in neurotechnology governance; (f) International developments in neurocognitive rights protection; (g) Recommendations for legislative or policy changes.

(2) The relevant Select Committee of the House of Commons shall review the annual report and may: (a) Hold hearings on the implementation of this Act; (b) Request additional information from the Secretary of State, the National Centre for Neurotechnology Regulation, or other bodies; (c) Make recommendations for improvements to the implementation of this Act; (d) Report to the House of Commons on its findings and recommendations.

(3) The National Centre for Neurotechnology Regulation shall provide such information and assistance as the Select Committee may reasonably require for the purpose of discharging its functions under this section.

(4) The Secretary of State shall respond to any report or recommendations made by the Select Committee within 60 days.

(5) The Secretary of State shall commission an independent review of this Act every five years, which shall: (a) Assess the effectiveness of the Act in protecting neurocognitive rights; (b) Evaluate the impact of the Act on innovation in neurotechnology; (c) Identify areas where the Act may need to be updated to address technological developments; (d) Consider international developments in neurotechnology governance; (e) Make recommendations for improvements to the Act or its implementation.

(6) The Secretary of State shall lay the report of the independent review before Parliament and shall respond to its recommendations within 90 days.

Section 80: Crown Application

(1) This Act binds the Crown, subject to subsections (2) and (3).

(2) No contravention by the Crown of any provision of this Act makes the Crown criminally liable.

(3) The provisions of this Act apply to persons in the public service of the Crown as they apply to other persons.

(4) This Act does not apply to: (a) Activities of the security and intelligence services to the extent that such activities are essential for the purposes of national security; (b) Activities of the Ministry of Defence to the extent that such activities are essential for the purposes of defence; (c) Activities carried out in the exercise of judicial functions.

(5) The Secretary of State may by regulations made by statutory instrument make provision for the application of this Act to the Crown.

(6) A statutory instrument containing regulations under subsection (5) may not be made unless a draft of the instrument has been laid before and approved by a resolution of each House of Parliament.

Section 81: Territorial Extent

(1) This Act extends to England and Wales, Scotland, and Northern Ireland, subject to the following provisions.

(2) Any amendment, repeal, or revocation made by this Act has the same extent as the provision to which it relates.

(3) The powers under this Act to make regulations may be exercised so as to make provision that extends to: (a) England and Wales; (b) Scotland; (c) Northern Ireland.

(4) The powers under this Act to make regulations may be exercised so as to make provision that extends to the Isle of Man, the Channel Islands, or any British overseas territory.

(5) Her Majesty may by Order in Council direct that any provision of this Act shall extend, with such modifications (if any) as appear to Her Majesty to be appropriate, to the Isle of Man, any of the Channel Islands, or any British overseas territory.

Section 82: Commencement

(1) This section and Sections 1, 2, 3, 4, 74, 80, 81, 83, and 84 come into force on the day on which this Act is passed.

(2) The remaining provisions of this Act come into force on such day as the Secretary of State may by regulations made by statutory instrument appoint.

(3) Different days may be appointed for different purposes.

(4) Regulations under subsection (2) may make: (a) Transitional, transitory, or saving provision; (b) Different provision for different purposes or areas.

Section 83: Review of the Act

(1) The Secretary of State must carry out a review of the provisions of this Act within 5 years of the commencement of this Act.

(2) The review must, in particular: (a) Set out the objectives intended to be achieved by this Act; (b) Assess the extent to which those objectives have been achieved; (c) Assess whether those objectives remain appropriate; (d) If those objectives remain appropriate, assess the extent to which they could be achieved in a way that imposes less regulation.

(3) The Secretary of State must: (a) Consult the National Centre for Neurotechnology Regulation, relevant national authorities, and such other persons as the Secretary of State considers appropriate in conducting the review; (b) Prepare a report on the review; (c) Lay a copy of the report before Parliament; (d) Publish the report.

(4) The Secretary of State may by regulations made by statutory instrument make provision for subsequent reviews of this Act.

