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**Establishment and Maintenance of Records Under the Public
Health Security and Bioterrorism Preparedness
and Response Act of 2002
Docket No. 02N-0277**

**Comments of the
National Soft Drink Association**

To the U.S. Food and Drug Administration

July 8, 2003

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Introduction

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 establishment and maintenance of records (68 FR 25187) under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act).

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 water, 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 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

The following recommendations are made by NSDA:

- (1) Allow transporters and non-transporters the flexibility to record production codes and lot numbers where appropriate and reasonable rather than “if available”.

- (2) Increase the protections given to product formulations. Access to such information should be requested only if there is a reasonable belief that a specific ingredient or ingredients have been adulterated and that this adulteration may lead to a serious health consequence or death.

Discussion

Today’s “soft drink companies” manufacture and distribute an increasingly large and diverse line of beverages. As previously noted in the introduction, these products include traditional carbonated soft drinks, bottled waters, ready-to-drink teas, sports drinks, juice and juice-based beverages and other carbonated and non-carbonated products. Along with this proliferation in product categories, consumer demand has driven an increase in the number of available package types and sizes. Combined, these two trends have resulted in a burgeoning number of stock keeping units (SKUs) for the beverage manufacturer and distributor. A single manufacturing facility may have over 500 SKUs.

In 2002, over 13 billion 24-8oz. equivalent cases of soft drinks (including carbonated and non-carbonated soft drinks) were sold in the United States. Most of these were sold using the direct store delivery (DSD) system, typical of the beverage industry.

DSD is unique among delivery/distribution methods in that the manufacturer keeps control and ownership of the product until the point at which it is delivered to the store.

Production Codes/Lot Numbers

The intent of the Bioterrorism Act regarding the maintenance and inspection of records as stated in section 306 (b) is to promulgate a regulation that would require persons who manufacture, process, pack, transport, distribute, receive, hold or import food to maintain records which "...are needed by the Secretary for inspection to allow the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food, including its packaging, in order to assess credible threats of serious adverse health consequences or death to humans or animals." The intent of the Bioterrorism Act can be carried out by continuing to provide manufacturers with flexibility on how recalls are conducted, and not by requiring records be maintained of production codes or lot numbers. Production codes alone will not guarantee that affected product is halted in the distribution chain or that its use is prevented.

Some companies in the soft drink industry utilize a lot code that contains many pieces of valuable information that is instrumental in product rotation, in determining the root cause of a product issue, defining the scope of the issue and tracing products in the marketplace. A "full" lot code may typically identify the minute the product was produced, the day that the product was produced, the specific facility that manufactured the product and the particular production line that filled the product. In a recall situation however, a 12 digit plus alphanumeric string is too complex to decipher, and would negatively impact the speed at which the recall could be conducted. To compensate for this fact, some companies will remove all affected product manufactured by a facility by

the date of production only, and then use the remainder of the code to diagnose and quantify the issue at a later time in a place where the product has been removed and secured from the trade.

While lot codes are useful in the field to the driver/salesperson in ensuring product freshness, there is no feasible method of establishing and maintaining records of each production code which may be found on a typical shipment. A typical route truck delivery may contain between 400-700 cases. A tractor-trailer shipment may hold between 1800-1950 cases. When considering the numerous products, packages and package sizes, dozens or even hundreds of production codes can typically be found on a single shipment.

In larger facilities, warehouse personnel and drivers/salespersons use portable electronic data management systems to assist in inventory control. Yet, even the most sophisticated systems do not allow for production code information to be either entered or retained. Further, many of the small and mid-size bottlers still rely on a paper-based manual system of inventory management. So although production codes are “available”, establishing and maintaining records of these codes is neither reasonable nor technically feasible.

Production demands require many facilities to take product from the production line directly to the shipping areas for immediate transport to customers. This process makes it commercially infeasible to stop and somehow record the dozens or hundreds of full lot codes that may be loaded onto a single truck for delivery. Moreover, the lot code information will not materially improve the quality of a recall versus the benefit of public notification.

Industry selling practices include customers that may decide to purchase product off the truck when the vehicle arrives at their store. Delivery personnel are already under significant time restraints from other agencies that regulate their time on the road, such as the Department of Transportation. Imposing additional recordkeeping responsibilities will not improve product tracing results since all potential customers are generally contacted in the event of a recall.

In the preamble to the proposal, FDA states that its “intent in developing these proposed regulations is to provide the proper balance between ensuring that FDA has information it needs to complete a tracing investigation and ensuring adequate and reasonable flexibility for industry to comply with these requirements.” Yet by requiring records which include production codes and lot numbers based on availability, no effort has been made to ensure “adequate and reasonable flexibility” for compliance capabilities. Ironically, the proposal, as written, provides a strong disincentive for manufacturers to continue to use production codes.

FDA’s current recall guidelines (21 CFR Part 7, subpart C) appear to recognize the complexities and highly individual circumstances involved in removing products from the marketplace. In Section 7.40 (a) of Subpart C, it is noted that a recall takes place because “manufacturers and distributors carry out their responsibility to protect the public health and well-being from products that present a risk of injury or gross deception or are otherwise defective.” Sections 7.41 through 7.59 provide “guidelines so that responsible firms may effectively discharge their recall responsibilities.”

