



INTERNATIONAL
BOTTLED WATER
ASSOCIATION

1706 '03 APR -4 P3:49

VIA Electronic Mail and by Hand

April 4, 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:
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 proposed regulations 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 Act during the Congressional debate. The provisions of the Act will enhance the safety and security of the food distribution system in the United States. IBWA commends FDA on moving expeditiously in developing implementing regulations and offers whatever assistance the bottled water industry can provide in the

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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timely promulgation of the regulations. It is imperative that companies have clarity on what specific actions must be undertaken and what procedures must be initiated in order to be in compliance with the Bioterrorism Act.

It is particularly important that the implementing regulations for Sections 305 and Section 307 be finalized prior to December 12, 2003, to avoid the self-executing provisions of the Bioterrorism Act. IBWA's comments below highlight issues that will be need to addressed in the rule making by FDA. Specifically, IBWA urges the following:

- 1. clarification of what is a "food" and a "facility" for purposes of registration of both domestic and foreign facilities;**
- 2. flexibility for companies to submit registrations and updates to FDA;**
- 3. reconsideration of the proposed data requirements to be included in the food facility registration and prior notice of imported food; and**
- 4. additional flexibility for submitting the prior notice of imported food.**

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, above all in times of disasters or emergencies. Bottled water is fully regulated as a packaged food product by the U.S. Food and Drug Administration (FDA) and bound by FDA's quality, safety, inspection, enforcement and labeling requirements. Bottled water products are required to comply at all times with FDA Standards of Quality. As a packaged food, bottled water is subject to the full array of FDA enforcement actions including warning letters, 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), 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 Implementing Regulations

IBWA commends FDA on the attention and resources the Agency is devoting to promulgating regulations prior to the statutory implementation date and providing an electronic registration and prior notice system for companies that manufacture, process, pack or hold food products. 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 ambitious timeline for promulgation of final regulations and implementation of an electronic registration prior notice system no later than October 12, 2003. This will provide affected companies with the necessary notice and guidance to establish their internal policies and procedures for compliance with the tight timelines of the Act. This is particularly critical for IBWA members with international operations. Developing instructions for the identification and registration of the foreign food facilities and prior notice procedures that will be impacted by the Act will be a time consuming endeavor. As indicated in IBWA's comments, there is a particular need for clarifying regulations in implementing the Registration of Food Facilities and revisions to the regulations implementing the Prior Notice of Imported Food. IBWA shares the goals of the Bioterrorism Act, which are to enhance our nation's food security without unnecessarily burdening either the food industry or FDA. However, the proposed regulations require several modifications in order to meet these goals.

In the proposed rule, FDA may have significantly underestimated the number of facilities to be covered by the regulations and the volume of prior notices for imported food. IBWA expresses hope that the systems being developed will be able to handle the registration of food facilities world wide in a matter of six to eight weeks (from the time of final publication to December 12, 2003). The breadth of the definition for covered facilities is more than envisioned by the Bioterrorism Act as explained later in these comments. In addition, given the framework and data elements for the prior notice for imports of food regulations, FDA's system may be overwhelmed with serious adverse impacts on trade.

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

Overview

According to Section 305 of the Act, all food facilities, both domestic and foreign, that manufacture, process, pack, or hold food are required to be registered with FDA before December 13, 2003. FDA is required to issue an identification number to each facility. FDA must issue implementing regulations by December 12, 2003, or the self-executing provisions of the Bioterrorism Act will require the owner, operator, or agent to register the food facility without regulatory guidance. The Act specifies that the following information must be contained and updated in a food facility registration:

1. the name and address of the facility;

the bottling plant by tanker truck. If it is connected by pipe to the bottling facility, the separation may be measured in hundreds of feet or further distances up to miles away. This is particularly true when a community water system provides the source water, but also applies to some spring water bottling operations.

IBWA respectfully requests that FDA address the issue of registration of facilities that manufacture, process, pack, or hold water that is used as an ingredient or additive in food products in the final regulations.

Are water collection and distribution facilities required to be registered as a food facility if the owner or operator of such facility knows that the water is to be used as a food ingredient? Are water collection facilities such as a pump house or spring house that are connected by pipe to the bottling facility and on the same property that is owned and operated by the bottler considered one location even if they are physically separated? If the determination of one location is dependent on distance, what should the general guideline be on the distance?

Will the definition of food and food facility also apply to community water systems that supply water to bottled water facilities or to bottled water sources that may also be a community water source? If a community water system produces bottled water from their water supply, will the community water system also be required to be registered as the water source along with the bottling facility?