(5) A statutory instrument containing regulations under subsection (4) is subject to annulment in pursuance of a resolution of either House of Parliament.

Section 84: Short Title

This Act may be cited as the Neurocognitive Rights and Advanced Neurotechnology Act 2025.

SCHEDULES

SCHEDULE 1: TECHNICAL DOCUMENTATION FOR HIGH-RISK NEUROTECHNOLOGY

(Section 28)

1. The technical documentation referred to in Section 28 shall contain at least the following information: (a) General description of the high-risk neurotechnology: (i) Name, version, and date; (ii) Provider identification and contact details; (iii) Intended purpose and use context; (iv) Target users or subjects; (v) Hardware components; (vi) Software components; (vii) Integration requirements; (viii) Performance characteristics. (b) Detailed description of the elements of the high-risk neurotechnology: (i) System architecture; (ii) Design and development process; (iii) Neural recording or stimulation specifications; (iv) Data processing algorithms; (v) User interface design; (vi) Configuration and calibration procedures; (vii) Testing methodology and results. (c) Information about neural data: (i) Types of neural data collected; (ii) Data pre-processing techniques; (iii) Data storage methods; (iv) Data transmission protocols; (v) Data retention periods; (vi) Data access controls; (vii) Data quality measures. (d) Risk management system: (i) Risk identification methodology; (ii) Risk analysis methods; (iii) Identified risks and evaluation; (iv) Risk mitigation measures; (v) Residual risk assessment; (vi) Risk monitoring mechanisms; (vii) Risk management update procedures. (e) Neural data governance: (i) Data governance framework; (ii) Roles and responsibilities; (iii) Data protection measures; (iv) Data access protocols; (v) Data breach response procedures; (vi) Data quality assurance; (vii) Data sharing policies. (f) Safety and security measures: (i) Safety features; (ii) Fail-safe mechanisms; (iii) Emergency shutdown procedures; (iv) Access control mechanisms; (v) Encryption methods; (vi) Intrusion detection systems; (vii) Vulnerability management procedures. (g) Human oversight measures: (i) Oversight mechanisms; (ii) Human-machine interface design; (iii) Intervention capabilities; (iv) Decision review procedures; (v) Oversight training requirements; (vi) Oversight documentation; (vii) Oversight evaluation methods. (h) Accuracy, reliability, and performance measures: (i) Performance metrics; (ii) Testing protocols; (iii) Validation procedures; (iv) Performance across different user groups; (v) Known limitations; (vi) Performance monitoring methods; (vii) Performance degradation detection. (i) Bias detection and mitigation: (i) Bias assessment methodology; (ii) Identified bias risks; (iii) Mitigation measures; (iv) Testing across diverse populations; (v) Performance disparities analysis; (vi) Monitoring for emergent biases; (vii) Bias mitigation evaluation. (j) Post-market monitoring system: (i) Monitoring plan; (ii) Data collection methods; (iii) Performance indicators; (iv) Adverse event detection; (v) Feedback collection mechanisms; (vi) Analysis procedures; (vii) Corrective action protocols. (k) Instructions for use: (i) User guidance; (ii) Installation procedures; (iii) Operation instructions; (iv) Maintenance requirements; (v) Error handling; (vi) Risk information; (vii) Support information. (l) Conformity assessment: (i) Conformity assessment procedure followed; (ii) Test results; (iii) Certification information; (iv) Declaration of conformity; (v) Approved body information where applicable; (vi) Standards applied; (vii) Compliance documentation. (m) Change management: (i) Change control procedures; (ii) Version control system; (iii) Modification assessment process; (iv) Re-validation procedures; (v) User notification procedures; (vi) Substantial modification criteria; (vii) Update documentation.

