IBWA
INTERNATIONAL
BOTTLED WATER
ASSOCIATION

VIA Electronic Mail and by Hand

July 8, 2003

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

Re: Implementing Regulations of PL 107-188:
Establishment and Maintenance of Records – Docket No. 02N-0277

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 proposed regulation implementing 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. Bottled water producers utilize a multi-barrier approach, from source to finished product, that helps ensure the safety and high quality of the product. 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. Enhanced cooperation and the sharing of information between the bottled water industry and governmental agencies will help provide the appropriate evaluations and responses to potentially hazardous events.

I. Summary

IBWA supported the Bioterrorism Act during the Congressional debate. The provisions of the Act are intended to enhance the safety and security of the food distribution system in the United States. IBWA commends FDA on devoting significant resources and soliciting input from stakeholders prior to proposing the regulation. IBWA

[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.

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shares the goal of making the regulations workable, while ensuring greater ability for FDA to respond to a potential threat of serious adverse health consequence to humans and animals. The final regulations must balance the specific needs of FDA for access to critical information with the potential adverse impact on commerce of the provisions. It is imperative to bear in mind that the purpose of the regulations is to provide FDA with a tool to address a credible threat of serious adverse health consequence or death to human or animals in a timely manner.

It is particularly important that the final regulations are practical and workable with a minimal burden on commerce and trade. For compliance purposes, reliance on current business records for a "look forward" at the recipient and a "look back" at the source needs to be incorporated into the regulations as much as possible. Although the proposed regulations have attempted to integrate the comments FDA received from stakeholders in 2002 and emulate current record keeping practices, additional refinements need to be made to the final rule to achieve an appropriate balance between the needs of FDA and its impact on commerce and burden on the food industry. Specifically, IBWA urges the following:

1. **refinement of the definition of "food" and the scope of the regulations;**
2. **flexibility in the format and method for companies to maintain the records;**
3. **focus on the ability to trace the product forward and back, rather than the specific data elements of the records; and**
4. **reasonable time frames for the production of records.**

II. Background

The bottled water industry has long been at the forefront of anticipating and responding to the need for safe, quality drinking water by consumers, particularly in times of emergency or disasters. Bottled water is fully regulated as a packaged food product by FDA and bound by FDA's good manufacturing practices, standards of quality, safety, inspection, enforcement and labeling requirements. As a packaged food, bottled water is subject to the full array of FDA enforcement actions including warning letters, and civil (seizure and/or injunction) and criminal penalties under the Federal Food, Drug, and Cosmetic Act's misbranding and adulteration provisions, which help further ensure that only safe, high quality bottled water products reach the marketplace.

In addition to federal and state regulations, members of IBWA are required to adhere to standards in the IBWA Model Code that, in several cases, are stricter than FDA and state bottled water regulations. As a condition of IBWA membership, bottlers must submit to annual, unannounced plant inspections by an independent, third-party audit organization to verify compliance with the IBWA Model Code.

Bottled water producers utilize a multi-barrier approach, from source to finished product, which helps ensure the safety and high quality of the product. Many of the steps in a multi-barrier system are effective in safeguarding bottled water from microbiological and other contamination. Some of these measures include source protection and monitoring, distillation, reverse osmosis, filtration, ultraviolet light, and ozonation. Hazard Analysis and Critical Control Point (HACCP) plans, which is required by the IBWA Model Code, also plays a key role in management of potential hazards. Bottlers are encouraged to "think outside the box" when considering potential hazards and preventive actions. Preparedness is the keystone of a HACCP program.

III. IBWA General Comments on the Proposed Regulations

IBWA sincerely commends FDA on the attention and resources the Agency is devoting to implementing the provisions of the Act. In addition, the Agency should be congratulated on the process of outreach to stakeholders before the regulation was proposed and providing personnel to explain the proposed regulation during the comment period. There are stringent time constraints imposed by the Act, and thus, this rulemaking only increases the importance of consideration by FDA of reasonable recommendations and requests for clarification from the regulated industries, including the bottled water industry.

IBWA supports FDA's timeline for promulgation of final regulations and the sliding scale for implementing them based on the size of the business. Although the records access provisions of the Bioterrorism Act are in effect now, the final regulations will give additional clarity to firms on the compliance procedures that they must develop. This is particularly important for IBWA members with international operations and the suppliers and transporters to the industry.

