IBWA
INTERNATIONAL
BOTTLED WATER
ASSOCIATION

December 23, 2003

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 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. Bottled water producers utilize a multi-barrier approach, from source to finished product that helps ensure the safety and high quality of the product. The following comments are provided to assist FDA in improving the workability of the implementing regulations, while meeting the objectives of the Bioterrorism Act.

I. Summary

IBWA commends FDA on their efforts to publish the interim final regulations and provide an operational online registration system within the very short timeline contained in the Bioterrorism Act and thus, not permit the self-executing provisions to be activated. 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

[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.

2002N-0278 C271

modification, and the limited experience with the workability of the regulation since they became effective.

FDA has also expended a significant amount of resources on education and outreach to assist impacted entities with compliance to the regulations. As a complement to those efforts, IBWA partnered with state/regional bottled water associations and conducted eight seminars during November and early December 2003 to educate the bottled water industry on compliance with the interim final regulations. Each seminar participant was provided a CD-ROM that contained the presentations, applicable FDA documents, and the interim final regulations. In addition, the interim final regulations were the subject of a number of IBWA Committee meetings and seminars at the World Wide Food Expo in Chicago, IL, on October 29 through November 1, 2003, of which iBWA was a sponsoring organization. IBWA has also publicized the requirements in the Association's weekly newsletter and bimonthly magazine.

IBWA is planning a number of educational programs for 2004 to continue education and awareness efforts on all the regulations implementing the Bioterrorism Act. IBWA looks forward to continued dialogue with FDA on guidance with compliance issues that may arise after the formal comment period is closed and also after the final regulations have been issued. Communications and cooperation are critical to the success in meeting the objectives of the Bioterrorism Act.

IBWA believes that the regulations have generally addressed many of the issues highlighted in comments provided before and during the rulemaking process. However, there are still a few areas that need further clarification and/or modification to improve the workability and compliance with the regulations. 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;**
3. **Review of the attached IBWA list of various types of bottled water with FDA Product Code Builder for the appropriate assignment of the product codes; 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 the Federal Unified Registration and Licensing System (FURLS), the online system for food facility registration. Without the online system, compliance and

usefulness of the registration process would have been seriously diminished and placed an extremely large burden on the food industry. As with other computer systems and programs, it is not without its glitches and challenges. However, the feedback received by IBWA from our membership is that the system is relatively user friendly and sufficiently flexible to address many of our earlier concerns with the adaptation of the system to the variety of corporate configurations and situations.

The ability to have multiple sub-accounts for managing the registration of facilities is appreciated. In addition, features such as "auto fill" and online tutorials have been beneficial to establishing accounts and registering facilities for the first time. However, maintenance and communication will be an ongoing challenge for both FDA and the food industry. It has been helpful to have access to a web page that provided information on current status of FURLS because there have been times, although infrequent, when the system was experiencing problems that did not permit a company to register their facilities. The result, prior to this access, was frustration from both the food entity trying to register and FDA.

Food Facilities

FDA specifically excluded nonbottled water drinking water collection and distribution establishments and structures from the definition of "food facility."[2] The preamble refers to public water systems regulated by the Environmental Protection Agency (EPA), which are regulated under Title IV of the Bioterrorism Act. IBWA has interpreted this exemption and advised the members of IBWA that pump houses or spring houses that are not at the same location of another food facility, such as a bottling plant or warehouse, are required to be registered and the location described as best as can be done, either with longitude and latitude descriptions or general locations, since many do not have a physical address.

With the use of the term "nonbottled water drinking water," it is presumed that all water collection and distribution systems that are not EPA regulated must register as a food facilities, for example those that provide water for other beverages, such as juice, and food manufacturing and are not EPA regulated.[3] This would also include foreign entities, which are not under EPA jurisdiction, such as Canadian bulk water companies selling to U. S. companies, regardless of the water eventual use.

The categories for food products either manufactured, processed or held within a facility needs further refinement. Processing aids, such as chlorine dioxide or carbon dioxide, do not neatly fit the broad general categories within the regulations, although they are stored in bottling plants and thus subject to the regulations.

