Neurotech

For Responsible Development by Enterprise *Guide book* vol. 2

2024/11/21 vol.2.2

Preface

"Neurotech Guidebook vol. 2 – For Responsible Development by Enterprise –," has been compiled to support the responsible development of neurotech products [Note 1] by enterprises in Japan. It summarizes key considerations, such as relevant laws and regulations, guidelines, safety and efficacy verification, and consumer communication. The guidebook in Japanese consists of the main text that provides an overview, and an annex for explaining the handbook in detail (the annex is omitted with the English version). Serving as a follow-up to "Neurotech Guidebook vol.1 – Where is Neurotech Today?, " aimed at individuals interested in the field of neuroscience, this guidebook targets enterprises exploring the development, sale, or use of neurotech products for general consumers in Japan, as well as those involved in the formulation or management of related policies or regulations.

Neurotech products for general consumers find applications in various non-medical fields such as healthcare, welfare, marketing, entertainment, sports, workplaces, and education. Currently, they are governed by laws and regulations similar to those concerning product functionality and safety applicable to general home appliances and healthcare gadgets. However, given their ability to read information from the brain, the organ governing thoughts and personalities, and to intervene in brain activity, the authors recognize need for further consideration regarding the impacts and safety of neurotech products. Yet, there are currently no standards regarding the efficacy and safety of neurotech products developed to maintain and enhance health conditions or non-medical device electroencephalographs. The lack of proper efficacy and safety validation could lead to unforeseeable disadvantages for consumers, such as physical damage or personal information leakage. Conversely, overly stringent regulations not commensurate with products' risks may increase the time and economic costs required for product development, leading to delays in product launch and diminishing consumers' opportunities to use beneficial, low-risk products as well as in the advancement of neuroscience driven by new scientific knowledge gained from the use of these products.

In light of these considerations, the authors have compiled a list of items to consider for enterprises when developing and selling neurotech products responsibly. Priorities are placed on compliance with laws, regulations, guidelines, and consumer protection. The contents of this guidebook are based on scientific evidence and information known at the time of writing as well as laws, regulations, and guidelines of Japan. The authors hope that individuals involved in or considering involvement in developing or selling neurotech products for general consumers are equipped with a better understanding of these considerations. However, it is important to note that this guidebook is neither a substitute for set standards and regulations nor to grant certification to products. Instead, its purpose is to stimulate discussions on standards and certification concerning neurotech products for general consumers and promote the sound development of the neurotech sector.

July 2024

Neurotech Guidebook Development Committee

Note 1: The term "neurotech" is short for neurotechnology. In this book, we use the term "neurotech products" to refer to products, systems, and services developed through integrating knowledge and technologies of the fields of neuroscience and engineering. For a detailed definition of neurotech, please refer to the Neurotech Guidebook vol.1 (https://brains.link/en/braintech_guidebook, last accessed on June 18, 2024).

Preface

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The Neurotech Guidebook Development Committee mainly comprises members of the R&D project under Moonshot Goal 1 led by the Cabinet Office of Japan, The "Liberation from Biological Limitations via Physical, Cognitive and Perceptual Augmentation" (Project Manager: Ryota Kanai). This project aims to create new industries, businesses and a society where individuals can pursue diverse lifestyles beyond existing constraints. The Neurotech Guidebook Development Committee planned the production of this guidebook to contribute to the achievement of the project's goal by preparing guidebooks to support the responsible development and spread of neurotech products. Although three committee members listed below have conflicts of interest (COI) related to neurotech, the Committee determined that it would be beneficial to include individuals who have experience of neurotech commercialization as the authors of this guidebook, considering that neurotech is a nascent industry. Accordingly, the Neurotech Guidebook Development Committee conducted its activities conforming to the COI management policy described at the end of this guidebook.

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Disclaimer: Please Read Carefully.

The authors have endeavored to thoroughly verify the accuracy of the items and descriptions in this guidebook to ensure the appropriateness of its contents. Nevertheless, regulations concerning neurotech are still under discussion, and much remains unknown about the brain. Meanwhile, technologies for neurotech products and services are advancing rapidly. Therefore, readers of this guidebook are requested to understand that the guidebook contains some uncertain elements. If you find revisions or corrections to the guidebook necessary, please contact the Secretariat of the Neurotech Guidebook Development Committee. The Committee will consider your feedback for future revisions and activities. The Neurotech Guidebook Development Committee assumes no responsibility for any health hazards or legal issues arisen as a result of referring to this guidebook. Furthermore, neurotech aimed at diagnosing or treating diseases or for use by minors are out of the scope of this guidebook.

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CONTENTS — Main

CONTENTS

Annex

(Available only with Japanese version)

Chapter

Chapter 1 Overview of this Guidebook

This guidebook in Japanese consists of the main text that summarizes the overview and an annex that details the guidelines. The guidelines are classified into the following four categories comprising detailed items (listed in the annex).

- Category A: Compliance with Laws, Regulations, and Guidelines
- Category B: Assurance of Safety
- Category C: Assurance of Scientific Validity
- Category D: Consumer Support and Protection

The authors have set these categories to cover the following three points indispensable for the responsible development and sale of beneficial, low-risk neurotech products.

POINT 1 Explanation of considerations in developing and selling neurotech products

This guidebook systematically explains the items that neurotech product developers and sellers should consider when developing or selling responsible, low-risk neurotech products for general consumers (Figure 1). What items should be considered in appropriately validating the safety and efficacy of neurotech products during development? What precautions should be taken when selling neurotech products to consumers unfamiliar with these products while avoiding risks of misuse and misunderstanding? In this guidebook, the authors have compiled a list of considerations for enterprises developing and selling responsible neurotech products, with a focus on compliance with relevant laws, regulations, and guidelines, as well as on consumer protection.

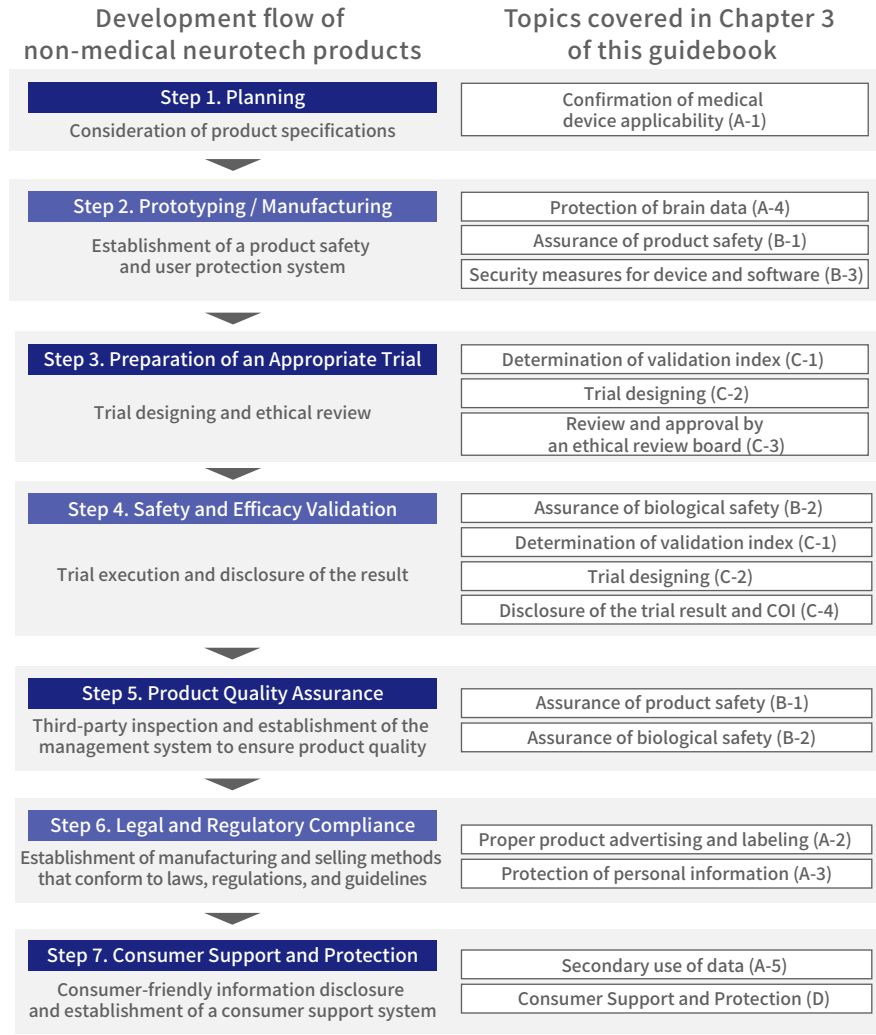


Figure 1. Correspondence between the development flow of neurotech products for general consumers and topics covered in Chapter 3 of this guidebook

