



4 September 2015

(15-4525)

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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

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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 (http://www.mfds.go.kr) Also available from: International Cooperation Office Ministry of Food and Drug Safety 187 Osongsaengmyeong2-ro, Osong-eup Heungdoek-guCheongju-si Chungcheongbuk-do, 363-700 Republic of Korea Tel: (+82) 43719-1564 Fax: (+82) 43-719-1550 Email: wtokfda@korea.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 |
| 5. Title, number of pages and language(s) of the notified document: Proposed amendments to the "Regulation of Review and Authorization on Biological Products, etc." (14 pages, in Korean) |
| 6. Description of content: <ul style="list-style-type: none">• Expand the definition of biobetters to include biological products with changes in the active ingredient content or dosage/administration• Delete the exemption clause for recombinant protein products for export, which would invalidate its submission of GMP records with at least one manufacturing unit when evaluating GMP (they would be subject to submitting records with at least three manufacturing units)• Require stem-cell products to be subject to long-term safety evaluation to enhance active monitoring of adverse events and strengthen post-marketing safety management |
| 7. Objective and rationale, including the nature of urgent problems where applicable: Protection of consumer health |
| 8. Relevant documents: MFDS Notification No. 2015-284 (28 August 2015) |

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| 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: WTO 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 |