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. In addition,

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[2] Subpart H Section 1.227 (b)(2)
[3] Federal Register, Vol.68, No. 197, Friday, October 10, 2003, pages 58909 - 58910

FDA needs to clarify the applicability of the collection and distribution structures for non-EPA regulated facilities that provide water for food products, including bottled water.

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. This would provide better consistency in application of the agencies' requirements and thus compliance by those importing food products to the United States. An example of the potential for confusion is the variation in the timelines for prior notice by the two agencies for the same modes of transportation. IBWA hopes that the timelines can be better harmonized between CBP and FDA as FDA finalizes the prior notice regulations.

Data Requirements

In the past, bottlers have experienced variations in interpretation of the appropriate product code on imported bottled waters. This is a result of complexity of the FDA product code builder and its application to bottled water. In addition, there are no product codes in the FDA Product Code builder for water samples used in analytical testing. IBWA has attempted to work with FDA in addressing any confusion that may exist for imported bottled water. In so doing, IBWA has developed a list of bottled water types that identify the standards of identity, containers, and processing; and applies a product code from the FDA product code builder to each bottled water type. IBWA submitted this list to FDA for review and concurrence on the proper application of the FDA product codes to the bottled water types. The need for a product code for water samples will be discussed later in these comments.

The facility registration number requirement presumes that it is available or can be obtained by the person responsible for the prior notice. This is likely to be the case for most " normal trade with the United States. However, in situations such as testing a competitor's product that is purchased in a foreign retail store and sent to the United States for analysis there would not be a registration number. This type of analysis may include a focus group evaluation of the tested products. It is unreasonable to expect a company that is developing a competing product to notify (request) their competitor to provide their registration number for testing being under taken.

In addition, there may be situations, in which a competitor or their channel of distribution have no intention of selling the product in the United States and therefore, would not want to register their facilities. In these instances, the registration number does not exist and the responsible party, the foreign manufacturer, is not aware of a need to register their facilities.

Water Samples for Analytical Testing

In a December 3, 2003, letter, IBWA requested FDA to use its enforcement discretion to not require prior notice of water samples for analytical testing. By way of reference, the letter is enclosed with these comments. Described below are IBWA's concerns with the impact of prior notice on water samples for analytical testing.

In order to comply with the FDA bottled water regulations, our members must sample and analyze source and bottled water on a regular basis for multiple analytes.[4] In addition, a number of states require such analyses for water being sold within their jurisdictions to be performed by laboratories holding specific state certifications. Thus, our members who export to the United States or import into the United States, 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.

Microbiological testing on source and bottled water is required on a weekly basis. Chemical, physical, and radiological testing is required annually. Each water sample for each analyte must be collected in a precise manner, at a particular point in the sourcing or bottling process, and often is subjected to unique packaging and preparation techniques, prescribed by EPA, so that the analytical results may be considered conclusive. Additionally, in the majority of cases, the sampled water must be analyzed within certain strict time frames of collection. Delays would 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 many instances, 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 declorinator,

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[4] 21 C.F.R. § 165.110.

such as sodium thiosulfate, with HCl to bring the pH to less than 2. Sometimes the containers must be filled to the top, leaving no headspace. In other circumstances, headspace is required, as the headspace gas is what ultimately will be sampled and analyzed. 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.

Under the Prior Notice Rule, FDA requires that each prior notice submission include the article's identity. This identity includes an estimated quantity. The preamble and the regulation state that the "estimated quantity" is described "from the largest container to the smallest packaging size".[5] We are concerned that this language will require a separate prior notice for each different sample container size, even for the same water from the same foreign source. The result would be that every sample in each shipment might require a separate prior notice, producing dozens of prior notices for each shipment – for thousands of shipments each year.