POINT 2 Visualization of risks associated with neurotech product use

Risk is defined as "the combination of the probability of harmful event and the severity of the impact of the event[1]." In developing products, it is important for developers to conduct "risk analysis[2]." Risk analysis comprises "risk assessment" on the basis of scientific judgment, "risk management" with policy or business management measures to limit risks, and "risk communication" to accurately inform consumers of risks[2]. Based on currently-known scientific evidence and available information, the authors have visualized risks associated with the use of neurotech products for general consumers (Figure 2).

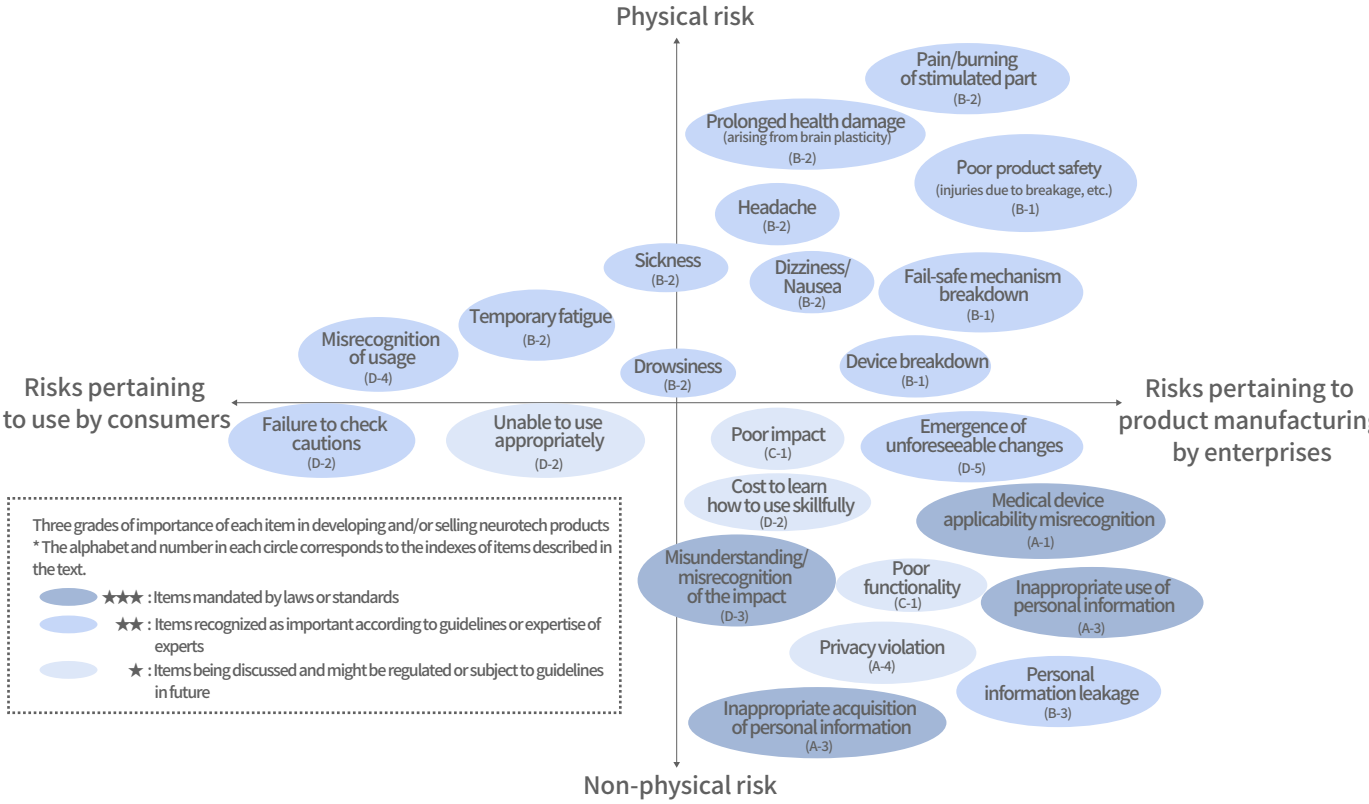


Figure 2. Overall picture of the risks associated with the use of neurotech products for general consumers
The horizontal axis represents the source of risks, either related to use by consumers or product manufacturing by enterprises, while the vertical axis represents the types of risks, whether physical or non-physical. The level of each risk is categorized into three grades. The alphabet and figure in each circle indicate the relevant item described in Chapter 3.

POINT 3 Learning about issues surrounding neurotech products with hypothetical cases

Understanding characteristics and issues surrounding neurotech products for general consumers can be challenging for many readers due to the limited number of products in the market. Accordingly, we have presented five hypothetical cases of the development and sale of neurotech products in Chapter 2, aiming to share the content and significance of Chapter 3, "Handbook for the Development and Sale of Neurotech Products," as well as the issues the authors consider important. We recommend readers to start exploring, before proceeding to Chapter 3, these hypothetical cases to understand the challenges in neurotech product development and sale.

Chapter 2 Challenges against the Development and Sale of Neurotech Products

This chapter presents five hypothetical cases of the development and sale of neurotech products for general consumers. As you read these cases, please consider whether there are any issues with the ways of claiming of products' effects and explaining how to use them, and, if any, think about how to modify them. By exploring these hypothetical cases, we hope readers can deepen understanding of challenges against the development and sale of neurotech products. Please note that particularly important items are highlighted as "Key Points," but they are only outstanding features of each case and all the points to consider are not covered.

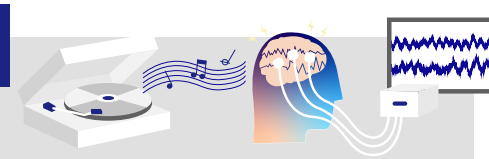
Hypothetical Case 1

EEG device to improve athletic performance with neurofeedback
- The importance of scientific evidence and methods of claiming effects -

Overview of the Hypothetical Case

An EEG device with five electrodes measures brainwaves, and when beta waves are predominant, music plays. Users train to control their brainwaves to keep dominant beta waves, checking it with music continuity. This training device product is claimed to improve the accuracy of physical movements and sports performance.

EEG-based Neurofeedback Device for Improving the Athletic Capacity



Product Overview

- Improve the sports performance with neurofeedback! POINT 1
- Guide the brain to the optimal state only by listening to the music! POINT 2

Expected Impact

- Become easier to start moving quickly at the timing of weak beta waves.
- Become able to modulate the beta wave level by the user's intention with neurofeedback training. POINT 3

Main Functions

1) Measure brainwaves with five electrodes.
2) Visualize the alpha wave with an app.
3) Self-modulate of the brain activity.
4) Record and manage training results.

How to Use/Warning

- Wear the device for 20 min. a day to do neurofeedback training.
- Stop using the device immediately when experienced any physical change.

Key Point 1. Clearly and specifically describe "What" effects can be expected with "What."

➡Check "A-2: Proper product advertising and labeling" and "D-3: Disclosure of expected impact information."