Recommendations

In this context, the definition of facility needs further clarification. Under the proposed regulation, FDA is allowing a number of physical buildings to be considered one location for purposes of registration.⁷ IBWA supports this approach as a method of reducing the burden of the registration process on bottlers and a recognition of the need for flexibility in the registration process. Further clarification is needed in the application of this approach to the registration of water sources.

Under the provisions on required information and elsewhere throughout the proposed rule, FDA seems to expect the facilities to have humans working or present in the facilities. In the case of many water sources in the bottled water industry, these facilities are remote without an address and often unmanned. They are secured and protected by a number of different methods by the owner and/or operator. **IBWA recommends that:**

water collection and distribution facilities that are connected physically or by pipe to the bottling plant be considered as one location, regardless of the distance involved.

FDA has requested comment on providing an exemption for facilities that are required to be registered with another federal agency.⁸ The inclusion of community

⁷ Subpart H-Registration of Food Facilities General Provisions §1.227 (2) Facility

⁸ Federal Register/Vol. 68 No. 22, page 5386

water systems in the food facility registration requirements for water sources would be one of the most compelling examples of the need to include such an exemption. Many of these systems are currently registered with U.S. Environmental Protection Agency (EPA), which provides substantial oversight and regulation of the facilities as purveyors of community water supplies and are covered by the Bioterrorism Act⁹. The FDA proposed required information for registration of a food facility is currently maintained by EPA for community water systems. In addition, the purpose and intent of the Bioterrorism Act are jointly shared between FDA and EPA, similar to the situation with the U. S. Department of Agriculture (USDA) on jointly regulated food products. Therefore, the requirement for registration of such systems with FDA will provide no increased protection of the food supply or facilitate the ability of FDA to investigate threats to the food supply.

IBWA recommends that:

- *those community water systems that bottle water should be required to register the bottling facilities with FDA since they are manufacturing a food that is not included in the EPA regulatory framework.*
- *clarification of these issues will assist bottlers and other companies in the bottled water industry with compliance to the registration provisions and assist in preventing inadvertent failure to register a food facility.*

Comments on Other Food Facilities Required to be Registered

The proposed definitions of “food” and “facility” also include a number of other types of equipment and products that are used in the bottled water industry. By including “a mobile facility traveling to multiple locations, that manufactures/processes, packs or holds food for human consumption” within the definition of facility, the proposed regulations could be interpreted as extending the registration requirements to tankers on trucks and trucks that deliver bottled water.¹⁰ Water for bottling purposes is often loaded into tankers at the water source and then hauled to the bottling plant for production of bottled water. Bottled water is also loaded into shipping containers or onto trailers that are used to move the products into the United States and around the United States. In addition, bottled water is loaded onto trucks for direct delivery to homes and offices for consumption at those locations. In any of these situations, the bottled water could be held for delivery to multiple locations. **IBWA does not believe that tankers and trucking containers were intended by Congress to be food facilities in enacting the Bioterrorism Act, and will exponentially complicate the registration process.**

The inclusion of the various delivery and hauling vehicles in the registration requirements will substantially alter the FDA estimates on the number of facilities to be

⁹ Public Health Security and Bioterrorism Preparedness and Response Act of 2002 – Title IV

¹⁰ Subpart H-Registration of Food Facilities General Provisions §1.227 (2) Facility

registered. **Does FDA intend to include all different types of carriers and containers covered under the food facility registration provisions?**

Under the proposed definition of "food," the manufacturers of bottles, water coolers and components, caps, seals, ozone equipment, carbon dioxide, water storage silos, plastic resins, chlorine, and glass could be required to register their production facilities, along with their distribution channels as food facilities.¹¹ The expansive definition of "food" that includes "products that migrate into food from food packaging and other articles that contact food" results in all of these types of products being potentially covered by the registration requirements. The definition could also substantially increase the number of facilities to be registered. **Is it FDA's intent that all these types of facilities be registered as food facilities?**

It is unclear on the impact of this definition on the foreign facility exemption in the Bioterrorism Act.¹² **Are the facilities that manufacture and export empty bottles, caps, seals, water coolers, or other similar products a "foreign food facility" if the product does not need further processing or packaging outside the United States?**

In addition, the current definitions may have unintended consequences for facilities that are not a part of the regular channels of distribution of food. An example of such a facility is a storage area in an office complex that takes delivery of 5-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. **Is the location that receives the bottled water a food facility, because it "holds" a food product? IBWA seek clarification so that IBWA members can assist their customers in compliance with the provisions of the final regulations.**

Recommendations

IBWA believes that the inclusion of mobile food facilities, as currently defined, is beyond the intent of Congress. **IBWA urges FDA to:**

- *redefine "mobile food facilities" to exclude conveyances as facilities that hold food products.*

Their inclusion in the definition is impractical since the registration form cannot be completed adequately. For example, shipping containers do not have an "address" for purposes of registration. If FDA used the registration information to inspect such "facilities," they may or may not find the "facility" at the registered address.

