



**The Kroger Co.**

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

112603  
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**Re: Docket No. 02N-0277 – Establishment and Maintenance of Records Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002**

Dear Madam/Sir:

The Kroger Co., headquartered in Cincinnati, Ohio, is the nation’s largest traditional grocery retailer. Kroger operates 2,496 supermarkets in 32 states. We also operate 792 convenience stores, 35 food distribution centers, and 41 manufacturing plants.

Kroger has been in business for 120 years and has led the way in serving consumer needs. Food safety is a top priority for Kroger. Every year we devote significant resources to ensure that Kroger is doing its part to protect and preserve the safety of the food and consumer products in our manufacturing, distribution and retailing operations.

The retail grocery industry is often referred to as the food-purchasing agent for the consumer and correctly so. Hundreds of millions of food packages move through Kroger’s distribution system on their way to consumers every day. We take our role as food-purchasing agent for our 70 million customers very seriously.

**Introduction**

Kroger appreciates the FDA’s efforts to develop a proposed regulation to effectuate the records maintenance provision (hereinafter the Records Regulations) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (hereinafter the Bioterrorism Act). Given the breadth and complexity of the nation’s food supply, this is a difficult task. With 120 years of experience in the grocery business,

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Kroger believes it has a unique perspective on the challenge of delivering food to consumers in a safe, economical manner. Kroger appreciates the opportunity to share this perspective with FDA and trusts that the agency will take its comments into account in preparing a final rule.

Kroger has significant concerns with several aspects of FDA's proposed rule.

Some of the proposed Records Regulations are unworkable given the current food distribution infrastructure. Many are unnecessary because adequate processes are already in place to respond to possible public health and safety threats. These processes are proven methods of quickly and effectively removing food and drug products from the distribution and retail channels in response to possible public health threats. And the cost of many of the proposals is extraordinarily expensive without commensurate benefits in advancing public health.

Kroger urges the FDA to review carefully the comments of those involved daily in delivering food products to millions of consumers and to work with manufacturers, distributors and retailers to develop a final rule that is workable, cost effective and produces meaningful public health benefits.

**1. The Infrastructure Needed to Track Lot or Code Numbers to the Retail Level Does Not Exist and Would Cost Billions to Create.**

FDA proposes to require lot or code number tracking of individual food products all the way to the retail shelf. Specifically, Section 1.337 would require that retailers' "one back" records include "the lot or code number or other identifier of the food (to the extent this information exists<sup>1</sup>)."

Implementing this proposal would require a fundamental, enormously costly change to the nation's retail food distribution system.

**The retail food industry does not track items by Lot or Code numbers. The infrastructure does not exist for tracking lot or code numbers at the distribution center level or the retail store level.**

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<sup>1</sup> In fact, requiring lot or code number tracking all the way to the retail shelf may actually be counter productive from the point of view of public health. Due to the enormous record keeping burden associated with the provision of lot or code numbers, the proposal, if finalized, might well discourage manufacturers from providing these numbers or encourage them to shorten the numbers so they provide less detailed information. Lot and code numbers contain a great deal of valuable information for manufacturers, assisting them in addressing quality variations and consumer complaints. Simplification or elimination of lot/code numbers would complicate these efforts, making the food industry less, not more, responsive to consumer concerns.

Lot and code numbers are created by manufacturers and, therefore, are not standard or universal within the industry. They vary widely as to content, and placement on shipping cases and consumer packages. They are created by individual manufacturers to meet their needs. Moreover, lot or code numbers often are long and complex and contain a wide range of information about when and where a product was produced. For example, a simple gallon milk container has 9 different lot and code numbers on it that would be required to be identified by the proposed Records Regulations.

Kroger Distribution Centers receive and ship hundreds of millions of consumer units daily. Electronic receiving systems throughout the industry rely upon Universal Product Bar Codes ("UPC") - - not lot or code numbers.

To add lot or code tracking would require an entirely new infrastructure system to be developed. This system would have to flow from manufacturer through distribution to retail. Building such a system would take years and would be extraordinarily costly.