In the proposed rule, FDA may have significantly underestimated the number of entities to be covered by the regulations and the volume of records to be impacted by the regulations. By requiring entities under the "food" definition of Section 201(f) of the Food, Drug, and Cosmetic Act (FDCA) and as well as transportation entities to comply with the record keeping requirements, the scope of the proposed regulations will impact, as an example, almost all of IBWA membership, including bottlers, distributors, and suppliers. The challenge is to provide a balance with regard to the scope of the regulations in terms of covered entities. Congress intended to provide FDA with an investigative tool with which the agency can quickly assess and contain a credible threat to the food supply. A test to meeting this balance is reasonableness of the regulatory requirements, not attempting to cover all possible scenarios. In accomplishing a proper balance, FDA should refine the scope of the proposed regulation to provide for a more workable final regulation. As proposed, the number of covered entities and the data elements for each record will not be easily integrated into current business practices. In some cases, the record keeping technology has yet to be developed, much less installed in corporate records.

IV. Docket No. 02N-0277 - Section 306 (Maintenance and Inspection of Records for Foods)

Overview

Under Section 306 of the Bioterrorism Act, FDA may, by regulation, create requirements regarding the establishment and maintenance, for not longer than two years, of records by persons (excluding farms and restaurants) who manufacture, process, pack, transport, distribute, receive, hold, or import food. These records are needed by FDA for inspection to allow the Agency to identify the immediate previous sources and immediate subsequent recipients of food, including its packaging, in order to address credible threats of serious adverse health consequences or death to humans or animals. The regulations under this section shall take into account the size of a business.

In addition, the Bioterrorism Act requires expedited rulemaking. It directs the Secretary to propose and finalize regulations "establishing record keeping requirements" within eighteen months of the effective date of the Bioterrorism Act. The seeming contradiction of a mandate for regulations within the law has been correctly interpreted by FDA to mean that the record keeping provisions must be coordinated with the other food safety provisions.[2] IBWA encourages FDA to maintain its current schedule for implementation of the food safety provisions. By so doing, the awareness, education and training for compliance with the provisions will be eased.

§1.326 – Who is subject to this subpart?

Comments on Scope of Covered Entities

IBWA supports the effort to coordinate the scope of the provisions on record keeping with the facilities registration provisions. However, a review of the statutory language suggests that Congress intended more entities to be covered by the record keeping provisions than under the facility registration. Specifically the transportation of food products is included in the statutory language for record keeping.[3] However, the specific records and method of retention are left to FDA in rulemaking.

Discussed below are specific situations that need revision or clarification in the final regulations. IBWA offers these examples as representative examples of the need for workability within the regulations and clarity to ensure compliance, particularly throughout the world.

Clarification of entities covered

Bottled water is distributed to a wide variety of businesses and consumers. The proposed scope of the regulations appears to cover many of the companies to whom

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[2] Public Health Security and Bioterrorism Preparedness and Response Act of 2002 - Section 306
[3] ibid.

bottled water is distributed. As with the food facilities registration proposed rule, it is unclear who exactly will have to maintain records. Such clarity will be needed so that the bottled water industry can ensure compliance with the regulations and also advise their customers and suppliers of their respective responsibilities under the final rule. As an example, office delivery of bottled water is a major segment of the bottled water industry. A storage area in an office complex may take delivery of five-gallon bottles of water to be redistributed to various offices throughout a multi-building office campus setting. The offices are controlled by one company, and rather than having a bottled water truck deliver water to multiple locations within the complex, the company has deliveries to one central location to be held for redistribution as needed. Each user of bottled water may be billed internally for the water use, but the orders are processed centrally. Would the bottled water customer (a business) also be required to maintain records because they "hold or distribute" a food product? Would they also be the immediate previous source for bottles that are returned to the bottler for reuse? As mentioned below in the recommendations, IBWA does believe the recordkeeping regulations should not apply to these retail customers.

Manufacturers and supply channels for contact materials

In comments submitted to Docket No. 02N-0276, IBWA and others suggested refinements to the entities to be required to be registered. In particular, FDA was urged in those comments to clarify the inclusion of water sources, bottled water equipment manufacturers, and other suppliers in the requirements to register. It is reasonable to request FDA to review the applicability of the regulations to such entities. A balance needs to be developed between the reasonableness and the usefulness of the information to FDA in addressing a credible threat of serious adverse health consequences or death. Materials that come into contact with food are included as food products. However, immediate access to the detailed information on many of these materials by FDA does not seem as necessary as with other food products within the definition. For example, given the technical challenges of having a bio-terrorist threat of serious adverse health consequence or death to humans from a stainless steel silo leeching pathogens into water in a bottling plant and the longevity of such silos, the usefulness of the recordkeeping requirements for silo manufacturers is questionable.

