WORLD TRADE ORGANIZATION

G/TBT/N/JPN/795

26 January 2024

(24-0567)

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1.	**Notifying Member:** JAPAN **If applicable, name of local government involved (Article 3.2 and 7.2):**
2.	**Agency responsible:** Ministry of Health, Labour and Welfare **Name and address (including telephone and fax numbers, email and website addresses, if available) of agency or authority designated to handle comments regarding the notification shall be indicated if different from above:**
3.	**Notified under Article 2.9.2 [X], 2.10.1 [ ], 5.6.2 [ ], 5.7.1 [ ], 3.2 [ ], 7.2 [ ], other:**
4.	**Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Nucleic acid, etc. (HS:30)
5.	**Title, number of pages and language(s) of the notified document:** Partial Amendment of the Act on the Safety of Regenerative Medicine; (1 page(s), in English)
6.	**Description of content:** Under the current Act on the Safety of Regenerative Medicine, when entrusting the manufacturing of processed cells used in regenerative medicine to a business which manufactures them in a foreign country, it is limited to a business which has obtained accreditation by the Minister of Health, Labour and Welfare prescribed in the Act. Gene therapy, etc. which does not use processed cells (medical care which uses nucleic acid, etc.) will be added to the scope of the Act, due to the partial amendment of the Act. Therefore, when entrusting the manufacturing of nucleic acid, etc. used for such medical care to a business which manufactures them in a foreign country, it is limited to a business which has obtained accreditation by the Minister of Health, Labour and Welfare prescribed in the Act as well as processed cells used in regenerative medicine.
7.	**Objective and rationale, including the nature of urgent problems where applicable:** The object of the partial amendment of the Act on the Safety of Regenerative Medicine is to establish a foundation for the research and the safe provision of cutting-edge medical technologies such as gene therapy, etc. and to promote them further.; Protection of human health or safety
8.	**Relevant documents:** This amendment will be published in "*KAMPO*" (Official Gazette) when adopted.

9.	**Proposed date of adoption:** The day specified by Cabinet Order (within a period of one year from the day of promulgation). **Proposed date of entry into force:** The day specified by Cabinet Order (within a period of one year from the day of promulgation).
10.	**Final date for comments:** 30 days from notification
11.	**Texts available from: National enquiry point [ ] or address, telephone and fax numbers and email and website addresses, if available, of other body:** Japan Enquiry Point International Trade Division, Economic Affairs Bureau, Ministry of Foreign Affairs Fax: (+81 3) 5501 8343 E-mail: enquiry@mofa.go.jp https://members.wto.org/crnattachments/2024/TBT/JPN/24_00715_00_e.pdf