GROCERY MANUFACTURERS OF AMERICA
MAKERS OF THE WORLD'S FAVORITE BRANDS OF FOOD BEVERAGES, AND CONSUMER PRODUCTS

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

Re: 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 Grocery Manufacturers of America, Inc.

Dear Sir or Madam:

The Grocery Manufacturers of America, Inc. ("GMA") is pleased to have this opportunity to provide comments on the proposal of the Food and Drug Administration ("FDA") to implement section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("the Bioterrorism Act"), which provides for the establishment and maintenance of certain records related to the production and distribution of food for consumption in the United States.

GMA is the world's largest association of food, beverage and consumer product companies. With U.S. sales of more than $460 billion, GMA members employ more than 2.5 million workers in all 50 states. The organization applies legal, scientific and political expertise from its member companies to vital food, nutrition and public policy issues affecting the industry. Led by a board of 42 Chief Executive Officers, GMA speaks for food and consumer product manufacturers at the state, federal and international levels on legislative and regulatory issues. The association also leads efforts to increase productivity, efficiency and growth in the food, beverage and consumer products industry.

1. General Comments

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GMA and its member companies share with the FDA the goal of enhancing the security of the food supply. Each of GMA's member companies has a deep and abiding commitment to food safety and food security. Our evaluation of FDA's proposals to implement the Bioterrorism Act has been heavily influenced by the commitment we share with FDA to provide a safe and secure food supply to the American people.

Section 306 of the Bioterrorism Act provides for access to records under certain specified circumstances and permits the FDA, by regulation, to require the establishment and maintenance of limited "chain of distribution" records. The proposal that FDA issued deals largely with the establishment and maintenance of records and only incidentally with the subject of records access. In these comments, GMA suggests some changes to the proposed requirements for the establishment and maintenance of records, which will preserve the value of those records in tracing the movement of food while reducing the burden on the food industry. We also suggest some changes to the records access provisions of the proposal that will better take into account some of the practical considerations in records maintenance and retrieval. Finally, we urge FDA to add some provisions to the regulation that will provide procedural protection when FDA exercises the records access authority under section 306 of the Bioterrorism Act.

2. *Establishment and Maintenance of Records*

a. *Lot and Code Numbers*

Under the proposal, nontransporters (food manufacturers) and transporters would be required to maintain records of the movement of food that include the lot or code numbers of the food products produced and distributed. This requirement is neither feasible nor necessary, and should be deleted from the final regulation.

Under the proposal, FDA would appear to have determined that the modest grant of authority under the Bioterrorism Act to require the maintenance of limited distribution records should result in a "cradle-to-grave" record keeping system that would trace every package of food distributed in the United States literally to the very shelf in a specific retail establishment in which it is sold. FDA fails to appreciate that it is not possible to know this information without major adjustments in the way the food industry, transportation industry and retailers

work. Moreover, FDA does not make the case – and we certainly cannot fathom what it would be – that protecting the public from food products that present serious risks to the public health necessitates the maintenance of records with lot or production code information captured at every step of the process of producing and distributing food.

Lot-by-lot tracking throughout the entire chain of food distribution is not possible. It is now common practice within the food industry to track product from production to a warehouse by lot number. It is typically not the case, however, for the lot numbers to be tracked once the product leaves a warehouse and enters the retail environment. (We explain below why it is not necessary to have this information.) In some instances, products are delivered to the retail store directly by representatives of the food manufacturer. In this so-called "direct store delivery" situation, the transporter who picks up say, snack products, from the food manufacturer's warehouse, delivers the products directly to retailers and stocks the shelves. The supplier of the product and the transporter (who is a representative of the supplier) will be able to trace the movement of the product, with lot numbers, from the warehouse to the transportation vehicle. Neither they, nor the retailer, however, will have the ability to determine the lot number of each bag of chips that are placed on the shelf of each retail establishment that the transporter visits with each load of product in his or her vehicle.

It would require substantial technological innovation and reworking of this delivery system for it to be possible to capture the lot number of each product as it was delivered to each retail location. Moreover, the difficulty does not exist merely in the direct store delivery situation. In other situations, food manufacturers may use independent delivery persons who pick up product from several manufacturers for delivery to retailers within a certain geographical area. There may well be as many as 75-100 different products on each truck. In this case, there will be a record that shows what lots of product were picked up by the independent delivery person, and that delivery person will have a record of what retail establishments were visited during the course of a working day, but the delivery person has no capability to capture the lot numbers of the products of several different manufacturers whose products are being delivered.

