

5 April 2019

(19-2181)

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Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

- 1. Notifying Member: UNITED STATES OF AMERICA
 - If applicable, name of local government involved:
- 2. Agency responsible: Food and Drug Administration
- **3.** Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers should be provided in addition, where applicable): HS Code(s): 2201; ICS Code(s): 67
- 4. Regions or countries likely to be affected, to the extent relevant or practicable:
 - [X] All trading partners
 - [] Specific regions or countries:
- 5. Title of the notified document: Beverages: Bottled Water, Proposed Rule. Language(s): English. Number of pages: 5

https://www.govinfo.gov/content/pkg/FR-2019-04-03/pdf/2019-06201.pdf https://members.wto.org/crnattachments/2019/SPS/USA/19 1970 00 e.pdf

- 6. **Description of content:** The Food and Drug Administration (FDA) is proposing to revise the quality standard for bottled water to specify that bottled water to which fluoride is added by the manufacturer may not contain fluoride in excess of 0.7 milligrams per liter (mg/L). This action, if finalized, will revise the current allowable levels for fluoride in domestically packaged and imported bottled water to which fluoride is added. We are taking this action to make the quality standard regulation for fluoride added to bottled water consistent with the recommendation by the US Public Health Service (PHS) for community water systems that add fluoride for the prevention of dental caries. This action, if finalized, will not affect the allowable levels for fluoride in bottled water to which fluoride is not added by the manufacturer (such bottled water may contain fluoride from its source water).
- 7. Objective and rationale: [X] food safety, [] animal health, [] plant protection, [] protect humans from animal/plant pest or disease, [] protect territory from other damage from pests.
- 8. Is there a relevant international standard? If so, identify the standard:
 - [] Codex Alimentarius Commission (e.g. title or serial number of Codex standard or related text):
 - [] World Organization for Animal Health (OIE) (*e.g. Terrestrial or Aquatic Animal Health Code, chapter number*):
 - [] International Plant Protection Convention (e.g. ISPM number):
 - [X] None

Does this proposed regulation conform to the relevant international standard?

- 2 -

[]Yes []No

If no, describe, whenever possible, how and why it deviates from the international standard:

- 9. Other relevant documents and language(s) in which these are available:
- **10. Proposed date of adoption (***dd/mm/yy***):** To be determined.

Proposed date of publication (dd/mm/yy): To be determined.

- 11. Proposed date of entry into force: [] Six months from date of publication, and/or (*dd/mm/yy*): To be determined.
 - [] Trade facilitating measure
- 12. Final date for comments: [] Sixty days from the date of circulation of the notification and/or (*dd/mm/yy*): 1 June 2019

Agency or authority designated to handle comments: [] National Notification Authority, [] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

Yinqing Ma, Center for Food Safety and Applied Nutrition (HFS-317), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, +(1 240) 402 2479

13. Text(s) available from: [] National Notification Authority, [] National Enquiry Point. Address, fax number and e-mail address (if available) of other body:

Text can be found in the Federal Register, Vol. 84, No. 64, page 12975 or on the internet at: <u>https://www.govinfo.gov/content/pkg/FR-2019-04-03/pdf/2019-06201.pdf</u>