Kroger estimates that temporary "fixes" to its computer programs and systems to permit greater tracking of lot or code numbers would involve a one-time cost to the company of \$130 million, and an annual increase in operating expenditures of \$230 million or more. The cumulative impact on the retail food industry - and in turn on consumers -- could easily reach billions of dollars. The cost of developing and implementing a lot or code based tracking system however, would not be the only concern. Kroger estimates it would need more than seven years to update all current systems to capture lot or code number information electronically - well beyond the timeframe FDA proposes for compliance with the proposed Records Regulations.

Even if retail grocery stores could develop a lot or code number tracking system, it would only cover about 80% of the food products in our stores. Grocery stores receive many bakery goods, beer, wine, soft drinks, snacks and other items through direct store delivery ("DSD"). Lot or code numbers are not tracked by the DSD companies or the retailer.

FDA makes reference in the preamble to the electronic tracking systems used by overnight parcel services. Those systems, however, involve far less complex information than FDA would require retailers to keep under the proposed Records Regulations. Even if systems capable of capturing lot or code information electronically at the distribution and retail level were readily available, (which they are not) the cost of implementing those systems would be astronomical.

The alternative to electronic tracking of lot or code numbers - manual tracking - would be unworkable. Unlike UPC codes, lot and code numbers are not scannable by any current technology. As stated before, product codes are complex and lack uniformity with respect to format and placement on individual consumer units. Unlike UPC codes, lot and code numbers are not standardized. The code may identify a production day,

batch, process, storage vessel and/or filling equipment, operator, and production time in hours, minutes and seconds. Moreover, for production reasons, some manufacturers place different lot codes on shipping cases and the individual consumer units in those cases. In some situations not all of the consumer units in a shipping case will have the same code.

Manually transferring lengthy, varied, and complex information of this type into records mandated in the proposed Records Regulations would result in numerous inaccuracies, undermining the records' value to FDA or the retailer. Missing just one piece of the code, or erroneously transcribing the code at some point in the latter stages of the distribution chain, would effectively prohibit the rapid traceback FDA envisions.

**2. Current Processes Quickly and Effectively Remove Products and Protect the Public Health. The Proposed Records Regulations Would Impede Rapid Response to Potential Public Health Emergencies.**

Despite the enormous investment tracking lot or code numbers would require in terms of time and money, there is no evidence that lot or code number tracking would offer any advantage over current practices in terms of public health protection. Government agencies, manufacturers and suppliers call upon retailers to remove product from retail shelves hundreds of times per year to protect public health. Systems are in place to remove questionable product quickly and efficiently. Through the use of UPC numbers, manufacturers, distributors, and retailers can effect a product recall in a fraction of the time FDA would need to trace food using product lot or code numbers.

Kroger believes Congress passed the Bioterrorism Act to help prevent malicious attacks against our food supply and to protect the health or safety of American consumers in the event of such an attack. In Kroger's view, if a food presents a credible threat of serious adverse health consequences or death, that food should be removed from retail stores quickly and completely.

Kroger uses the 1982 Johnson & Johnson Tylenol recall as our model. In an emergency situation of this type, the magnitude of the threat demands immediate removal of product, regardless of lot or code number. Circumstances simply do not permit a painstaking search to identify the individual stores that received particular lots or codes of product. Moreover, even if lot or code number information were readily available and searchable, Kroger questions whether limiting product removal directions to specific retail stores would ever be prudent, given the likelihood of human error in recording and tracking lot and code numbers.

Current systems in place at Kroger and throughout the grocery industry enable retailers to identify the suppliers that delivered food to their distribution centers on given dates, as well as the quantities and types of product delivered. Retailers also can identify

the distribution centers that shipped product to specific retail stores on a given date, and other information about that product. Thus, in the event of an emergency, retailers can pinpoint the distribution center that received and shipped potentially affected product and move rapidly to remove that product from all retail stores that may have received it. That is the system in place now, and it has served industry and the public well for many years.

Forcing retailers to keep records linking specific retail stores with specific lot or code numbers of product would cost billions of dollars yet do nothing to expedite the emergency removal process. Records identifying the group of retail stores that may have received a specific lot or code of product from the relevant distribution center should be sufficient.

