

May 14, 2004

Documents Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Interim Final Regulations of PL 107-188:
Food Facility Registration – Docket No. 02N-0276
Prior Notice of Imported Food – Docket No. 02N-0278

Dear Sir or Madam:

The International Bottled Water Association (IBWA)¹ appreciates the opportunity to submit additional comments to the U.S. Food and Drug Administration (FDA) on the interim final regulations on food facility registration and prior notice of food importation that implement the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) (Pub. L. No. 107-188).

IBWA is dedicated to helping ensure the safety and quality of bottled water. IBWA is committed to preventing potential adverse events, both natural and man-made, through monitoring and testing, risk assessment, risk management, appropriate controls and procedures, and due diligence. Prior to the December 12, 2003, interim regulations' effective date, IBWA conducted a series of eight seminars that were three and one half hour long in six regions of the country to educate bottlers, distributors, and bottled water suppliers on the interim final regulations and the requirements for compliance with the regulations by the bottled water industry. IBWA also produced a CD ROM for seminar participants, and for other IBWA members at a nominal charge, that contained the IBWA presentation and materials, the interim final regulations, and FDA's supporting materials.

In addition, IBWA has continued this education process through 2004 by conducting additional seminars at five state and regional bottled water associations meetings. IBWA has also publicized the interim final regulations in the Association's newsletter and bimonthly publication.

¹ IBWA is the trade association representing all segments of the bottled water industry. Founded in 1958, IBWA member companies includes U.S. and international bottlers, distributors and suppliers. IBWA is committed to working with state and federal governments, in concert with the IBWA Model Code, to set stringent bottled water standards for safe, high quality products. As a condition of membership, IBWA bottlers must submit to an annual, unannounced inspection for compliance with the Model Code by an independent third party.

I. Summary of Comments

IBWA sincerely appreciates this opportunity to provide FDA with additional input on the areas of the interim final regulations that need further clarification and/or modification, and the experience with the workability of the regulation since they became effective.

IBWA commends FDA on the timely implementation of the Federal Unified Registration and Licensing System (FURLS), the online system for food facility registration. This is a prime example of excellence from the agency. With only a few technical difficulties, this system has been relatively simple for bottlers, distributors, and suppliers to use to register their food facilities, according to reports from IBWA members. This has been true for initial registrations and also for the updating of facility information. As a user friendly and secure system, it is impressive that FDA has had as few technical difficulties with the system.

IBWA also applauds FDA and Customs and Border Protection for the cooperation integrating the on-line system for prior notice. IBWA urges continued efforts to integrate the two systems so that the timelines and prior notice information requirements do not have to be duplicated. Such further combining of the systems should increase compliance while reducing burdens on importers.

The importation of analytical samples (not intended for human or animal consumption) however needs to be addressed. The importation of water samples for analytical testing is currently experiencing difficulties at the borders of the United States. This is likely the result of confusion regarding the treatment of "dual use" products under the prior notice interim final regulation and the lack of appropriate identifying codes for paperwork and shipment containers. Many states require analyses for water being sold within their jurisdictions be performed by laboratories holding special certifications. In order to export to the United States, bottlers must use laboratories that are capable of performing FDA/Environmental Protection Agency (EPA) required methodologies and that hold multiple state certifications for all of the analytical parameters required. There are currently very few, if any, laboratories outside the United States capable of performing such a broad scope of FDA/EPA required analyses, and that also hold all of the required state certifications. Therefore, source water and bottled water samples are routinely imported into the United States to qualified laboratories. As the regulations are enforced, the impact on such samples will be significant on imported bottled water and United States testing laboratories.

IBWA believes that the following recommendations will improve the workability and compliance with the regulations while maintaining the letter and spirit of the Bioterrorism Act. Specifically, IBWA urges FDA to:

- 1. Continue dialogue with the food industry on security and implementation of the final regulations;**
- 2. Provide greater harmonization with the Bureau of Customs and Border Protection requirements, including the submission timelines;**

- 3. Develop a code for use when importing products that are “dual use,” but are not intended for human or animal consumption; and**
- 4. Use enforcement discretion to determine that water samples for analytical testing do not require prior notice.**

II. Docket No. 02N-0276 - Registration of Food Facilities

IBWA Comments

IBWA commends FDA on the attention and resources the Agency devoted to developing FURLS. The feedback received by IBWA from our membership is that the system is user friendly and sufficiently flexible to adapt to the variety of corporate configurations and situations. Those who have used it update their registration information indicate that it was a very simple process.

