



25 June 2024

(24-4674)

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Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

1. Notifying Member: <u>REPUBLIC OF KOREA</u> 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: Documents are available from the Ministry of Food and Drug Safety website (www.mfds.go.kr). Also available from: International Cooperation Office Ministry of Food and Drug Safety 187 Osongsaengmyeong2-ro, Osong-eup, Heungdoek-gu Cheongju-si, Chungcheongbuk-do, 28159 Republic of Korea Tel: (+82) 43 719-1564 Fax: (+82) 43-719-1550 Email: intmfds@korea.kr
3. Notified under Article 2.9.2 [X], 2.10.1 [], 5.6.2 [X], 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): In Vitro Diagnostic Medical Devices
5. Title, number of pages and language(s) of the notified document: Proposed partial amendments to the "Regulation on In Vitro Diagnostic Medical Device Group and Class by Group";; (7 page(s), in Korean)
6. Description of content: The proposed amendments to the Regulation on In Vitro Diagnostic Medical Device Group and Class by Group is as follows: - Establishment of 6 new items (IVD reagents for concentrating hematopoietic cell, etc.)
7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety
8. Relevant documents: MFDS NOTIFICATION No. 2024-304, 24 June 2024
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 [] or address, telephone and fax numbers and email and website addresses, if available, of other body:

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