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BOTTLED WATER REPORTER | AUG / SEP 2011

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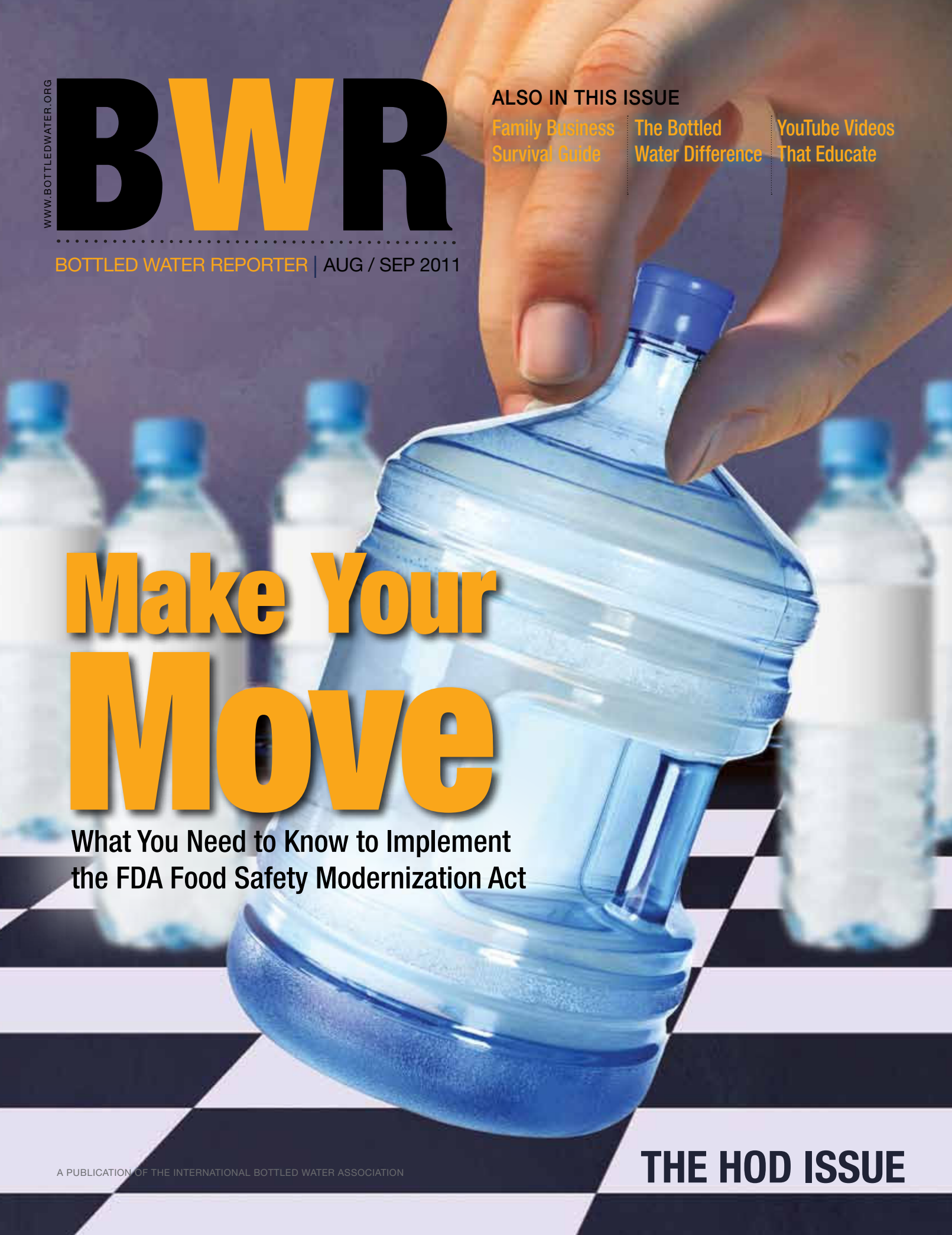

Make Your Move

What You Need to Know to Implement the FDA Food Safety Modernization Act

A PUBLICATION OF THE INTERNATIONAL BOTTLED WATER ASSOCIATION

THE HOD ISSUE

FDA Food
How to

Although bottled water is already subject to more regulation than most foods, the industry will still have to implement changes to comply with the U.S. Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA), which was enacted into law on January 4, 2011, after three years of debate within Congress. FSMA's cornerstone responsibility is to ensure that manufacturers make safe food. Included in that responsibility are obligations intended to impose a science- and risk-based approach to food safety that focuses on prevention.

Safety Modernization Act: Start Preparing Now

By Maile Gradison Hermida

Four primary requirements in the law will most affect the bottled water industry's daily operations:

- preventive controls
- supply chain management
- records maintenance and access by FDA
- food defense plans.