Food Categories

One area of confusion with the current system is the food category section of the registration. This section appears to need further refinement. There are a number of various ingredients and processing aids, such as chlorine dioxide or carbon dioxide, that do not neatly fit the broad general categories within the regulations, although they are stored and used in bottling plants and thus subject to the regulations. Either further clarification of the current categories or the addition of categories would be helpful in maintaining facility registrations.

Recommendations

IBWA urges FDA to continually review the categories to further refine them to include more descriptive definitions and possibly add categories to cover such food products as processing aids that do not neatly fit the current categories.

IBWA urges FDA to continue the outreach effort and improve the communication opportunities for feedback on the system directly from users and their trade associations. Building such cooperative relationships will enhance the effectiveness of the Bioterrorism Act.

III. Docket No. 02N-0278 – Prior Notice for Food Importation

IBWA Comments

Coordination with Customs

IBWA again commends FDA for the work with Customs and Border Protection in developing a single submission system for the information satisfying the prior notice requirements. By eliminating duplication of submissions and the integration of the systems, substantial hindrances to trade may be avoided. IBWA strongly urges FDA continue working with the CBP to harmonize the two agencies requirements for submission of imported food information as much as possible. IBWA recommends that

the timelines for prior notice be better harmonized with CBP as FDA finalizes the prior notice regulations. This will be particularly helpful in managing the prior notice with food imports from Canada, which is generally by truck or rail. Utilizing one system and one set of timelines should provide adequate notice to FDA and improve compliance with the prior notice requirements.

Dual Use Products

In the past, bottlers have experienced variations in interpretation of the appropriate product code on imported bottled waters and analytical samples. This is a result of complexity of the FDA product code builder and its application to bottled water. The issue is now compounded because there are no product codes in the FDA Product Code builder or under CBP for water samples used in analytical testing. The result has been confusion and delays in the importation of bottled water. CBP agents have begun to refuse entry for lack of prior notice for analytical samples after reviewing the shipping documents that show the container contents as analytical water samples, even when they are not intended for human consumption and not in consumer packaging. IBWA urges FDA to provide guidance to CBP and the bottled water industry on how to proceed with importing water samples for analytical testing. In IBWA's prior comments on the interim final regulation and a December 3, 2003, letter to FDA, to which FDA has yet to respond, IBWA outlined the rationale to classify such samples as "dual use" and not intended for human consumption.

Sampled water must be analyzed within certain strict time frames of collection. Delays can render the samples useless, requiring additional sampling and causing production delays until reliable sample results could be obtained. To ensure analysis occurs within specified time frames, these samples are routinely sent to the analyzing laboratory using international express courier services such as Federal Express or DHL. Such shipping methods also enable the laboratories to maintain a reliable chain of custody for the sample.

In addition, foreign bottled water facilities may not be registered with FDA as a food facility because the decision to export to the United States is pending the outcome of the test results. According to the interim final rule on prior notice, it is not possible to properly fill out the prior notice without a facility registration number. To require a foreign company to secure a U.S. agent and complete the food facility registration process before a decision to do business in the United States is made places an undue burden on international trade. The necessary information to establish the sender and the recipient of the water samples is contained in the paperwork of the courier service.

As IBWA has explained in the earlier communications, water samples for analytical testing are clearly not intended for human or animal consumption. Sample preparation at the point of collection requires addition of acids to reduce the sample's pH, or preservatives to ensure the analysis will reveal the presence of particular analytes. Packaging materials, sizes, and volumes vary depending upon the targeted analyte; not upon the convenience of the collection site. For instance, a sample for metals analysis must be collected in a 500 mL plastic unpreserved bottle, where as a sample being analyzed for organic chemicals, such as benzene, must be collected in

two 40 mL glass amber vials containing a dechlorinator, such as sodium thiosulfate, with HCl to bring the pH to less than 2. These are clearly not the type of articles that can be used or diverted in to the stream of commerce and pose a threat to consumers of the United States.

For “dual use” products, such as water samples for analytical testing, a code needs to be developed so that the products can be readily identified and move smoothly through entry into the United States. This product code(s) will clarify the contents as not intended for human consumption and eliminate any confusion at the border on the need for prior notice.