2. For high-risk neurotechnology that continues to learn or adapt after deployment, the technical documentation shall additionally include: (a) Learning system

description: (i) Learning mechanisms; (ii) Learning boundaries; (iii) Learning data sources; (iv) Learning parameters; (v) Learning constraints; (vi) Learning oversight; (vii) Learning monitoring. (b) Adaptation management: (i) Adaptation monitoring procedures; (ii) Performance drift detection; (iii) Boundary enforcement mechanisms; (iv) Security measures for learning data; (v) Adaptation approval processes; (vi) Rollback capabilities; (vii) Adaptation documentation.

3. The technical documentation shall be presented in a clear, organised, and searchable manner, with a table of contents and clear references between different sections.
4. The technical documentation shall be kept up to date throughout the lifecycle of the high-risk neurotechnology, with clear version control and change history.
5. The technical documentation shall be made available to competent authorities upon request, in electronic format whenever possible.

SCHEDULE 2: UK DECLARATION OF CONFORMITY

(Section 39)

1. The UK declaration of conformity referred to in Section 39 shall contain the following information: (a) Neurotechnology name and type, and any additional information enabling unambiguous identification of the neurotechnology. (b) Name and address of the provider or, where applicable, their authorised representative. (c) A statement that the UK declaration of conformity is issued under the sole responsibility of the provider. (d) A statement that the neurotechnology in question is in conformity with this Act and, if applicable, with any other relevant UK legislation that provides for the issuing of a UK declaration of conformity. (e) References to any designated standards or common specifications in relation to which conformity is declared. (f) Where applicable, the name and identification number of the approved body, a description of the conformity assessment procedure performed, and identification of the certificate issued. (g) A statement of the intended purpose of the neurotechnology. (h) Where applicable, a reference to any UK-type examination certificate or UK design examination certificate issued by an approved body. (i) 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.
2. The UK declaration of conformity shall be written in English.
3. The UK declaration of conformity shall be kept up to date.
4. The UK declaration of conformity shall be made available to competent authorities upon request.
5. A single UK declaration of conformity may be drawn up for multiple neurotechnology products, provided that it clearly identifies each product covered by it.

SCHEDULE 3: CONFORMITY ASSESSMENT BASED ON INTERNAL CONTROL

(Section 53)

1. The conformity assessment procedure based on internal control is the conformity assessment procedure where the provider verifies the compliance of the high-risk neurotechnology with the requirements of this Act and declares on their sole responsibility that these requirements have been fulfilled.

2. The provider shall: (a) Establish a quality management system that effectively implements the requirements of this Act; (b) Draw up the technical documentation in accordance with Section 28 and Schedule 1; (c) Examine the information contained in the technical documentation to assess the compliance of the high-risk neurotechnology with the requirements set out in Part 4 of this Act; (d) Design and implement procedures to ensure that the production process and its monitoring ensure compliance of the manufactured high-risk neurotechnology with the technical documentation and with the requirements of this Act; (e) Verify that the design and development process of the high-risk neurotechnology and its post-market monitoring as referred to in Section 38 is consistent with the technical documentation; (f) Affix the UKCA marking to the high-risk neurotechnology in accordance with Section 40; (g) Draw up a written UK declaration of conformity in accordance with Section 39 and Schedule 2; (h) Keep the technical documentation, the UK declaration of conformity, and any relevant documentation at the disposal of the competent authorities for a period of ten years after the high-risk neurotechnology has been placed on the market or put into service.

3. The provider shall take all measures necessary so that the manufacturing process and its monitoring ensure compliance of the manufactured high-risk neurotechnology with the technical documentation and with the requirements of this Act.

4. The provider shall continuously monitor the performance of the high-risk neurotechnology after it has been placed on the market or put into service, and shall implement any necessary corrective actions.

5. If the provider becomes aware of any serious incident or malfunction, they shall report it to the competent authorities in accordance with Section 50.

SCHEDULE 4: CONFORMITY ASSESSMENT WITH THE INVOLVEMENT OF AN APPROVED BODY

(Section 53)

1. The conformity assessment procedure with the involvement of an approved body is the conformity assessment procedure where the provider verifies the compliance of the high-risk neurotechnology with the requirements of this Act with the involvement of an approved body.