What is an "improvement in sports performance" specifically? It may be increased power, faster movements, reduced fatigue, or fine-tuned finger movements. Simply stating an "improvement in sports performance" may bring about excessive expectations or misunderstandings among consumers. Thus, it is important to describe specifically which and to what extent sports performance indicators are expected to change. From the perspective of the Act against Unjustifiable Premiums and Misleading Representations, product providers are required to be able to present a reasonable basis for such a representation at any time (Article 7, Paragraph 2 of the Act).

Key Point 2. If the product is intended to maintain or improve health condition, verify its safety and clearly and specifically describe risks and precautions for use (safety considerations).

➡Check "B: Assurance of Safety," "D-1: Disclosure of product property information," and "D-4: Disclosure of information to prevent unintended usage and misuse."

The expression "Guide the brain to the optimal state" sounds attractive, but what are the actual effects? Is there any problem with safety? For products manufactured to maintain or improve health, it is essential to clarify their specifications and usage methods from the perspective of securing safety. In addition to the safety test results, it is also important to provide detailed information on potential risks and unknowns to enable consumers to use products without concern.

Key Point 3: When claiming effects, verify them with scientific procedures, receive third-party evaluation, and disclose the results in an understandable manner.

➡Check "C: Assurance of Scientific Validity."

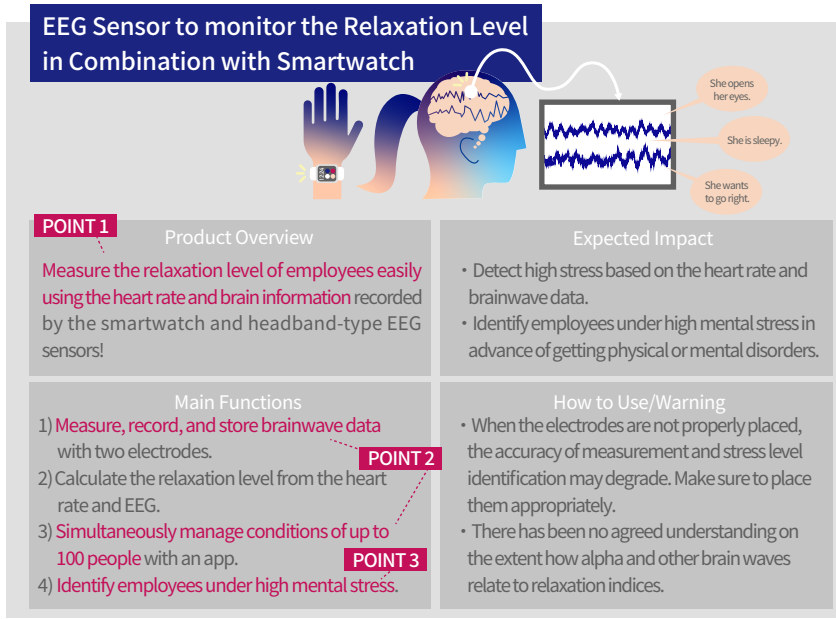
When claiming effects such as "improvement," "enhancement," or "become able to do XX," please make sure to verify these effects with scientific procedures. The results of verification should be disclosed after receiving third-party evaluation. Furthermore, product labeling should be in consistent with these results.

Hypothetical Case 2

EEG sensor to monitor relaxation level combined with a smartwatch
- The importance of personal information and privacy protection -

Overview of the Hypothetical Case

By measuring the heart rate with a smartwatch and brainwaves with headband-type EEG sensors, the product calculates the relaxation level of the user. The product claims to help monitor and manage employees' stress levels, contributing to improved mental health and productivity.



Key Point 1. Brain information may contain privacy-related information, such as medical history and risk of disease onset.

➡Check "A-4: Protection of brain data."

Neural signals including brainwaves can sometimes identify a history of psychiatric or neurological diseases, such as depression or epilepsy, and the risk of their onset. Therefore, if brain data is linked to personal information, there is a risk of revealing, against their will, the medical history or disorders of persons who shared their brain data. When medical history or disorders of product users might be identified based on recorded brain data, consider treating it as "sensitive personal information." Even if such a concern is absent, neurotech providers are recommended to obtain informed consent before measuring, recording, and using brain data.

Key Point 2. When making a third party manage and store brain data, refer to personal information management and leakage prevention measures.

➡Check "A-3: Protection of personal information" and "B-3: Security measures for device and software."

When developing systems or products that manage and store brain data, consider establishing a data management system referring to the safety management measures stipulated by the Act on the Protection of Personal Information. Information security is also crucial, especially if such a system connects to the internet.

Key Point 3. Casual identification of relaxation or stress level of others based on biometric information may violate privacy.

➡Check "A-4: Protection of brain data."

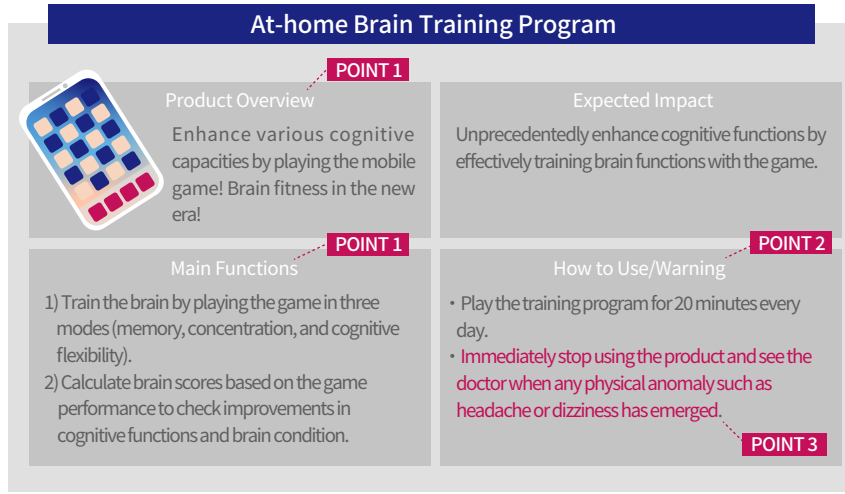
Identification of the relaxation or stress level of others using a neurotech product without their consent may violate privacy and personal rights. With such a product, it is essential to establish a privacy policy and a system to require the acquisition of the consent before start using the product from the person whose brain data will be monitored.

Hypothetical Case 3

Home-based brain training program
- The importance of safety assurance and consumer protection -

Overview of the Hypothetical Case

A mobile game program that claims to improve cognitive functions, such as memory and concentration. The product is advertised as a way of at-home brain training to enhance cognitive capacities.



Key Point 1. Refer to medical device standards when preparing product description.

➡Check "D-1: Disclosure of product property information."

Neurotech products for general consumers may be marketed as health enhancement devices. Even if the product is not intended to affect human physical functions or structure, there might be unknown risks associated with neurotech products due to their novelty. Therefore, even if the product does not qualify as a medical device, consider including detailed information in product packaging, etc. as indicated in "D-1: Disclosure of product property information."

Key Point 2. Clearly describe how to use and warnings using visual information, tutorials, etc. for easier understanding.

➡Check "D-2: Disclosure of appropriate usage information," and "D-4: Disclosure of information to prevent unintended usage and misuse."

Information on how to use the product should be presented in a way that can prevent general consumers' misunderstandings, visually demonstrating correct usage with illustrations, photos, etc. Video tutorials that help users learn proper usage based on visual information are also beneficial. Furthermore, it is important to clarify warnings against inappropriate usage and provide information on the risks that may arise from inappropriate usage.

Key Point 3. Add what to do and where to contact when experiencing physical discomfort.

➡Check "D-4: Disclosure of information to prevent unintended usage and misuse" and "D-5: Description of consumer protection information."