As you can see from the above, water samples enter the United States from multiple foreign locations in various shipping containers, packaging configurations, quantities, volumes, and frequencies. Each shipment may contain any number of the sampling variables described herein. Obviously, none of these samples are intended for consumption in the United States by humans or animals – indeed, in many circumstances, consumption of water samples treated for analysis would be dangerous. It would be relatively simple to design special package labeling to designate or highlight the package contents as samples for analytical testing and not human or animal consumption. This would assist FDA and CBP in identifying the contents of the package and expediting the review for importation of the samples.

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.[6] 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."[7] 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

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[5] *See* n.1 at 58978. *See also* 21 C.F.R. § 1.281(a)(5)(iii).
[6] *See* n.1 at 58986-87.
[7] *See id.* at 58987.

> believes that the substance is reasonably expected to be directed to a food use. [8]

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. Our members take great care and go to great lengths to ensure their source water sites and their processing facilities are secure. The samples are shipped by way of express courier, which renders them capable of being tracked throughout the shipping process to the destination. This mode of shipment also enables our members to ensure a proper chain of custody for each sample is adequately maintained. These efforts have not only proven effective for avoiding shipping losses but also enhance sample traceability, should it become necessary to identify where any given sample has been. Furthermore, the water quality sampling and analysis process promotes bottled water safety and security by continually ensuring the quality of bottled and source water intended for U.S. consumption.

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, for example, compliance will be improved when food products are shipped with non-food products.

In addition, IBWA urges FDA to continue working with the food industry in clarifying issues of compliance, education, and workability as the regulations are fully implemented. Cooperation between FDA and the food industry is essential in the prevention, mitigation, and recovery from a bioterrorism threat. This new paradigm must be developed to manage the security and safety of the food supply in the United States.

IBWA requests FDA review of the product codes for bottled water types, which have been previously submitted. This will provide an easy reference for FDA and CBP staff and also those involved in the importation of bottled water. IBWA intends to post the chart on our website as a reference. A copy of the chart of bottled water types and the FDA product code that IBWA has assigned using the FDA Product Code Builder is enclosed with these comments.

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[8] *Id.*

IBWA recommends that FDA permit the importation of quality assurance samples that will be used for taste testing or quality control that includes human consumption without the facility registration number of the foreign manufacturer or processor. In its place, the prior notice should include the manufacturer's name and location along with the identification of the person sending the samples.

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." [9] 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.

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. IBWA appreciates the efforts put forth by FDA in promulgating the interim final regulations prior to December 12, 2003, and also addressing most of the initial concerns of the industry. 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

Enclosures (2)

[9] *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).

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October 17, 2003

Dr. Henry Kim
Center for Food Safety and Applied Nutrition
U.S. Food and Drug Administration
Harvey W. Wiley Federal Building
5100 Paint Branch Parkway
College Park, MD 20740-3835

Dear Henry:

The International Bottled Water Association (IBWA) is preparing a number of materials to assist members in registering their facilities and complying with new prior notice requirements under the October 10, 2003 FDA interim final rules.

As part of that effort, we are seeking to provide our international members with correct FDA product codes for bottled water products imported into the United States. We employed the FDA Product Code Builder web site to derive the codes on the enclosed list. The FDA product description and codes we derived are preceded in the attached table by a product description that is in line with FDA's standard of identity for bottled water.

All codes were developed under industry code 29 (soft drink/water).

We have attached a separate page with the list of codes, and would very much appreciate FDA's review of these codes for correctness. We believe that disseminating the correct codes will benefit all parties during the import process, including the importer as well as U.S. Customs and FDA.

If you have any questions, please don't hesitate to contact me at (703) 683-5213, extension 111 or by email at bhirst@bottledwater.org.

