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Know Your Bottled Water

Security, Safety importing/exporting and record maintenance issues affecting the industry.

Bottled water is fully regulated by the U.S. Food and Drug Administration (FDA) as a food product and subject to FDA's extensive food safety and labeling requirements. Bottled water is a product that is affected by both general food as well as bottled water-specific legislation, regulations and standards. The International Bottled Water Association (IBWA) tracks and takes action on a number of relevant issues. The goal is to ensure fair and equitable treatment of bottled water companies and to help the industry continue to deliver safe, high-quality bottled water products to a thirsty consumer market. In 2001, IBWA was engaged on both the federal and state legislative fronts, working hard to represent the bottled water industry and seeking the adoption of sensible, effective laws and regulations.

New Bottled Water Regulations

The tragic events of Sept. 11, 2001, have changed many of the issues confronting the bottled water industry and the food industry overall. Elected officials and regulators have refocused on the security and safety of the food supply and infrastructure and are placing greater emphasis on risk assessments, planning and prevention, and government and industry response plans. These new initiatives may present challenges and change for the bottled water industry and others within the food and drinking water industries.

Most immediate and significant are new requirements dictated by the Public Health Security and Bioterrorism Response Act (bioterrorism law) that was signed into law by President George W. Bush on June 12, 2002. The provisions of the bioterrorism law address a wide variety of issues. However, the food provisions including bottled water and to some extent the public water provisions are of particular interest to the bottled water industry. The key provisions of interest to bottlers are

- food facility registration,
- maintenance and inspection of records, and
- prior notice for importation of food products.

IBWA worked with other members of a broad-based food industry coalition to provide input to Congress as it considered this legislation. FDA will be charged with interpretation and enforcement of the new law and has been authorized to make grants to the states to assist in the examinations, inspections and investigations. In addition, FDA may award "food safety grants" to expand participation in programs designed to enhance food safety.

Food Facility Registration

Every facility that manufactures, processes, packs or holds a food for human consumption must be registered with FDA by Dec. 11, 2003. FDA has until then to promulgate regulations implementing the food facility registration provisions. However, if it fails to finalize regulations by that date, the obligation to register is still on the bottler. (See Registration Requirements sidebar.)

A registrant must apprise FDA of changes to such information "in a timely manner." A facility includes any factory, warehouse or establishment that manufactures, processes, packs or holds food for human consumption. A foreign food facility is a facility that manufactures, processes, packs or holds food for export to the United States without further processing or packaging outside the United States. The law specifically excludes farms, restaurants, other retail food establishments, non-profit food establishments in which food is prepared for or served directly to the consumer, and fishing vessels not engaged in processing. Failure to register is a "prohibited act" under the Food, Drug

Food Facilities

Registration Requirements

Registration for a food facility must include the following information.

- The name and address of each facility.
- All trade names under which it does business.
- When determined necessary by the Secretary through guidance, the general food category.


Regulations

and Cosmetic Act. If a foreign facility is not registered, the food product will be held at the point of entry until the facility registers.

Specific bottled water issues yet to be resolved include questions such as, "Is a pump house, springhouse or water storage facility classified as a food facility?" A determination whether to impose user fees is an issue for rulemaking under the expedited rulemaking provisions of the new law. IBWA will be working with FDA to have these and other issues clarified.

Record Maintenance and Inspections

The records access provision of the law expands FDA's authority to review records of food producers if the agency has a "reasonable belief" that the food is adulterated and poses a health risk to humans. It extends to all records relating to the manufacture, processing, packing, distribution, receipt, holding or importation of the food, without regard of the format or the location at which they are held. The new law mandates that records show from whom a purchase was made and to whom a food product was sold (one look forward; one look backward). Records must be maintained for two years and FDA may promulgate implementing regulations by Dec. 11, 2003. It is a prohibited act to refuse FDA access to and the opportunity to copy such records.

Prior Notice of Importation

By Dec. 11, 2003, FDA must promulgate final regulations that require importers of food products to provide prior notice to FDA. The required information includes the identity of the article; its manufacturer and shipper; its grower (if known within the specified notice period); the country of origin and country from which it is shipped; and the article's anticipated port of entry. If FDA does not finalize regulations, the law specifies a minimum of eight hours and a maximum of five days prior notice. Failure to provide notice will result in the product being held at the port of entry until notice is given.

The new bioterrorism law also may be affected by the creation of a Department of Homeland Security which, according to the current configuration of the new department, is to include the Federal Emergency Management Administration (FEMA). As community water systems develop their risk assessments and response plans as required under the water provisions of the new law, they also must identify alternative water sources in the case of a disaster. This has been the traditional role of FEMA. The responsibilities of the proposed Department of Homeland Security have yet to be determined. However, the requirement for community water systems to identify alternative water sources will be required, regardless. One alternate source is, of course, bottled water.

There remain many questions and concerns about the full impact of the new authority granted to FDA. As the provisions are implemented, IBWA will be engaged with Congress and FDA to ensure the smooth transition with the new requirements.

State Regulatory Update Section

In the state regulatory arena, IBWA's activity currently is focused on states undergoing regular review of their bottled water regulations. With the Texas Department of Health in the midst of revising its rules related to bottled water, IBWA on April 17, 2002, submitted comments to the department. Among the recommendations made to the department, IBWA is requesting the removal of the current requirement for a minimum chlorine residual of 0.5 mg/L for bulk water hauling from source to the bottling facility. The State of Texas regulates bottled water under the same authority as its public water systems and requires each to maintain a residual chlorine level. However, where public systems must maintain residual chlorine levels until the point of distribution (e.g., the tap), bottled water producers currently are required to chlorinate water as it is transported from the source to the plant. IBWA contends that this source water is an ingredient for bottled water that will be properly handled at the plant through ozonation or other protective measures at the plant to help ensure its safety. This makes advance chlorination of source water in transport an unnecessary and inefficient step. The department also is being asked to expand its scope of responsibility for bottled water to encompass the entire process pathway from natural water source (wellhead or spring) to finished, packaged food product.

Revised rulemaking also is underway in Massachusetts. On Feb. 22, 2002, IBWA submitted comments to the Department of Public Health in response to proposed changes to the bottled water regulations. Of particular concern, IBWA urged more clarity on the definition of minimal treatment and testing requirements. It was requested that the source labeling requirement be deleted, as FDA already has considered and rejected such a proposal as not being material fact. Regarding a proposal by the state that would require the printing of a permit number on each bottled water label, IBWA suggested that the permit numbers expected to be required as part of soon-to-be enacted federal bioterrorism legislation (HR 3448) be used as a single national permit number, thus easing labeling requirements for multistate sellers.

IBWA will continue to work with lawmakers and regulators at the federal and state levels to help ensure a fair and balanced legislative environment and the continued protection of bottled water consumers across the United States. WQP

About the Author

Joseph K. Doss is the president of the International Bottled Water Association (IBWA). Founded in 1958, IBWA is an authoritative source of information about all types of bottled waters. Member companies account for more than 80 percent of all bottled water sales in the United States. For more information, call 800-WATER-11; www.bottledwater.org.

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