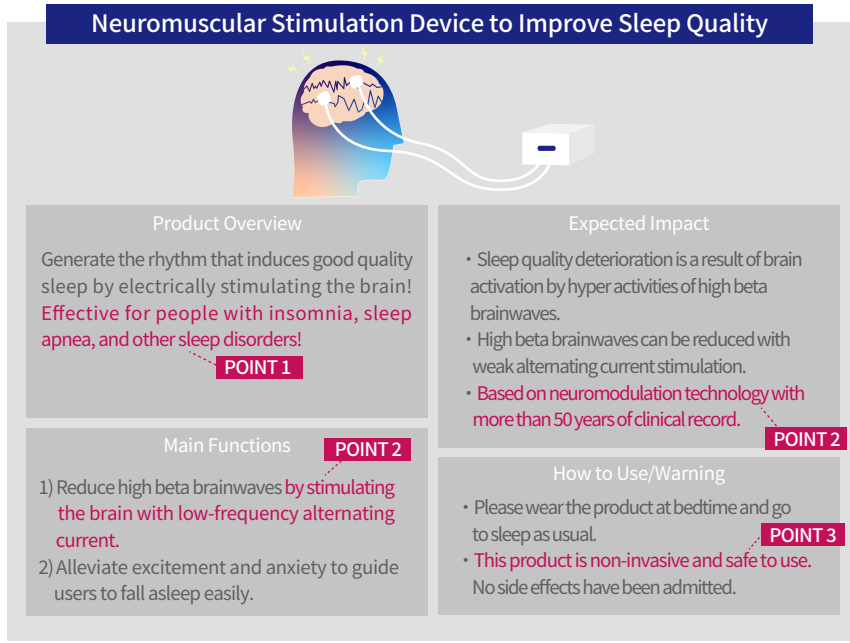
It is essential to provide information on what to do and where to contact when experiencing physical discomfort, the necessity to consult a medical institution, and external organizations to report the incident.

Hypothetical Case 4

Neuromuscular stimulation device to improve sleep quality
- The applicability of medical device standards and risks of brain stimulation -

Overview of the Hypothetical Case

A headband-type alternating current stimulation device that delivers mild electrical stimulation to the head during sleep, claiming to improve sleep quality and induce relaxation.



Key Point 1. Products intended for "diagnosis, treatment, or prevention of disease" may qualify as medical devices.

➡Check "A-1: Confirmation of medical device applicability."

Neurotech products may need to be developed as medical devices depending on their purposes of use or their effects. Consult the pharmaceutical affairs department of your prefecture[3] for the medical device applicability and the Software as a Medical Device (SaMD) centralized consultation desk or the Compliance and Narcotics Division, Pharmaceutical Bureau of the Ministry of Health, Labour and Welfare for SaMD applicability.

Key Point 2. Technologies that stimulate the brain with electricity or magnetism (neuromodulation) are not recommended for use by general consumers.

➡Check "A-1: Confirmation of medical device applicability" and "B-2: Assurance of biological safety."

Neuromodulation-based products, which directly apply physical or chemical stimulations to the brain or nerves, are considered to have higher risk potential than products using other types of neurotechnologies. Academic societies have cautioned against the casual use of neuromodulation-based products by general consumers[4]. When developing and marketing these products, consider the necessity of limiting the scope of users in light of product specifications and risks as well as consulting the pharmaceutical affairs department of your prefecture[3].

Key Point 3. Being non-invasive does not necessarily mean being safe.

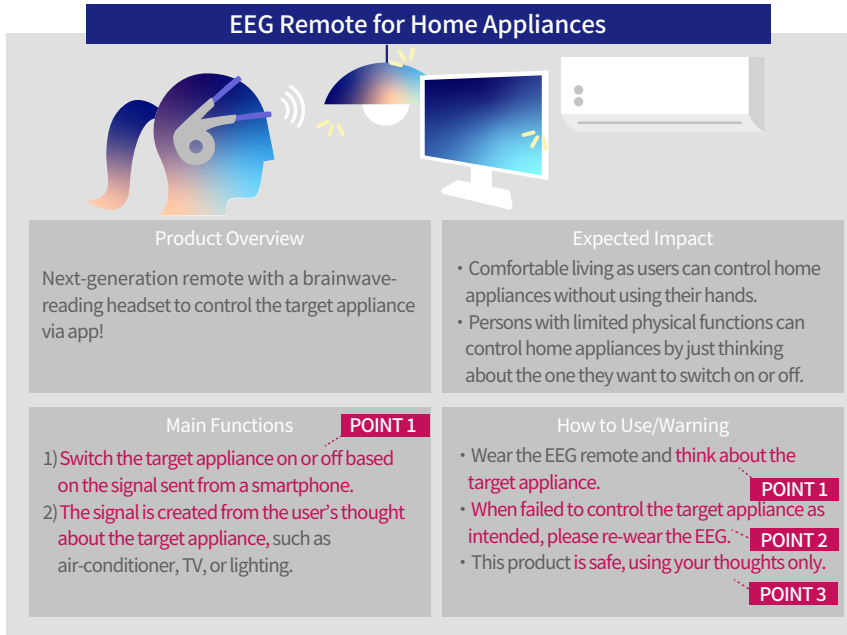
➡Check "B-1: Assurance of product safety" and "B-2: Assurance of biological safety."

Even if a product is non-invasive and scarcely damages the skin, it might still cause health problems due to its mechanism, principle, performance, or usage method. To protect consumers, it is recommended that the product be tested to verify its biological safety in addition to safety as a product and to disclose the results.

Hypothetical Case 5 EEG remote for home appliances - Characteristics of brainwaves, brain plasticity, and the challenges of measuring brain waves -

Overview of the Hypothetical Case

A headset with embedded EEG sensors that reads users' brainwaves to control home appliances. The product claims that users can control the target appliance telepathically by sending signals to it via a smartphone.



Key Point 1. Explain what can and cannot be done with the product specifically because it is difficult to decode intentions from brainwaves 100% accurately.

➡Check "D-3: Disclosure of the expected impact information."

Since highly accurate interpretation of thoughts from brainwaves is difficult, users might fail to control the target appliance in the way they intended. To prevent misuses and consumers from having excessive expectations or worries, it is important to clarify what can and cannot be done with the product, including the extent and safety of these functionalities.

Key Point 2. Establish a system to enable proper use of the product because brainwave measurement is not easy.

➡Check "D-2: Disclosure of appropriate usage information."

Brainwaves are biological signals easily contaminated by noise. If the measurement device is not properly worn or if the head moves slightly, the measured data might be contaminated by noise, resulting in inaccurate measurement. With products that measure brainwaves, it is particularly important to establish mechanisms to secure the correct usage of the product and to enable users to check whether their usage is correct or not.

Key Point 3. Many remain unknown with the safety of long-term use.

➡Check "B-2: Assurance of biological Safety" and "D-4: Disclosure of information to prevent unintended usage and misuse."

"Mind-control systems" that read brainwaves to control appliances, assistive devices, games, or avatars are not products to promote or maintain health conditions and might be recognized not to trigger physical function changes. However, we cannot rule out entirely the possibility that long-term use of such systems might generate physical impacts, because of the brain's plasticity, and resulting symptoms.
Such unknown risks are unavoidable when introducing new technologies. Therefore, it is recommended that neurotech developers and sellers be track the health of product users and review risks as necessary. It may also be beneficial to collect safety-related information and share, for efficient risk reviewing, adverse events, if any, with a consortium of neurotech product developers and sellers, for example.

Chapter 3 Handbook for the Development and Sale of Neurotech Products

Structure of the Handbook

Internationally, concerns have been pointed out with neurotech products for general consumers: "lack of rules and regulations," "inadequate verification of efficacy and safety," and "insufficient consumer protection," etc.[5] This guidebook addresses these concerns and outlines the items required to consider for developing and marketing beneficial, low-risk neurotech products and services for general consumers. These items are classified into the following four categories (Figure 3):

- Category A: Compliance with Laws, Regulations, and Guidelines
- Category B: Assurance of Safety
- Category C: Assurance of Scientific Validity
- Category D: Consumer Support and Protection

With each category, key important items are listed and explained in detail (Table 1). Each item is marked with one of three symbols (★★★, ★★, ★) according to the stringency of the set regulations or rules at present.