2. The provider shall apply to an approved 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 authorised representative, their name and address as well; (b) A written declaration that the same application has not been lodged with any other approved body; (c) The technical documentation referred to in Section 28 and Schedule 1.

4. The approved body shall examine the technical documentation to assess whether: (a) The high-risk neurotechnology complies with the requirements set out in Part 4 of this Act; (b) The risk management system is adequate and has been properly implemented; (c) The neural data governance system complies with the requirements of this Act; (d) The quality management system is adequate; (e) The post-market monitoring system is appropriate.

5. Where the approved body concludes that the high-risk neurotechnology complies with the requirements set out in Part 4 of this Act, it shall issue a 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.

6. The provider shall inform the approved body that has issued the technical documentation assessment certificate of any planned substantial modification to the high-risk neurotechnology.

7. The approved body shall examine the planned modification and decide whether: (a) The planned modification requires a new conformity assessment; (b) The planned modification requires an addendum to the technical documentation assessment certificate; or (c) The planned modification does not require any changes to the technical documentation assessment certificate.

8. The approved body shall inform the provider of its decision. If the approved body decides that a new conformity assessment is required, the provider shall make a new application for conformity assessment.

9. The approved body may, with a justified request, ask the provider for any information or data that is necessary to properly conduct the conformity assessment, including access to the high-risk neurotechnology and its components for testing purposes.

10. The approved body shall keep a record of all documents and activities related to the conformity assessment for a period of ten years after the assessment has been completed.

11. The provider shall keep the technical documentation, the technical documentation assessment certificate, and any relevant documentation at the disposal of the competent authorities for a period of ten years after the high-risk neurotechnology has been placed on the market or put into service.

SCHEDULE 5: REQUIREMENTS FOR APPROVED BODIES

(Section 54)

1. An approved body shall meet the following requirements: (a) Organisational and general requirements: (i) Legal status and structure: - Be established under the law of the United Kingdom - Have full documentation of its legal personality and structure - Be independent of the providers it assesses (ii) 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 (iii) Confidentiality: - Have documented procedures for maintaining confidentiality - Ensure staff maintain professional secrecy - Protect proprietary information obtained during assessment activities (iv) Liability: - Take out appropriate liability insurance - Have financial stability and resources to conduct activities (v) 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 (b) Resource requirements: (i) 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 authorisation - Have systems to ensure competence monitoring and continuous training (ii) 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 (iii) Subcontracting: - Where subcontracting occurs, ensure adequate supervision - Maintain register of subcontractor qualifications and work - Have written agreement covering confidentiality and conflicts of interest (c) Process requirements: (i) Application handling: - Document procedures for handling applications - Verify completeness of documentation - Establish agreements with providers on timing and conduct of assessments (ii) 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 (iii) Reporting: - Provide clear assessment reports - Have documented procedure for report review and approval - Ensure traceability of assessment decisions (iv) Follow-up activities: - Conduct appropriate surveillance - Have procedures for handling changes to approved neurotechnology - Respond to information affecting conformity status

(v) Appeals:

- Document procedures for appeals against decisions
- Inform providers of right to appeal
- Maintain records of all appeals and their resolution

(d) Specific competence for neurotechnology:

(i) 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

(ii) Specialised 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

(iii) 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

(e) Documentation and records:

(i) Records system:

- Maintain records demonstrating fulfilment of requirements
- Document qualifications, training, and authorisation of personnel
- Keep records of subcontractors
- Maintain assessment records for required periods

(ii) Public information:

- Make publicly available information about assessment types
- Publish certification procedures
- Disclose conflicts of interest policies

(iii) Document control:

- Control conformity assessment documents
- Ensure availability of current procedures
- Identify document changes and review status

(f) Coordination and cooperation:

(i) Participation in standardisation:

- Participate in relevant standardisation activities
- Contribute to neurotechnology standards development

- Maintain knowledge of evolving standards

(ii) Coordination with other approved bodies:

