NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| **1.** | **Notifying Member:** Republic of Korea  **If applicable, name of local government involved (Article 3.2 and 7.2):** |
| **2.** | **Agency responsible:** Ministry of Food and Drug Safety  **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:**  International Cooperation Office Ministry of Food and Drug Safety 187 Osongsaengmyeong2-ro, Osong-eup, Heungdeok-gu Cheongju-si, Chungcheongbuk-do, 28159 Republic of Korea  Tel: (+82) 43 719-1564 Fax: (+82) 43-719-1550 Email: [intmfds@korea.kr](mailto:intmfds@korea.kr) Website: [www.mfds.go.kr](http://www.mfds.go.kr) |
| **3.** | **Notified under Article 2.9.2 [****],** **2.10.1 [****],** **5.6.2 [****X],** **5.7.1 [****],** **other****:** |
| **4.** | **Products covered (HS or CCCN where applicable, otherwise national tariff heading. ICS numbers may be provided in addition, where applicable):** Biological Products; Other (HS 300190); Other (HS 300490) |
| **5.** | **Title, number of pages and language(s) of the notified document:** Enforcement decree of the Act on advanced regenerative medicine and advanced biological products regarding safety and support (71 page(s), in Korean) |
| **6.** | **Description of content:**  - As the "Act on Safety and Support of Advanced Regenerative Medicine and Advanced Biological Products" is established, "Enforcement Decree of the Act on Safety and Support of Advanced Regenerative Medicine and Advanced Biological Products" is enacted to prescribe the matters delegated by the Act and those necessary for its implementation.  - Article 31: to prescribe facility standards required for the notification of importing business of advanced biological products.  - Article 32: to prescribe  facilities, equipment, human resources, and quality management system required for the approval of human cell management business, etc.  - Article 34-36: 1) to stipulate that long-term follow-up investigations may be conducted on certain advanced biological products containing stem cell treatments, animal tissue and cells, gene therapy products and other advanced biological products that need to be monitored for adverse events over a specific period after administration. 2) to prescribe matters related to the designation as a subject of such investigations, the withdrawal of the designation, etc. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** Protection of human health or safety |
| **8.** | **Relevant documents:**   * MOHW Public Notification No. 2020-0299 (21 April 2020) * G/TBT/N/KOR/891 |
| **9.** | **Proposed date of adoption:** To be determined  **Proposed date of entry into force:** To be determined |
| **10.** | **Final date for comments:** 60 days from notification |
| **11.** | **Texts available from: National enquiry point [****X]** **or address, telephone and fax numbers and email and website addresses, if available, of other body:**  Technical Barriers to Trade (TBT) Division Korean Agency for Technology and Standards (KATS) 93, Isu-ro, Maengdong-myeon, Eumseong-gun, Chungcheongbuk-do,  Republic of Korea, 369-811 Tel.: (+82) 43 870 5525  Fax: (+82) 43 870 5682 E-mail: [tbt@korea.kr](mailto:tbt@korea.kr)  Website: <http://www.knowtbt.kr>  <https://members.wto.org/crnattachments/2020/TBT/KOR/20_3285_00_x.pdf> |