Sincerely,

INTERNATIONAL BOTTLED WATER ASSOCIATION

Robert R. Hirst

Robert R. Hirst
Director, Technical Affairs

RRH/rh

DRAFT FDA FOOD PRODUCT CODES FOR USE IN PRIOR NOTICE OF FOOD IMPORTS

FDA Standard of Identity Description	FDA Product Code Description	Product Code
Bottled spring, mineral, artesian well, well water in PET, PC, or HDPE (includes sparkling)	Water/Ice – Nonflex Plastic – Packaged Food (Not Commercially Sterile) – Bottled Spring or Mineral Water	29 W H T 02
Bottled spring, mineral, artesian well, well water in PET, PC, or HDPE (includes sparkling) – full or flash pasteurized	Water/Ice – Nonflex Plastic – Pasteurized – Bottled Spring or Mineral Water	29 W H O 02
Purified water (R.O., distilled, deionized) in PET, PC, or HDPE	Water/Ice – Nonflex Plastic – Packaged Food (Not Commercially Sterile) – Bottled Water	29 W H T 01
Purified water (R.O., distilled, deionized) in PET, PC, or HDPE	Water/Ice – Nonflex Plastic – Packaged Food (Not Commercially Sterile) – Bottled Water	29 W H T 01
Purified water (R.O., distilled, deionized) in PET, PC, or HDPE – full or flash pasteurized	Water/Ice – Nonflex Plastic – Pasteurized – Bottled Water	29 W H O 01
Bottled spring, mineral, artesian well, well water in glass (includes sparkling)	Water/Ice – Glass – Packaged Food (Not Commercially Sterile) – Bottled Spring or Mineral Water	29 W C T 02
Bottled spring, mineral, artesian well, well water in glass (includes sparkling) – full or flash pasteurized	Water/Ice – Glass – Pasteurized – Bottled Spring or Mineral Water	29 W C O 02
Purified water (R.O., distilled, deionized) in glass	Water/Ice – Glass Plastic – Packaged Food (Not Commercially Sterile) – Bottled Water	29 W C T 01
Purified water (R.O., distilled, deionized) in glass – full or flash pasteurized	Water/Ice – Glass – Pasteurized – Bottled Water	29 W C O 01

FDA Standard of Identity Description	FDA Product Code Description	Product Code
"Enhanced" waters (with added fluoride, essences, or supplements) in PET, PC, or HDPE	Water/Ice – Nonflex Plastic – Packaged Food Commodity (Not Commercially Sterile) – Water and Ice (N.E.C.)	29 W H T 99
"Enhanced" waters (with added fluoride, essences, or supplements) in glass	Water/Ice – Glass – Packaged Food Commodity (Not Commercially Sterile) – Water and Ice (N.E.C.)	29 W C T 99

IBWA
International Bottled Water Association

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December 3, 2003

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Robert E. Brackett, Ph.D
Director
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Harvey W. Wiley Federal Building
5100 Paint Branch Parkway
College Park, MD 207040-3835

Re: Request for FDA Enforcement Discretion for Water Samples under Prior Notice of Food Importation Rules

Dear Dr. Brackett:

The reason for this correspondence is to communicate the significant adverse impact on the bottled water industry of the U.S. Food and Drug Administration's (FDA's) recently issued interim final rule requiring prior notice of virtually all imported foods. 1/ Herein we specifically request that, in accordance with its stated intentions, FDA commit to exercising its enforcement discretion with respect to requiring prior notice for samples of source water and finished bottled water that may be imported into the United States solely for analytical testing, as required by FDA.

The International Bottled Water Association (IBWA) represents bottled water manufacturers, processors, importers, and distributors both domestic and international who identify and develop sources of water and process and bottle water for sale in the United States and elsewhere. Many of our members, and their products, are subject to regulations recently promulgated under the authority of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. 2/ Our members' bottled water meets the highest quality standards, including those required under 21 C.F.R. §§ 110, 129, 165.110, and the regulations of each state within which bottled water is sold.

1/ *See Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002,* 68 FR 58974 (Oct. 10, 2003) (hereinafter the "Prior Notice Rule").

2/ *See* Public Law 107-188 (hereinafter the "Bioterrorism Act").

As you know, in order to comply with such standards, our members must frequently sample and analyze source and bottled water on a regular basis for multiple analytes. 3/ In addition, many states require such analyses for water being sold within their jurisdictions be performed by laboratories holding special certifications. Therefore, in order to export to the United States, our members 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.