¹¹ Subpart H-Registration of Food Facilities General Provisions §1.227 (4) Food

¹²Public Health Security and Bioterrorism Preparedness and Response Act of 2002 - § 305 (b)(3)

IBWA urges FDA to:

- *clearly state whether facilities, both domestic and foreign, that produce bottles, caps, seals, water coolers, ozone equipment, carbon dioxide, water storage silos, plastic resins, chlorine, and glass or that hold bottled water for redistribution within an office complex need to register with FDA.*
- *clarify the applicability of the registration provisions to the channels of distribution for those companies.*
- *address the foreign food facility exemption as it applies to products that could fall within “products that migrate into food from food packaging and other articles that contact food” part of the food definition.*

How and Where to Register - §1.231

Comments on How to Register

IBWA strongly supports FDA’s efforts to develop and implement an online, electronic registration system for registering food facilities. We urge FDA to include in their development a method of handling duplicate registrations, since both the owner and operator of a facility are responsible for registration. Often they are not the same, particularly in the case of spring sources and distribution centers. There is no description in the proposed regulation or the preamble to the proposed regulation that gives any indication on how, if at all, this will be resolved. If one corporation owns a spring source and the rights are leased exclusively to another corporation for bottling water, it is unclear in the proposed regulations who has the responsibility for registration. **Per the earlier discussion on unmanned facilities at the spring site, will the bottler incur responsibility for registration as an “operator,” along with the owner of the spring site?**

How will FDA determine if, in fact, there are duplicate registrations? As is the case with spring water sources, they often do not have a physical address and thus may be described differently by the owner and the bottler. Even with the same addresses in the case of distribution centers, how will FDA determine that the registrations are for the same facility?

Once the determination is made that there are duplicate registrations for a food facility, the responsibility for the registration must only reside with one party. FDA must provide guidance on how this determination will be made and how the parties involved will be notified. **If it is with the owner, and not the operator of the facility, how can they maintain the records accurately? If the responsibility resides with the operator, how will a change in ownership, but not the operation of a facility be handled?**

These issues are further discussed in IBWA’s comments on §1.234, page 11. Because the purpose of the registration is to develop an inventory of food facilities with contact information, which can be utilized by FDA to investigate and manage threats

against the food supply and to maintain an accurate account of the registered facilities, it is critical that the data base not include duplicate registrations.

As part of the online registration system, it must be secure enough to prevent tampering with a company's information. Facilities must be registered one time and the information must be updated in a timely manner. Concern by IBWA's members has been expressed with the security of their information. The preamble to the proposed rule does not discuss how FDA will address this issue. IBWA is confident that FDA shares these concerns.

IBWA also commends FDA on permitting a corporate headquarters to submit multiple registrations on behalf of their facilities. This will substantially ease the burden for companies that operate a number of facilities throughout the world. The challenge for these entities will be to ensure the timely updates of the registration information. This will be discussed below.

Recommendations

Technically, the use of such common programs as Microsoft Excel or Access would permit a company to input and review for accuracy all the required information and submit it en mass. IBWA, as mentioned above, supports FDA in allowing a corporate headquarters to register all their facilities. **IBWA suggests that:**

- *FDA provide an additional option that would permit a company to upload their database of all their facilities to FDA for registering of the facilities.*

IBWA suggest that the registration system has the following capabilities:

- *an ability to print the screen with the submitted information should also be an option available for the company. This ability will provide backup information for a company's registration.*
- *permit updates and cancellations of the registration information from the basic electronic registration screen.*
- *a secure system of either passwords or electronic signatures needs to be a part of the electronic registration system. The technology for such security is readily available and critical to maintaining the integrity of the data base.*

Lastly, IBWA recommends that:

- *for duplicate registrations, FDA inform all parties of the submitted information and request a determination from them 1) if it is for the same facility, and 2) who the responsible party for the facility will be.*

Information to be Submitted - §1.232 and §1.233

Comments on the Information Required to be Submitted

FDA has included substantially more information to be submitted for registering a food facility than is required under the Bioterrorism Act. Within the statute, the required

information for registering a facility is 1) the name of the facility, 2) the address of the facility, 3) the trade names, and 4) the general food category when determined necessary by the Secretary. There are not references, either in the Bioterrorism Act or the legislative history, to the inclusion of individual names in the registration. In fact, the self-executing registration provision of the Bioterrorism Act does not contain such contact information. If FDA fails to publish a final rule, a company will only need to inform FDA of the three items listed in the statute unless the Secretary determines a general food category to also be listed.

