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Consumer neuro devices within EU product safety law: Are we prepared for big tech ante portas?

Elisabeth Steindl

Department of Innovation and Digitalisation in Law, Research Platform Governance of Digital Practices, University of Vienna, Schenkenstraße 4, Vienna A-1010, Austria

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ABSTRACT

Previously confined to the distinct medical market, neurotechnologies are expanding rapidly into the consumer market, driven by technological advancements and substantial investments. While offering promising benefits, concerns have emerged regarding the suitability of existing legal frameworks to adequately address the risks they present. Against the background of an ongoing global debate on new policies or new 'neurorights' regulating neurotechnology, this paper delves into the regulation of consumer Brain-Computer Interfaces (BCIs) in the European Union (EU), focusing on the pertinent product safety legislation.

The analysis will primarily examine the sector-specific product safety law for medical devices, the Medical Devices Regulation (MDR). It will meticulously delineate which consumer BCIs fall within its scope and are obliged to comply with the requirements outlined. The tech-based approach of Annex XVI MDR, coupled with recent amendments, show that the EU has adopted a forward-thinking rationale towards regulating health-related risks associated with consumer BCIs within existing EU medical devices legislation, while abstaining from over-regulating aspects therein that are beyond its core objectives.

Supplementary, the paper will discuss developments in EU horizontal product safety law, regulating all consumer BCIs that are not subject to sector-specific product safety legislation. In their recently adopted General Product Safety Regulation (GPSR), the EU has introduced several provisions addressing digital products. Inter alia, these changes will enhance the horizontal regulation of consumer BCIs.

Overall, within the context of product safety law, the recent adaptations affirm notable efforts by the EU to refine the legal framework that governs consumer BCIs, striking a delicate balance between effective technology regulation and not impeding innovation.

1. Introduction

Over the past decade, neurotechnologies have made unprecedented progress in the health and research sectors, fuelled by investments from both governmental and private entities. Private investment in neuro tech companies has surged, witnessing a 22-fold increase from 2010 to 2020, reaching $7.3 billion and totalling $33.2 billion by 2020.[1] Notably, non-invasive Brain-Computer-Interfaces (BCIs) for recreational and mental augmentation purposes are experiencing significant market growth, expanding into the direct-to-consumer market. Projected growth indicates a substantial expansion of the neurotechnology devices market, estimated to reach $24.2 billion by 2027.[2]

The ongoing developments are giving rise to concerns about the adequacy of our current legal framework and its ability to keep pace with the breath-taking advancements in this domain. These concerns have reached policymakers and international organisations. The OECD has adopted Recommendations on Responsible Innovation in Neurotechnology.[3] UNESCO has issued a report on the risks and challenges of

E-mail address: elisabeth.steindl@univie.ac.at.

[1] UNESCO, Scientific Advancements Innovations and Major Trends, (2023), at 9. https://doi.org/10.54678/OCBM4164.

[2] Ibid.

[3] OECD, Recommendation of the Council on Responsible Innovation in Neurotechnology. (2019). https://legalinstruments.oecd.org/en/instruments/OECD-LEGAL-0457 (accessed 5 Jan 2024).

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neurotechnologies for human rights.[4] Under the Spanish Presidency of the Council of the EU, the Telecommunications and digital ministers have launched the León Declaration on European Neurotechnology.[5] Calls for new 'neurorights' stir passions globally. At the same time, colleagues are demanding a thorough analysis of the existing legal framework in avoidance of hasty decisions.[6]

2. Big tech is waiting in the wings

The rapid expansion of BCIs into the direct-to-consumer market, driven by substantial investments of big tech companies, is an area that sparks particular apprehensions about a potential under-regulation. A glance at the companies that are investing money in BCI deployment reveals the Who is Who of big tech. The Amazon Alexa Fund invests in AI-powered neural interfaces to unlock speech/smart home controls and to develop new adaptive interfaces for assisted reality technology.[7] Bill Gates' and Jeff Bezos' private investment firms are putting money into a company called Synchron, developing a minimally invasive endovascular brain implant.[8] Meta is working on a neural interface *via* an EMG (electromyography) wristband to interact with AR or VR devices.[9] Elon Musk continues to promote Neuralink, which has been approved by the U.S. Food and Drug Administration (FDA) for human trials.[10] The Google Spin-off Nextsense is exploring earbuds to perform EEGs through the ear in order to collect brain signals. The collected brain signals could be used for identification, to monitor epilepsy and predict seizures, for interaction with one's digital devices, or to keep people fit and healthy by learning how they sleep and how they walk.[11] Apple has increased their number of neuro scientific researchers to study health neurotechnology and filed a patent for EEG-integrated AirPods.[12]

The given main purpose for neuro tech research in many of the above-mentioned cases is a medical one. Considering the companies involved, commercial interests further down the line are however evident. Moreover, the cited examples for deployment illustrate vividly how close the use for clearly medical purposes and the use for commercial purposes are one to another. While there is an overall-consensus that the existing regulation of neurotechnology in the distinct medical context is reasonably robust, with an adequate amount of testing and scrutiny foreseen to ensure safety and efficacy, warnings that BCIs in the consumer sector lack regulation are increasing.

The following analysis aims to examine the regulation of consumer BCIs within the framework of EU product safety legislation. The paper will explore whether or not, and under which conditions, consumer BCIs fall within the scope of the sector-specific product safety law for medical devices, the Medical Devices Regulation (MDR). Subsequently, the paper will discuss the regulation of all consumer BCIs falling outside the scope of sector-specific legislation by horizontal product safety law, focusing on various adaptations for digital products in the newly adopted General Product Safety Regulation (GPSR).

3. The MDR incorporates specific consumer BCIs

In the EU, the sector-specific product safety law for medical devices is the Medical Devices Regulation (EU) 2017/745 (hereinafter referred to as MDR), along with the In Vitro Diagnostic Medical Devices Regulation (EU) 2017/746 (IVDR). Material scope of the MDR is the placing on the market, making available on the market or putting into service of medical devices for human use (as well as accessories for such devices).[13] Medical devices themselves are defined as 'any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination' for specific medical purposes.[14]

All BCIs that have an intended medical purpose are within the scope of the MDR and have to comply with its requirements. The extent and severity of the requirements depend upon the risk class that the device is classified with. As mentioned earlier, the existing regulatory regime for distinct medical BCIs is presently considered adequate; moreover, it is not the focus of this paper. Therefore, details about the regulation of medical BCIs according to the MDR are not discussed here.

