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**Prior Notice of Imported Food Under the Public Health Security and Bioterrorism
Preparedness and Response Act of 2002
Docket No. 02N-0278**

**Comments of the
National Soft Drink Association
to the
U.S. Food and Drug Administration**

April 4, 2003

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Introduction

0009 '03 APR -4 P17.55
The National Soft Drink Association is pleased to submit comments in response to the proposal of the U.S. Food and Drug Administration (FDA) regarding the prior notice of imported food (68 Fed. Reg. 5428, February 3, 2003).

The National Soft Drink Association (NSDA) is the national trade organization of the beverage industry. NSDA's member companies produce 95% of all soft drinks consumed annually in the United States. NSDA member companies also produce and distribute purified waters, ready-to-drink teas, sports drinks, juice and juice-based beverages and other carbonated and non-carbonated products. In addition, the vast majority of the beverage licensors who manufacture concentrates and/or syrups from which soft drinks and other beverages are made belong to the Association. It is on behalf of these members that we submit these comments.

Special Note

As noted in the preamble to this rulemaking, the events of September 11, 2001, highlighted the need to enhance the security of the U.S. food supply. NSDA supports the goals of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) and FDA's efforts to implement Title III of the Act. NSDA and its member companies recognize the unique nature of this rulemaking and feel a shared sense of responsibility with FDA to ensure the security of the U.S. food supply. The intent of these comments therefore, is to offer constructive ideas that will enhance food security while creating a system that is both workable and efficient.

Summary of NSDA Position

Three changes to FDA's proposal are suggested in these comments:

- (1) The prior notice requirements must be modified so as not to interfere unnecessarily with the shipment into the US each year of thousands of samples of food ingredients and food products that are imported solely for analytical use and cannot make their way into the domestic food supply.
- (2) The prior notice system should contain a "blanket prior notice provision" that would allow firms, that in their ordinary and regular course of business ship product or ingredients into the United States, to file a prior notice that would cover shipments for up to one year.
- (3) The scope of the information required to be included in the prior notice needs to be narrowed. Requiring lot numbers and/or product codes is neither feasible nor necessary. Further, the prior notice submission should apply to an entire shipment rather than to each food item.

Discussion

Major beverage companies typically have facilities located in the United States, and throughout the rest of the world. Beverages, as well as concentrates, ingredients and packaging materials are regularly involved in international commerce.

A considerable amount of commerce routinely involves shipments between the U.S., Canada and Mexico. In addition, it is important to recognize that many facilities operate 24 hours a day, 7 days a week. Shipments, whether they contain raw materials or packaging, often cross international boundaries within a matter of only a few hours after they are produced and loaded onto a trailer. These shipments occur 24 hours a day, 7 days a week.

Analytical Samples

The extensive quality assurance programs associated with the beverage industry are well known throughout the food industry and around the world. These programs involve four primary types of analytical sampling: (1) routine quality assurance samples

of ingredients, beverage bases, or finished goods; (2) non-routine or investigative quality assurance samples; (3) samples of ingredients or packaging from suppliers; and (4) consumer-initiated samples. None of these samples enters the U.S. food supply; rather, they are used for analytical purposes only.

Typically, these samples are small in size. They are also shipped directly to a laboratory or other non-retail facility such as a company-owned testing lab that employs controls that ensure that such samples are not used in the production of food for public consumption. Such samples can easily be labeled as being “samples” or “for analytical purposes only.”

Routine quality assurance samples are frequently shipped by production facilities and from the marketplace to company-owned laboratories. One major company alone receives as many as 10,000 such samples from outside the U.S. each year. The marketplace samples are typically purchased by an independent contractor at retail. While the company-owned laboratory expects to receive such samples, there is no mechanism by which it receives prior notice that a particular shipment of samples is being shipped. As a result, although such shipments of samples are routine, they are not scheduled. The amount of intra-/ and inter-company communication and coordination that would be required to ensure that a prior notice would be timely filed for each such shipment would be extremely burdensome.

Likewise, suppliers routinely submit samples of ingredient and/or packaging materials to our companies' laboratories. These samples are small, often weighing less than 115 g (4 oz.). The samples are analyzed for purposes of evaluating potential new suppliers and assuring the quality of ingredients and packaging materials from existing

suppliers. Again, one NSDA member company alone receives as many as 20,000 samples from suppliers outside the U.S. each year. These samples are frequently sent to the U.S. by the suppliers at the behest of manufacturing facilities that wish to use the materials in question. As with the routine quality assurance samples, the company-owned laboratory receives no prior notice of these routine but unscheduled shipments of analytical samples.

Consumer-initiated samples from outside the U.S. pose an even more problematic scenario. From time to time, a consumer will report a situation that prompts a company to perform testing on a sample in order to rule out concerns about a larger lot of product being sold at the retail level. Time is of the essence in completing analytical testing on these samples to determine whether an issue exists. These samples are therefore shipped to a company-owned laboratory where they are then given the highest priority. Delays in this process would be costly and could represent a potential threat to public health.