Although the emergency contact information is not included in the Bioterrorism Act as required information, it is arguably useful information for FDA to carry out the objectives of the statute. However, it should not be restricted to persons being listed. Many corporations have emergency numbers or contact points for communicating with them in times of emergency. **FDA should recognize this and provide the flexibility in the final regulations for an emergency contact point for the corporation or facility, rather than the restrictive provisions of the proposed regulations.**

In most situations, listing one contact person is not reasonable, both in terms of the purpose of the contact information and the reality of the marketplace. The proposed regulations specify the inclusion of cell phone, home phone, and e-mail addresses, which far exceed the statutory requirements and also raise privacy concerns. It fails to recognize the fact that these contact persons may not be available at all times. They could be sick, on vacation, or otherwise not able to be contacted by FDA. Most companies have contingency plans for such situations, and multiple persons who may have the responsibility.

Under subsection (d) of §1.232, the proposed regulations require "trade names" the facility uses. **IBWA respectfully requests that the term "trade name" be further defined so that it is clearly understood.** Clarification of the term "trade names" will provide FDA with a better compliance with the regulations and a consistent understanding of the requirements for registration and updates by affected companies.

Under subsection (f) of §1.232, information on the U.S. agent must be included for foreign food facilities. This information can be submitted by the foreign company. **IBWA supports this ability, which will ensure that the registration information is accurate, and will reduce the burden of registering the facility.** However, the proposed regulation does not require the U. S. agent to have an actual relationship with the foreign company. It is assumed, but not required.

Recommendations

IBWA recommends that:

- *the proposed regulations be amended to permit but not require multiple emergency contact persons or an emergency contact point on the registrations. This will provide more flexibility to companies and a more useful database for FDA.*

IBWA suggests that:

- *“trade names” be defined for purposes of registration as names under which the company and its subsidiaries are “doing business as,” (d.b.a.), and “also known as,” (a.k.a.). It should not refer to products or lines of products unless that is also the d.b.a. or a.k.a for the facility.*

Updating Registration Information - §1234

Comments on Updating Registration Information

As stated above, the electronic, online system for registration should be designed to permit a company to use the original information screen as the starting point for updating or canceling the registration. Security of such a system must prevent unauthorized changes to the registration information, but be flexible enough to accommodate employee turn over and corporate restructurings.

The proposed rule requires an update to be submitted within 30 days of a change of the “agent in charge” of a facility.¹³ However, this is not one of the required sets of information to be submitted either under §1.232 or §1.233. As discussed above on §1.232, IBWA urges that FDA provide flexibility in listing emergency contact information on the registration form. Updating information on specific individuals must be more flexible, particularly for those that operate multiple facilities, or could result in inadequate information or failure to comply with the restrictive provisions.

The regulations do not speak to the required procedure for mergers and acquisitions. **Will the acquiring company be required to register the facilities as “new” food facility registrations? Will the acquired company be required to cancel their registration? Or can the acquiring company update the information on the “original” registration?** With the consolidation within the bottled water industry, as within other industries, the process for handling the registration of the facilities needs to be explicit.

Recommendations

IBWA recommends that:

- *FDA delete any reference to “agent-in-charge” from the regulations since it is not a required data element in registration of a food facility.*
- *the registration information updates be as simple as possible and be based on the original information which should be visible online to the person responsible for the updates.*

The 30 calendar day requirement for updating information resulting from a change in ownership or individuals is far too short for acquisitions or mergers, and is not a realistic timetable. **IBWA recommends:**

¹³ Subpart H-Registration of Food Facilities General Provisions §1.234 (a)

- *for changes in ownership, a minimum of 60 days be required for updating information on the registration form. In addition, for mergers and acquisitions, the original registration form should be used with a change in the name of the owner and/or operator of the facility and the trade names. Thus, the facility registration will not generate a new number or a "new" registration. This will avoid the need to "cancel" a registration.*

