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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

December 24, 2003

2002N-0278

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Introduction

The National Soft Drink Association (NSDA) is pleased to submit comments in response to the interim final rule of the U.S. Food and Drug Administration (FDA) regarding the prior notice of imported foods (68FR 58973) under the Public Health Security and Bioterrorism Preparedness Act of 2002 (the Bioterrorism Act).

The National Soft Drink Association is the national trade organization of the beverage industry. NSDA's member companies produce 95% of all soft drinks consumed annually in the U.S. NSDA member companies also produce and distribute purified water, ready-to-drink teas, sports drinks, juice and juice -based beverages and all 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 previous comments, 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.

Today's comments reflect this recognition and are intended to assist FDA in ensuring food security while providing a system that is both workable and efficient.

Summary of NSDA's Position

NSDA appreciates FDA's positive response to the Association's comments addressing the Agency's February 3, 2003 proposal (68 FR 5428). The Agency's approach to many of the concerns and suggestions expressed in these comments was constructive and will make the prior notice system more workable.

However, one additional issue, that of analytical samples, must be addressed by FDA in order to prevent unnecessarily burdensome prior notice submissions from interfering with the otherwise efficient administration of the prior notice process. In issuing its final rule, NSDA suggests that FDA:

(1) Exclude analytical samples which will not enter the U.S. public food supply.

If FDA determines that it cannot exclude analytical samples, the following alternatives should be considered:

(2) FDA should at least explicitly waive the requirement for the manufacturer's registration number when a shipment consists of :

(a) ingredients or finished goods manufactured by a facility that does not make products for consumption in the U.S. (and therefore has no registration number) or

(b) products made by a competitor (who is unlikely to be willing to supply the shipper with his/her registration number).

(3) In addition, FDA should at least permit samples from multiple sources and in multiple package sizes that are shipped together in a single

shipment to be covered by only one prior notice, rather than requiring, as in the interim final rule, a separate prior notice for each package size and type from every different manufacturer.

(4) Finally, FDA should also establish a greatly simplified prior notice procedure for samples sent to the U.S. solely for analytical purposes. For example, a U.S. analytical facility that could establish, to FDA's satisfaction, adequate controls to ensure that any sample it receives does not enter into manufacturing or commerce should be able to file a blanket prior notice to cover all analytical samples addressed to that facility. When a sample addressed to that facility and clearly marked as containing analytical samples only reaches the U.S. border, FDA would merely have to confirm that the facility had filed such a blanket prior notice.

Discussion

Much of the beverage industry's reputation for ensuring quality and food safety can be attributed to extensive quality assurance programs. These programs involve the pre-approval of ingredients, oversight of the product at the time of manufacturing and marketplace sampling. Extensive sampling and analytical testing helps ensure the integrity of the products to our consumers.

In comments submitted to FDA on April 4, 2003, NSDA detailed four basic types of analytical samples which would be covered under the prior notice proposed rule: (1) routine QC/QA samples, (2) non-routine or investigative samples, (3) samples of ingredients from suppliers or prospective suppliers and (4) consumer-initiated samples.

All of these samples are typically small in size, shipped directly to a company-owned analytical laboratory, and not used in production of food for public consumption.

The effect of FDA's prior notice interim final rule on the beverage industry's analytical sampling practices is significant. Unless modifications are made to the interim final rule, it will not be possible for much of the beverage industry's sampling and analytical functions to be performed in the U.S.

In order to appreciate the magnitude of the impact of the prior notice requirements on the industry's analytical sampling programs, FDA must first recognize the number of samples which will be subject to prior notice under the interim final rule. In its April 4, 2003 comments, NSDA cited one company's estimate of 10,000 samples per-year solely from that company's marketplace sampling program of finished products. A more inclusive estimate, which looks at industry-wide overseas analytical samples shipped to the U.S. from all sources, approaches 100,000 samples annually.

To reiterate, these are analytical samples which are typically small in size, are clearly marked as analytical samples, are shipped to company owned laboratories and which will not enter the public food supply.

Routine QA/QC samples originate from a number of different sources. All manufacturing facilities affiliated with major franchise companies must routinely submit samples which are pulled at the time of production. These typically include finished product samples, but may also include treated water samples, syrup samples and sweetener samples. These samples are collected, labeled, and packaged in clearly marked containers along with the appropriate accompanying paperwork, and shipped to a company owned and operated central laboratory in the U.S.

These manufacturing facilities include bottlers/canners which routinely ship finished products into the U.S. as well as those which do not otherwise ship products into the U.S. The bottlers/canners which routinely ship products into the U.S. will have a facility registration number as required under FDA's facility registration final rule. For these manufacturers, the submission of a prior notice will be unnecessarily burdensome and costly.

