Protecting Public Health

FDA adopts zero-tolerance standard for E. coli in bottled water

By Jill Culora

A long-standing International Bottled Water Association (IBWA) zero-tolerance standard for* E. coli *in bottled water has recently been adopted by the Food and Drug Administration (FDA) and will become legally enforceable before the end of the year.

The new rule amends the FDA's bottled water regulations to require that bottled water manufacturers test both source water and the finished product for total coliform. If any coliform organisms are detected, bottled water manufacturers must determine whether any of the coliform organisms are *E. coli*, an indicator of fecal contamination.

Under the final rule, bottled water containing *E. coli* will be considered adulterated, and source water containing *E. coli* will not be considered safe or sanitary and will be prohibited from use in the production of bottled water.

"The FDA's final rule reflects IBWA's 'Code of Practice' standard, which was adopted in 2001 and with which all IBWA bottler members must meet," said Joe Doss, IBWA president and CEO. "The IBWA applauds this extra measure of safety for the consumer. Our members work hard and long to protect against *E. coli*. Now it's the law of the land for all bottled water products."

The FDA published the new rule in the May 29, 2009, Federal Register, and it will be legally enforceable on Dec. 1, 2009. Primary elements of the new FDA rule are:

- Bottled water manufacturers that obtain their source water from other than a public water system must test their source water at least weekly for total coliform. If that source water is total coliform positive, the manufacturer must conduct follow-up testing to determine whether any of the total coliform organisms are *E. coli*.
- Source water found to contain *E. coli* will not be considered water of a safe, sanitary quality as required for use in bottled water.
- Before a bottler can use source water from a source that has tested positive for *E. coli*, the bottler must take appropriate measures to rectify or otherwise eliminate the cause of *E. coli* contamination of that source in a manner sufficient to prevent its recurrence. A source previously found to contain *E. coli* will be considered negative for *E. coli* after five samples collected over a 24-hour period of time from the same sampling site that originally tested positive for *E. coli* are tested and found to be *E. coli* negative.
- Bottlers must maintain records of corrective measures taken to rectify or eliminate *E. coli* contamination.
- If any coliform organisms are detected in weekly total coliform testing of finished bottled water, follow-up testing must be conducted to determine whether any of the coliform organisms are *E. coli*.
- Analyses conducted to determine compliance with the standards for microbiological quality for total coliform and *E. coli* must be made in accordance with the multiple-tube fermentation and membrane filter methods.
- If *E. coli* is present in bottled water, then the bottled water is deemed to be adulterated under section 402(a)(3) of the Federal Food Drug and Cosmetic Act and is banned from sale or distribution.

The rule draws attention to one of many ways in which bottled water standards and regulations are different from municipal water systems without being inferior. As mandated by federal law, the FDA's bottled water standards must be no less stringent and no less protective of the public health than the EPA's regulation of public drinking water.

Other laws and regulations that are specific to bottled water include:

Standard of Identity

Bottled water must meet a specific standard of identity and be clearly labeled as such. The FDA has uniform definitions for the following bottled water classifications:

Spring Water. Bottled water derived from an underground formation from which water flows naturally to the surface of the earth. Spring water must be collected only at the spring or through a borehole tapping the underground formation feeding the spring.

Purified Water. Water that has been produced by distillation, deionization, reverse osmosis (RO) or other suitable processes while meeting the definition of purified water in the U.S. Pharmacopoeia may be labeled as purified bottled water.

Other suitable product names for bottled water treated by one of the above processes may include "distilled water" if it is produced by distillation, "deionized water" if it is produced by deionization or "RO water" if the process used is RO.

Mineral Water. Bottled water containing not less than 250 parts per million (ppm) total dissolved solids may be labeled as mineral water. Mineral water is distinguished from other types of bottled water by its constant level and relative proportions of mineral and trace elements at the point of emergence from the source. No minerals can be added to this product.

Sparkling Bottled Water. Water that after treatment, and possible replacement with carbon dioxide, contains the same amount of carbon dioxide that it had as it emerged from the source. Sparkling bottled waters may be labeled as "sparkling drinking water," "sparkling mineral water," "sparkling spring water," etc.

Artesian Water/Artesian Well Water. Bottled water from a well that taps a confined aquifer in which the water level stands at some height above the top of the aquifer.

Well Water. Bottled water from a hole bored, drilled or constructed in the ground and taps the water aquifer.

By law, FDA's standards of identity regulations pre-empt state laws that are different from the FDA regulation.

Standard of Quality

The FDA establishes standards of quality regulations that set the allowable levels of substances that may be in a given food product. The FDA Standards of Quality for bottled water establish limits for microbiological, physical, chemical and radiological substances for both source water and finished bottled water products. The FDA has established standards for more than 90 substances pursuant to the Standards of Quality for bottled water.

Most FDA bottled water quality standards are the same as the EPA's maximum contaminant levels (MCL) for public water systems. The few differences are usually the result of the substance not being found in bottled water or the substance being regulated under FDA's food additives program.

In some instances, however, FDA bottled water standards of quality are more stringent than the EPA's public drinking water standards (e.g., copper, fluoride, lead, and phenols). The FDA has not established specific bottled water standards of quality for acrylamide and epichlorohydrin because they cannot be used in the production of bottled water.

If pathogenic microorganisms are present in bottled water and potentially injurious to public health, the FDA has the authority to classify the product as adulterated and subject it to enforcement action, such as seizure of the product. This would apply to microorganisms such as *Cryptosporidium*, *Legionella*, *Giardia lamblia* and other viruses that are generally found in surface water; however, the agency has not established standards of quality for these because bottled water is produced from either groundwater sources that, by definition, must not be under the influence of surface water or from municipal water systems that are already compliant with EPA's Surface Water Treatment Rule.

Bottled water products, whether from groundwater or public water sources, are produced utilizing a multibarrier approach. From source to finished product, a multibarrier approach helps prevent possible harmful contamination to the finished product as well as storage, production and transportation equipment.

Measures in a multibarrier approach may include one or more of the following: source protection and monitoring, RO, distillation, microfiltration, carbon filtration, ozonation, ultraviolet light or other safe and effective methods.

Many of the steps in a multibarrier system may be effective in safeguarding bottled water from microbiological and other contamination. The piping in and out of plants is also maintained through regular sanitation procedures. In addition, bottled water products are bottled in a controlled, sanitary environment to prevent contamination during the filling operation.

Notifying the Public

Every bottled water product leaving the plant must meet the FDA's standards of quality. If a bottled water product is found not to meet FDA requirements, it can be recalled and removed immediately from the market to protect consumers.

Under the FDA's recall procedures, it is recommended that each bottled water producer have a recall plan in place before a recall is conducted. The plan is expected to detail when and how to notify consumers of a potential health concern.

The notification system for public water systems differs from the FDA's requirements for bottled water because, unlike bottled water, public water systems cannot reverse the flow of the water if a problem is discovered once it leaves the plant. Accordingly, if municipal water does not meet EPA standards, the only available remedy is to notify the affected community because the consumers have no choice as to which public water system they use.

Bottled water is regulated as a food product by the FDA, which has expertise in all facets of food safety and production and has established stringent standards of identity and quality for bottled water. The partnership of government regulation and industry standards provides several layers of public health protection. *wqp*

Jill Culora is a freelance writer and media consultant to the IBWA. Culora can be reached by e-mail at jculora@bottledwater.org.

For more information on this subject write in 1006 on the reader service card.

WEBresources ➤➤➤

Related search terms from www.waterinfolink.com: bottled water, regulations, *E. coli*

For more information related to this article, visit www.wqpmag.com/lm.cfm/wq090906