V. Docket No. 02N-0278 – Prior Notice of Imported Food

Overview

The Bioterrorism Act includes provisions under Section 307 to require prior notice for the importing of food in order to provide FDA with a tool with which it can deploy resources and identify "high risk" shipments. The system will allow FDA to respond effectively to bioterrorism and other public health emergencies that might be a result of imported food. Specifically, the Bioterrorism Act established that the following information shall be in the prior notice:

1. the identity of the article of food;
2. the manufacturer and shipper,
3. the grower, if known;
4. originating country;
5. country from which the article was shipped; and
6. the anticipated port of entry.¹⁴

During Congressional consideration of the Bioterrorism Act there was substantial controversy surrounding the minimum and maximum time for which notice can be provided. In Conference Committee, the Conferees agreed to the self-executing provision after December 12, 2003, of no less eight hours and no more than 5 days. FDA was provided authority to permit flexibility in implementing those minimum and maximum time-frames.

Congress was clear that an appropriate balance must be achieved within the prior notice provisions between the needs of FDA to meet the goals of the statute and the impact on international trade and commerce.

IBWA General Comments on Prior Notice of Imported Food

IBWA is very concerned that the proposed regulation cannot meet this balance and thus will adversely affect imports of food. The breadth of the products covered, the data elements required, the timelines for prior notice, and responsibility for the notice, combine to seriously impair the ability of FDA to achieve its mandate. Although FDA has worked diligently with U.S. Customs, dual systems for transmitting information on imported food products will be required. This was not envisioned when the Bioterrorism Act directed FDA to consult with the Secretary of the Treasury.

¹⁴ Public Health Security and Bioterrorism Preparedness and Response Act of 2002 - § 307(a)

These factors do not recognize the realities of food importation and place substantial additional burdens on the importation of food. IBWA recognizes that the Bioterrorism Act anticipated changes to current business practices and procedures for importation, but the substantive revamping of business as proposed is not justified. The movement of goods, particularly with the North American trading partners, will be seriously impaired without modification in the final regulations. Detailed below are IBWA's concerns with the proposed regulation.

§1.277 - Definitions - Food

Comments on Food Definition

The definition of food in the proposed rule is much broader than anticipated by Congress in the Bioterrorism Act. FDA has chosen to expand the products, which would be covered by the prior notice provisions to include food contact materials. When the prior notice provision is read in context of foreign food facility registration requirements, it does not seem likely that the Congress that intended foreign manufacturers of bottles, caps, seals, water coolers, and water cooler components be required to provide prior notice for importation of their products. Under the Bioterrorism Act, the term "foreign facility" means a facility that "manufactures, processes, packs, or holds food, but only if food from such facility is exported to the United States without further processing or packaging outside the United States."¹⁵ This logic should also extend to the prior notice requirements. Bottles, caps, and seals, for example, are not intended for human consumption, and do not need further processing or packaging before exportation to the United States. **In other words, the bottle or water cooler manufacturer should not be required to provide prior notice of importation of empty bottles destined for a bottling plant in the United States just as they should not be required to register their foreign facility.**

Without this interpretation of the statute, the foreign facility distinction is rendered meaningless. The Bioterrorism Act would then be a substantial impediment to free trade. As an example, plastic bottle manufacturers that provide plastic bottles solely to foreign bottlers who fill the bottles with water and export bottled water to the United States would not be required to register. However, if they sold empty bottles or bottle preforms to U.S. bottlers, they would have to register as a food facility and prior notice. It is difficult to understand FDA's hypothesis that a potential terrorist would take the time and to overcome the technical challenges to contaminate plastic that might migrate into a food product and will not be discovered before injuring citizens in the United States.

The scope of the definition and the impact of the process for importation will reduce the amount of research and development being done in the United States on food products. For example, research on consumers' preferences for various types of bottled water will be easier to be do in Canada. It will also interfere with the quality analysis done by bottlers of foreign sources, products, ingredients, or other similar

¹⁵ Public Health Security and Bioterrorism Preparedness and Response Act of 2002 - § 305 (b)(3)

ingredients and products. For example, a bottler may want to have private label bottled water produced in Canada for one of their retail customers. Before deciding on a supplier and possibly throughout the life of the contract, the U.S. bottler will require a quality analysis of the potential suppliers products be performed by their laboratory. The constant flow of small quantities of product may be hindered by the proposed regulations. Thus, it will be much easier and less costly for international companies to have analysis and testing done elsewhere in the world. This concept also extends to ingredients and additives, which are used in the research and development in bottled water.