[Three grades of items according to the stringency of set rules and regulations]

★★★	Items mandated by law or standards
★★	Items recognized as important according to guidelines or expertise of experts
★	Items being discussed and might be regulated or subject to guidelines in future

Please note that some items may not apply depending on the intended effect or technical structure of the product to be developed. Additionally, explanations of some items might be insufficient or lack appropriate references due to spatial limitation. When developing or marketing a product, please refer to the original text of laws and guidelines cited. For products that require specific, unique handling, it is recommended to consult a lawyer or the relevant governmental offices. There are systems to support business activities in fields in which the scopes of current laws and regulations are vague, such as the Gray Zone Elimination System, Special Measures on Regulations on New Business Activities, and Regulatory Sandbox[6]. Some may be eligible for such systems.

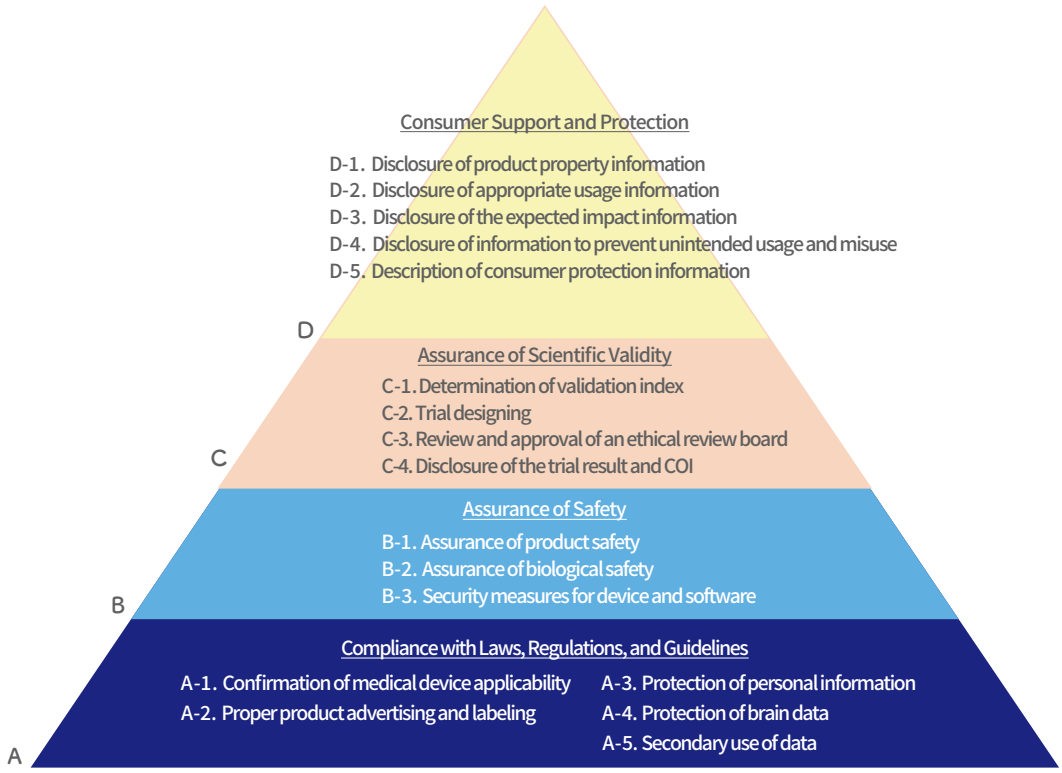


Figure 3. Structure of Chapter 3 "Handbook for the Development and Sale of Neurotech Products"

Table 1: List of Items in "Handbook for the Development and Sale of Neurotech Products"

A. Compliance with Laws, Regulations, and Guidelines	Stringency of Rules or Regulations
A-1. Confirmation of medical device applicability	
For neither "diagnosing, treating, nor preventing diseases"	★★★
For neither "affecting the physical structure nor functions"	★★★
Fall within the scopes of neither program medical devices nor medical device programs	★★★
Tips for the cases where the possibility of being classified as a medical device cannot be completely rejected	★★
Preparation for the possibility of being classified as a medical device in future	★
A-2. Proper product advertising and labeling	
Do not fall within the scope of exaggerated quality representations	★★★
Do not fall within the scope of exaggerated trade terms representations	★★★
Reasonable grounds for representations of the product efficacy or standards exist	★★
The grounds have been demonstrated by a generally accepted method/methods	★★
Tips for the cases where the possibility of violating the Act against Unjustifiable Premiums and Misleading Representations cannot be completely rejected	★★
A-3. Protection of personal information	
Confirmation of whether the information to be collected constitutes personal information	★★★
(When acquiring personal information) Proper acquisition	★★★
(When acquiring personal information) Specification, disclosure, and notification to the identifiable person of the purpose of use	★★★
(When altering the specified and disclosed purpose of use of personal information acquired) Disclosure of the truth and notification to the identifiable person	★★★
(When acquiring sensitive personal information) The identifiable person's consent on the acquisition	★★★
(When storing and managing personal information) Establishment of a system to manage the security of personal information	★★★
(When storing and managing personal information) Supervision of management of the security of personal information	★★★
(When storing and managing personal information) Handling of personal data leakages, etc.	★★★
(When storing and managing personal information) Handling of requests for personal information disclosure by the identifiable person	★★★
(When storing and managing personal information) Immediate and appropriate processing of complaints concerning personal information handling	★★★
A-4. Protection of brain data	
(When acquiring brain data) Proper acquisition by appropriate methods and establishment of terms of use	★★
(When acquiring brain data) Establishment of a mechanism to protect privacy	★
(When handling brain data) Consideration to eliminating chances of personal profiling and inappropriate data use	★
(When using brain data for profit) Specification of the purpose of use and introduction of the ban on inappropriate data use	★
A-5. Secondary use of data	
Use of the pseudonymized personal information	★
Use of the anonymized personal information	★
(When using the anonymized personal information) Proper anonymized personal information processing	★★★
(When using the anonymized personal information) Proper security management	★★★
(When using the anonymized personal information) Disclosure of preparation of anonymized personal information and its provision to third parties	★★★
(When using the anonymized personal information) Prohibition against identifying persons	★★★

Table 1: List of Items in "Handbook for the Development and Sale of Neurotech Products" (Cont.)

Category B. Assurance of Safety	Stringency of Rules or Regulations
B-1. Assurance of product safety	
Safe material choices and manufacturing conforming to public standards	★★
Confirmation with the Electrical Appliances and Materials Safety Act	★★
Check on the necessity of electrical safety testing	★★
Consideration of testing for electromagnetic interference (electromagnetic compatibility) as well as for electrical safety	★
Check on the necessity of acquisition of the technical regulations conformity certification under the Radio Act of Japan	★★
Risk assessment based on the risk management process and measures against identified risks	★
Assurance of safety over the entire product lifecycle	★★
Inspection of products on sale in stores and in stock	★★
B-2. Assurance of biological safety	
Understanding of risks associated with the use of neurotech products	★★
Safety validation referring to literature and similar cases and scientific procedure-based testing	★★
(With products for brain activity modulation or training) Establishment of a validation system with involvement by a doctor/doctors	★★
Guarantee of safety against misuses or abnormal uses and explanation of risks pertaining to them	★★
Explanation of the effect of long-term use	★
B-3. Security measures for device and software	
Understanding of information security threats with Internet of Things (IoT)	★★
Appointment of the person in charge of information security	★★
Introduction of measures to secure information security with IoT	★★
User awareness raising concerning information security	★★
Consideration of approaches to raising user awareness	★
Preventive measures against cyber-attacks: information gathering and analysis and external communication of the measures	★
Implementation of information security-related risk management processes	★

Table 1: List of Items in "Handbook for the Development and Sale of Neurotech Products" (Cont.)