The law also includes new and enhanced enforcement powers for FDA, which underscore the importance of compliance with the new requirements because the law has "new teeth." Although key FSMA provisions have not yet become effective, FDA will soon be issuing implementation regulations and the bottled water industry would be well served to begin preparations now.

Preventive Controls

Often hailed as the most significant provision of the law, all registered facilities are now required to implement preventive controls (i.e., food safety plans). Facilities will be required to conduct an analysis of hazards that are reasonably likely to occur and base that analysis on the principles underscoring Hazard Analysis and Critical Control Point (HACCP) plans. For hazards that may occur naturally or may be unintentionally introduced, facilities must identify and evaluate known or reasonably foreseeable hazards that may be associated with the facility. FSMA contains a list of such potential hazards, which includes the well-known biological, chemical, and physical hazards, as well as more novel hazards that many facilities may not currently assess, including drug residues, parasites, and natural toxins.

FSMA WEBINAR

Since March 2011, Hogan Lovells and IBWA have offered a webinar that presents an overview of the Food Safety Modernization Act (FSMA) to IBWA's members. Take the webinar at bit.ly/FSMAwebinar.

After conducting a hazard analysis, facilities must put into place controls designed to significantly reduce or prevent those hazards. The law defines several types of preventive controls, including sanitation, training, environmental monitoring, and supplier verification activities that relate to food safety. In addition, current Good Manufacturing Practices (cGMP) are identified as a type of control. While bottled water will remain subject to its specific cGMP regulations in *21 C.F.R. Part 129*, the industry should take note that the FDA is planning to update and modernize the cGMP regulations in *21 C.F.R. Part 110* to which the industry also is subject.

Facilities also must identify when it is necessary to implement preventive controls at critical control points (CCPs), which are defined as "a point, step, or procedure in a food process at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce such hazard to an acceptable level." FSMA envisions that some facilities may not have CCPs, but companies without any CCPs will likely have to justify that conclusion to FDA during an inspection.

Preventive controls must be implemented through monitoring, corrective actions, and verification activities. The law specifies that verification mechanisms include environmental and product testing. In that context, environmental testing refers to external swabs on plant equipment and the surrounding areas within the facility to verify the effectiveness of the company's sanitation program.

Recommended Actions: Although preventive controls analyses will be similar to the HACCP plans that IBWA members are already required to have in place, some limited adjustments will likely be necessary when FDA issues its new regulations. All HACCP plans should be reviewed for adequacy under the new law. In addition, if they have not done so recently, facilities should review their hazard analysis to ensure it is still relevant to the facility and to new and emerging threats. Companies also should consider whether their preventive controls, including any CCPs, may need to be revised in light of the new requirements.

For example, the law identifies recall plans as a type of control, but many facilities likely do not consider such plans to be a control within their existing HACCP plans. Another area of preparation will be to develop food safety plans for warehouses and sources, which may not currently have HACCP plans.

Those obligations apply to all facilities that are required to register with FDA under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act), which include all bottling facilities, water sources, and warehouses. The preventive controls aspects of the legislation become effective on July 5, 2012. However, Mike Taylor, the deputy commissioner of foods at FDA, has stated publicly that the agency is planning a "common sense" approach to implementation and will not enforce compliance until there has been adequate time for the industry to consider and implement the agency's forthcoming regulations.

Supply Chain Management

The second key area of focus is the supply chain management, which is considered a preventive control under the law. Manufacturers need to know who their suppliers are and have a strategy in place for assuring their adherence to food safety requirements. It will be appropriate to make a plan that is risk-based depending on product type and facility history. The goal of supplier verification is to ensure product is not adulterated or misbranded due to the presence of undeclared allergens. Those responsibilities apply to all suppliers, whether domestic or foreign, and become effective when the preventive controls requirements take effect, in July 2012. The domestic obligations are part of the preventive controls requirements, discussed above, and apply to all facilities that are required to register under the Bioterrorism Act.

In addition to requiring supply chain verifications as a preventive control, the law includes a specific set of obligations for foreign suppliers. Under the Foreign Supplier Verification Program (FSVP), all importers (defined as the "U.S. owner or consignee" of a food) must verify that the foods they import are produced in compliance with FDA's processes and procedures (including preventive controls), are not adulterated, and are not misbranded because of the presence of undeclared allergens. The FSVP obligations take effect on January 4, 2013; although, as noted above, FDA has stated the agency will defer enforcement until after final regulations are issued and there is a reasonable time for implementation.

Supply chain verification will be necessary for all domestic and foreign ingredient suppliers, such as suppliers of salts, minerals, and flavors. For companies that bottle teas, energy drinks, or similar products, this requirement would include all ingredients listed on the label. Although not specified explicitly in the law, the supply chain verification requirements also will likely apply to food contact materials such as PET resin, PET bottles, and product caps.

