



25 June 2024

(24-4673)

Page: 1/2

Committee on Technical Barriers to Trade

Original: English

NOTIFICATION

The following notification is being circulated in accordance with Article 10.6

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| 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 Approval/Report/Review, etc.";; (23 page(s), in Korean) |
| 6. Description of content: The proposed amendments to the "Regulation on In Vitro Diagnostic Medical Device Approval/Report/Review, etc." are as follows: A. Allow occasional reporting of minor matters of in vitro diagnostic medical devices and extend the quarterly reporting period. B. After changing in vitro diagnostic medical devices, it was not possible to manufacture (import) the existing devices, but if the change was not due to side effects, manufacture (import) of the existing devices is allowed for six (6) months. |
| 7. Objective and rationale, including the nature of urgent problems where applicable: Protection of human health or safety |

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| 8. Relevant documents: MFDS NOTIFICATION No. 2024-306, 25 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: 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@kats.go.kr Website: http://www.knowtbt.kr https://members.wto.org/crnattachments/2024/TBT/KOR/24_03944_00_x.pdf |