Debates on how to integrate consumer BCIs into the legal regime for medical devices had already commenced under the predecessor legislation to the MDR, the Medical Devices Directive 93/42/EEC (hereinafter referred to as MDD).[15] One potential resort to include BCIs without a clear medical purpose within the scope of the medical devices legislation was ignited by the third indent of Article 1(2)(a) MDD that, similar to the MDR, listed 'investigation, replacement or modification of the anatomy or of a physiological process' in the definition for medical devices. In the meantime, the CJEU has decided this scholarly dispute. In CJEU C-219/11 Brain Products GmbH vs BioSemi VOF, the court was asked whether a product which is intended for the purpose of investigation of a physiological process constitutes a medical device, within the terms of the third indent of Article 1(2)(a) MDD, only in the case where there is an intended medical purpose. The CJEU came to the conclusion that the investigation of a physiological process falls within the scope of the MDD only if the intended purpose, defined by its manufacturer, is medical (section 18) and that in interpreting Article 1(2)(a) MDD the medical use must be regarded as inherent (section 32). Including BCIs without a distinct medical purpose into the medical devices legislation

[4] UNESCO, The risks and challenges of neurotechnologies for human rights, (2023). https://doi.org/10.54678/POGS7778.

[5] Léon Declaration on European Neurotechnology. A Human Centric and Rights-Oriented Approach. (2023) <https://spanish-presidency.consilium.europa.eu/media/o4rh53jr/le%C3%B3n-declaration.pdf> (accessed 4 Jan 2024).

[6] See, for instance, Jan Christoph Bublitz, Novel Neurorights: From Nonsense to Substance' *Neuroethics* (2022) 15:7, https://doi.org/10.1007/s12152-022-09481-3; Sjors Ligthart, Christoph Bublitz, Susie Alegre, Neurotechnology: we need new laws, not new rights. *Nature* 620, 950 (2023). doi: https://doi.org/10.1038/d41586-023-02698-z.

[7] Cognixion, Cognixion Raises $12 Million to Advance Assisted Reality Tech for Millions Affected by Communication Disabilities <https://www.cognixion.com/blog/2021/11/16/cognixion-raises-12-million-to-advance-assisted-reality-tech-for-millions-affected-by-communication-disabilities> (accessed 9 January 2024).

[8] Businesswire, Synchron Raises $75M Series C Led by ARCH Venture Partners to Advance Endovascular Brain-Computer Interface <https://www.businesswire.com/news/home/20221213006045/en/Synchron-Raises-75M-Series-C-Led-by-ARCH-Venture-Partners-to-Advance-Endovascular-Brain-Computer-Interface> (accessed 9 January 2024).

[9] Tomislav Bezmalinovic, Meta reveals new research: avatars, AR and brain-computer interface' <https://mixed-news.com/en/meta-reveals-new-research-avatars-ar-and-brain-computer-interface/#Neural_interface> (accessed 9 January 2024).

[10] Rachael Levy, Marisa Taylor and Akriti Sharma, Elon Musk's Neuralink wins FDA approval for human study of brain implants (Reuters 26 May 2023) <https://www.reuters.com/science/elon-musks-neuralink-gets-us-fda-approval-human-clinical-study-brain-implants-2023-05-25/> (accessed 9 January 2024).

[11] Stephen Levy, This Startup Wants to Get in Your Ears and Watch Your Brain, wired 14 Apr 2022 <https://www.wired.com/story/nextsense-wants-to-get-in-your-ears-and-watch-your-brain/> (accessed 9 January 2024).

[12] Niel Smith, Apple expanding its footprint in Neuroscience and related technology <https://www.myhealthyapple.com/apple-expanding-its-footprint-in-neuroscience-and-related-technology/> (accessed 9 January 2024). United States, Patent Application Publication <https://image-ppubs.uspto.gov/dirsearch-public/print/downloadPdf/20230225659> (accessed 9 January 2024).

[13] Article 1(1) MDR.

[14] Article 2(1) MDR.

[15] See e.g. Hannah Maslen and others, The regulation of cognitive enhancement devices: extending the medical model, *Journal of Law and the Biosciences*, Volume 1, Issue 1, March 2014, Pages 68–93 <https://doi.org/10.1093/jlb/lst003>. Commission staff working document impact assessment on the revision of the regulatory framework for medical devices. SWD/2012/0273 final.

simply by subsuming them as 'investigation of a physical procedure' has thus been ruled out as an option by the CJEU.

Deviating from the former MDD, which solely applied to medical products and their accessories, the EU has expanded the scope of the MDR, now including specific products without an intended medical purpose. This means a notable departure from the traditional concept of medical devices legislation. Article 1(2) in conjunction with Annex XVI MDR incorporates an exhaustive list of non-medical products within the medical devices framework. The list of products encompasses contact lenses, products intended to be surgically introduced for modifying the anatomy of the body (with the exception of tattooing products and piercings), substances used for facial or other dermal or mucous membrane filling (again excluding tattoos), equipment to reduce, remove or destroy adipose tissue, as well as high intensity electromagnetic radiation emitting equipment for skin resurfacing, tattoo or hair removal or other skin treatment. The last section in Annex XVI MDR adds equipment 'intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain'[16] to the list.

In contrast to BCIs with an intended medical purpose, which fall directly within the scope of the MDR as per Article 1(1) MDR, Article 1 (2) in conjunction with Annex XVI MDR therefore pro-actively integrates specific BCIs without an intended medical purpose into the regulatory framework of the MDR. According to Article 1(2) MDR, 'the state of the art, and in particular existing harmonised standards for analogous devices with a medical purpose, based on similar technology' must be taken into account. Given that BCIs are often initially developed and designed for the medical market before expanding into non-medical domains and that they sometimes can be utilised in both contexts, this requirement will not be an impediment for their inclusion into the MDR. Article 1(2) MDR provides further that Annex XVI MDR shall apply 'as from the date of application of common specifications adopted pursuant to Article 9′. Despite the initial expectation for these common specifications (hereinafter referred to as CS) for Annex XVI MDR to be adopted by 26 May 2021,[17] they were, in fact, only adopted in late 2022 and have become applicable in June 2023.[18]

Collectively, Annex XVI and the newly adopted amendments outline clearly the categories of consumer BCIs that the EU intends to integrate into the regulatory framework of the MDR, as well as those it does not. A thorough analysis of the individual legal documents and the risks addressed therein illustrates the rationale guiding the regulation of specific consumer BCIs within EU medical devices legislation.