**3. Requiring Companies to Identify a “Responsible Individual” in Each Record Kept under the Proposal Would Have No Utility.**

FDA proposes to require that companies identify a “responsible individual” in each one up/one back record kept under the proposal. Kroger questions the utility of this proposed requirement, given the rapid pace at which individuals change jobs and employers within the food industry. In many cases, the individual identified as “responsible” for a transaction will not be in that position when and if FDA examines the records at some time in the future. Accordingly, Kroger recommends that FDA eliminate the proposed requirement that records identify a “responsible individual.” Alternatively, if the agency desires an individual point of contact within a company, the proposal should be revised to permit companies to identify a single, management-level individual in all records who has authority and responsibility for regulatory compliance and who would be in a position to respond to the agency’s needs in the event of an investigation, concern, or threat.

**4. The Proposed Definition of Perishable Food is Unworkable, Conflicts with Common Regulatory Definitions of that Term, and Should Be Changed.**

The definition of “perishable food” proposed by the agency is inconsistent with prevailing regulatory definitions of that term. As defined by FDA, Kroger estimates that few, if any foods, would qualify as perishable. To date, Kroger has identified only a few foods sold at retail that are “not heat-treated, not frozen and not otherwise preserved in a manner so as to prevent the quality of the food from being adversely affected if held longer than 7 days under normal shipping and storage conditions,” namely bread, fish and store prepared food.

Not only is the proposed definition of perishable too narrow, the conflict with other regulatory definitions of perishable is clear. Thirty years ago, the National Conference of Weights and Measures, working in conjunction with state agencies with responsibility for the regulation of foods, defined perishable, semi-perishable, and long-

term shelf life foods. The National Conference undertook this task to assist in the establishment of a uniform method for presenting open code date labeling for foods. The definitions, which have since been adopted by numerous states and local jurisdictions with open date code regulations, are:

- “Perishable Food means any food for which a significant risk of spoilage, loss of value, or loss of palatability occurs within 60 days of the date of packaging”
- “Semi-Perishable means any food for which a significant risk for spoilage, loss of value, or loss of palatability occurs only after a minimum of 60 days, but within 6 months, after the date of packaging”
- “Long Shelf-Life means any food for which a significant risk of spoilage, loss of value, or loss of palatability does not occur sooner than six months after the date of packaging, including foods preserved by freezing, dehydrating, or being placed in a hermetically sealed container”

Kroger urges FDA to take these definitions into account in formulating a definition of perishable food for inclusion in the final records maintenance regulation.

#### **5. FDA Should Harmonize the Proposal’s Record Retention Requirements with Those in Other Applicable Regulations.**

FDA proposes that companies retain records kept under the rule for two years. For perishable foods, that time would be shortened to one year. Although seemingly simple and straightforward, these timeframes would be difficult and confusing for some companies to apply in practice because of the other record retention requirements (of varying lengths) with which they must comply. Accordingly, Kroger urges FDA to review the record keeping retention periods now in effect for specific food categories (e.g., acidified foods, low acid canned foods, bottled water, juices, seafood, and milk) and work to harmonize the proposal’s record retention requirements with those periods. The burden of having to comply with different record retention requirements for the same product is obvious. Moreover, the value of a two-year record retention period for a product with a shelf life of 60 days seems questionable, particularly in light of the additional costs extended retention obligations would impose.

#### **6. Companies Should Have at Least One Day to Make Records Available to the Agency.**

FDA proposes to require that records kept under the proposal be made available to the agency within four hours of a request made during normal business hours, or within eight hours during other times. Kroger operates facilities across five time zones. An agency request for records may be between 8 a.m. and 6 p.m. at the facility at which it is made but outside of those normal business hours for purposes of the facility at which the records are kept. Moreover, like most other businesses, Kroger’s computer systems are periodically taken “off line” for routine maintenance. During these periods, data is

unavailable for searching. Likewise, data that has been generated but not yet uploaded on computer systems is unavailable for searching. In light of these and similar considerations, Kroger urges FDA to revise the proposal to allow companies at least 24 hours to make records available to the agency.