Reports of analysis on samples that have been collected and submitted to the laboratory in containers other than those outlined by the appropriate FDA/EPA approved methods are flagged with a qualifier of “improper sampling container” and the results are therefore “invalid” or “suspect.” To avoid this, the laboratories routinely send sampling kits to the sample collector with precise instructions to avoid repetitive sampling and unnecessary and costly delays. The development of a code(s)

Under FDA’s Prior Notice rule, imported water samples intended for analysis under 21 C.F.R. § 165.110 are products with “multiple uses” or dual use.² FDA notes in its preamble to the Prior Notice rule that “an item may be food even if the food is not yet in the form in which it will be used for food.”³ A water sample, collected and imported for analysis under FDA and EPA guidelines, is just such an item. FDA provided a standard for determining whether prior notice is required for an imported item with multiple uses, saying:

FDA will consider a product as one that will be used for food if any of the persons involved in importing or offering the product for import (*e.g.*, submitter, transmitter, manufacturer, grower, shipper, importer, or ultimate consignee) reasonably believes that the substance is reasonably expected to be directed to a food use.⁴

In the case of water samples collected, treated, prepared, and imported for analysis under FDA’s and EPA’s regulations and guidelines, no person associated with the importation has any expectation that the item will be directed to food use. In fact, as noted before, consuming water samples would often be hazardous. Samples are discarded or destroyed (*e.g.*, disposed down a drain) after the analyses are completed and retained portions are no longer needed for confirmatory analyses. This practice further removes any risk that water samples could be converted or diverted to a food use.

IBWA further submits that there is a lack of any real bioterrorism threat associated with these water samples. In fact, the water quality sampling and analysis process promotes the goals of the Bioterrorism Act and bottled water safety and

² See n.1 at 58986-87.

³ See *id.* at 58987.

⁴ *Id.*

security by continually ensuring the quality of bottled and source water intended for U.S. consumption. The unintended consequence of the application of the prior notice provision to water samples may be less testing of water by United States laboratories as foreign laboratories become certified or the ability to have foreign water tested for compliance with United States standards becomes much more expensive and difficult.

Recommendations

IBWA urges FDA to continue and improve the coordination with Customs and Border Protection. The closer harmonization there is between the requirements for prior notice the more efficient and less confusion there will be among all parties involved in international trade. By synchronizing the timelines compliance will be improved when food products are shipped with non-food products.

IBWA urges FDA to use its enforcement discretion and not require prior notice for samples of water that are used for analytical testing. The controls already implemented by the bottled water industry and their shippers, coupled with the very small quantities involved in these water sample shipments, argues strongly for the exercise of enforcement discretion regarding the applicability of the prior notice rule to imported bottled or source water samples for analysis under the rigorous FDA/EPA sampling and testing regime.

In this regard, FDA has publicly stated that it will “actively consider the exercise of its discretion in the enforcement of the Prior Notice interim final rule.”⁵ IBWA does not believe that Congress intended this regulation to apply to the importation of bottled and source water samples for testing analysis, which are intended for either human or animal consumption.

IBWA recommends that FDA permit the importation of analytical samples that are not intended for human or animal consumption without the facility registration number of the foreign manufacturer or processor. Since the products are not “food,” this requirement should not apply.

IBWA requests FDA review of the product codes and develop codes for products that are “dual use,” but not intended for human or animal consumption. This will provide an easy reference for FDA and CBP staff and all those involved in the importation of bottled water. It will also reduce conflicts over the need for prior notice for specific shipments of water samples for analytical testing.

IV. Conclusion

IBWA looks forward to working with FDA in implementing the provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. In addition IBWA appreciates the efforts put forth by FDA in promulgating the interim final regulations and now permitting the opportunity to provide additional comment on the

⁵ See FDA's Fact Sheet on FDA's New Food Bioterrorism Regulation: Interim Final Rule – Prior Notice of Imported Food Shipments, at <http://www.cfsan.fda.gov/~dms/fsbtac13.html> (last viewed Dec. 1, 2003).

IBWA Comments on Docket No. 02N-0276 and Docket No. 02N-278
May 14, 2004
Page 7 of 7

interim rules. IBWA pledges our continued educational outreach to assist the bottled water industry in complying with the regulations and ensuring a safe, quality bottled water for the consumers.

If you need further information or have any questions, please do not hesitate to contact IBWA or me at (703) 683-5213 ext. 108, or at pdonoho@bottledwater.org.

Sincerely,

Patrick B. Donoho
Vice President, Government Relations