

WORLD TRADE ORGANIZATION

G/SPS/N/USA/410

4 April 2001

(01-1697)

Committee on Sanitary and Phytosanitary Measures

Original: English

NOTIFICATION

1.	Member to Agreement notifying: <u>UNITED STATES</u> If applicable, name of local government involved:
2.	Agency responsible: Food and Drug Administration - FDA
3.	Products covered (provide tariff item number(s) as specified in national schedules deposited with the WTO; ICS numbers may be provided in addition, where applicable). Regions or countries likely to be affected, to the extent relevant or practicable: Bottled water
4.	Title and number of pages of the notified document: Beverages: Bottled Water (Direct Final Rule); and Beverages: Bottled Water; Companion Document to Direct Final Rule (Proposed Rule). (11 and 10 pages respectively)
5.	Description of content: The Food and Drug Administration (FDA) is amending its bottled water quality standard regulations by establishing allowable levels for three residual disinfectants (chloramine, chlorine, and chlorine dioxide) and three types of disinfection by-products (DBP's) (bromate, chlorite, and haloacetic acids (HAA5)). FDA also is revising the existing allowable level for the DBP total trihalomethanes (TTHM). Finally, FDA is revising, for the three residual disinfectants and four types of DBP's only, the monitoring requirement for source water found in the current good manufacturing practice (CGMP) regulations for bottled water. As a consequence of FDA's amending the quality standard for these residual disinfectants and DBP's, bottled water manufacturers are required to monitor their finished bottled water products for these disinfectants and DBP's at least once each year under the CGMP regulations for bottled water. Bottled water manufacturers also are required to monitor for these contaminants at least once each year in their source water, unless the bottlers meet the criteria for source water monitoring exemptions under the CGMP regulations. This direct final rule will ensure that the minimum quality of bottled water, as affected by the previously mentioned disinfectants and DBP's, remains comparable with the quality of public drinking water that meets the Environmental Protection Agency's (EPA's) standards. FDA is issuing a direct final rule for this action because the agency expects that there will be no significant adverse comment on this rule. Elsewhere in this issue of the Federal Register, FDA is publishing a companion proposed rule under the agency's usual procedure for notice-and-comment rulemaking to provide a procedural framework to finalize the rule in the event the agency receives significant adverse comment and withdraws this direct final rule. The companion proposed rule and direct final rule are substantively identical.
6.	Objective and rationale: <input checked="" type="checkbox"/> food safety, <input type="checkbox"/> animal health, <input type="checkbox"/> plant protection, <input type="checkbox"/> protect humans from animal/plant pest or disease, <input type="checkbox"/> protect territory from other damage from pests

7.	An international standard, guideline or recommendation does not exist [X]. If an international standard, guideline or recommendation exists, give the appropriate reference and briefly identify deviations:
8.	Relevant documents and language(s) in which these are available: 66 FR 16858, 28 March 2001 (Available in English)
9.	Proposed date of adoption: This rule is effective 1 January 2002.
10.	Proposed date of entry into force: This rule is effective 1 January 2002.
11.	<p>Final date for comments: Submit written comments by 11 June 2001. If FDA receives no significant adverse comments during the specified comment period, the agency will publish a document in the Federal Register no later than 5 July 2001, confirming the effective date of the direct final rule. If the agency receives any significant adverse comment during the comment period, FDA intends to withdraw this direct final rule by publication in the Federal Register no later than 5 July 2001.</p> <p>Agency or authority designated to handle comments: Food and Drug Administration [] National notification authority, [] National enquiry point, or address, fax number and E-mail address (if available) of other body: The full text, including directions for submitting objections, will be sent upon request to the address in paragraph 12.</p>
12.	<p>Texts available from: [X] National notification authority, [X] National enquiry point or address, fax number and E-mail address (if available) of other body:</p> <p>United States SPS Enquiry Point/Notification Authority USDA/FAS/FSTSD ATTN: Carolyn F. Wilson Room 5545 South Agriculture Building Stop 1027 1400 Independence Avenue, S.W. Washington, D.C. 20250 Tel: (202) 720-2239 Fax: (202) 690-0677 E-mail: ofsts@fas.usda.gov</p>