**7. Retail Store Delicatessens Should Be Regarded as Restaurants and Excluded from the Final Regulation.**

FDA proposes to exclude restaurants from the records maintenance regulation, in accordance with the literal language of the Bioterrorism Act. The operations of retail store delicatessens, and the products those delicatessens prepare, are the same as carry out restaurants. Like carry out restaurants, retail store delicatessens prepare food for immediate consumption by consumers. Accordingly, Kroger believes the delicatessen operations of retail grocery stores should be completely excluded from the final records maintenance regulation. A final regulation that imposes records maintenance obligations on in-store retail delicatessens, but excludes carry out sandwich shops and other restaurants from those requirements, would bestow an unfair economic advantage on the latter.

**8. FDA Must Carefully Instruct Its Personnel With Respect to the High Legal Standard the Agency Must Satisfy to Gain Access to Records Kept Under the Final Records Maintenance Rule.**

Further guidance from the agency with respect to the scope and implementation of the Bioterrorism Act's records access and records maintenance provisions is essential in order to avoid misunderstanding and confusion among FDA personnel and the regulated industry. Already, citing the Bioterrorism Act, FDA personnel conducting routine inspections have demanded access to records that the Act makes available to the agency only when the agency has a "reasonable belief that an article of food is adulterated and presents a threat of serious adverse health consequences or death." It is critical that FDA's inspection force understand the high legal standard the agency must meet before it may legally gain access to records under the Bioterrorism Act and the records maintenance regulation.

To ensure that that standard is properly applied, Kroger suggests that FDA implement a policy requiring approval of Bioterrorism Act records access requests by the FDA District Director for the District in which the request is made, or an FDA official senior to the District Director. This precaution is being implemented with respect to issuance of detention orders and is necessary with respect to records access as well. Without review by high level agency officials, Kroger fears that expansive but unfounded document requests will proliferate, diverting valuable time and resources away from more productive endeavors.

### **9. The Effective Date of the Final Regulation Should Be Extended**

Kroger asks the agency to review carefully the effective date it proposes in light of the substantial amount of time industry will need to modify prevailing business systems to ensure compliance. By way of comparison, it took 24 years for the food industry to implement the UPC Code in just 106 supermarkets. In 1997, the Universal Product Code Council announced that it hoped expansion of the number of digits in the UPC bar code could be completed in eight years. The complexity of the UPC bar code is comparable to the complexity of the information manufacturers, distributors, transporters, and retailers will be required to track under the proposed Records Regulations. FDA must take this complexity into account in setting an appropriate effective date for the regulation. The various effective dates, depending upon a firm's size, creates a problem for Kroger where independent businesses deliver products to distribution centers or retail stores. These independent businesses may be exempt for upwards of 18 months, while Kroger would be responsible at a much earlier date. This creates voids in the prescriptive chain of custody that Kroger would be required to comply with in the regulation.

#### **Summary**

The Bioterrorism Act was intended to enhance the safety and security of the nation's food supply. Kroger fully supports that mission and has committed substantial resources to it. The proposed rule, by requiring lot or code number tracking to the retail store level, would impose enormous burdens on the retail food industry with no evident enhancement in safety or security. Kroger knows from experience that lot or code numbers – while useful for certain purposes and in certain contexts – are far too complex and unwieldy to rely upon in emergency situations. To protect the public in the event of a terrorist threat to food, FDA and industry must act quickly. Laborious examination of records identifying the particular retail stores that received specific lots or codes of product simply is inconsistent with the rapid response required.

If finalized as written, the proposed Records Regulation would be the single costliest government control the retail food industry has faced. A large portion of the costs required to comply would inevitably be passed on to the consumer. Kroger urges FDA to reconsider the proposal carefully and to modify the information requirements at the retail level to better reflect existing business systems and the real world challenges of removing potentially dangerous food from sale quickly and completely for the benefit of consumers.

Sincerely,



David B. Dillon  
Chief Executive Officer