The same applies to other non-routine or investigative samples. If a manufacturer suspects that a finished product does not meet the intended specifications, priority testing is needed to determine how best to resolve the situation in a timely manner. Again, these samples are not used in making product for public consumption. They are used, disposed of, or retained solely by the company-owned laboratory.

The intent of both the Bioterrorism Act and FDA's prior notice of imported food proposal is to address the security of foods and ingredients entering the U.S. food supply. NSDA proposes that if a sample shipment is (a) addressed to a permanently established analytical facility, (b) used solely for analytical purposes and properly disposed of in a

manner that precludes its use in manufacturing food for public consumption and (c) are generally small in size and volume, an exemption from prior notice is warranted.

Alternatively, NSDA submits that where shipments of samples which are not used in the production of food for public consumption and do not enter the U.S. food supply, the prior notice regulation should provide a means by which a U.S. quality analysis facility could file an “open-ended” prior notice that would be deemed to cover all such shipments of samples. In the absence of such a provision, the large number of these samples will needlessly overburden FDA’s prior notice system, will impose an unreasonable burden on companies’ quality assurance efforts, and will serve no useful purpose.

Blanket Prior Notice Provision

In the beverage industry, international shipments, especially between the U.S., Canada, and Mexico, routinely occur 24 hours a day, 7 days a week. Many of these shipments occur within hours of the product being manufactured and loaded onto a trailer. Most of these shipments are predictably consistent as to their general content.

A mechanism is needed to minimize the impact on commerce that would result from requiring a separate prior notice to be filed for every one of these shipments. NSDA submits that the rule should allow a firm to file a “blanket” prior notice that would cover all substantially similar shipments to be made over an extended period of time--for example, one year. Firms would be allowed to amend this Prior Notice Submission as the salient details of a particular shipment become known. For example, a firm may regularly import bottled water from a foreign country for sale in the United States. The

only variable may be the quantity per shipment, the size of the individual packages contained within the shipment, and the number of shipments per day or week.

The “blanket” Prior Notice Submission would still provide FDA with the required information to afford the Agency adequate time to adjust its inspection efforts, if warranted. A “blanket” submission would identify the country of origin, the shipper, the manufacturer and the anticipated port of entry. An Amendment would then be filed to furnish any other required data.

Scope of Information

The scope of the information that FDA proposes to be included in a prior notice submission needs to be narrowed. Some of this information goes beyond both the requirements and the intent of the Bioterrorism Act and is unduly burdensome. This is especially true when combined with the minimum “noon of the day before” timeframe proposed by FDA.

As previously noted, international shipments, especially between the U.S., Canada and Mexico, routinely occur 24 hours a day, 7 days a week. Many shipments currently cross international borders within hours of the product being manufactured.

First, the prior notice submission should apply to the entire shipment of a similar food, rather than to each individual food item. Under the proposed rule, each food item would require a separate prior notice. This is a significant burden for the beverage industry. Typically, shipments of soft drinks and other beverages will involve a number of flavor types, as well as a variety of package sizes. A shipment of soft drinks may contain colas, diet colas, lemon-lime products, root beers, bottled waters, juice drinks, etc. In addition, the multiple package types and sizes within those groups could result in

dozens, if not hundreds of food items, all on one trailer. Such detailed information would not provide FDA with any meaningful information, nor would such information even be available at the time FDA is requesting it.

Further, NSDA submits that the requirement that prior notice include information such as lot numbers and production codes would impose an unreasonable burden while providing no benefit to the security of the food supply. In addition, these numbers and codes are often not even known until the product is actually loaded on trucks for transport, which often occurs within hours of the shipment reaching the border.

NSDA is concerned that, as proposed, the prior notice requirement that prior notice requirement will result in a logjam of so much non-essential information that the system will be overloaded. NSDA strongly suggests that FDA narrow the scope of information that it is seeking in its prior notice submission to general product categories (for example, soft drinks) and eliminate entirely the request for lot numbers and product codes.

Conclusion

NSDA recognizes the challenges that face FDA in implementing Section 307 of the Bioterrorism Act. However, the proposal would burden the food industry without a commensurate enhancement to the security of the food supply. NSDA submits that FDA has underestimated the impact that these requirements, if implemented as proposed, will have on international commerce.

Requiring prior notice for every shipment of quality assurance samples intended for analytical use only will needlessly overburden the entire system. The prior notice rule should be revised to exempt such quality assurance sample or alternatively, to permit

such samples to be covered by an “open-ended” prior notice submission by the receiving facility.

The regulation should also be revised to permit a “blanket” prior notice for routine international shipments, especially those from Canada and Mexico.

Likewise, the scope of information required by FDA in its proposal should be narrowed in the final rule. The prior notice should apply to shipments of similar foods rather than to individual food items. Lot numbers and product codes are often unknown in the period that FDA has proposed.

These three changes to FDA’s proposal will result in a more efficient and workable system and will eliminate unnecessary reporting which will otherwise clog the system. These changes will not undermine the effectiveness of the prior notice system in fulfilling the purposes of the Bioterrorism Act.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Mike Redman". The signature is fluid and cursive, written in a professional style.

Michael Redman
Technology Director