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:** Documents are available from the Ministry Food and Drug Safety (MFDS) website ([www.mfds.go.kr](http://www.mfds.go.kr)). Also available from:International Cooperation OfficeMinistry of Food and Drug Safety187 Osongsaengmyeong2-ro, Osong-eup, Heungdeok-gu, Chengju-si, Chungcheongbuk-do, 28159 Republic of KoreaTel: (+82) 43 719-1564Fax: (+82) 43 719-1550Email: wtokfda@korea.kr |
| **3.** | **Notified under Article 2.9.2 [****X],** **2.10.1 [ ],** **5.6.2 [ ],** **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):** Quasi‑drugs |
| **5.** | **Title, number of pages and language(s) of the notified document:** Proposed amendment to the "Regulation on Quasi-drug Approval, Notification and Review" (46 page(s), in Korean) |
| **6.** | **Description of content:** All mosquito and tick repellents and other related insect repellents shall be subject to a safety and efficacy review, including the ones previously exempted\*, thus increasing the number of products subject to the safety and efficacy review and required documents for registration, to better align the country's regulation with the international standards.\*Products have the same type of active ingredients, specifications, ingredient quantity (level of concentration for liquid products), formulation, indications and usage, dosage and administration as the products that have already been approved and registered. |
| **7.** | **Objective and rationale, including the nature of urgent problems where applicable:** For balanced review of 'quasi-drug products' approval, notification and examination and strengthened safety management |
| **8.** | **Relevant documents:** * MFDS NOTIFICATION No. 2019-82 (14 February 2019)
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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 date of 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) DivisionKorean Agency for Technology and Standards (KATS) 93, Isu-ro, Maengdong-myeon, Eumseong-gun, Chungcheongbuk-do, 27737 Republic of KoreaTel.: (+82) 43 870 5525 Fax: (+82) 43 870 5682E-mail: tbt@kats.go.kr website: <http://www.knowtbt.kr><https://members.wto.org/crnattachments/2019/TBT/KOR/19_1545_00_x.pdf> |