Category C. Assurance of Scientific Validity	Stringency of Rules or Regulations
C-1. Determination of validation index	
(With products equipped with biological measurement function) Determination of validation indices for measurement-related performance	★★
(With products equipped with biological measurement function) Determination of validation indices for signal processing-related performance	★★
(When examining efficacy) Determination of appropriate indices for the claimed effect of the product	★★
C-2. Trial designing	
Determination of the trial design	★★
(When conducting a trial setting a control group) Control group setting	★★
(When conducting a randomized controlled trial (RCT)) Determination of the method of randomization	★
(When conducting an RCT) Trail planning based on the SPIRIT	★
(When conducting a neurofeedback trial) Planning, analysis, and reporting based on the CRED-nf	★
Determination of appropriate participant groups and the number of participants	★★
Bias reduction with blinding	★★
Confirmation of successful blinding	★
Measures for cases that are hard to blind	★
Determination of the statistical method to employ	★★
Appointment of the person in charge of the trial and understanding of its responsibility	★
Preparation of a trial plan document	★★
Advance publication of the trial procedure (preregistration)	★★
Advance briefing to participants and acquisition of free will-based consent from them	★★
C-3. Review and approval of an ethical review board of medical or research institution, etc.	
(When conducting a human trial) Implementation of validation trials conforming to the Declaration of Helsinki	★★
(When conducting a human trial) Implementation of validation trials conforming to the Ethical Guidelines for Medical and Health Research involving Human Subjects	★★
(When conducting a human trial) Review by an ethical review board of medical/research institution, etc.	★★
Disclosure of the result of the ethical review	★★
C-4. Disclosure of the trial result and conflict of interest (COI)	
Disclosure of the trial result and its method	★★
(When conducting an RCT) Reporting of the RCT result conforming to CONSORT	★
COI management and disclosure	★★

Table 1: List of Items in "Handbook for the Development and Sale of Neurotech Products" (Cont.)

Category D. Consumer Support and Protection	Stringency of Rules or Regulations
D-1. Disclosure of product property information	
The name and address of the product provider are described	★★★
Specification and characteristics of the product are clearly indicated	★★
The basic functionality is clearly indicated	★★
(For biological measurement-based products) Information on measurement and signal processing performance is clearly indicated	★
The period and scope of the warranty and how to get a repair or an exchange are described	★★
The product safety policy is described	★★
D-2. Disclosure of appropriate usage information	
How to use the product is described in an easy-to-understand manner	★★
Movies and tutorials on how to use the product are available	★
Programs to check if the usage of the product is appropriate and to correct it, when necessary, are provided to users	★
D-3. Disclosure of the expected impact information	
Do not include terms indicating that the product is a medical device	★★★
Do not include false or exaggerated statements in the advertisement	★★★
The expected impact is specifically described	★
The methods and results of functionality and impact testing are disclosed	★★
The impact is described by comparing those of other products or widely used approaches	★
Individual differences in the impact of the product use have been examined and the results of the examination are disclosed	★
D-4. Disclosure of information to prevent unintended usage and misuse	
Precautions for the use of the product are described	★★
Warnings for hazardous handling are presented using graphics, symbols, etc.	★★
Precautions and risks specific to neurotech products are described	★★
Information on potential hazards resulting from inappropriate usage is described	★★★
The explanation that brain data to be obtained using the product is limited is described	★
The product is equipped with some fail-safe mechanism to prevent foreseeable misuse events	★
Action to take if users experience physical discomfort while using the product is described	★★
Information on where to seek public consultation is described	★★
Information on product safety and foreseeable misuses is updated as per actual circumstances	★
D-5. Description of consumer protection information	
A system to accept inquiries from users, such as the establishment of a contact desk, is established	★★★
The process and structure to address any changes in users' health conditions is established	★★★
The process and structure to communicate with stakeholder departments and managers immediately after detection of an abnormal event is established	★★★
The process and structure to address any incident emerged conforming to the steps stipulated by the government is established	★★★

Column 1: International Trends in the Regulation and Ethical Standards of Neurotech

In recent years, discussions on regulations and ethical standards concerning neurotechnology have become increasingly active, especially in Europe and the United States. Most of these discussions concern soft law, a broad concept that includes guidelines established voluntarily by private stakeholders, as well as legal interpretations presented by governments[7].

Although these soft laws are not legal regulations, understanding global trends in rule-making related to the field of neurotechnology, especially those concerning product development and sale, is crucial for enhancing the international credibility and industrial competitiveness of neurotech products made in Japan.

International trends in guideline formulation for the field of neurotechnology

[Recommendations concerning the development of neurotechnology]

Example 1: The OECD (Organisation for Economic Co-operation and Development) Note2 adopted the "OECD Recommendation on Responsible Innovation in Neurotechnology" on December 11, 2019[8]. This recommendation presents nine principles to maximize the benefits for both businesses and consumers while minimizing various risks arising at each stage (research, technology transfer, investment, commercialization, introduction of regulations, etc.) of developing products using neurotechnology (See P.18 for details). Furthermore, the recommendation emphasizes the importance of the following three concepts to achieve responsible innovations:

- **Future-oriented approach**
  Stakeholders should engage in product development not by following the conventional regulations but by utilizing advanced governance methods (e.g., testbeds, regulatory sandbox, new technology assessment methods, foresight strategies) to construct governance for achieving responsible innovations with stakeholder engagement.
- **Inclusiveness**
  To achieve responsible innovation, it is essential to eliminate technological disparities and inequalities in accessibility so as to involve diverse stakeholders and citizens in the innovation process.
- **Goal orientation**
  Stakeholders should aim to achieve responsible innovations that can satisfy research, commercial, and societal needs through formulating goal-oriented policies, coordinating relevant institutions, and facilitating citizen's engagement.

[Recommendations concerning the applicability as medical devices]

Example 2: The UK Regulatory Horizons Council (RHC) Note 3 released the "Neurotechnology Regulation" on November 30, 2022[9]. This report proposed 14 recommendations for regulating and governing neurotechnology in future and organized and presented the current circumstances surrounding the field of neurotechnology and relevant regulations. The following recommendations are proposed among others:

- **Recommendation 7:**
  All brain modulation devices (invasive and non-invasive) should be regulated under the medical devices framework, irrespective of the purpose for which they are marketed, as proposed by the Medicines and Healthcare products Regulator Agency (MHRA) Note 4. This recommendation should also extend to devices that modulate all neural tissue, and not just the brain.
- **Recommendation 8:**
  Non-invasive devices that only record neural information (i.e., neurorecording wearables) for non-medical purposes should not be regulated by the MHRA but should be compliant with general consumer protection, security, product safety, privacy and sectoral regulations, according to their use cases.

Note 2: Founded in 1961, OECD is an international organization pursuing improvements in international policies and economic growth. Its membership comprises 38 nations at present. Aiming to contribute to the world economy by coordinating policies among member nations and facilitating their economic growth, OECD performs research and analyses concerning economic, social, and environmental issues, among others, and provides information beneficial to policy formulation.

Note 3: An independent expert committee established in the U.K. in 2019, providing the Government with neutral, expert advice on regulatory reforms that aim to support rapid, safe introductions of technological innovations by identifying impacts of these innovations. RHC mainly engages in preparation of reports on regulations for promoting innovations and policies related to new technologies.

Note 4: Agency under the Department of Health and Social Care of the U.K. responsible for approving and securing safety of drugs and medical devices. Established in 2003, MHRA engages in auditing adverse effects of drugs and medical device incidents, licensing the marketing of drugs and medical devices, and preparing clinical trial standards, etc.