- Participate in coordination groups for approved bodies
- Exchange experiences with other approved bodies
- Work toward harmonised application of requirements

(iii) Cooperation with authorities:

- Cooperate with market surveillance authorities
- Inform competent authorities of certificate suspensions or withdrawals
- Respond to information requests from authorities

(g) Continuous improvement:

(i) Feedback mechanisms:

- Collect feedback from clients and stakeholders
- Analyse complaints and appeals
- Track performance metrics
- Implement corrective and preventive actions

(ii) 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

(iii) Performance evaluation:

- Conduct regular self-assessments
- Participate in external assessments
- Review and analyse assessment outcomes
- Implement improvements based on evaluations

2. Approved bodies shall meet these requirements on an ongoing basis and shall be subject to assessment by the United Kingdom Accreditation Service (UKAS) to verify their compliance.

3. The Secretary of State shall ensure that information on the assessment, designation, notification, monitoring, and review of approved bodies is publicly available.

SCHEDULE 6: THE NATIONAL CENTRE FOR NEUROTECHNOLOGY REGULATION

(Section 56)

1. The National Centre for Neurotechnology Regulation (in this Schedule referred to as "the Centre") shall consist of: (a) A Chair appointed by the Secretary of State; (b) Between 6 and 10 other members appointed by the Secretary of State; (c) A Chief Executive appointed by the Board with the approval of the Secretary of State.

2. The Secretary of State shall ensure that the Board includes members with expertise in: (a) Neuroscience and neurotechnology; (b) Ethics and philosophy; (c) Data protection and privacy; (d) Regulation and law; (e) Consumer protection; (f) Medical devices and healthcare; (g) Human rights.

3. In appointing members, the Secretary of State shall have regard to the desirability of the Board including members who: (a) Have experience of the neurotechnology industry; (b) Have experience of civil society organisations working on neurocognitive rights; (c) Have experience of academic research in relevant fields; (d) Have experience as users of neurotechnology; (e) Reflect a diversity of perspectives.

4. The Chair and other members shall hold and vacate office in accordance with the terms of their appointment, but: (a) No appointment shall be for a term of more than 5 years; (b) A person who ceases to be a member shall be eligible for re-appointment, but may not serve more than two consecutive terms.

5. The Secretary of State may by order remove a member from office if satisfied that: (a) The member has been absent from meetings of the Centre for a period longer than 6 months without the permission of the Centre; (b) The member has been convicted of a criminal offence; (c) The member has been made bankrupt, has had their estate sequestrated, has made a composition or arrangement with or granted a trust deed for their creditors; (d) The member is otherwise unable or unfit to carry out their functions as a member.

6. The Centre may: (a) Pay to the Chair and other members such remuneration and allowances as the Secretary of State may determine; (b) Pay to or in respect of the Chair and other members such sums by way of pensions, allowances, or gratuities as the Secretary of State may determine.

7. The Centre may: (a) Appoint employees; (b) Pay to its employees such remuneration and allowances as it may determine; (c) Pay to or in respect of its employees such sums by way of pensions, allowances, or gratuities as it may determine; (d) Provide and maintain for its employees such pension schemes as it may determine.

8. The Centre shall determine its own procedure, including the quorum for meetings and the establishment of committees.

9. The Centre may: (a) Acquire and dispose of property; (b) Enter into contracts; (c) Accept gifts of money, land, or other property; (d) Invest money not immediately

required for the purpose of its functions; (e) Do anything which appears to it to be necessary or expedient for the purpose of, or in connection with, the exercise of its functions.

10. The Centre shall not borrow money except with the consent of the Secretary of State.

11. The application of the seal of the Centre shall be authenticated by the signature of: (a) The Chair or another member; or (b) An employee who has been authorised by the Centre to authenticate the application of the seal.

12. The Centre shall keep proper accounts and proper records in relation to the accounts, and shall prepare for each financial year a statement of accounts in such form as the Secretary of State may direct.

13. The statement of accounts shall be submitted to the Secretary of State at such time as the Secretary of State may direct.