4. Annex XVI provides a general outline

Prior to delving into the specific types of consumer BCIs integrated in Annex XVI MDR, it is crucial to understand the fundamental distinction between BCIs with an intended medical purpose and those without, as only the latter are eligible for inclusion in Annex XVI MDR. What might initially appear a straightforward distinction swiftly becomes a challenging terrain to navigate, riddled with complexities and intricacies.

Article 2(1) MDR lists the following as medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations,

Consumer BCIs are typically applied in domains like well-being (eg relaxation or meditation), enhancement (eg concentration), leisure (eg gaming), security (eg authentication) or convenience (eg interaction with a device). Neither of these domains is intuitively associated with one of the medical purposes listed in Article 2(1) MDR. Moreover, Recital 19 MDR explicitly stipulates that 'software intended for life-style and well-being purposes is not a medical device'. BCIs for well-being or life-style purposes are therefore not considered medical BCIs.

The demarcation lines between devices with an intended medical purpose and those without remain, however, blurry. While pure commercial purposes, such as leisure or convenience or even security, are less likely to be misclassified, there are lingering uncertainties and ambiguities surrounding the terms well-being and enhancement.

The term 'well-being' is not defined in the MDR. In general, well-being is understood as a very broad concept, encompassing many aspects, from physical to mental, emotional and social dimensions. Holistic approaches to mental health do not support drawing a precise boundary between mental health, indicating an intended medical purpose of a device if used for eg diagnosis, prevention, monitoring or treatment, and simple well-being. The transitions are fluid. The term 'enhancement' is not defined in the MDR either. The Oxford dictionary describes enhancement as 'the act of increasing or further improving the good quality, value or status of somebody/something'.[19] A similar notion of improving something or someone was also underlying the definition of enhancement in the first institutional EU study on enhancement in 2009.[20] The Sienna project, an EU-funded H-2020 project dedicated to explore ethical and legal issues in emerging technologies, minimally adapts the definition in the 2009 EU study and describes human enhancement as a 'modification aimed at improving human performance and brought about by science-based and/or technology-based interventions in or on the human body.'[21]

The 2009 EU study already anticipated up-coming difficulties in distinguishing medical treatments from human enhancement.[22] According to the study, therapeutic devices generally aim to correct or compensate for some disease state and to restore it to 'normality'. In order to differentiate therapeutic, ie medical purposes, from enhancement purposes, a clear threshold for what is 'normal' as opposed to what is 'abnormal' would need to be set – yet, this oftentimes is a matter of opinion and perspectives. Arguably, the deficit model of disability is controversial; for example, there are members of the deaf community that consider cochlear implants rather a form of enhancement than therapeutic. Moreover, the very same devices that are able to correct any form of impairment could be used to lead to enhanced performance in

[16] Section 6 Annex XVI MDR.

[17] See Article 1(2) MDR.

[18] Commission Implementing Regulation (EU) 2022/2346 of 1 December 2022 laying down common specifications for the groups of products without an intended medical purpose listed in Annex XVI to Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices. OJ L 311/60. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R2346> (accessed 9 January 2024).

[19] Oxford Learner's Dictionaries, Enhancement <https://www.oxfordlearnersdictionaries.com/definition/english/enhancement> (accessed 9 January 2024).

[20] Christopher Coenen et al, STOA Human enhancement study. (2009) <https://www.europarl.europa.eu/stoa/en/document/IPOL-JOIN_ET(2009)417483> (accessed 9 January 2024).

[21] Sienna Project, D5.6: Recommendations for the enhancement of the existing legal frameworks for genomics, human enhancement, and AI and robotics. (2020), at 11.

[22] Christopher Coenen et al, STOA Human enhancement study, at 17.

people that do not have such an impairment, just like a BCI used to treat cognitive impairment associated with dementia could lead to above-average cognition.[23] Or, like one of the BCI start-ups frames it: 'For some people, we make things easy, and for other people, we make things possible.'[24]

Whether a BCI is considered a medical device and falls directly within the scope of the MDR, as per Article 1(1) MDR, or not is based on whether the device has an intended medical purpose.[25] Article 2(1) MDR stipulates that any software 'intended by the manufacturer' for use in one of the medical purposes listed is a medical device under the MDR. The manufacturer's pivotal role is reiterated in Article 2(12) MDR, which states that the intended purpose refers to 'the use for which a device is intended according to the data supplied by the manufacturer on the label, in the instructions for use, or in promotional or sales materials or statements, and as specified by the manufacturer in the clinical evaluation'. Even the guidance provided by the MEDDEVs, the medical device documents, insists that 'only the intended purpose as described by the manufacturer of the product is relevant for the qualification and classification of any device'.[26] Arguably, the exact wording of all the data supplied — the description, the label, the instructions, the promotional material — is at the discretion of the manufacturer.

In this context, the definitional ambiguities surrounding the terms well-being, life-style and enhancement described above were problematic for the regulation of BCIs under the MDD. It meant that the very same device could be identified for regulation as a medical device when marketed as such, but not when marketed 'off-label'.[27] Eventually, the higher costs and the additional effort and time required for certifying a device as a medical device encouraged manufacturers to rather under-qualify their applications as simple well-being devices for the consumer market in order to circumvent tedious admission procedures under the MDR and strict controls on the medical market.

The introduction of Annex XVI into the MDR represents an innovative instrument that provides an additional regulatory safeguard for BCIs, mitigating the definitional uncertainties.[28] Unlike the otherwise purpose-based approach in the MDR for determining, whether a device qualifies as a medical device or not, Section 6 Annex XVI MDR solely considers the technical aspects of a BCI. The purpose of deployment is irrelevant for Annex XVI MDR. This means that any consumer BCI, whether it be for well-being, enhancement, leisure, convenience, authentication, or anything in between or beyond, is eligible for Annex XVI and will thus fall into the scope of the MDR, provided all required criteria are met. Through the introduction of Annex XVI MDR as a purpose-neutral safety net, the EU has ingeniously addressed the practice of BCIs being falsely under-qualified as well-being/enhancement devices by manufacturers, attempting to bypass the MDR. This effectively eliminates the risk of BCIs falling entirely outside the scope of the MDR due to a mere understatement by the manufacturer.