Microbiological testing on source and bottled water is required on a weekly basis. Chemical, physical, and radiological testing is required annually. Each water sample for each analyte must be collected in a precise manner, at a particular point in the sourcing or bottling process, and often is subjected to unique packaging and preparation techniques, prescribed by EPA, so that the analytical results may be considered conclusive. Additionally, in the majority of cases, the sampled water must be analyzed within certain strict time frames of collection. Delays would 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 many instances, 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 declorinator, such as sodium thiosulfate, with HCl to bring the pH to less than 2. Sometimes the containers must be filled to the top, leaving no headspace. In other circumstances, headspace is required, as the headspace gas is what ultimately will be sampled and analyzed. 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

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3/ *See* 21 C.F.R. § 165.110.

collector with precise instructions to avoid repetitive sampling and unnecessary and costly delays.

As you can see from the above, water samples enter the United States from multiple foreign locations in various shipping containers, packaging configurations, quantities, volumes, and frequencies. Each shipment may contain any number of the sampling variables described herein. Obviously, none of these samples are intended for consumption in the United States by humans or animals – indeed, in many circumstances, consumption of water samples treated for analysis would be dangerous.

Under the Prior Notice Rule, FDA requires that each prior notice submission include the article's identity. This identity includes an estimated quantity. The preamble and the regulation state that the "estimated quantity" is described "from the largest container to the smallest packaging size". 4/ We are concerned that this language will require a separate prior notice for each different packaging size, even for the same food from the same foreign manufacturer. The result would be that every sample in each shipment might require a separate prior notice, producing dozens of prior notices for each shipment – for thousands of shipments each year.

We are preparing comments to the Prior Notice rule on behalf of our members to obtain an exemption for water samples that are collected and tested under the authority of 21 C.F.R. § 165.110, however, until the interim final rule is finalized we request FDA agree to exercise its enforcement discretion with regard to requiring prior notice for imported water samples exclusively for analytical testing. We believe this is consistent with language in the preamble to the rule; would reduce the burdens on the prior notice system; and would result no additional public health, safety, or security risk to consumers or the U.S. food supply. We also believe it makes good sense.

Under FDA's Prior Notice rule, imported water samples intended for analysis under 21 C.F.R. § 165.110 are products with "multiple uses". 5/ 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." 6/ 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:

4/ *See* n.1 at 58978. *See also* 21 C.F.R. § 1.281(a)(5)(iii).
5/ *See* n.1 at 58986-87.
6/ *See id.* at 58987.

> 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. 7/

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.

We should further emphasize a lack of any real bioterrorism threat associated with these water samples. Our members take great care and go to great lengths to ensure their source water sites and processing facilities are secure. The samples are shipped by way of express courier, which renders them capable of being tracked throughout the shipping process to the destination. This mode of shipment also enables our members to ensure a proper chain of custody for each sample is adequately maintained. These efforts have not only proven effective for avoiding shipping losses but also enhance sample traceability, should it become necessary to identify where any given sample has been. Furthermore, the water quality sampling and analysis process promotes bottled water safety and security by continually ensuring the quality of bottled and source water intended for U.S. consumption.

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." 8/ We believe that the applicability of this regulation to the importation of

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7/ *Id.*

8/ *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).

bottled and source water samples for analysis appropriately falls within the realm of FDA's "enforcement discretion."

We are preparing comments to assist the FDA in what we hope is the promulgation of an eventual exclusion from the interim final rules for both registration and prior notice requirements for these imports. Because these rules become effective on December 12, 2003, we urge the agency to exercise its enforcement discretion with respect to imported bottled and source water quality samples, based upon this dialogue. It would seem preferable, if not desirable, that FDA not apply the registration requirements without first understanding the significant impact the regulations will have on our members, with very little resultant public health benefit or enhanced bioterrorism preparedness.

We look forward to hearing your response to the issues we have raised. If you have any questions or need more information, please do not hesitate to contact us.

Sincerely,

Patrick Donoho

Patrick Donoho
Vice President, Government Relations

Cc: L. Robert Lake, FDA
Leslye Fraser, FDA
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