Recall strategy, addressed in Section 7.42, stresses the need that “such strategy must take into account the individual circumstances of the recall.” Nowhere in the recall

strategy or in the recall guidelines is there either a requirement or a recommendation that records of production codes or lot numbers be established or maintained by the firm.

However, in general guidance to industry, Section 7.59, FDA stresses the importance of both production codes and recordkeeping.

Section 7.59 (a) states:

“Use sufficient coding of regulated products to make possible positive identification and to facilitate effective recall of violative lots.”

Section 7.59 (c) further advises:

“Maintain such product distribution records as are necessary to facilitate location of products that are being recalled. Such records should be maintained for a period of time that exceeds the shelf life and expected use of the product and is at least the length of time specified in other applicable regulations concerning records retention.”

Current FDA recall guidelines recognize the importance of production codes and records establishment and maintenance but at the same time, allow flexibility in how this recordkeeping function is carried out. FDA’s proposal is inconsistent with existing policy and removes all flexibility, replacing it with a system that is neither workable nor reasonable.

The only responsible position to take in the event of a serious product issue or life-threatening situation is to warn the public through the media to prevent further use or distribution of the product. The communication vehicle used to disseminate the warning should be based on the severity of potential harm or health consequences. Use of the media is also necessary to influence customers to check their store stock and for consumers to check their refrigerators and pantries for the affected product.

Recipe

FDA's decision to exclude recipes from the records availability requirements is prudent. However, defining recipe as only the "quantitative formula used in the manufacturing of food, but not the identity of the individual ingredients of the food," negates trade secret protection. Soft drink companies have gone to great lengths to protect product formulations. Typically, the exact ingredients used in a formulation of a given soft drink may be known by only 2 or 3 of the most trusted individuals within the company. In discussing the definition of the term "recipe" in the preamble to the proposal (at 25195), FDA justifies the exclusion of the identity of ingredients from that protected category as follows:

The Act currently requires manufacturers to disclose to the public the ingredients they use on the labels of their food products. It is critical to a tracing investigation that the ingredients and the sources of the ingredients are identified.

What this reasoning ignores, of course, is that food manufacturers are explicitly exempted from disclosing the specific contents of their flavor mixtures by section 403(i)(2) of the Act and 21 CFR Sections 101.4(b)(1) and 101.22(h)(1). The purpose of this exemption is to protect a food manufacturer's trade secrets.

The demand that companies make formulations available to FDA inspectors or other outside authorities must occur only after the highest criteria are established and met. Section 414 (a) of the Bioterrorism Act provides that when the Secretary has a reasonable belief that a food is adulterated and presents a threat of serious adverse health consequences or death to humans or animals, records must be made available. In the absence of any criteria defining that "reasonable belief", affected companies must be

provided with a framework which ensures that such subjective judgments will not be overused or misused.

In the one hundred plus year history of the soft drinks industry, there has never been any public health incident which has warranted that specific “recipes” or formulations be provided to FDA or any other public health agency. The anticipated occurrence of any event in which a product specific formulation would be relevant to an investigation is dubious, at best.

The Bioterrorism Act provides that records be provided if the Secretary determines that a “reasonable belief” criteria has been met. NSDA contends that before a product’s confidential ingredient list is made available, FDA must also meet a similar “reasonable belief” standard for a specific ingredient or ingredients contained in the product. The Secretary must also have a “reasonable belief” that a specific ingredient or ingredients have been adulterated and that this adulteration may lead to a serious health consequence or death.

The process described by the regulation must also explicitly require that, if FDA seeks access to records that disclose the identity of the specific ingredients in a flavor mixture, concentrate, or beverage base, it must explain, in a writing signed by the District Director, why such access is essential to the investigation and cannot be avoided. We believe that in virtually all such investigations -- at least those involving the soft drink industry -- the manufacturer and FDA will be able to identify the source of the adulteration conclusively before any disclosure of records identifying the specific ingredients in a flavor mixture, concentrate, or beverage base becomes necessary. The regulation should therefore require that FDA's written explanation demonstrate, by

specific reference to the developments in the investigation up to that time, why such disclosure cannot be avoided.

Without this relevancy criteria, fishing expeditions, with unintended negative consequences, will likely result.

Summary

NSDA recognizes the difficult task that FDA faces in promulgating regulations that not only fulfill its obligations under the Bioterrorism Act but further, provides a means by which records can be established and maintained in a workable system which allows for a rapid response to a perceived threat to the food supply. NSDA commends FDA in its efforts to work with the food industry in developing these rules.

Two changes must be made in FDA's proposal in order to achieve flexibility and balance necessary for a workable system:

- (1) Allow transporters and non-transporters the flexibility to record production codes and lot numbers where appropriate and reasonable rather than "if available".
- (2) Increase the protections given to product formulations. Access to such information should be requested only if there is a reasonable belief that a specific ingredient or ingredients have been adulterated and that this adulteration may lead to a serious health consequence or death.

The changes will result in a more realistic and workable system, with benefits to both FDA and the food industry. More importantly, it will provide a framework which will enhance the security of the U.S. food supply.