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

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

McLane Company, Inc. welcomes this opportunity to comment on the U.S. Food and Drug Administration's proposed rule to implement the recordkeeping provision of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the "Act" or "Bioterrorism Act").

**1. Introduction**

McLane is one of the nation's largest wholesale distributors of food and non-food products to convenience stores, quick service restaurants, drug stores, mass merchandising retailers, wholesale clubs and movie theaters. We employ approximately 14,500 people in the United States, operating 36 distribution centers in 22 different states and a fleet of approximately 1,900 tractors and 2,500 trailers. We receive and hold food in our distribution centers and deliver it to our customers on our own tractor-trailers.

McLane supports efforts to ensure the security of the nation's food supply, and we appreciate the receptive and cooperative manner in which FDA has approached the implementation of the Bioterrorism Act. An open and active dialogue between FDA and industry is especially imperative given that the Act provides the agency with very little time to implement its expansive requirements. These impending regulations have the potential, however, to be highly disruptive to the flow of food in commerce. Accordingly, after carefully considering the proposed rule we have identified a number of areas of concern that we hope FDA will take into account as it proceeds in this important effort.

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## **2. Definitions of "transporter" and "nontransporter"**

As explained above, McLane is a distributor that transports food to its customers. Under the proposed rule it appears that McLane is a "nontransporter." A "transporter" is defined as a domestic person who has possession, custody, or control of food for the sole purpose of transporting it. Since McLane does more than simply transport food, McLane is a nontransporter.

We request that the final rule confirm that a distributor like McLane is a nontransporter. A food distributor should not automatically be considered a transporter simply because it delivers food using its own truck fleet. If FDA were to consider the same company a transporter for some purposes and a nontransporter for other purposes, this would create tremendous confusion regarding what records are required to be retained.

## **3. Lot numbers and lot tracking**

McLane's business primarily involves the distribution of less-than-full-case quantities of food and non-food products. This is because the convenience stores and other customers that we serve do not regularly sell or consume full-case quantities, nor does their limited storage space allow them to back-stock full-case quantities of every item. Therefore, our distribution system largely revolves around breaking pallets down to cases, cases down to inner pallets, and inner pallets down to individual items. In doing so, we may take from multiple open pallets or cases of a given product, representing multiple different lots, in order to fill a single order.

Given our operations, information matching lots of incoming products to lots of shipped products is not "reasonably available" within the meaning of proposed § 1.337(a).<sup>1</sup> In this respect our distribution environment is markedly similar to the "commingling" illustration FDA cited in the preamble to the proposed rule, which described silos that contain flour from several different suppliers or lots:

[S]ome food processors commonly store raw materials like corn syrup and flour in tanks and silos. In some instances, these tanks

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<sup>1</sup> It appears that proposed § 1.337(a) applies only to manufacturers and processors, not to distributors. That subsection requires that records include information identifying "the specific source of each ingredient that was used to make every lot of finished product." FDA could not have intended to require a distributor to retain ingredient information for the tens of thousands of SKUs it handles. The final rule should confirm that nontransporters who are not manufacturers or processors are not required to retain ingredient information.



and silos are not dedicated by suppliers, but are topped off as supplies run low, resulting in routine commingling of raw ingredients from a number of suppliers. ... FDA acknowledges that changing this longstanding system to require dedicated supplier storage to facilitate source specific recordkeeping would involve significant financial costs.

Similar to a silo containing flour from several different suppliers or lots, McLane's distribution environment is built around "bins" that are often filled with several different open pallets and cases, potentially representing numerous lots' worth of product.

McLane does not currently track every item by lot number. To do so as required by the proposed rule would require extensive and costly systems and operational changes. In fact, in the less-than-full-case distribution environment an effective lot tracking system would require the manufacturer, processor or distributor to affix or otherwise correlate the respective lot number to every individual product.