14. The Secretary of State shall send a copy of the statement of accounts to the Comptroller and Auditor General.

15. The Comptroller and Auditor General shall: (a) Examine, certify, and report on the statement of accounts; (b) Send a copy of the certified statement and report to the Secretary of State; (c) Send a copy of the certified statement and report to the Centre.

16. The Secretary of State shall lay before Parliament a copy of the certified statement and report.

17. The financial year of the Centre shall be the period of 12 months ending with 31st March in each year, except that the first financial year shall be the period beginning with the day on which the Centre is established and ending with the 31st March following that day.

18. The Centre shall send to the Secretary of State, as soon as possible after the end of each financial year, a report on the exercise of its functions during that year.

19. The Secretary of State shall lay a copy of each such report before Parliament.

20. The Centre shall: (a) Establish a Scientific Advisory Committee to provide expert advice on scientific matters relevant to the Centre's functions; (b) Establish a Stakeholder Forum to facilitate engagement with stakeholders; (c) Establish such other committees as it considers appropriate.

21. The Centre may pay to the members of its committees such remuneration and allowances as it may determine.

22. The Public Records Act 1958 shall apply to the Centre as if it were a government department.

23. The Centre shall be: (a) A public authority for the purposes of the Freedom of Information Act 2000; (b) A public authority for the purposes of the Environmental Information Regulations 2004; (c) A data controller for the purposes of data protection legislation.

24. In Part 2 of Schedule 1 to the House of Commons Disqualification Act 1975 (bodies of which all members are disqualified), at the appropriate place insert "The National Centre for Neurotechnology Regulation".

25. In Part 2 of Schedule 1 to the Northern Ireland Assembly Disqualification Act 1975 (bodies of which all members are disqualified), at the appropriate place insert "The National Centre for Neurotechnology Regulation".

SCHEDULE 7: TRANSITIONAL PROVISIONS

1. Neurotechnology already placed on the market or put into service before the commencement date for Part 3 of this Act may continue to be made available on the market or put into service for a period of 24 months from that commencement date.

2. During the transitional period of 24 months referred to in paragraph 1: (a) Providers of high-risk neurotechnology shall: (i) Undertake an assessment of their neurotechnology against the requirements of this Act; (ii) Develop a plan for bringing their neurotechnology into compliance with this Act; (iii) Implement any necessary changes to their neurotechnology; (iv) Undergo conformity assessment in accordance with Part 6 of this Act; (v) Register their high-risk neurotechnology in the UK database in accordance with Section 52 of this Act. (b) Providers of other neurotechnology shall: (i) Undertake an assessment of their neurotechnology against the requirements of this Act; (ii) Develop a plan for bringing their neurotechnology into compliance with this Act; (iii) Implement any necessary changes to their neurotechnology; (iv) Ensure compliance with the general provisions of this Act.

3. Any neurotechnology that does not comply with the requirements of this Act by the end of the transitional period shall be withdrawn from the market.

4. The Secretary of State may by regulations made by statutory instrument extend the transitional period for specific categories of neurotechnology by up to 12 months where justified by exceptional circumstances.

5. A statutory instrument containing regulations under paragraph 4 is subject to annulment in pursuance of a resolution of either House of Parliament.

6. Until the National Centre for Neurotechnology Regulation is fully operational, its functions shall be performed by the Secretary of State.

7. Until the Neurocognitive Rights Court is established, its functions shall be performed by the Upper Tribunal.

8. The Secretary of State shall: (a) Publish guidance on compliance with this Act during the transitional period; (b) Establish a helpdesk to assist providers in understanding and implementing the requirements of this Act; (c) Support capacity building for competent authorities and approved bodies; (d) Facilitate knowledge sharing among stakeholders.

9. The first review of this Act under Section 83 shall take place within 5 years of the date on which the last provision of this Act comes into force.

10. The Secretary of State may by regulations made by statutory instrument make such transitional, transitory, or saving provisions as the Secretary of State considers appropriate in connection with the coming into force of any provision of this Act.

