

ENVIRONMENTAL ASSESSMENT

Bottled Water Quality Standard

1. DESCRIPTION OF THE PROPOSED ACTION:

The Food and Drug Administration (FDA) is proposing to amend the quality standard for bottled water to require that bottled water be free of coliform bacteria.

Under Section 410 of the Federal Food, Drug, and Cosmetic Act (the act; 21 U.S.C. 349), whenever the EPA prescribes interim or revised national primary drinking water regulations under section 1412 of Title XIV of the Public Health Service Act (The Safe Drinking Water Act), FDA is required to consult with EPA and within 180 days after promulgation of such drinking water regulations "either promulgate amendments to regulations under this chapter applicable to bottled drinking water or publish in the Federal register ... reasons for not making such amendments." The purpose of the proposed action is to fulfill FDA's obligation under section 410 of the act and to maintain the quality standard for bottled water that is compatible with EPA's drinking water standards.

In the June 29, 1989, *Federal Register* notice (54 FR 27544), EPA published a final rule promulgating National Primary Drinking Water Regulations to establish a maximum contaminant level goal (MCLG) of zero and to revise the maximum contaminant level (MCL) for coliform bacteria in drinking water. The new rule based compliance with the MCL on a maximum allowable number or percentage of samples that test positive for coliform bacteria. The new rule specified the use of any of four analytical methods for the determination of total coliform bacteria: the Membrane Filter technique, the Multiple Tube Fermentation technique, the Presence/Absence Coliform test, and the Minimal Media *ortho*-nitrophenyl- β -D-galactopyranoside, 4-methylumbelliferyl- β -D-glucuronide technique (Minimal Media ONPG-MUG test) also known as the Autoanalysis Colilert System.

In addition, whenever heterotrophic bacteria interference is indicated for a total coliform test, the system must invalidate that sample (unless total coliforms are detected) and collect another sample for analysis for total coliforms using an analytical method that is less sensitive to interference by high levels of heterotrophic bacteria (e.g., the Minimal Media ONPG-MUG test).

FDA's current good manufacturing practice regulations (21 CFR Part 129), require that source waters for bottling be of a safe, sanitary quality (§ 129.35(a)(1)). Therefore, when bottlers encounter coliforms in bottled water, FDA considers it reasonable and appropriate that bottlers test source water for the presence of coliforms. If coliforms are present, the bottlers must treat source waters to remove coliforms. FDA is

proposing in § 103.35(b)(1) to provide that coliform bacteria not be present in bottled water. FDA is adopting 100 ml as the sample volume to be analyzed. The four tests specified by EPA will also be specified by FDA in the proposed quality standard for coliform bacteria in bottled water. Similar to EPA's action, FDA is proposing in § 103.35(b)(1) to invalidate a test result from any analytical unit (unless total coliforms are detected) that indicates evidence of interference because of the presence of heterotrophic bacteria. The agency is proposing that, if possible, another sample from the same lot should be analyzed for compliance purposes using media less susceptible to interference from heterotrophic bacteria (i.e., the Minimal Media ONPG-MUG test).

2. ENVIRONMENTAL CONSEQUENCES OF THE PROPOSED ACTION:

a. Background information

- (1) Information provided by the International Bottled Water Association (IBWA) sets the current market for bottled water at about two billion gallons (1). The IBWA estimates that source water for bottled water is approximately 40% municipal water, with the remaining 60% from spring or private well water (2). The spring and well water sources are considered ground water sources.
- (2) According to IBWA, most of the bottled water industry uses ozonation as the method of disinfection, although a small percentage of companies use ultraviolet (UV) irradiation (2).

b. Environmental consequences:

According to information provided by the IBWA, companies already comply with the proposed standard for coliform bacteria. Coliform counts in bottled water are zero, hence no action or treatment will be necessary for companies to comply with the proposed standard. This information is consistent with data from the FDA FY 90 Bottled Water Survey, which reported Most Probable Numbers (MPN) of well below 2.2 for coliform bacteria in all samples of bottled water (3). According to IBWA, if coliform bacteria are detected in bottled water, the recommended treatment would be to sanitize the plant, including all contact surfaces, holding tanks, and pipelines. If coliform bacteria were detected on a regular basis, companies would change source water. However, because coliforms are not currently found in bottled water, changing source water is not likely to occur. Sanitizing as a treatment method is not expected to have an impact on the environment. Companies already participate in a sanitation regimen as specified in FDA's current good manufacturing practice

regulations (21 CFR Part 129). The frequency of this regimen may increase in order to eradicate coliform bacteria. This increased sanitation would increase the volume of effluents from the bottling plant, although the concentration in effluents of the chemicals used to sanitize would not change. FDA assumes that companies comply with Federal, State, and local regulations that regulate the releases of effluents from bottling plants. If there were any increases in effluents due to the proposed action, companies would have to maintain compliance with the current regulations.

No adverse environmental impacts are expected through the use of any of the four testing methods proposed for the detection of coliforms. Two of the four methods are already in FDA's current bottled water regulations (Membrane Filter and Multiple Tube Fermentation technique). According to IBWA, most companies have already been using the Minimal Media ONPG-MUG method to detect coliforms (2). The types of analyses required by the proposal are performed by laboratories within the bottling companies or by laboratories that participate in the drinking water laboratory certification program or by other contract laboratories. FDA assumes that laboratories analyzing bottled drinking water meet the requirements of the Resource Conservation and Recovery Act and any other applicable environmental statutes, and that laboratory reagents are disposed of in a manner that avoids or minimizes environmental introductions. This proposed regulation is not expected to change that situation.

Information available to the agency indicates that most companies are using the Minimal Media ONPG-MUG test when testing for coliform bacteria because the test is less susceptible to interfering organisms than the other tests (2). Therefore, coliform tests will most likely not have to be invalidated due to interference from heterotrophic bacteria.

The above analysis has demonstrated that there will be no adverse environmental impact of the proposed action.

3. MITIGATION MEASURES:

Since no adverse environmental effects are expected to be associated with the proposed action, no measures need to be taken to avoid or mitigate such effects.

4. DESCRIPTION OF REGULATORY ALTERNATIVES TO THE PROPOSED ACTION AND THE EXPECTED ENVIRONMENTAL CONSEQUENCES:

Section 410 of the Federal Food, Drug and Cosmetic Act requires FDA either to promulgate bottled drinking water regulations, or to publish reasons for not doing so, after EPA has set national regulations for drinking water. Hence, an alternative to this proposed action is not to establish a revised standard for coliforms. However, if no revised standard is set for coliform bacteria, there is potential for environmental impact in the form of adverse human health effects from exposure to these organisms at levels that are higher than the proposed standard.

Available information indicates that the current level of coliform bacteria in bottled water, i.e., its absence, is already in compliance with the proposed standard. There is no reason to suspect that coliform bacteria would increase in the absence of an FDA action. Consequently, the magnitude of any impact would be expected to be very small.

5. COMPARATIVE ANALYSIS OF PROPOSED ACTION AND ALTERNATIVES:

Little, if any, environmental impact is expected from either the proposed action or no action because, for the most part, companies are already in compliance with the proposed quality standard. The proposed action is preferred to no action because FDA has evaluated the health risks involved and has determined that the proposed quality standard is appropriate in protecting public health.

6. LIST OF PREPARERS:

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7. REFERENCES:

1. International Bottled Water Association (IBWA), 113 North Henry Street, Alexandria, VA 22314; personal communication with Tyrone Wilson and Geary Campbell, December 30, 1991.
2. International Bottled Water Association (IBWA), 113 North Henry Street, Alexandria, VA 22314; personal communication with Tyrone Wilson, February 10, 1992.
3. FDA FY 90 Bottled Water Survey. (1990)