Annex XVI functions as an exemption to the overarching principle that the MDR is applicable solely to medical devices. Annex XVI integrates specific products without an intended medical purpose within the scope of medical devices legislation. Section 6 Annex XVI MDR stipulates that '[e]quipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain' falls within the scope of the MDR, notwithstanding they do not have an intended medical purpose. The requirements listed in Section 6 must be considered cumulatively.

The terms 'brain stimulation' and 'to modify neuronal activity in the brain' are not defined in the MDR. In a very expansive sense, any experience that people make can stimulate their brain and modify their neuronal activity. One could argue that, for example, BCIs collecting brain data to recommend specific music with the intention of inducing states such as calmness, relaxation, increased happiness, or reduced stress are modulating the affective state and with it the neuronal activity of the users.[29] The scholarly literature has, however, rejected such an excessively broad understanding.[30] Instead, the wording alludes to the technical terminology employed in neurotechnology/neuroscience, distinguishing between BCIs solely monitoring or recording brain activity and those modulating neural activity.[31] Annex XVI MDR incorporates only the latter category.

Not within the scope of Annex XVI and effectively not within the scope of the MDR are therefore consumer BCIs for the sole purpose of storing or archiving neural data as well as BCIs that merely record or monitor neural data to prompt an external action, such as the movement of an external device or gadget. In fact, the currently available consumer neuro devices usually only monitor or record neural activity without modulating it. They only 'read' brain signals, but they do not 'write into' the brain. Consequently, the common consumer BCIs on today's consumer market fall outside the scope of Annex XVI MDR.

At the same time, it is important to note that as soon as consumer neurotechnology were to promote BCIs with the additional capability of not just monitoring/recording but also modulating neuronal activity, these devices would promptly fall within the scope of Annex XVI, provided that all necessary criteria are met cumulatively.

5. Common specifications add the small print

The Common Specifications (CS)[32] to Annex XVI MDR are legally defined in Article 2(71) MDR as a 'set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device, process or system'. The CS shall address the 'application of risk management as set out in Annex I for the group of products in question and, where necessary, clinical evaluation regarding safety.'[33] Article 9(4) MDR confirms that

[23] Charles E. Binkley, Michael S. Politz, and Brian P. Green, Who, If Not the FDA, Should Regulate Implantable Brain-Computer Interface Devices? *AMA Journal of Ethics* (2021) <https://journalofethics.ama-assn.org/article/who-if-not-fda-should-regulate-implantable-brain-computer-interface-devices/2021-09> (accessed 9 January 2024).

[24] Amazon Science, Cognixion gives voice to a user's thoughts <https://www.amazon.science/latest-news/cognixion-gives-voice-to-a-users-thoughts> (accessed 9 January 2024).

[25] See also Paul Quinn, The EU commission's risky choice for a non-risk based strategy on assessment of medical devices, *Computer Law & Security Review* 33 (2017) 361–370, https://doi.org/10.1016/j.clsr.2017.03.019.

[26] European Commission, Medical Devices: Guidance document. MEDDEV 2.1/6 (2016), 9 <https://ec.europa.eu/docsroom/documents/17921/attachments/1/translations> (accessed 6 January 2024).

[27] Hannah Maslen and others, The regulation of cognitive enhancement devices: extending the medical model, *Journal of Law and the Biosciences*, Volume 1, Issue 1, March 2014, Pages 68–93, at 82 <https://doi.org/10.1093/jlb/lst003>.

[28] For devices not listed in Annex XVI MDR, the definitional ambiguities described and their regulatory impact are still ongoing. See, for instance, Elisabeth Steindl, Safeguarding privacy and efficacy in e-mental health: policy options in the EU and Australia, *International Data Privacy Law*, 2023; ipad009, <https://doi.org/10.1093/idpl/ipad009>.

[29] See, for instance, Elisabeth Hildt, Affective Brain-Computer Music Interfaces—Drivers and Implications. *Front. Hum. Neurosci.*, 29 June 2021, Sec. Brain-Computer Interfaces Volume 15 – 2021, https://doi.org/10.3389/fnhum.2021.711407.

[30] See similar in Hannah Maslen and others, The regulation of cognitive enhancement devices: extending the medical model (2014), at 74.

[31] See e.g. Nam, Chang S. and Nijholt Anton and Lotte Fabien (ed), Brain–Computer Interfaces Handbook. Technological and Theoretical Advances (2018).

[32] Commission Implementing Regulation (EU) 2022/2346 OJ L 311/60. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32022R2346> (accessed 7 January 2023).

[33] Article 1(2) MDR.

'manufacturers of products listed in Annex XVI shall comply with the relevant CS for those products'.

The CS provide additional precision and specificity regarding the exact type of consumer BCI that the EU aims to integrate into medical devices legislation. The requirements for Annex XVI-BCIs are outlined in Article 1(1) CS in conjunction with Annex VII CS. Annex VII CS confirms that the CS apply to 'equipment intended for brain stimulation that apply electrical currents or magnetic or electromagnetic fields that penetrate the cranium to modify neuronal activity in the brain […]. Such equipment includes devices for transcranial alternating current stimulation, transcranial direct current stimulation, transcranial magnetic stimulation and transcranial random noise stimulation'.[34]

The BCIs currently available on the consumer market usually come as headbands, wristbands, helmets, or patches; they all apply transcranially (argumentum: 'electrical currents or magnetic or electromagnetic fields that penetrate the cranium' pursuant to Section 6 Annex XVI MDR). Previously, there had been scholarly debates on whether the requirement for Annex XVI-BCIs to function transcranially might create a normative loophole. This could occur when applications, such as those explored by companies like Neuralink and Synchron (designed to be introduced into the body and to apply intracranially), enter the consumer market.[35] The CS have unequivocally addressed this question, reiterating the transcranial aspect multiple times. The consistent emphasis on the required transcranial characteristic of the BCI serves as a clear indication that the exclusion of intracranial BCIs is intentional.