Water Sources

Likewise, a requirement for water sources (spring houses, pump house, or community water systems) to maintain records as a nontransporter of food products should also be reconsidered. Like farms, which are exempt from the regulations, the water source is the origination of the food product. The bottler in their records will capture any potential concerns of a serious threat of adverse health consequences. The detail of records required under the proposed regulation will not exist in many cases, because the water comes directly out of the ground into the bottling facility. There is no immediate previous source of the food ingredient – water.

Foreign Bottles

For foreign bottle companies, the proposed regulations will be extremely confusing. As proposed, a Canadian bottle manufacturer will be required to keep records, including individual production codes, as a non-transporter for all empty bottles sent to bottled water Company A in the United States. However, those same records will not have to be kept by the company for bottles sent to Company A's Canadian subsidiary, which will bottle water in the bottles prior to shipment to the United States. It would appear that FDA has extended its authority beyond the actual intent of Congress by requiring the bottle manufacturer to maintain records in their foreign facilities for only those bottles shipped empty to the United States.

Water Coolers

This is further complicated when applied to water coolers and their component parts. Company X may manufacture water coolers in China and import it them to this country through their United States subsidiary. Under the definitions in the proposed regulations, the water cooler would be considered a food product because of the food contact material provision within the definition of food under proposed regulations on food facility registration and record keeping. The applicability of the proposed regulations is less clear for the component part manufacturers, e.g. spouts, piping, gaskets, etc. If Company Y manufactures spouts in Korea for Company X, it appears that the record keeping requirements and Company Y's responsibilities under the Bioterrorism Act would be driven by the specific facts of each transaction. For example, in the case of Company Y delivering the spouts to the manufacturing plant in China, where the parts are assembled and the water coolers are shipped to the U.S., Company Y would not be covered by the record keeping provisions. However, if Company Y sent the spouts directly to the United States as replacement parts, they would then be covered by the proposed regulations, along with the transporters of the parts.

Harmonization of definitions

IBWA supports the efforts by FDA to synchronize the implementation of regulations of the Bioterorism Act. This is particularly important for the foreign entities in understanding and complying with the regulations. As mentioned earlier, IBWA commented in Docket No. 02N-0276 that refinements and clarification to the definition of "food" need to be incorporated into the final regulations. Those suggestions also apply to this proposed regulation. The examples above for foreign suppliers to the bottled water industry under the proposed regulations would create illogical and burdensome requirements for entities engaged in trade with the United States and would have a minimal impact on potential bioterrorist threats to the food supply.

IBWA urges FDA to promulgate the final regulations as expeditiously as possible in order to enhance compliance with the provisions of the Bioterrorism Act. By finalizing the regulations in conjunction with the facility registration and prior notice for importation of food product regulations, the education and training that will be necessary for compliance with the regulations can be done together and the internal policy and procedures for companies can be designed to meet all of the obligations under the rule.

It is precisely for this reason that Congress intended regulations to be promulgated within eighteen months of the effective date of the Bioterrorism Act.

Recommendations

Clarification and refinement of the scope of the regulations needs to be incorporated into the final regulations. The proposed rule encompasses a vast number of entities worldwide. The balance between the information needs of FDA to react to a serious threat and the burdens on trade and commerce are a delicate and vital component to the success of the Bioterrorism Act.

In addition, the scope of the record maintenance requirements needs to be harmonized with the other implementing regulations. This will reduce potential confusion and assist entities in compliance. IBWA respectfully suggests that the scope of the regulations for foreign entities focus on finished food products for human or animal direct consumption, rather than following the current definition of food, which includes food contact material. By differentiating between foreign companies and domestic and by limiting the scope of the Bioterrorism Act to food products that do not undergo further processing, the Bioterrorism Act would permit FDA to require records be maintained on finished food products.

IBWA urges FDA to:

- *Clearly state which entities, both domestic and foreign, that produce bottles, caps, seals, water coolers, cooler parts, bottling and storage equipment, or that hold bottled water for redistribution within an office complex or similar situations, need to maintain records under this regulation.*
- *Clarify the applicability of the record keeping provisions to the channels of distribution for those companies mentioned above.*
- *Consider modification of the foreign entities exemption for purposes of the foreign food products that could fall within "products that migrate into food from food packaging and other articles that contact food" part of the food definition.*

§ 1.327 Who is excluded from all or part of the regulations in this subpart?