Recommendations

IBWA recommends that final regulation:

- *delete "including substances that migrate into the food from food packaging and other articles that contact food," from the definition of food in the prior notice final regulation. By concentrating on the finished product, FDA will not be overwhelmed by the volume of notices and will be able to meet the requirements of the law in protecting the security of the food supply.*

IBWA also recommends that:

- *FDA develop an "open ended" prior notice requirement for products used in research, development, and quality analysis. This prior notice would be extended to small packages that are sent directly to registered facilities for quality analysis, or research and development purposes. This could be fashioned after similar programs by other agencies to accommodate research and development. IBWA suggests that the shipments contain a certifying statement describing the intended use of the items.*

Requirements to Submit Prior Notice of Imported Food

§1.285 - Who is authorized to submit prior notices

Comments on Persons Authorized to Submit

FDA has limited the authority to submit a prior notice of imported food to the importer, purchaser or their agent of the food products. However, if the product is being trans-shipped through the United States, the in-bound carrier may provide the notice. The proposed regulation could significantly hamper the free flow of international trade.

In many cases, the information for the prior notice may not or cannot be available to the purchaser or importer as required by the proposed regulations. It is difficult to imagine how the purchaser or importer might be able to obtain the information, given the realities of the movement of product and the responsibility of each party in that movement. For example, an international bottled water producer exports bottled water to North America via container ship. The ship docks in Montreal and unloads the cargo of bottled water, some of which is destined for a warehouse in Chicago, Illinois. The exporter and the importer are the same company. They have contracted with a freight

train to transport the bottled water to the United States. However, they do not know how the train will be routed, where the containers will enter the United States, and much less the day on which they will cross the border. In addition, the time between loading the containers onto a train and the train crossing the Canadian border can be less than the time frame specified or much longer, depending on the route to Chicago.

It is entirely unclear how the shipper will know if adequate prior notice was given on the shipment in the ship or train or truck. If the responsibility rests with the person receiving the product in the United States, a carrier with multiple products will not necessarily know if all the purchasers have sent a proper notice to FDA unless they have a copy of the actual notice sent. Given the timelines of the proposed regulation, such a transfer of paper work will likely be unattainable.

Recommendations

IBWA recommends that:

- *FDA consider permitting shippers or exporters who are not U.S. residents to submit prior notice. This is often the case today for shipments between Canada and the United States for companies with an established business relationship. By requiring the submitter to reside in the United States, the proposed regulations will place substantial operational and economic burdens on trade with Canada in particular.*

§1.286 - When Must the Prior Notice be Submitted

Comments on When Notice Must be Submitted

The maximum time limit of 5 days for prior notice reflects the Bioterrorism Act provisions and was a subject of substantial debate in Congress.¹⁶ IBWA supports this limit. The additional requirement of prohibiting the submission of the prior notice until all the information is available is unduly restrictive, particularly in light of the information required to be submitted under §1.288.

In addition, to require submission of the prior notice no later than noon of the preceding day of arrival does not reflect the production and distribution realities of the world's commerce. Shipments from Canada may be produced and delivered in a matter of twenty-four hours, door-to-door. Given the extensive information being required, of which some will not be available until after noon of the preceding day, FDA has underestimated the interruption of the orderly movement of product across our borders.

FDA recognizes this fact in some degree by permitting a one-time amendment to the prior notice, up to two hours prior to arrival. But this does not adequately address the issues involved. Under the amendment process, the submitter must have anticipated the amendment, not had the information available and so noted on the prior notice. Even so, the amendment may only provide a limited greater specificity about the

¹⁶ Public Health Security and Bioterrorism Preparedness and Response Act of 2002 - §307(c)(2)

product's identity. One can only envision that the result will be that trucks will be loaded in Ontario and sit idle until the requisite time has elapsed.

The timelines pose challenges, particularly for cargo trucked from Canada or Mexico, but also for product arriving by ship. These requirements can be divided in to areas of concern: 1) the narrow window for arrivals; and 2) the by noon requirement on the preceding day and the minimum 2 hour time to provide prior notice updates and amendments.

The one hour early and three hours late prediction on arrivals is far to precise for most commercial trade, particularly considering the importer is the authorized person to give prior notice. The timing of arrival of a carrier at a port of entry is affected by a wide variety of factors that will change the arrival time, which cannot be controlled or anticipated by the shipper, importer, or the border crossing. For example, trucks, ships, and trains may have mechanical difficulties; traffic may be greater or lesser than expected; a wildcat strike may occur on the dock; accidents or weather may affect the ability of the carrier to arrive at the port of arrival at the anticipated time. Any one or several of these events can cause the difference in the arrival time at the port of arrival to exceed one hour early or be late by more than three hours and thus trigger the need for an update of the prior notice. Furthermore, because of the requirement that the original notice be provided by noon of the day before the anticipated arrival of the article of food at the port of arrival, unexpected delays at facilities (problems with production; mechanical problems with trucks that delay loading and departure, for example) will either necessitate frequent updates or new notices altogether.