In addition, Annex VII CS specifies that the CS do not apply to invasive devices (ruling out once more intracranial applications).[36] Recital 6 CS affirms that 'invasive devices intended for brain stimulation, such as electrodes or sensors that are partially or totally introduced into the human body, should not be covered by this Regulation'. Invasive intracranial consumer BCIs are therefore irrefutably outside the scope of Annex XVI MDR.

Excluding invasive intracranial consumer BCIs from the scope of Annex XVI MDR aligns with the devices currently available on the consumer market. Devices that necessitate drilling a hole into one's skull (as in the case of Neuralink) or introducing an endovascular device into the brain *via* a blood vessel (as in the case of Synchron), not for an intended medical purpose but for enhancement, well-being, leisure, or convenience, are not considered standard market practices. As of now, BCIs with such characteristics are not available on the consumer market.

Should invasive intracranial BCIs without an intended medical purpose, however, become a reality in the consumer market in the future, the EU Commission would still have the option to adapt Annex XVI MDR accordingly. Article 1(5) MDR provides that the positive list in Annex XVI MDR can be amended 'in order to protect the health and safety of users or other persons or other aspects of public health'.[37]

In the CS, the EU legislators also delineate the specific risks they aim to address through the inclusion of particular consumer BCIs in the MDR. For instance, Annex VII CS anticipates possible different neural responses and thus unintended effects on vulnerable groups,[38] such as in particular on minors or young adults, or unforeseen neural effects by excessive, frequent and cumulative long-term use that might lead to structural changes in the brain.[39] Manufacturers are required to analyse, eliminate or at least reduce psychological risks,[40] neural and neurotoxicity risks,[41] cognitive side-effects,[42] auditory threshold shifts,[43] changes of the brain functioning,[44] long-term effects of repeated stimulation[45] and even atypical or other idiosyncratic effects.[46] Considering the devices here in question are products without an intended medical purpose, the inventory of potential risks and adverse outcomes is remarkably exhaustive and specific, focusing on severe health-related harms.

Further, the CS outline general safety and performance requirements for Annex XVI-products and require – where necessary – clinical evaluation regarding safety. Clinical evaluation is evidently an important element in the MDR. However, providing clinical evaluation in a medical sense is not a reasonable requirement for products without an intended medical purpose. Article 61(9) MDR clarifies that the requirement for products without an intended medical purpose 'shall be understood as a requirement to demonstrate the performance of the device. Clinical evaluations of those products shall be based on relevant data concerning safety, including data from post-market surveillance, PMCF, and, where applicable, specific clinical investigation. Clinical investigations shall be performed for those products unless reliance on existing clinical data from an analogous medical device is duly justified.'

With regard to consumer BCIs, Annex VII CS specifies that the 'intended performance shall be described in such a way that the consumer understands which non-medical effects can be expected from the use of the device (for example enhanced intelligence or improvement in mathematical ability)'.[47] This provision is remarkable, as it is likely the first instance ever that EU hard law verbatim addresses human enhancement.[48] Despite its seemingly random nature, this provision represents a significant step, officially incorporating the concept and purpose of enhancement into an actual piece of EU legislation. In addition, by including this provision, the EU underscores the before implicit assumption that enhancement is perceived as a distinct concept, separate from a medical purpose. By integrating 'enhanced intelligence or improvement of mathematical abilities' in Annex VII CS and giving it as an example for 'non-medical' effects, the EU confirms that, in fact, enhancement is not considered a medical purpose under EU medical devices legislation. The question surrounding a precise distinction between enhancement and medical purpose remains, however, unaddressed.

Once established that a consumer BCI falls within the scope of Annex XVI MDR, strict adherence to the requirements stipulated by the MDR becomes mandatory. The regulatory regime in the MDR follows a risk-based approach. The level of requirements increases with the risk class – the higher the risk class, the higher the requirements. Determining the correct risk class is therefore highly relevant. However, until lately, discerning the accurate risk class for Annex XVI-products (and the regime following thereof) has been a perplexing challenge in legal analysis.

[34] Section 1 Annex VII CS.
[35] Idem.
[36] Section 1 Annex VII CS.
[37] The 'similarity between a device with an intended medical purpose placed on the market and a product without an intended medical purpose in respect of their characteristics and risks' (Art 1 sec 5 MDR), which is a requirement for the amendment, is unlikely going to be an obstacle here since intracranial invasive BCIs are already used in the distinct medical field.
[38] Section 3.2.b Annex VII CS.
[39] Section 3.2.d Annex VII CS.
[40] Section 3.3.a Annex VII CS.
[41] Section 3.3.b Annex VII CS.
[42] Section 3.3.c Annex VII CS.
[43] Section 3.3.d Annex VII CS.
[44] Section 3.3.e Annex VII CS.
[45] Section 3.3.f Annex VII CS.
[46] Section 3.3.h Annex VII CS.
[47] Section 5 Annex VII CS.
[48] See also Sienna Project, D3.2: Analysis of the legal and human rights requirements for Human Enhancement Technologies in and outside the EU (2020), at 35. The Project itself developed a set of ethics guidelines addressing human enhancement in research and development, which has been included in the ethics review guidance for the Horizon Europe funding programme. See Yasemin J. Erden, Philip A. E. Brey, Ethics guidelines for human enhancement R&D. *Science* 378, 835-838 (2022). DOI:10.1126/science.add9079.

6. An amendment upgrades the risk class

In their Guidelines, the Medical Device Coordination Group 2021–2024 (MDCG)[49] states that 'Annex XVI products should be classified in accordance with the classification rules in Annex VIII of the MDR and taking into account possible provisions within the relevant implementing acts covering Annex XVI devices.'[50]

Alas, Annex VIII MDR is not exactly fit for purpose when it comes to the classification of products without an intended medical purpose. The section most suitable for BCIs is Rule 11 Annex VIII MDR. Rule 11 stipulates that software 'intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa' (or higher) and that software 'intended to monitor physiological processes' is classified as class IIa. The definition 'intended to provide information […] to take decisions with diagnosis or therapeutic purposes' is problematic for Annex XVI-BCIs as they do not have an intended medical purpose. If they were intended to provide information for diagnostic or therapeutic purposes, they would have an intended medical purpose and be considered a medical device. If they were intended to only 'monitor physiological processes' they would not be considered stimulating BCIs, which is a prerequisite for the qualification as Annex XVI-BCI.