Recommended Actions: To prepare for implementation of the new supply chain obligations, companies should ensure that they can identify their suppliers. Companies should begin developing risk-based plans to ensure the quality of incoming ingredients and food contact materials, which should include an assessment of any co-manufacturers. As a starting point, it's helpful to consider current procedures to qualify and audit suppliers, and examine practices relating to testing for incoming ingredients and food contact materials.

Records Maintenance and Access

Records maintenance and access by FDA is an essential area of new responsibilities that should not be overlooked. When the preventive controls regulations become effective, FDA will have legal access to food safety plans and related documents, including all testing results. FDA's access will extend to corrective actions and the related rationale for the actions taken. The agency also will have access to documents related to monitoring of the supply chain. FSMA gives FDA significantly expanded records access, which previously was limited to emergency situations under the Bioterrorism Act. These changes will reshape the character of FDA inspections, which likely will become more focused on the review of records.

Recommended Actions: Because of the expanded access by regulators, good documentation practices will be critical. Companies should assess their current recordkeeping practices to ensure that records are complete, well-organized, and readily accessible. In addition, companies should develop established plans to document corrective actions and ensure that the records explain the adequacy of and basis for those actions. Records present an opportunity for companies to show FDA that a company is in control of its processes; therefore, records maintenance is an area where preparation is essential. If an action was taken but

not documented, it did not happen at all in an inspector's eyes. Companies also may want to review and consider their internal records retention plans. Under the law, all food safety plan related records are required to be kept for two years. Those same records retention requirements also apply to records created under the FSVP.

Food Defense Plans

Facilities also will be required to develop food defense plans, which address *intentionally* introduced hazards (by definition, these hazards are not reasonably foreseeable). This hazard analysis must include hazards that may be introduced by acts of terrorism. Facilities are required to implement appropriate mitigation steps for those hazards. (IBWA conducted extensive training on food defense in the bottled water context after 9/11.)

Recommended Actions: Companies should review their food defense plan in light of FSMA's requirements, or begin creating a plan if they do not have one already. Because food defense protects against intentional contamination, creation of those plans may require a different set of expertise than is used to assess preventive controls. FDA has created a number of online tools, such as CARVER + Shock (www.fda.gov/Food/FoodDefense/CARVER/ucm2006923.htm) and a Food Defense Mitigation Strategies Database (www.fda.gov/Food/FoodDefense/ucm245544.htm), that may be helpful when considering potential risks and mitigation steps.

FDA's Enforcement Authorities

FSMA gives FDA increased enforcement powers through several vehicles. As discussed above, the agency will now have routine access to a broad array of records. In addition, the law mandates increased inspection frequency so that all domestic facilities that are considered "high risk" must be inspected at least once every three years. "Non-high risk" facilities must be inspected at least once every five years. The agency will need to define food safety "risk" through rulemaking, and it will likely consider a combination of the inherent risks of a food and a facility's compliance history when assessing whether a facility is classified as "high risk" for inspection purposes.

At this time, it appears the agency will not consider bottled water to be an inherently higher risk product, although a particular company with a history of compliance problems could be designated as high risk and be subject to more frequent inspections.

The law also gives FDA the authority to suspend a facility's registration—essentially pulling its permit to operate—in situations where the agency has significant concerns about a food's safety. This new powerful authority is expected to be used sparingly. In addition, FSMA gives FDA the legal authority to require mandatory recalls, although companies will always have the option to conduct a recall voluntarily first. Fees will apply to any company subject to a mandatory recall. New fees also apply when the agency conducts re-inspections of facilities (e.g., if a second inspection takes place after concerns are raised during an initial inspection). Finally, FSMA gives FDA limited, expanded authority to administratively detain a food temporarily before bringing a seizure action in Federal Court.

Recommended Actions: Given FDA's new enforcement authorities and the new "teeth" that FSMA provides, the best preparation is to ensure facilities are in compliance with the new law and any new FDA regulations. Although inspections by FDA are infrequent, facilities should be prepared for the agency to conduct an inspection at any time. Positive inspections can help avoid resulting enforcement actions by the agency as well as the assessment of re-inspection fees. In addition, companies should continue to conduct voluntary recalls as they did prior to FSMA's enactment, so as not to trigger the need for FDA to require a mandatory recall.

Time to Take Advantage

The bottled water industry is well positioned to get a head start on implementation of FSMA's requirements. Because the key provisions of the law are not effective right away, companies should take advantage of this time to begin reviewing their current practices and thinking about changes that may be necessary in light of the new law. FDA will be issuing a substantial volume of new regulations and guidance documents, but enough is known now for companies to position themselves ahead of the curve. Companies also should stay tuned to learn about more specific requirements as new regulations are issued by the agency during the next one or two years. **BWR**

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