By Kristin Safran and Barbara L. Marteney, National Testing Laboratories, Ltd.

Bottled Water and the FDA Standards of Quality

Bottled water is classified as a food product and regulated by the U.S. Food and Drug Administration (FDA). The FDA has regulations that dictate

- What bottled water can be called (Standards of Identity),
- How bottled water can be produced (Good Manufacturing Practices),
- What can and cannot be on the label (labeling requirements), and
- The contaminants for which bottled water must be tested along with the allowable limits for each (Standards of Quality).

This article will focus on the last item, the Standards of Quality (SOQs). Bottlers may feel that every time they turn around they have to do more testing, especially over the last few years. To a point, those feelings are valid. In 2002, bottlers were required by FDA to add an analysis for the disinfectants and disinfection byproducts (chlorine, chloramine, chlorine dioxide, HAAs, bromate and chlorite) to their annual tests. In addition, the FDA recently announced that it plans to add uranium to the list of required parameters effective in December 2003.

The fact that bottlers are having to test for more now than they did a couple of years ago won't be much of a surprise to anyone in the industry. The driving forces behind why more testing continues to be added, however, often are misguided. Many bottlers speculate that the FDA is being lobbied to add requirements; others simply blame the bureaucrats at the FDA. In realty, the true driving force behind the addition of parameters to the FDA SOQs is the U.S. Environmental Protection Agency's Safe Drinking Water Act (SDWA).

Originally passed in 1974 and amended in 1996, the SDWA is the federal law that allows the EPA to set National Primary Drinking Water Standards (NPDWSs). The EPA goes through an extensive and ongoing process to determine which contaminants should be regulated and at what level. The

The fact that bottlers are having to test for more now than they did a couple of years ago won't be much of a surprise to anyone in the industry.

The driving forces behind why more testing continues to be added, however, often are misguided.

Many bottlers speculate that the FDA is being lobbied to add requirements; others simply blame the bureaucrats at the FDA.

The true driving force behind the addition of parameters to the FDA SOQs is the U.S. Environmental Protection Agency's Safe Drinking Water Act.

Photo courtesy of RainSoft.

EPA promulgates standards for those contaminants that have demonstrated occurrences at levels that pose a potential health risk. These standards are developed with the goal of ensuring that public water supplies are safe to drink, but they also directly impact the FDA SOQs.

In order to ensure that bottled water is regulated at least as stringently as public water systems, the 1996 SDWA amendments included a "hammer clause." This clause states that when EPA promulgates interim or revised NPDWS regulations, the FDA has 180 days to either promulgate amendments to regulations establishing an SOQ for bottled water or publish reasons for not making such amendments. If FDA fails to promulgate rules within the specified time period, the EPA NPDWS regulations become the SOQs for bottled water.

Normally, when the FDA promulgates a rule for addition of a new standard within the time frame allowed, the SOQ is equivalent to that of the EPA maximum contaminant level. However, FDA usually substitutes the complicated monitoring program applied to public water supplies of waivers, system size schedule tiers and reduced monitoring programs with a simple annual requirement for sources and products. The disinfectants and disinfection byproducts are an example of FDA promulgating its own rules for parameters added by the EPA to the NPDWS within the allowable time frame as described above. As a result of these additions, bottlers were required, as of January 2003, to be in compliance with the SOQ and begin annual testing of all products and some sources for HAAs, bromate, chlorite, TTHMs, chlorine, chloramine and chlorine dioxide.

In contrast, what often is referred to as the "nine stayed parameters" is a prime example of the repercussions when the FDA cannot fully promulgate an SOQ and monitoring frequency within statutory requirements. On the last day of the 180 day period, the FDA

About the Authors
Kristin M. Safran and Barbara L. Marteney of National Testing Laboratories, Ltd. specialize in consulting with bottled water companies regarding testing requirements and bottled water quality. They maintain contacts with bottled water regulators, industry associations and the FDA regarding regulatory changes and other issues that impact bottlers. Marteney and Safran also are active in IBWA committees. They have authored numerous articles and given various presentations on these topics. Marteney and Safran can be reached by phone at 800-458-3330 or 440-449-2525. Marteney at extension 217 and Safran at extension 215. E-mail: food-bev@ntllabs.com.

issued notice that they were unable to promulgate rules regarding the monitoring for the synthetic organic compounds (SOCs)—glyphosate, endothall, diquat and 2,3,7,8-tcdd dioxin—that were included in the "nine stayed parameters." Therefore, the monitoring frequency for these parameters would be the same as specified in the NPDWS regulations.

Unfortunately, the NPDWS regulations for these contaminants contain many options based on state plans for implementation and system classifications determined by source types and population served. For example, some states were allowed to present data to EPA and obtain statewide waivers for some or all of these parameters so that public water systems in the state don't have to test for them. In addition, the NPDWSs have two different sets of monitoring schemes: one for large systems serving a more than 10,000 population and one for small systems serving less than 10,000.

This raised a couple of questions.

- How do in-state waiver programs apply?
- Is bottled water a large system or a small system?

The answers to these questions determine how frequently testing is to be required. Unfortunately, there are no answers to these questions, and the FDA has been unable to finalize the guidance document it promised in 1998 to help give clarification to these issues.

Without the guidance from FDA, industry and regulators were left to speculate what the correct interpretation of monitoring frequency was. The International Bottled Water Association adhered to virtually a literal interpretation, which required finished product water to be testing for the SOCs—glyphosate, endothall, diquat and 2,3,7,8-tcdd dioxin—for four consecutive quarters during the first three-year monitoring period and annually thereafter, as well as annual source testing. Regulators for the states of Georgia, Massachusetts and California determined that, until advised otherwise by FDA, they would require these four parameters annually on source and product and not require any quarterly testing. The majority of state regulators took a stance that they will require additional testing when FDA advises them of how frequently that testing should be performed. In short, failure of FDA to fully promulgate both the SOQ and the monitoring frequency prior to the statutory deadline resulted in tremendous confusion as bottlers, state regulators and the FDA seem unsure as to what is required to be in compliance.

While the nine-stayed parameters outcome was not a desirable one, several lessons were learned.

- FDA needs encouragement to address the industry issues within statutory deadlines.
- FDA's many priorities may not always allow sufficient resources to devise alternative monitoring schedules to the present annual requirements within the statutory time frame.
- If the industry submits "adverse comments" to a direct final rule of adding NPDWS parameters to the FDA SOQs, FDA most likely will let the hammer fall.
- The hammer falling results in confusion between the industry and regulators and, depending on regulation interpretation, may significantly increase testing costs.
- It benefits the industry to be proactive in tracking potential NPDWS add-ons and to have strong communication with FDA prior to FDA issuing the draft rules.

In conclusion, future years most likely will bring additional testing requirements as the EPA adds parameters to the NPDWS's forcing FDA to attempt to draft rules as well. While there is not much that the industry can do to prevent new parameters from being added, it can be proactive by learning about upcoming changes and preparing for their impact. WQP

For more information on this subject, write in 1013 on the reader service card.

LearnMore!
For more information related to this article, go to www.waterinfocenter.com/lm.cfm/wq060303