Up until lately, the ultimate recourse has rested on the last sentence in Rule 11. As a catch-all element it provides that all 'other' software is classified as risk class I. Considering software not only in the context of Rule 11 but rather as an active device in general, as suggested by the MDCG,[51] comes to the same conclusion: Rule 13 stipulates that all 'other active' devices shall be classified as class I.

Risk class I is the lowest risk class in the MDR. It does not involve a notified body or any third-party conformity assessment, which are also relevant for classification under related acts.

By way of derogation from Annex VIII MDR, the EU Commission has adopted a new implementing regulation.[52] This implementing regulation brings much-needed clarity to the legal puzzle of determining the accurate risk class for Annex XVI-BCIs. It provides for an up-classification of Annex XVI-BCIs to risk class III according to Article 1 (c) of the Commission implementing regulation. The reasons given for up-grading Annex XVI-BCIs to the highest risk class available under the MDR are again severe health-related side effects, such as 'atypical brain development, abnormal patterns of brain activity, increase metabolic consumption, fatigue, anxiety, irritability, headaches, muscle twitches, tics, seizures, vertigo and skin irritation' as well as long-lasting effects and possible unintended effects difficult to reverse.[53]

7. The MDR follows a pro-active, yet system-compatible approach

Integrating non-medical BCIs in the MDR may initially have seemed contradictory to the overall systematics and objectives of medical devices legislation. However, the details in the two recently adopted amendments eloquently illustrate the intentions that the legislators are pursuing. The EU does not incorporate the entirety of consumer BCIs in medical devices legislation or a mere accidental selection of consumer BCIs. Instead, the EU selectively integrates only those consumer BCIs into medical devices legislation that currently present evident and severe health-related risks: transcranial consumer BCIs that not only monitor/record but also modulate neuronal activity, or in simpler terms non-invasive BCIs that do not only 'read' but also 'write into' the brain. The comprehensive array and the complexity of the potential harms that are addressed in the CS underlie a profound understanding of the current state of the art and the advancements in neurotechnology. The risks addressed align seamlessly with the primary purpose of the MDR. In light of future developments in the consumer neurotechnology market, the MDR allows for eventual adaptations in Annex XVI MDR.

The comprehensive analysis of Annex XVI MDR along with the relevant amendments shows that the EU has adopted a remarkably forward-thinking and well-calibrated policy approach. According to this approach, severe health-related risks associated with specific consumer BCIs are diligently regulated within the sector-specific product safety law for medical devices. At the same time, the EU abstains from hindering innovation by over-regulating aspects therein that can and should be regulated by other legal frameworks.

The technical criteria required by Annex XVI MDR admittedly exclude the major part of the currently available consumer BCIs. They typically only record or monitor neural data and eventually prompt an external action, such as eg initiating a specific music to relax. It is, however, important to understand that the nature of the risks associated with these consumer BCIs is not primarily health-related. Like in other well-being, life-style, consumer health or commercial applications, their predominant risks are related to privacy and data protection.[54] A system-compatible response to these challenges would be to address them through the framework for privacy and data protection and the available instruments therein.

8. The GPSR enhances the horizontal regulation

Consumer BCIs that are not within the scope of the MDR (or any other sector-specific product safety law) fall back to horizontal product safety legislation, currently the General Product Safety Directive (2001/95/EC) (hereinafter referred to as GPSD), to the extent that the products are intended or likely to be used by consumers.[55] The GPSD imposes general safety requirements on products considering the characteristics of the product, its effect on other products, the presentation of the product, and categories of consumers at risk when using the product.

The GPSD was originally proposed in 2000, but much has changed since then. The rise of concerns surrounding digital product safety, among other issues, led the EU to re-evaluate its overarching legal framework for general product safety. The EU opted for a comprehensive reform, adopting a new regulation that would supersede the outdated directive. As of 13 December 2024, the General Product Safety Regulation (EU) 2023/988 (hereinafter referred to as 'GPSR') will repeal and replace the GPSD along with the Food Imitating Product Directive

[49] The Medical Device Coordination Group 2021-2024 (MDCG) is a body established by Article 103 MDR. It is composed of representatives of all Member States and chaired by a representative of the European Commission.

[50] Medical Device Coordination Group 2021-2024, Guidance on classification of medical devices (2021), at 5. <https://health.ec.europa.eu/system/files/2021-10/mdcg_2021-24_en_0.pdf> (accessed 9 January 2024).

[51] See Medical Device Coordination Group 2021-2024, Guidance on classification of medical devices (2021), at 11.

[52] Commission Implementing Regulation (EU) 2022/2347 OJ L 311/94 <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex:32022R2347> (accessed 7 January 2024).

[53] Recital 7 of the Implementing Regulation (EU) 2022/2347 OJ L 311/94.

[54] See, for example, John Torous, Ariel D. Stern and Florence T. Bourgeois, Regulatory considerations to keep pace with innovation in digital health products, *npj Digital Medicine* (2022) 5:121, <https://doi.org/10.1038/s41746-022-00668-9>. Sara Gerke and Delaram Rezaeikhonakdar, Privacy aspects of direct-to-consumer artificial intelligence/machine learning health apps, *Intelligence-Based Medicine*, Volume 6 (2022) <https://doi.org/10.1016/j.ibmed.2022.100061>.

[55] See also Commission staff working document impact assessment on the revision of the regulatory framework for medical devices. Accompanying the documents Proposals for Regulations of the European Parliament and of the Council on medical devices, and amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and on in vitro diagnostic medical devices /* SWD/2012/0273 final */, section 1.1.2 <https://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex:52012SC0273> (accessed 9 January 2024).

(87/357/EEC). This regulatory shift is an important step in modernising the legal framework for product safety, aiming to address new technologies in the digital era. The transition from a directive to a regulation, which is directly applicable in all EU Member States, emphasises its importance in streamlining EU general product safety and enhancing consumer protection.