[Recommendations on neurorights]

Example 3: The Council of Europe issued a report titled "Common Human Rights Challenges Raised by Different Applications of Neurotechnologies in the Biomedical Fields[10]" in October 2021. The report suggests that the fundamental rights and freedoms related to the human brain and mind should be regarded as the essential foundation of all other rights and freedoms.

Example 4: In October 2022, the United Nations Human Rights Council adopted a resolution on "Neurotechnology and Human Rights[11]." The resolution proposes several key points, including "Bearing in mind that neurotechnology allows the connecting of the human brain directly to digital networks through devices and procedures that may be used, among other things, to access, monitor and manipulate the neural system of the person," "Recognizing that neurotechnology could be promising for human health and innovation, but that, at the same time, the continued development of some of its applications may pose a number of ethical, legal and societal questions that need to be addressed, including in human rights terms," and "Mindful that the impact, opportunities and challenges of neurotechnology with regard to the promotion, protection and enjoyment of human rights are not fully understood, and of the need to analyse them further in a coherent, holistic, inclusive and comprehensive manner in order to leverage the full potential of neurotechnology to support human progress and development for all."

Example 5: UNESCO (United Nations Educational, Scientific and Cultural Organization) held its first international conference on the development of an ethical framework for the field of neurotechnology on July 13, 2023, to announce its report titled "Unveiling the Neurotechnology Landscape: Scientific Advancements, Innovations and Major Trends[12]." In the report, UNESCO highlighted the need for evidence that supports policy-making and advocated for ethical governance to ensure that the development and deployment of neurotechnology should be advanced with respect to human rights, fundamental freedoms, and human dignity in order to protect individuals and society. The International Bioethics Committee (IBC), an advisory committee comprising experts of UNESCO, emphasized that "neurorights" encompass certain human rights already admitted in national and international laws and human rights documents.

Understanding the OECD Recommendation on Responsible Innovation in Neurotechnology

The "OECD Recommendation on Responsible Innovation in Neurotechnology" was adopted by the OECD Council on December 11, 2019, as the first international recommendation in the field of neurotechnology. It aims at facilitating support for governments and innovators and is considered an important international norm. This guidebook has been prepared, covering the contents of the recommendation (Figure 4).

Concerns related to human rights such as human dignity, freedom, privacy, identity, and social justice are inherent in the field of neurotechnology. For example, there are risks associated with neurotechnology, including the collection, analysis, leakage, or misuse of individuals' brain data and manipulation, coercion, or alteration of individuals' will or emotions. Moreover, neurotechnology may generate novel inequalities or discrimination or expand them among individuals or groups.

To address these risks, the OECD Working Party on Biotechnology, Nanotechnology, and Converging Technologies (BNCT) has promoted a project focused on establishing principles for responsible innovation in the field of neurotechnology. The "OECD Recommendation on Responsible Innovation in Neurotechnology" comprises outcomes of the BNCT's project, specifically a series of principles and proposals for addressing and foreseeing the ethical, legal, and social challenges associated with development, dissemination, and management of neurotechnology.

Correspondence between the 2019 OECD Recommendation and the items in this guidebook

	A. Compliance with Laws, Regulations, and Guidelines	B. Assurance of Safety	C. Assurance of Scientific Validity	D. Consumer Support and Protection
1) Promote responsible innovation in neurotechnology to address health challenges.	A-3. Protection of personal information A-4. Protection of brain data		C-1. Determination of validation index C-2. Trial designing C-3. Review and approval of an ethical review board	D-5. Description of consumer protection information
2) Prioritise assessing safety in the development and use of neurotechnology.	A-1. Confirmation of medical device applicability	B-1. Assurance of product safety B-2. Assurance of biological safety B-3. Security measures for device and software	C-1. Determination of validation index C-2. Trial designing C-3. Review and approval of an ethical review board C-4. Disclosure of the trial result and COI	D-5. Description of consumer protection information
3) Promote the inclusivity of neurotechnology for health.	A-3. Protection of personal information A-4. Protection of brain data A-5. Secondary use of data			D-2. Disclosure of appropriate usage information D-3. Disclosure of the expected impact information D-4. Disclosure of information to prevent unintended usage and misuse
4) Foster scientific collaboration in neurotechnology innovation across countries, sectors, and disciplines.	A-5. Secondary use of data		C-2. Trial designing C-4. Disclosure of the trial result and COI	
5) Enable societal deliberation on neurotechnology.			C-4. Disclosure of the trial result and COI	D-3. Disclosure of the expected impact information D-4. Disclosure of information to prevent unintended usage and misuse
6) Enable the capacity of oversight and advisory bodies to address novel issues in neurotechnology.	A-1. Confirmation of medical device applicability A-2. Proper product advertising and labeling A-3. Protection of personal information A-4. Protection of brain data	B-1. Assurance of product safety	C-1. Determination of validation index C-3. Review and approval of an ethical review board	
7) Safeguard personal brain data and other information gained through neurotechnology.	A-3. Protection of personal information A-4. Protection of brain data A-5. Secondary use of data	B-3. Security measures for device and software		
8) Promote cultures of stewardship and trust in neurotechnology across the public and private sector.	All items of Chapter 3			
9) Anticipate and monitor the potential unintended use and/or misuse of neurotechnology.	A-2. Proper product advertising and labeling			D-4. Disclosure of information to prevent unintended usage and misuse D-5. Description of consumer protection information

Figure 4. Relation between the OECD Recommendation on Responsible Innovation in Neurotechnology (from 1) to 9))and items described in this guidebook (from A to D)

Column 2 : The Concept of Cognitive Liberty

Cognitive liberty is positioned as one of the neurorights. Neurorights are defined as "principles of ethical, legal, social, or natural freedoms and rights related to the human brain and mind, that is, basic normative rules for protecting and preserving the human brain and mind[13]."Cognitive liberty is the core of neurorights. While cognitive liberty has multiple definitions, the Center for Cognitive Liberty & Ethics defines it as "the right of each individual to think independently and autonomously, to use the full spectrum of his or her mind, and to engage in multiple modes of thought[14,15]." According to Nita Farahany, the author of "The Battle for Your Brain: Defending the Right to Think Freely in the Age of Neurotechnology," cognitive liberty consists of three main components: mental privacy, freedom of thought, and the right to self-determination over brain and mental experience[16]. Additionally, cognitive liberty is considered to include the following two rights[17]:

- The right to freely use neuroscience-based technologies
- The right not to be coerced by impacts of neuroscience-based technologies

Cognitive liberty is not merely a political assertion; some see cognitive liberty as a prerequisite for all legal concepts related to individuals, that is, "an implicit premise of any legal order based on individual self-determination[18]." This is because self-determination regarding one's own cognition is essential for free will and any kind of free action. However, it is also pointed out that "cognitive liberty, like other freedoms, is not absolute and must consider the balance with other social interests[19]." Cognitive liberty is a subject still being discussed to the present.

Consideration of cognitive liberty in handling brain information

To protect the personal brain data and other information obtained using neurotechnology, stakeholders should take the following actions[8]:

- Provide clear information to the general public and research participants regarding the collection, storage, processing, and potential use of personal brain data collected for health purposes.
- Secure systems to obtain consent from persons who are to provide their personal information by adequately ensuring individual autonomy protection, including consideration for special cases with persons who are to provide their personal information with limited decision-making capacity.
- Facilitate opportunities for individuals to choose how their data is used and shared, including access to, modification, and deletion of their personal data.
- Introduce and manage policies to protect personal brain information from being used to discriminate against or improperly exclude specific individuals or groups, particularly in commercial, legal, employment, or insurance contexts.
- Prevent unauthorized use of information obtained using neurotechnology by signing data access agreements, for example, as per necessity.
- Reinforce confidentiality and privacy measures, and limit security breaches by introducing strict security standards, etc.
- Secure traceability not only of the data collected and processed but also of the medical practices using neurotechnology.