Comments on the scope of the exclusions

IBWA urges FDA to harmonize, to the extent possible the exclusions from recordkeeping with the other implementing regulations of the Bioterrorism Act. As currently drafted the proposed regulations will regulate the entities engaged in the specified activities, which is different from the approach taken in the food facility registration, wherein an entity engaged in production and direct retail sales from the same facility were exempt from registration. The proposed regulations on recordkeeping regulate the records of merchandise transfers by entities, but not transactions. By exempting sales directly to consumers, the regulations could avoid the potential confusion posed by the proposed exclusion of certain entities.

By focusing on the establishments or facilities, rather than the sale directly to consumers, the proposed regulation will unintentionally encompass a number of large transactions under § 1.345 of the subpart. IBWA does not believe it was the intent of Congress that detailed records are kept on consumer purchases. As IBWA indicated in comments to FDA in August 2002, the focus of the record keeping regulations should be on business-to-business transactions. For example, Internet sales of finished food products would have to record and maintain detailed records of each consumer's purchase and retain those records for two years.

The expansion of the record keeping requirements to consumer purchases raise significant privacy issues and access questions. It is simple to avoid these issues by exempting sales directly to consumers from the provisions of § 1.345, regardless if the facility from which those sales are made is used exclusively for retail sales. The transaction, rather than the facility should be excluded from the requirements of § 1.345.

Recommendations

IBWA urges FDA to extend the exemption for retail facilities to other retail transactions for purposes of § 1.345. Records of consumers' purchases should be excluded from the provisions of detailed record keeping under § 1.345, regardless of the type of facility. The sales from a facility that manufacturers or processes and sells directly to consumers from the facility should be exempt from the record keeping provisions for the sales directly to consumers, as the location is exempt from registration.

IBWA urges FDA to:

- *Include in the exclusions from the record keeping provisions of § 1.345 all transactions directly to consumers, regardless of type of facility.*

§ 1.328 What definitions apply to this subpart?

General comments on the definitions

FDA has requested comment on the differences in treatment between transporters and nontransporters in the regulations. In addition, FDA is seeking comment on the treatment of foreign entities within the proposed regulation. IBWA has provided comment on the issues involved with foreign entities previously in these comments for the record. Therefore, they will not be repeated. With respect to the dual requirements for record keeping, IBWA urges FDA to be clearer in the definitions. Specifically, the transporter requirements should only apply to unaffiliated commercial transportation companies that may transport food products. Company owned and/or operated vehicles should not trigger an additional set of record keeping requirements for food companies.

The difficulty in workability of this framework for the regulation lies in the information availability to the transportation company and the responsibility for information. Given the all encompassing definition of "food" within the proposed rule,

how will a company know a sample of a food product is contained in a small package for delivery? In the converse, how will a nontransporter know if the exact product was delivered to the appropriate person?

Recommendations

To expect to be able to have precise traceability of all food products, ingredients, additives, and packaging, is unrealistic. The expense and burden of such a system could have a dramatic adverse impact on commerce. FDA would be better served by developing a system to contact the appropriate companies to engage their assistance in addressing threats to the food supply. The basic difference between the two approaches is one of communication/cooperation versus interdiction/enforcement. In creating a new paradigm, the FDA and the entire food industry can help ensure the security and safety of the food supply in the United States in this new era.

IBWA urges FDA to:

- *Maintain the distinction between nontransporter and transporter within the definitions.*
- *Modify the application of the regulation to foreign entities to limit it to finished product that is consumed by humans or animals.*
- *Revise the application of the proposed regulation on retail sales to sales to consumers, regardless of the facility type.*

§ 1.337 What information is required for identification of immediate previous source?

Comments on data elements for records

The proposed requirements for information on the immediate previous source of food is far too detailed and begs the question about the production of such records. Although much of the proposed required information is available in some company records, it may not include the level of detail specified in the proposed rule given the broad definition of food. As an example, production codes for bottles are available, but may not be specifically associated with a particular lot number of bottled water. Discussed below are examples of some of the concerns with the detail of the records to be required under the proposed rule.

Sources

As the principle ingredient in bottled water, source water should be viewed in the same manner as other primary agricultural food ingredients, such as flour in cookies. If water were pumped from a spring source, the immediate previous source would be the aquifer from which it came. Would that have to be noted on each production run of a bottling facility if it was the sole source of water for bottling? If water is blended during the bottling process, how would quantity of each source be determined if it was commingled in a storage silo and was used in two different lots of bottled water?