Remaining faithful to the core objectives of a piece of horizontal legislation, the GPSR is a safety net for all products not covered by other EU legislation and ensures protection against unsafe products. Pursuant to Article 1, the primary objective of the GPSR is to improve the functioning of the internal market while providing for a high level of consumer protection. Under the GPSR, a safe product is defined as 'any product which, under normal or reasonably foreseeable conditions of use, including the actual duration of use, does not present any risk or only the minimum risks compatible with the product's use, considered acceptable and consistent with a high level of protection of the health and safety of consumers'.[56]

As a piece of horizontal legislation, the GPSR does not specifically address safety or health-related risks associated with the use of BCIs. Nevertheless, legislators have introduced provisions in the mandatory general safety assessment for digital and smart products, which can be expected to positively influence the regulation of consumer BCIs once the GPSR becomes applicable.

The criteria for product safety assessment have been modernised and up-dated in the GPSR to more appropriately address the concerns associated with digital products. The comprehensive, though non-exhaustive, catalogue for assessing the safety of products in Article 6 GPSR now includes the following aspects:

- Characteristics of the product (design, construction, technical features, instructions, packaging), Article 6(1)(a) GPSR
- Interaction with other products, Article 6(1)(b, c) GPSR
- Product labelling, Article 6(1)(d) GPSR
- Consumer-specific aspects (e.g., affected consumer groups with a specific regard to vulnerable consumers, gender-specific differences in health and safety), Article 6(1)(e) GPSR
- Appearance of the product, if it is likely to encourage the consumer to use the product in a way other than intended (Article 6(1)(f) GPSR)
- Cybersecurity features (Article 6(1)(g) GPSR)
- Evolving, learning, and predictive functions of the product (Article 6 (1)(h) GPSR).

Several of the newly introduced assessment criteria, such as the requirement to consider interaction with other products and to take into account the device's evolving, learning, and predictive functions, will be relevant for consumer BCIs. Recital 23 GPSR elaborates further on aspects, which are specifically addressing digital products, including BCIs. The Recital points out that the 'assessment should take into account the health risk posed by digitally connected products, including the risk to mental health, especially of vulnerable consumers' and that the safety of a product should be assessed considering its entire lifespan.[57]

Notably, Article 6(1)(g) GPSR acknowledges the significance of cybersecurity, underscoring its essential role in product safety assessment. Article 6(1)(g) is further supported by Recital 25 GPSR, which highlights the risk of external intervention through hacking or alteration of a product's characteristics. As concerns about the hacking of BCIs and the risks of third parties reading, influencing, or altering people's thoughts (in the future) have been discussed in the context of BCIs, these considerations could have a significant impact. Similarly, Recital 26 GPSR stresses the need to ensure that relevant economic operators[58] and national authorities take into account specific cybersecurity risks associated with new technologies where applicable sectoral legislation may not apply. The reiterated emphasis on cybersecurity aspects in the GPSR underscores the commitment of EU legislators to substantially enhance digital product safety in these particular areas. The concerted efforts to improve general product safety legislation in the area of cybersecurity is highly relevant for consumer BCIs.

Complementing the risk assessment criteria above, Article 9 GPSR builds out the role of internal risk assessments. Accordingly, the manufacturer will be obliged, without exception, to conduct an internal risk analysis and create technical documentation for every product, containing at least a general description of the product and its essential characteristics relevant for the safety assessment.[59] The manufacturer must also retain the technical documentation for ten years.[60] There is no de minimis clause exempting less complex trivial products. Considering the product risks of emerging consumer BCIs, the manufacturer's obligations may thus become significantly more complex in the future.

Article 20 GPSR establishes obligations for economic operators in the event of accidents related to product safety. Primarily, it is the responsibility of the manufacturer to promptly report a product-related accident resulting in death or adverse health effects to the competent authorities of the Member State where the incident occurred, from the moment they become aware of it. The report has to be submitted through the so-called Safety Business Gateway (Article 20(1) GPSR). Importers and retailers, according to Article 20(3) GPSR, must report such incidents to the manufacturer, who must then fulfil their obligation under Article 20(1) GPSR. If there is no manufacturer established in the Union, the EU economic operator is responsible for making the report (Article 20(4) GPSR). These Safety Business Gateways are part of the EU legislators' effort to harmonise and enhance market surveillance and the recall of dangerous products.[61] This new regime will also enhance consumer protection concerning BCIs.

Article 2(5) GPSR provides that the so-called precautionary principle will have to be taken into account by all stakeholders. The precautionary principle was initially outlined in Article 191 of the Treaty on the Functioning of the European Union, seeking to elevate environmental protection by making preventative decisions in situations that involve risks. In February 2000, the EU Commission expanded on the concept of the precautionary principle in a communication, offering guidance on its practical implementation.[62] According to the Commission, the application of the precautionary principle requires 'the identification of potentially dangerous effects resulting from a phenomenon, product, or process, where scientific evaluation does not allow the risk to be determined with sufficient certainty'.[63] In the realm of product safety law, this principle entails halting the distribution or mandating the withdrawal from the market of certain products likely to be hazardous,

[56] Article 3(2) GPSR.
[57] Recital 23 GPSR.
[58] Under the GPSR, products from outside the EU will be only allowed to enter the EU market if there is an EU-based economic operator responsible for ensuring compliance with specific obligations outlined in the GPSR. As illustrated in the beginning, the market for neuro tech development is predominantly driven by companies outside the EU. Having information on a mandatory economic operator responsible in the EU will allow authorities to take easier corrective actions.
[59] Article 9(2)(1) GPSR.
[60] Article 9(3) GPSR.
[61] See, inter alia, Chapter VI and VII GPSR.
[62] EU Commission, Communication from the Commission on the precautionary principle (COM/2000/0001 final).
[63] Ibid, Summary, sec 4.

especially in cases where scientific data does not permit a comprehensive risk assessment. The burden of proof shifts from the consumer to the producer, manufacturer, or importer whenever action is taken under the precautionary principle. The producer, manufacturer, or importer then have to demonstrate the absence of danger.