These bottlers which do not otherwise ship products into the U.S. would not normally have a registration number, as their products do not enter the U.S. food supply. Yet, solely in order to submit QA samples, these companies will now be required to register their facilities before they can supply a facility registration number on their prior notice submission.

For those marketplace collected samples, the process becomes further complicated. Franchise companies have established extensive worldwide marketplace sampling programs to ensure that the products which are sold at the retail level meet all company-established quality parameters. Shoppers are hired to collect company trademark products, package these according to company-established protocol, enclose purchase information and ship these to designated laboratories in the U.S. These shoppers often have no way of knowing the identity of the specific manufacturing facility and have absolutely no way of knowing the facility's registration number. Further, in many, if not most cases, that manufacturing facility will not have a registration number because it does not ship products into the U.S.

The practice of sampling and analyzing competitors' products is common in the food and beverage industry. This type of marketplace sampling would also be adversely

affected by FDA's prior notice requirements. These samples could not be shipped to U.S. laboratories since the facility registration number would not be known.

The same scenario faces those who ship non-routine investigative samples. These samples may originate from a number of sources, but are generally the result of concerns that an identified finished product may not meet a company's quality specifications. If the sample is identified at a manufacturing facility either by plant personnel or by a company's field personnel, the question of whether the facility ships to the U.S. and therefore has a registration number becomes an issue. If the sample is pulled from the marketplace, the same issues previously described prevents the unencumbered shipment of the product to a U.S. laboratory.

Consumer-initiated analytical samples present yet another challenge. When a consumer expresses a concern about either the quality or safety of a purchased beverage, the consumer is instructed to ship that product to the U.S.-based franchise company laboratory for a timely analytical assessment. Even in the unlikely event that somehow the consumer could identify with certainty the manufacturing facility at which the beverage was produced, and that facility routinely shipped product to the U.S. and therefore had a facility registration number and was willing to share that number with the consumer, it is unlikely that the consumer would go through the process of filing a prior notice in order to ship the product to a U.S. laboratory. A more likely scenario is that the manufacturing facility is unknown and has no registration number because it does not do business in the U.S. Consumer-initiated samples, now an important part of our companies' quality assurance programs, will cease to exist under FDA's interim final rule.

In NSDA's April 4, 2003 comments, the large number of samples received from current and prospective ingredient suppliers to our companies was described. One company alone reports receiving 20,000 such samples annually. Again, such samples are usually small in size (less than 115 grams or 4 oz.), are clearly marked and are used solely for analytical purposes. The samples are frequently sent to the U.S. by suppliers at the behest of manufacturing facilities that wish to use the materials in question. Often, the company-owned laboratory receives no prior notice of these routine but unscheduled shipments.

Many of these overseas suppliers or prospective suppliers do not otherwise ship products into the U.S. or even do business with manufacturing facilities that have U.S. distribution. The only thing that many, if not most, of these suppliers would ship into the U.S. would be samples intended for analytical purposes only. Such suppliers, many small local companies, are reluctant to obtain an FDA facility registration number and file a prior notice when they do no business in the U.S.

Conclusion

NSDA recognizes the many challenges faced by FDA in implementing Section 307 of the Bioterrorism Act and commends the Agency for its efforts to create a workable system which addresses food security concerns. The Agency has addressed many of the industry's concerns with the proposed rule and has put in place significant improvements in the interim final rule.

However, FDA has underestimated the impact that the inclusion of analytical samples will have on the food industry as well as on FDA's prior notice system. Approximately 100,000 such samples are shipped into the U.S. for the beverage industry

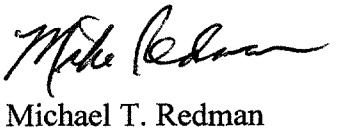
alone. The problem created by the inclusion of such samples in FDA's prior notice of reported foods system range from unnecessarily burdensome to the absolute inability to comply when considered along with FDA's facility registration requirements.

In its interim final rule, FDA went to great lengths to point out that analytical samples would be included in the prior notice of imported food requirements. Unfortunately, FDA did not provide a mechanism which would make such inclusion workable or, in many cases, even possible.

Analytical samples are inherently and fundamentally different from other shipments of imported foods. FDA's decision to treat these in the same manner detracts from an otherwise practical approach.

The intent of the Bioterrorism Act is to address the security of foods entering the U.S. food supply. Small samples of food which are intended solely for analytical purposes, are clearly marked as such, are shipped to company-owned laboratories and which never enter the U.S. food supply should be excluded from FDA's prior notice of imported foods final rule. If FDA concludes that it is not possible to exclude analytical samples, reasonable alternatives, such as those previously outlined by NSDA, must be considered. Such action will not diminish food security in the U.S. Rather, it will allow resources to be used more efficiently.

Respectfully submitted,



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