Moreover, the potential benefit of investing in a lot tracking system is lessened significantly by the fact there are often no lot numbers available to be tracked. A large number of suppliers do not mark their product with any kind of lot number at all. And even on products that bear a lot number, for several reasons that number can often be difficult or impossible to identify and capture:

- There is currently no standardized format or method for lot numbers. They typically vary anywhere from five to 16 characters. A pallet or carton may bear several different character strings, and it is not always clear which is the lot number, if one exists at all.
- There is currently no standard location for lot numbers to appear on a carton or pallet. Locating and identifying the lot number (if one even exists) amongst all six sides of the container can exponentially slow receiving and processing time, particularly if numerous cases or cartons are stacked on a pallet or otherwise.
- A pallet could conceivably contain a dozen or more cases or cartons representing up to a dozen or more different lots' worth of product. In order to identify and capture each individual lot number, a distributor would be required to undertake the grossly inefficient task of breaking down the entire pallet and then rebuilding it from the ground up.



- Lot numbers are sometimes available but not readable, for instance if printed in faint dot-matrix print that has been smudged or molested in the shipping process.
- Many suppliers' lot numbers currently are not in machine-readable format, which means our teammates would be required to enter the number (if available and discernable) by hand, in an era when we are striving to move toward automation and digitization efficiencies.
- Some suppliers identify lot numbers only on the product invoice or other shipping documents and not on the product containers themselves. In the case of a multiple-lot shipment, matching these lot numbers to specific product is impossible.

In sum, distributors are being required to recognize and handle any type of marking a supplier might choose to make anywhere on a pallet or case to distinguish it as a "lot" – and we must deal with hundreds of suppliers. Until FDA requires, or industry voluntarily adopts, standardization of lot numbering, many of the products we receive will not bear lot numbers that are reasonably capable of being efficiently or reliably identified, captured and recorded. Accordingly, McLane is not persuaded that the benefits of lot tracking outweigh the enormous burden that would be imposed were we required to adapt all our systems to track lot numbers.

Moreover, the language in the Bioterrorism Act is clear in authorizing a regulation to require the maintenance of records that show the person from whom a distributor received a product and the person to whom the distributor sent a product. There is nothing in the language of the Act or in its legislative history that would support an interpretation of the recordkeeping requirement that includes a requirement that products received be directly associated with products that are shipped.

Just as FDA expressly declined in the proposed rule to require significant changes of the food processors that commingle flour in silos, FDA should likewise exempt distributors from having to incur the significant financial costs of overhauling their longstanding systems to enable source-to-destination specific lot tracking.

#### **4. *Responsible Individual***

The Bioterrorism Act does not require that firms retain records identifying a "responsible individual" for each article of food. Nor do we believe this information is necessary to a tracing investigation. Moreover, under the facility registration proposed rule, FDA itself will possess the name of an emergency



contact person for each registered food facility. Instead of requiring the name of a specific individual, FDA should require that records include the name of a responsible individual or department.

If FDA nevertheless determines that the name of a specific individual is absolutely essential, FDA should allow a firm to designate a single individual within the corporation who has overall responsibility for the food and/or vehicle as that organization's "responsible individual" for purposes of all required records under the rule. Allowing a single individual or position to serve as the organization's "responsible individual" would promote efficiency and economy both in the organization's operations as well as FDA's response to any threat. If a company were allowed to designate a single individual or position, each of its business partners would be able to add that name as a predetermined field in its address books and other automated shipping/receiving systems, rather than having to manually fill it in on every transaction, which risks having the name listed incorrectly or often left blank. Moreover, in the event of an FDA investigation, it would provide FDA with a single point of contact to facilitate and coordinate on the company's behalf.

For the same reasons, in the context of records pertaining to transporters FDA should allow the "responsible individual" to be someone within the corporation who has overall responsibility for the vehicle and the food being transported, and not require that the vehicle operator be listed as the responsible individual in every case. In the trucking industry, drivers do not have ready access to all the product and transport records FDA needs in its investigation. Moreover, by many industry accounts turnover among truck drivers exceeds 100% annually - meaning the "responsible individual," if a truck driver, will often have moved on to another company, which would add difficulty and time to FDA's investigation. To be sure, drivers are highly important sources of information in certain FDA investigations. However, a single individual or position within the corporation who has overall responsibility for the vehicle and the food will better serve FDA's investigatory efforts because this individual can provide FDA not only with prompt access to that driver, but also with any other documents, information or response measures required across the entire organization.