Consumer BCIs could offer an ideal context for implementing the precautionary principle within the framework of general product safety law. Applied wisely and diligently, the precautionary principle could facilitate an appropriate level of safety and consumer protection linked to emerging consumer BCIs while concurrently fostering innovation. As all stakeholders are obligated to adhere to Article 2(5) GPSR, the precautionary principle could, for instance, encourage the adoption of industry-wide respected guidelines, limits, and best practices. The GPSR itself suggests employing soft law instruments as additional elements to be taken into account for assessing the safety of products (Article 8 GPSR). In the context of consumer BCIs, certification schemes or comparable third-party conformity assessment frameworks (Article 8(1)(d) GPSR) as well as product safety codes of good practice applicable in the relevant sector (Article 8(1)(h) GPSR) could offer practical means for manufacturers to address and demonstrate compliance with the precautionary principle. Linking soft regulatory tools with the precautionary principle required by the GPSR could ultimately encourage the development of a safe and sustainable market for consumer BCIs, enhancing the overall standard of product safety for consumer BCIs in the EU. Given the sensitivity of emerging neurotechnology, it would, however, be prudent to include an element of third-party assessment, as suggested by the GPSR in Article 8(1)(d).

Simultaneously, the precautionary principle allows for the prohibition of emerging BCIs in cases where science has not yet fully assessed and determined with sufficient certainty all potential risks associated with these new applications, carefully taking into account the potentially adverse effects, the scientific data available and the extent of scientific uncertainty. Any decision made under the precautionary principle is subject to review in light of new scientific data. Therefore, if new evidence allows for a re-evaluation of the risks involved, the decision can be revoked, and the application can be made available on the European market.

9. Conclusion

Rapid advancements in neurotechnology together with conspicuous investments by big tech players into neuro scientific research over the past few years have stirred a debate on whether our legal frameworks are prepared for the expansion of BCIs into the direct-to-consumer market. This paper focuses on recent legislative developments affecting the regulation of consumer BCIs within EU product safety law. The article examines recent clarifications by the EU Commission on the regulation of specific consumer BCIs within the systematics of the sector-specific product safety law for medical devices, the MDR. In addition, several regulatory enhancements in the newly adopted GPSR, the horizontal EU law for product safety, and their possible impact on the regulation of consumer BCIs are discussed.

The MDR regulates the product safety for all devices with an intended medical purpose in the EU. Additionally, Annex XVI MDR integrates a group of products without an intended medical purpose into the scope of the MDR, among them specific consumer BCIs. This departure from traditional approaches in medical devices legislation demonstrates the EU's progressive stance in regulating certain challenges posed by the evolving landscape of emerging neurotechnologies within medical devices legislation. In contrast to the purpose-based approach followed by the MDR in general, Annex XVI MDR does not consider the purpose of the device; instead, it only relates to the technical aspects of the BCI. Two recently adopted amendments have significantly clarified the exact scope and implications of Annex XVI MDR. Following Annex XVI MDR in conjunction with the common specifications, only modifying, non-invasive and transcranial consumer BCIs have to comply with the requirements of the MDR. Moreover, the EU up-classifies Annex XVI-BCIs to risk class III, which is the highest risk class available under the MDR classification scheme. In anticipation of future developments, such as the commercial exploitation of invasive BCIs on the consumer market, the MDR allows for amendments of Annex XVI.

The combined impact of both amendments shed light on the EU's comprehensive policy towards regulating specific consumer BCIs under medical devices legislation. Only those consumer BCIs that currently pose severe health-related risks are included in Annex XVI. Consumer BCIs primarily raising data protection and privacy concerns fall instead outside the scope of medical devices legislation. Annex XVI MDR together with the recent amendments show that the EU is actively pursuing a coherent and system-compatible policy approach, meticulously applying appropriate regulatory mechanisms to different types of consumer BCIs, based on their specific risks and implications. By determining so clearly which consumer BCIs should be subject to the MDR and its related norms and which consumer BCIs should remain outside its scope, the EU is applying a forward-thinking strategy. This strategy ensures an important equilibrium, allowing the EU to regulate the expanding field of consumer BCIs under medical devices legislation whenever necessary to safeguard specific health-related risks, while avoiding over-regulation where the nature of the risks is not primarily health- but privacy-related.

All BCIs falling outside sector-specific product safety law are subject to horizontal product safety legislation. With the adoption of the GPSR, the EU legislators are modernising general product safety law, aiming to make it fit for the digital age. As a general legislation, the GPSR does not address specific products or technologies. The GPSR does therefore not encompass any provisions specifically tailored to BCIs. Nevertheless, the modernisations will affect the standard of regulation for consumer BCIs. The GPSR includes an up-dated list of criteria for assessing product safety, with a specific focus on new technologies. The provisions stipulate enhanced cybersecurity requirements, introduce a lifespan approach, mandate accident reporting to authorities, enforce stricter rules for market surveillance, and provide detailed recommendations for managing product safety recalls. All these adaptations are expected to positively influence the regulation of consumer BCIs.

If applied thoughtfully and not merely paid lip service, the mandatory implementation of the precautionary principle in the GPSR, involving all stakeholders, holds the potential to serve as a beneficial regulatory tool for emerging consumer BCIs, striking a reasonable balance between regulation and innovation beyond the MDR. When coupled, for instance, with soft regulatory tools, it could foster a safe and sustainable market for consumer BCIs in the EU.

In response to the initial question of whether we are prepared for the expansion of neuro devices to the mass consumer market, particularly BCIs, driven by significant investments from big tech companies, the analysis indicates that EU legislators have been diligent in adapting and modernising the relevant EU legal frameworks within the context of EU product safety law. Their policy decisions reflect a remarkably well-informed and progressive approach, regulating imminent health- and safety-related risks while fostering innovation. Moreover, the framework allows for adaptations in light of emerging risks.

Undoubtedly, the new regulatory regimes in both legal pieces, the MDR and the GPSR, will encounter numerous challenges when tested in practice by emerging consumer BCIs, with enforcement being one of the most significant challenges. However, the comprehensive analysis of the pertinent legislation within the context of product safety in the EU could not substantiate a broad and general assertion that consumer BCIs lack regulation or are under-regulated.

Simultaneously, it is paramount to underscore that these findings do not diminish the potential risks to data protection and privacy associated with consumer BCIs; rather, they acknowledge their significance. Product safety legislation is, however, not the appropriate framework to address these risks. The EU has a fairly robust data protection and privacy framework in place. Any privacy-related shortcomings should be

carefully analysed and duly managed within this framework, leveraging existing tools whenever possible and exploring further appropriate options therein.

Declaration of competing interest

The author declares that she has no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

No data was used for the research described in the article.