11. A statutory instrument containing regulations under paragraph 10 is subject to annulment in pursuance of a resolution of either House of Parliament.

SCHEDULE 8: CONSEQUENTIAL AMENDMENTS

1. In section 2 of the Data Protection Act 2018 (protection of personal data), after subsection (2) insert: "(2A) This Act has effect subject to the Neurocognitive Rights and Advanced Neurotechnology Act 2025, which provides additional protections for neural data."

2. In section 3 of the Data Protection Act 2018 (terms relating to the processing of personal data), after subsection (14) insert: "(14A) 'Neural data' has the same meaning as in the Neurocognitive Rights and Advanced Neurotechnology Act 2025."

3. In Schedule 1 to the Data Protection Act 2018 (special categories of personal data and criminal convictions etc data), after paragraph 1 insert: "1A. This condition is met if the processing is necessary for the purposes of exercising or performing the rights and obligations of the controller or the data subject under the Neurocognitive Rights and Advanced Neurotechnology Act 2025."

4. In Schedule 1 to the Freedom of Information Act 2000 (public authorities), after paragraph 80 insert: "80A. The National Centre for Neurotechnology Regulation."

5. In Schedule 1 to the Public Records Act 1958 (definition of public records), after paragraph 4(4) insert: "(4A) The National Centre for Neurotechnology Regulation."

6. In Schedule 2 to the Parliamentary Commissioner Act 1967 (departments and authorities subject to investigation), at the appropriate place insert: "The National Centre for Neurotechnology Regulation."

7. In Part 3 of Schedule 1 to the House of Commons Disqualification Act 1975 (disqualifying offices), at the appropriate place insert: "Chief Executive of the National Centre for Neurotechnology Regulation."

8. In Part 3 of Schedule 1 to the Northern Ireland Assembly Disqualification Act 1975 (disqualifying offices), at the appropriate place insert: "Chief Executive of the National Centre for Neurotechnology Regulation."

9. In the Consumer Rights Act 2015, after section 2(7) insert: "(7A) 'Neurotechnology' has the same meaning as in the Neurocognitive Rights and Advanced Neurotechnology Act 2025."

10. In the Human Rights Act 1998, after section 1(2) insert: "(2A) The rights and freedoms set out in Schedule 1 shall be interpreted in a manner that is compatible with the neurocognitive rights established in the Neurocognitive Rights and Advanced Neurotechnology Act 2025."

11. In the Medical Devices Regulations 2002 (S.I. 2002/618), after regulation 2(1) insert: "(1A) This regulation has effect subject to the Neurocognitive Rights and Advanced

Neurotechnology Act 2025, which provides additional requirements for neurotechnology that qualifies as a medical device."

12. In the Equality Act 2010, after section 4 insert: "4A Neural characteristics (1) In this Act, neural characteristics means any characteristics related to an individual's neural function, structure, or data. (2) A reference to neural characteristics is a reference to an individual's neural characteristics or the neural characteristics of a class of persons. (3) The Secretary of State may by regulations specify conditions under which discrimination on the basis of neural characteristics may amount to discrimination on the basis of disability for the purposes of this Act."

13. In the Tribunals, Courts and Enforcement Act 2007, in Schedule 6 (tribunals for the purposes of section 30), after paragraph 38 insert: "38A. The Neurocognitive Rights Court."

14. The Secretary of State may by regulations made by statutory instrument make such other amendments of primary legislation as are necessary or expedient in consequence of any provision of this Act.

15. A statutory instrument containing regulations under paragraph 14 may not be made unless a draft of the instrument has been laid before and approved by a resolution of each House of Parliament.

16. The Secretary of State may by regulations made by statutory instrument make such amendments of subordinate legislation as are necessary or expedient in consequence of any provision of this Act.

17. A statutory instrument containing regulations under paragraph 16 is subject to annulment in pursuance of a resolution of either House of Parliament.

São Paulo, Brazil

October 07th 1988

3:45am