

Testing Bottled Water

Continually Evolving Regulations: D/DBPs

by Barbara L. Marteney & Kristin Safran

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The Bottled water industry continues to strive to produce a quality product which inspires consumer confidence.

One of the most important (and sometimes the most complex) area of the bottled water business is compliance with federal, state, and industry regulations. As the EPA continues to evaluate contaminants in drinking water for regulation under the Safe Drinking Water Act (SDWA), the FDA must review these regulations for their suitability for bottled water.

On March 28, 2001, the U.S. Food and Drug Administration (FDA) published a Direct Final Rule for Disinfectants and Disinfection Byproducts (D/DBPs) in the Federal Register.

On July 5, 2001, the FDA confirmed the effective date of January 1, 2002 for the D/DBPs final rule. Therefore, bottled water “on the shelf” as of January 1, 2002 must be in compliance for D/DBPs regulations.

The rule establishes allowable levels for the following.

	<u>MCL (mg/l)</u>
Residual disinfectants:	
Chloramine*	4.0
Chlorine*	4.0
Chlorine Dioxide*	0.8
Disinfection byproducts (DBPs):	
Bromate	0.010
Chlorite	1.0
Haloacetic Acids (HAAs)	0.060

* Awaiting FDA and state guidance regarding methodology, certification and frequency of testing requirements.

The rule also revised allowable levels for the DBPs Total Trihalomethanes (TTHMs) to an MCL of 0.080 mg/l.

In the Federal Register, FDA states: *“FDA recognizes that some bottled water products may be in the marketplace and remain there for 2 or more years. Thus, there may be some products already in interstate commerce on the effective date that have not been tested under the new part 129 requirements for disinfectants and disinfection by-products and that do not meet the revised standard of quality.”*

“Under 403(h)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343 (h)(1)), such products are considered to be misbranded if they do not meet the revised quality standard for the three residual disinfectants and the four types of DBPs unless they bear a statement of substandard quality. However, FDA believes that it would be appropriate to exercise its enforcement discretion as to those bottled water products that: (1) Are already in interstate commerce before January 1, 2002; (2) do not meet the revised quality standard for the three residual disinfectants and the four types of DBPs; and (3) do not bear a statement of substandard quality – provided that such products are not adulterated. Therefore, the agency does not plan to take enforcement action against such bottled water products, provided that such products are safe.”

In short, although bottled water on the shelf as of January 1, 2002 would be out of compliance if it does not comply with the bromate MCL, the FDA does not currently intend to take any action such as an off-the-shelf study. If any other organization should decide to perform such a study, non-compliance could result in the need for a recall.

Bottled water “on the shelf” as of January 1, 2002 must be in compliance for D/DBPs regulations.

Source Water Requirements

Only sources which are treated with chlorine-based disinfectants or ozone will require testing for DBPs and residual disinfectants. Bottlers using public water supply (PWS) sources and those receiving source water via disinfected tanker transport would be required to do this testing.

Frequency of Testing

For 2001, the IBWA is requiring quarterly bromate and bromide testing on all types of finished product water and quarterly bromide and chloride testing on all types of source water (including municipal sources).

As of January 1, 2002, the FDA will be requiring testing *“at least”* annually on all types of finished product water and chlorinated or ozonated sources for the D/DBPs. We are awaiting clarification on frequency of testing from the FDA.

Some states are expected to require quarterly bromate/bromide monitoring but we are still waiting for more information.

Sources of Contaminants

Bromate can be formed when bromide, a naturally occurring inorganic ion, is exposed to ozone. The conversion of bromide to bromate varies based upon the amount of bromide present, matrix of the water, and total concentration/time of ozone exposure (CT Value). The maximum amount of bromate which could be formed can be calculated by multiplying the bromide level present in the raw source by 1.6. Therefore sources with bromide above 0.0063 mg/l of bromide could exceed the allowable limits for bromate.

THMs & HAAs are formed as a result of chlorine disinfections. They are formed when chlorine reacts with organic matter in the water. TTHMs is the sum (in mg/l) of the concentration of the trihalomethane compounds:

Trichloromethane (chloroform)
Dibromochloromethane

Bromodichloromethane
Tribromomethane (bromoform)

Chlorite is a disinfection byproduct which is formed as chlorine dioxide decomposes.

These regulations and recommendations may be subject to change; therefore, bottlers should verify the current requirements with their laboratory representative before ordering any testing.

About the Authors:

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