Lot Numbers

Bottled water lot numbers, according to the draft rule, must record the production code for the bottles that were used for that particular production. It is unclear from the proposed rule that the bottle production number must also be forwarded along with the lot number for the bottled water to the next immediate recipient. This point will be discussed in IBWA's comments on § 1.345. The application of this rule to five-gallon bottles that are refilled is both problematic and extremely burdensome. The systems are not developed to recapture the production codes of bottles that are returned to them from consumers. The technology to trace a bottle completely through its life cycle has not been developed and is not operational yet in the industry. It is more workable solution to require the records of receipt to show the particulars of the bottle order when it is originally entered into inventory by a bottler.

Responsible persons

The requirement for a responsible person to be recorded and maintained as one of the data elements for each food product may pose significant compliance issues beyond the Congressional intent. The scope of the products and entities covered by the proposed regulations will have a unique impact to the bottled water industry. In addition, there is no definition of a responsible person within the regulation, which will be required from both the previous source, as well as the transporter.

Does the proposed rule require that a responsible person for the nontransporter, as wells as the transporter, be recorded and maintained for each group of bottles used? Must this record be included in the production records for each lot number of bottled water? In the case of the return of a home delivery of five-gallon bottles, the nontransporter of the bottles would be the person (home or office) from whom the bottles were returned to the bottler. In order to return the bottles, the person would have to create a record of the return to be maintained in their home, including the production code of the bottle. This is surely not the intent of Congress in creating the recordkeeping requirement.

Descriptions

The proposed rule requires very detailed descriptions of the products received. Specific brands, varieties, by quantity and by packing, must be noted in the records by date. For bottle caps, information on how they were packed must also be recorded, such as "blue 12 oz. caps in box of 10,000 on July 8, 2003."

This level of detail is of questionable usefulness when measured against the added cost of developing the systems to capture and maintain the information. It is doubtful that FDA will receive a credible threat of serious adverse health consequence or death to humans or animals that specifies "blue 12 oz. caps in cartons of 10,000 from Mr. X from Company A that was delivered on July 8, 2003."

Recommendations

The goal of this provision can be viewed as providing FDA with access to documented information that can be used to facilitate Agency investigation and

response in the event an article of food presents "a credible threat of serious adverse health consequences or death to humans or animals." In this provision, IBWA recommends FDA apply the record maintenance requirements to business-to-business transactions. In implementing this provision, FDA should not take a prescriptive, or "one size fits all," regulatory approach.

It is important that FDA not require a complete revamping of records for food products. As FDA is aware, many food products contain ingredients that are from multiple sources and are fungible. In the case of bottled water ingredients, water sources should not be required to maintain records under this provision. The purpose of the record provisions should be adequately served by looking at the bottling plant's records to see the sources of the water, thus narrowing the potential source of a health threat under investigation to a limited number of possibilities. Thus, the "traceability " and goal of the Act could be accomplished without unnecessarily burdening current business practices.

IBWA requests flexibility in record keeping for containers. For example, a bottler may purchase five-gallon bottles from Supplier A and six months later purchase more five-gallon bottles from Supplier B to meet new customer demand and to replace worn bottles. Bottled water in these containers is delivered to homes and offices, but also to distributors and retailers for resale. The bottles are eventually returned to the bottler to be refilled and reused. The recording of all the data elements for bottles particularly after refilling and reusing, would be an enormous undertaking for each specific bottle and for each exact location of every bottle. The complexity of such a record keeping system would be extremely cost prohibitive. IBWA recommends that only the original purchase record be required to be maintained, and not follow the bottle through its life cycle of use.

IBWA urges FDA to:

- *Provide a definition of responsible person, if included in the final regulation.*
- *Recognize the fungible nature of water as an ingredient in bottled water.*
- *Require less data elements for records, particularly food contact materials .*

§ 1.345 What information is required for the immediate subsequent recipient?

Comments on data elements for records

Many of the comments above regarding the information requirements for records from the immediate previous source also apply to this section. The level of specificity on many records is not currently kept in a location as defined under the proposed regulations. In addition, the use of the term responsible person is not defined, but required. Is this the Chief Executive Officer of a company or the person to whom the product is delivered?