##### **5. Food-contact materials**

As part of our business we regularly distribute to our customers many non-food items that do not come into contact with food at any time in our custody, but which are designed or intended for ultimate use in contact with food. For instance, we supply single-use plates, cups, utensils, wrappers, straws, lids, stirrers and the like to convenience stores, quick service restaurants and others.



We are informed and believe that a number of companies and industry organizations, including the Society for the Plastics Industry, Inc., are submitting comments on the portion of the proposed rule that would regulate these types of non-food materials as "foods" for purposes of this proposed rule. We echo their comments, particularly those that emphasize Congress' intent to exclude food-contact materials, the lack of clarity in the proposed rule, and the burdens that outweigh the benefits of recordkeeping as to food-contact materials.

We urge FDA to exempt food-contact materials from the rule. At the very least, the final rule should limit the scope of food-contact materials that are considered "foods" for purposes of this rule. If any non-food item that may ultimately come into contact with food is to be considered a food-contact substance, then the definition of "food" will have virtually unlimited scope. This would impose a heavy record keeping burden while providing little, if any, additional public health protection. As one commenter has noted, FDA has not cited any specific instances wherein foodborne illness outbreaks were attributed to food-contact articles, and it seems unlikely that terrorists would attempt to contaminate food indirectly by tampering with empty cups, spoons or the like. There should be a regulatory carve-out for finished products that are intended to come into contact with food but which are not in contact with food when distributed.

## **6. *Record availability requirements***

Section 1.361 of the proposed rule states that the required records must be readily available for inspection and photocopying or other means of reproduction within four hours of a request if the request is made between 8 a.m. and 6 p.m., Monday through Friday, or within eight hours of a request if made any other time. We believe these time periods are reasonable for records of recent transactions, e.g. the most recent four to six months, as these records usually are kept onsite. However, in a large-volume environment such as ours – which handles tens of thousands of products every day – space constraints dictate that records of older transactions typically must be kept in offsite storage, sometimes on computer tape. These records are not always susceptible of immediate recall.

We suggest that FDA require companies to make records available in a reasonable period of time. The courts have been able to determine what constitutes a reasonable period of time in other contexts, and can do the same here. If FDA nevertheless determines that a maximum time frame is necessary, FDA should allow 24 hours' response time for records pertaining to transactions that occurred more than four months prior to the date of the request.



FDA should keep in mind that companies and officials who fail to meet FDA's deadline for making records available to the agency will face potential criminal liability. The Bioterrorism Act makes failure to comply with the records access regulations a prohibited act. Under relevant case law, violation of FD&C § 301 is a strict liability misdemeanor. In addition, company executives can be personally criminally prosecuted for prohibited acts. *See United States v. Park*, 421 U.S. 658 (1975); *U.S. v. Dotterweich*, 320 U.S. 277 (1943). Given the potential for criminal liability, imposing a hard-and-fast four-hour deadline for records access would be unfair.

### **7. Compliance dates**

If FDA implements a final rule that requires significant changes to be made by industry – for example, lot tracking or immediate access to even the oldest records – six months will be insufficient time to implement these changes across a large-scale, multiple-location organization such as ours. We suggest FDA allow a grace period of one year prior to enforcing any of the rule's requirements against any organization that is taking good faith steps to achieve compliance.

### **8. Conclusion**

McLane appreciates the opportunity to participate in this rulemaking and we request that FDA consider these comments carefully. We hope you will find them useful. If we may provide any additional information in this matter or if we may be of assistance in any other way, please do not hesitate to contact me at 254.771.7915 or bart.mckay@mclaneco.com.

Respectfully submitted,

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