Failure to file an update results in the notice being deemed ineffective.¹⁷ This requirement will either result in many more updates than FDA's assumes, or many more ineffective notices. As an example, an Ontario bottler has a facility located about two hours from the U.S. border. The bottler expects a truck to depart for the border on Wednesday at 2:00 p.m. The facility notifies the customer who files a notice by noon on Tuesday for the anticipated 4 p.m. arrival on Wednesday. On Wednesday, problems are encountered in loading the truck, which delay the departure by two hours. At this point, it would appear that the initial notice is still effective because the arrival is still within the window provided in the proposed rule. The truck encounters a very long line to cross the border and is not certain of when they will cross. The truck driver informs his dispatcher of the delay. Persons employed by the facility to work with U.S. Customs brokers and importers relay the information to the purchaser to handle the timely update. They are not immediately available and thus miss the deadline for updates. FDA then concludes that the notice has not been effective and refuses admission. The truck must then be held at the port of entry or, if so directed by FDA, moved to a secure facility. The resulting disruption to the flow of food into the United States seems disproportionate to the offense – an unavoidable thirty-minute delay in the arrival of the product at the port of entry.

¹⁷ Subpart I Prior Notice of Imported Food - § 1.294(d)

Another example: an order is placed by a retailer in Detroit with this same bottler in Ontario for a truckload of bottled water on Monday, for delivery the following Friday. On Thursday, prior notice is given by the retailer. On Friday afternoon, the truck is loaded, but the forklift operator damages a pallet of bottled water. A new pallet is picked from the storage racks, but has a different lot number and placed in the truck. The truck proceeds to Windsor and arrives in less than two hours. The only other option will be to short the order by one pallet, which would also be require an amendment to the notice. The retailer would not know in the periods outlined that bottled water with a different lot number was loaded on the truck. Even if they were made aware, they could not update the prior notice because they did not anticipate an amendment when they filed the original prior notice. Neither the bottler nor the shipper are allowed to update the notice. **Must the truck wait another day before departure to ensure an adequate notice has been sent and they can cross the border?**

These issues flow, not from the concept of prior notice, but in the application of the prior notice system proposed by FDA. This may result from FDA trying to accomplish too many functions through the prior notice provisions.

Recommendations

More flexibility and reasonable time frames must be incorporated in the final regulations to permit the free flow of products as envisioned under the Bioterrorism Act. **IBWA suggests that FDA:**

- *Expanding the types of persons with the authority to provide prior notice and*
- *a more reasonable time line for the prior notice. A rolling four-hour window would be a reasonable alternative to the strict minimum of the proposed regulation. This could apply to specific categories of food product and product from our contiguous neighboring countries. As discussed below, the updates and amendments to the prior notice are contingent on the final regulations' information requirements.*

§ 1.288 - Information Required in a Prior Notice

Comments on the Information Required in a Prior Notice

FDA has substantially expanded the information required to be submitted from six items enumerated in the Bioterrorism Act to seven pages of data fields.¹⁸ FDA has not explained why most of the additional information is necessary to perform the required tasks to meet the objectives of the statute. Just to identify a product, FDA will require five data elements: 1) FDA product codes; 2) common or usual name of the product; 3) trade or brand name of the product if different from the common or market name; 4) quantity of the product by package size; and 5) lot or production code.¹⁹

¹⁸ Subpart I Prior Notice of Imported Food - §1.288

¹⁹ Ibid.

Some of the information is of questionable value to FDA in the context of determining potential threats from imported food while exponentially complicating trade.

Lot numbers and the precise quantity of each package size of the product for each notice are the starkest examples of the type of information that is of minimal value and will place an unreasonable burden on trade. Shipments from multiple facilities of the same product will have different lot codes, which under the FDA format will require separate prior notices. It is highly unlikely that FDA will receive intelligence that identifies a specific lot number as a potential threat. Moreover, FDA cannot verify the correct information without conducting a complete unloading of the conveyance.

Under the construction of the proposed rule, the product lot codes technically do exist, but are not readily available until the bottled water is actually being loaded onto the truck. Therefore, an update would not be a mechanism for ensuring the prior notice is accurate. As in an example used above in §1.286, last minute occurrences may change the “anticipated inventory” to be shipped. The most unlikely person in the process to know this information is the importer.