Positive freedom in cognitive liberty: Fair access to brain function enhancement

Discussion concerning cognitive liberty encompasses not only the negative freedom to refuse interference with individuals' consciousness or thoughts but also the positive freedom to enable broader individuals who wish to enhance their brain functions using neurotechnology to access it. Accessibility by persons who want to use neurotech products to these products is also considered to be protected as cognitive liberty.

Ethical and autonomy considerations in the use of advanced technologies

The integration of neurotechnology and AI in recent years is creating more advanced technologies. Overseas project examples include a smart at-home care system comprising equipment to measure brain activities or other biological data, communication technologies, and AI to monitor the user's physiological conditions or daily habits, and based on such data, care and medical services required are to be delivered to the users. However, such a system raises concerns about excessive technological intervention in human consciousness and behavior. It is particularly important to consider transparency, privacy and data protection, fairness and bias elimination, and respect for autonomy[20]. At present, it is important to limit the use of advanced technologies such as those using neurotechnology and AI in combination to auxiliary functions, for example, support for users' decision-making.

Column 3 : Development of Neurotech Products and Medical and Clinical Research

When advancing the development of neurotech products for general consumers, developers are deemed responsible for determining carefully whether tests they will conduct are within the scope of medical and clinical research or not and whether medical and clinical research is required for the product being developed.

The Neurotech Guidebook Development Committee believes that some neurotech products for general consumers, depending on their purpose and effects of their use, should be developed and tested following the "Ethical Guidelines for Medical and Health Research involving Human Subjects[21]." These guidelines define medical research as "activities involving human subjects to be carried out for the purpose of obtaining knowledge contributing to maintain and promote people's good health and improve quality of life." Additionally, explanatory material for the "Ethical Guidelines for Medical and Health Research involving Human Subjects [Note 5]" provide examples of medical research, including "research in the fields of medical science, clinical medicine, public health, preventive medicine, dentistry, pharmacy, nursing, rehabilitation, laboratory medicine, and medical engineering, as well as epidemiological and qualitative research using information related to individual health in the fields of caregiving, welfare, food hygiene, nutrition, environmental hygiene, and occupational health and safety, and research using AI in these fields." Even when testing neurotech products for general consumers that are intended neither to maintain or promote health nor improve quality of life, the Neurotech Guidebook Development Committee recommends that developers refer to these ethical guidelines. This is because medical research planning and implementation methods are equipped with the participant protection mechanism.

However, it is important to note that clinical research is out of the scope of this guidebook. Clinical research (trials) is defined under the Clinical Trials Act as "research to clarify the efficacy or safety of pharmaceuticals [Note 6] by the use of such pharmaceuticals in humans[22]." However, the neurotech products for general consumers within the scope of this guidebook are not intended for the prevention, diagnosis, or treatment of diseases, or for understanding the pathology of diseases or injuries. Therefore, their development and testing are not considered to fall under the scope of clinical research in principle. Under the Clinical Trials Act, however, human trials to be conducted to clarify efficacy that goes beyond maintaining or improving health conditions may be considered clinical trials using unapproved medical devices.

Note 5: In the explanatory materials for the "Ethical Guidelines for Medical and Health Research involving Human Subjects" provided by the Ministry of Health, Labour and Welfare (dated April 17, 2023), "research in fields such as medical science, clinical medicine, public health, preventive medicine, dentistry, pharmacy, nursing, rehabilitation, laboratory medicine, medical engineering, as well as epidemiological and qualitative research using information related to individual health in the fields of caregiving, welfare, food hygiene, nutrition, environmental hygiene, and occupational health and safety, and research using AI in these fields" are listed as medical research examples.

Note 6: The term "pharmaceuticals" refers to "pharmaceuticals (excluding in-vitro diagnostics), medical devices, and regenerative medicine products."

Chapter 5

Neurotech Guidebook vol. 2 Development Process

Under the R&D project for the Moonshot Goal 1 of the Moonshot Research & Development Program, titled "Liberation from Biological Limitations via Physical, Cognitive and Perceptual Augmentation" (Project Manager: Ryota Kanai, Representative Organization: Advanced Telecommunications Research Institute International), the BMI Usage Guidelines Development Committee was established in July 2021 to formulate "BMI Usage Guidelines[23]." In September 2022, the Project Team published the "Neurotech Guidebook vol.1," summarizing the current state of neurotech products for general consumers. In July 2023, the Team released the "Neurotech Evidence Book," compiling the results of a literature review on the efficacy and safety of neurotechnology.

Through the process of preparing these documents, the Team recognized that the dissemination of "reliable neurotech products for general consumers" that are beneficial to users and with limited risks requires norms and rules that providers of these products can refer to in developing and selling these products responsibly. Based on this recognition, the Team started drafting "Neurotech Guidebook vol.2" to consolidate key items to consider in developing and selling neurotech products. We first researched regulations and ethical standards in the field of neurotechnology, being progressively developed worldwide in recent years (Column 1: International Trends in the Regulations and Ethical Standards of Neurotech). Referring especially to the "OECD Recommendation on Responsible Innovation in Neurotechnology[8]," we prepared this guidebook by relating international recommendations to Japan's laws, standards, and norms. The drafting was led by the Neurotech Guidebook Development Committee members, and the contents have been modified in light of feedback from two lawyers who contributed to securing consistency among the contents of this guidebook and Japan's laws. Following the completion of drafting, the Team exchanged opinions with enterprises involved in neurotech product development and sale to identify the guidebook's usefulness and relevance in practical applications and accordingly updated the draft contents. Additionally, we had the draft contents reviewed, seeking their advice, by the Ministry of Health, Labour and Welfare and the Consumer Affairs Agency, both of which are likely to be involved in rule-making for the field of neurotechnology, as well as the Center for Research and Development Strategy (CRDS) of the Japan Science and Technology Agency, participating in the OECD Neurotechnology Governance Project. Following third-party evaluations by the External Evaluation Committee members, public comments were solicited on the draft. We again modified the draft referring to the comments submitted by the public. With the cooperation of many experts and enterprise representatives, this guidebook has been finalized as it is. The Neurotech Guidebook Development Committee will continuously update the contents of the guidebook as necessary, taking into account further progress in relevant research and discussions.

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Chapter 6

COI Management and Disclosure

The term "Conflict of Interest (COI)" refers to situations where the social responsibility of professionals engaged in education and research may conflict with interests arising from industry-academia collaborations. COI can be broadly categorized into economic COI, which involves financial relationship with a specific company or organization or the acquisition of research funding, and academic COI, which pertains to non-economic COI related to scholarly activities or expertise. In preparing this guidebook, the Neurotech Guidebook Development Committee recognized the potential influence of not only the COIs of individuals involved in the preparation process but also the COIs of the institutions, such as universities and academic societies, to which the committee members belong. Therefore, in accordance with the "Minds Manual for Guideline Development 2020 ver. 3.0[24]," the Committee established a COI management method and published COI guidelines in advance of the preparation of the Neurotech Guidebook vol.2. Specifically, the Committee obligated all members, secretariat, and the External Evaluation Committee members to disclose the presence or absence of COIs by declaring economic and academic COIs of the three years preceding their appointment. Additionally, they are required to report annually COIs of the previous year that exceed the set criteria, if any. If the Committee found an error with the self-declaration submitted by members, they are obligated to promptly correct their declaration and notify the secretariat.

Based on the COI declarations submitted by the members, the Committee verified the presence of any conflicts of interest. If a conflict was identified, we assessed the need for a management plan. The criteria for declaring economic and academic COIs are published on our website[23]. Furthermore, the details of the declarations are made public simultaneously with the release of the guidebook. Through these efforts, we strive to ensure that the contents of the guidebook remain neutral and appropriate, thereby fostering trust for the use of neurotechnology within society. Should you have any comments regarding the contents of this book or COI management, please contact the secretariat for the Neurotech Guidebook Development Committee. Your feedback will be referred to as valuable input in future revisions and activities.

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