Of particular note is application of lot numbers or production numbers to delivery records. For delivery trucks with multiple service stops, it will be impossible to ensure the appropriate lot numbers are delivered to particular customers. For the small package bottled waters, a retailer may receive a variety of brands, sizes, and types of bottled water with multiple lot numbers in one delivery. The tracking of specific lot numbers is not currently done with the precision prescribed in the proposed rule.

In addition, bottles used for bottled water often have production codes. IBWA sincerely urges FDA not to require tracking of the production numbers of bottles in addition to lot numbers. For the home and office delivery segment of the bottled water industry, the technology is not available to maintain the precise records of each five-gallon bottle in inventory. Even the most sophisticated systems have yet to develop the software to accomplish this task.

As indicated earlier in IBWA's comments, direct sales to consumers should be exempt from the provisions of this subpart. The delivery of a food product to a consumer for their consumption should not be covered by the proposed requirements. This should also apply to bottles, caps, seals, and other such food contact items. Once they are delivered to a bottler who will use them in the production of a food product, the records should be treated as a retail sale. A potential definition would incorporate the sale of a product to a person that does not resell the specific product.

Recommendations

The application of the record maintenance requirements should be limited to the business-to-business transactions. The "look forward" section should not apply to the person to whom the bottled water has been delivered for consumption. Unlike most food products, bottled water can be delivered directly to consumers' homes and offices. In many respects, it is very similar to retail grocery stores that deliver food products to homes.

IBWA strongly suggests that FDA not hold companies responsible for the delivery of specific lot numbers being delivered to specific locations. The systems for accomplishing such a task are not readily available or affordable for many companies. This also assumes that FDA will not require concurrent recording of bottle production codes and bottled water lot numbers. Rather, IBWA urges FDA to view the production process as incorporating a number of elements to produce a new product, which has identifiable components and ingredients, and which can be identified.

IBWA urges FDA to:

- *Remove the requirement of a lot number to a specific destination;*
- *Define "a responsible person;"*
- *Exempt sales directly to consumers from the requirements of this subpart.*

§ 1.361 What are the record availability requirements?

Comments on the availability requirements

The Bioterrorism Act requires records to be accessible at reasonable times, within reasonable limits, and in a reasonable manner. Given the nature of the record keeping requirements, the potential threats to human or animal health, and the tight timelines incorporated in the proposed regulations, it is difficult to envision if the proposed regulation meets the statute's reasonableness standard. Although most of the information is likely to be available within four hours, the actual records may not be able to be produced within that period of time.

Given the detail of the proposed required information, the storage and retrieval of the information may be particularly difficult, depending on the request. If an FDA officer presents a request for the water source(s) of a brand of bottled water with a specific lot number, it is probable that the information can be produced within the proposed timeline. However, records are not kept in a searchable database. Therefore, responses to specific requests for unique records may not be located within the four-hour limit.

In addition, specific records may be stored at an off site location, but the information may be available within the time limits. IBWA urges FDA to consider a two tiered standard for production of information and records in comments submitted in August 2002. Such a system may be particularly useful in situations of serious threat to health as addressed in the Bioterrorism Act.

Recommendation

IBWA recommends that FDA provide flexibility in the storage of historical records and the access and production of such records. In some cases, companies will archive the records electronically on storage tapes and thus not have them "readily available." Others, because of space requirements, will store the physical records offsite. Given the range in sizes of bottled water producers, from family-owned, small businesses to large corporate entities, such flexibility is vital. In order to facilitate an investigation, access to the information contained on the records seems to be the critical, time-sensitive need, rather than an examination of the physical record itself. A requirement to be able to provide information, rather than records, quickly to FDA in the case of imminent potential harm is more practical than establishing a record storage requirement that would specify how and where records must be maintained. Of course, the physical record will be produced after it has been retrieved by the company.

IBWA urges FDA to:

- *Develop a system that allows for information to be disclosed to FDA from records, with the actual record production later.*
- *Maintain a reasonableness standard in implementing the timeliness provisions by recognizing that records are not kept in searchable databases by every food company.*

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. Again, we strongly urge FDA to promulgate expeditiously the regulations in order to allow sufficient time for companies to design and implement policies and procedures to comply with the provisions of the Act.

If you need further information or have any questions, please do not hesitate to contact Patrick Donoho, IBWA Vice President of Government Relations at (703) 683-5213 ext. 108, or at pdonoho@bottledwater.org; or me at (703) 683- 5213 ext. 105, or at jdoss@bottledwater.org.

Sincerely,

Joseph Doss
President