It is also equally hard to fathom the need for FDA to know whether there are 10 pallets of 12 oz. spring water and 12 pallets of 8 oz. bottles of spring water from company A to make the decision to detain, inspect, sample or hold a shipment. It is hard conceive of how this information will facilitate the inspection process. **When the product arrives at the border, how is FDA going to determine if the information is accurate without unloading the truck?** It seems that the more useful information is to know that 22 pallets of spring water from company A are arriving at the border.

The multiplicity of data elements on product identity alone have the potential of having two fundamental results, at least in the short term: 1) the number of amendments anticipated will fall very short of the actual filings, or 2) the number of inadequate prior notices will be significantly more than projected. Either result will adversely affect the ability of FDA to meet the basic objective of instituting a prior notice system.

The electronic prior notice system should be designed to reduce the data entry requirements for the prior notice to minimize typographical errors and omissions and reduce the burdens of the system on the importation of food products into the United States. **It would seem technically and reasonable to integrate the registration and prior notice systems.** Thus, an importer could enter a facility registration number and much of the form would be completed.

IBWA noted that the term consignee and owner are used extensively throughout the regulations and the proposed prior notice form. However, there are no definitions of these terms. Depending on the facts of a specific situation, reasonable people could differ on the owner or consignee or importer definitions. If FDA maintains the extensive data elements for prior notice, these types of terms must be explicit.

Recommendations

IBWA recommends that:

- *duplication of information under the registration provisions and with U.S. Customs should be eliminated as much as feasibly possible. As discussed previously, FDA and U.S. Customs systems should be combined to facilitate the flow of information and ease the burdens on international trade. We certainly hope that this can be accomplished in a relative short period of time.*
- *the information on product identity (144 cases of Brand X bottled water) should be limited to a general description of the product, which should be sufficient for FDA to achieve the fundamental purpose of the prior notice provision.*

§1.278 - Consequences of Failing to provide Adequate Prior Notice

Comments on Consequences of Failing to Provide Prior Notice

This subsection of the proposed regulations follow, to a large degree, the intentions of Congress to prevent potentially harmful product from entering the United States. However, IBWA has concerns about the application of the proposed regulations to the importation process. These concerns are not related to the proper role of FDA in ensuring the safety of the food supply in the United States. They are, instead, related to problem solving to facilitate the free flow of trade, and the FDA's ability to meet the objectives of the prior notice provisions.

Under the proposed regulations, FDA can place a food product on hold and deny entry for an inadequate prior notice. The adequacy of the notice will be determined at the point of arrival. As described above, the potential for "minor" data elements missing or not "timely" provided may result in product, for which the prior notice was originally given and any other cargo in the same container, being held at the port of arrival or removed to a secure facility. **It is not clear that if FDA orders the movement of a product to a secure facility because of inadequate notice, the product that is not subject to the prior notice can be extricated at the arrival port and moved into commerce.**

As mentioned earlier in the comments, the carrier is not likely to have all of the documentation of the prior notice that has been submitted. In addition, the carrier, as proposed in the rule, would not have the ability to "cure" a deficient notice because they are not authorized to submit the prior notice or amendments or updates. **It is unclear how the holds will be communicated and resolved without substantial expense to the importer and FDA.** If FDA determines that a product has the potential to be a threat or is the subject of an intelligence alert for bioterrorism, the cooperation of the manufacturer and others is both important and appropriate in reducing the threat or determining the validity of the intelligence. **As recent experiences with FDA and the importation of bottled water have indicated, it is not often readily apparent on how to resolve issues of FDA holds.**

Recommendations

IBWA recommends that:

- *FDA develop a method of communicating not only that a product is being held, but also the necessary steps to have the product released. Currently there is no systematic means of engaging the bottler or other food producer in addressing bioterrorism threats or events.*
- *there needs to be a process for expeditiously correcting the deficiencies in the prior notice and immediately permitting the product to proceed through the port of arrival. This is particularly important for technical problems with the prior notice. The errors should be able to be remedied immediately and the food cleared in a matter of hours. Where food arrives without notice at all or with major deficiencies in the notice, IBWA recognizes that the process of filing a notice or correcting errors will take time and that such a pattern may reasonably cause FDA to decide to examine closely the shipment.*

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 policy and procedures to comply with the provisions of the Act. Without the timely issuance of regulations, it will be very difficult to ensure the proper registration and procedures by food manufacturers and others affected by the Act's provisions. This is particularly true given the self-executing construction 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