



25 April 2022

(22-3236)

Page: 1/2

Committee on Sanitary and Phytosanitary Measures

Original: English

## NOTIFICATION

### *Addendum*

The following communication, received on 21 April 2022, is being circulated at the request of the Delegation of the United States of America.

#### Beverages: Bottled Water, Final Rule

The Food and Drug Administration (FDA or we) is revising 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), which available data suggests provides an optimal balance between the prevention of dental caries and the risk of dental fluorosis. This final rule revises the current allowable levels, which range from 0.8 to 1.7 mg/L, 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 2015 recommendation by the US Public Health Service (PHS) for community water systems that add fluoride for the prevention of dental caries. This action 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).

This rule is effective 21 June 2022. The compliance date is 17 October 2022.

<https://www.govinfo.gov/content/pkg/FR-2022-04-20/pdf/2022-08273.pdf>  
[https://members.wto.org/crnattachments/2022/SPS/USA/22\\_2974\\_00\\_e.pdf](https://members.wto.org/crnattachments/2022/SPS/USA/22_2974_00_e.pdf)

#### **This addendum concerns a:**

- Modification of final date for comments
- Notification of adoption, publication or entry into force of regulation
- Modification of content and/or scope of previously notified draft regulation
- Withdrawal of proposed regulation
- Change in proposed date of adoption, publication or date of entry into force
- Other:

**Comment period: (If the addendum extends the scope of the previously notified measure in terms of products and/or potentially affected Members, a new deadline for receipt of comments should be provided, normally of at least 60 calendar days. Under other circumstances, such as extension of originally announced final date for comments, the comment period provided in the addendum may vary.)**

- Sixty days from the date of circulation of the addendum to the notification and/or (dd/mm/yy): Not applicable

**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:**

For access to the docket to read background documents or comments received, go to <https://www.regulations.gov> and insert the docket number found in brackets in the heading of this final rule into the "Search" box and follow the prompts, and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, +(240) 402 7500.

FOR FURTHER INFORMATION CONTACT: David Whitman, Center for Food Safety and Applied Nutrition (HFS-820), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, +(240) 402 3754, [David.Whitman@fda.hhs.gov](mailto:David.Whitman@fda.hhs.gov); or Deirdre Jurand, Center for Food Safety and Applied Nutrition, Office of Regulations and Policy (HFS-024), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, +(240) 402 2378.

**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. 87, No. 76, page 23434 or on the internet at: <https://www.govinfo.gov/content/pkg/FR-2022-04-20/pdf/2022-08273.pdf>.

---