It is important for FDA to appreciate that the problem with the proposed requirement for lot-by-lot tracking is not merely the impossibility of capturing the

information with current technology and distribution systems and practices. The problem is also that FDA apparently has concluded that it and the industry reasonably need such information to address any public health event involving food products. This is wrong.

First, if there is a serious public health problem with a food product and product needs to be removed from the market (recalled), few food manufacturers would attempt to remove the product by "lot number" and no retailer would attempt to implement a lot-specific recall. Doing so is simply too risky, too complex, and too burdensome. Rather, the food manufacturer would implement a much broader recall of the affected product, and retailers would remove all of the affected product from their shelves without regard to lot codes. To the extent that FDA believes that having lot tracing down to the retail level will benefit the food industry by permitting a more narrowly tailored recall, for example, we submit that there is no basis in the experience of the industry to support that conclusion.

Even without the lot information down to the retail level, it is still possible to locate particular lots of product that left warehouses. When the food manufacturer knows that certain lots were in warehouse "x" on a specific date, it is possible to identify the specific retailers that received one of the several lots of food. This is important because the manufacturer can then be said to have a record that identifies the immediate subsequent recipient of the food.

Unlike most packaged food products, food packaging and food contact items do not have lot numbers, except where the lot number for the food to be contained in the package is directly imprinted onto the package. The creation of a system for lot numbering of packaging and food contact items would be a major and costly undertaking and there is no basis to believe that it would enhance the safety of the food supply. FDA should reaffirm in the preamble to the final regulation that there is no requirement to include lot numbers on packaging and other food contact items.

To briefly summarize: (1) the food industry cannot now capture lot information to the retail level; (2) neither the food industry nor FDA needs the lot information to the retail level; (3) lot information is not required on food packaging and food contact items, and (4) the requirements of the Bioterrorism Act are met even without the lot information for food products in records of product distributed.

b. Responsible Individual

Under the proposal, FDA would require that in every transaction involving the movement of food through the entire chain of distribution, records be maintained which contain the identity of the "responsible individual." It is not clear from the proposal whether the "responsible individual" is the same as the "emergency contact person" for purposes of facility registration, sometimes the same, or never the same. It is equally unclear whether the term refers to the person who loaded a pallet of product onto a loading dock, the person who loaded it onto a truck, the driver of the truck and so forth. What is clear, however, is there is little value in burdening the distribution process with a requirement to capture the names of various "responsible individuals" when, for facilities that are registered, FDA will already possess designated emergency contact information. For transporters, it should be sufficient to require that the transporter designate a "responsible individual" and that a nontransporter who uses a specific transporter be able to identify the responsible individual at the transporter. There is no demonstrated need for the record of each commercial transaction involving the distribution of food to contain the name of a responsible individual, whomever FDA intends for that person to be.

c. Identification of Specific Ingredients/Lots

Under the proposal, food manufacturers would be required to maintain records that connect a specific source of an ingredient with a specific quantity of finished product (proposed 1.337(a)). In its pre-proposal comments, GMA argued that it was not feasible to connect ingredients and finished product in cases where the ingredient was commingled. FDA recognized this in the proposal; GMA supports the flexibility that FDA has built into this proposed requirement. With a slight additional modification, we believe that this requirement will be workable.

The proposed modification relates to the use of "ingredients" that are classified under FDA regulations as "processing aids" and "incidental additives." As FDA well knows, these two categories include substances used for a variety of regulated purposes in facilities in which food is prepared, processed and packed. The categories do not include ingredients that are added to food where the substance will be present in significant quantities in the finished food or have a technical or functional effect in the finished food. Because the

substances that are categorized as processing aids or incidental additives are often used in the food production facility, but not in the food itself, it would be difficult, to say the least, to connect a specific quantity or lot of a processing aid with a specific lot of finished product.

FDA should treat processing aids and incidental additives as it proposes to treat ingredients that are commingled. In this way, a company would need to be able to identify the source(s) of the processing aids and incidental additives in use in a facility when specific food products were produced, but would not be required to know the specific source of the processing aid or incidental additive used to produce a specific lot of food.

d. Exemption for Food Packaging and Other Similar Items

In the proposal, FDA recognizes that the risks to human and animal health from outer food packaging are negligible. Accordingly, FDA proposed to exclude outer food packaging from the requirement to establish and maintain records. FDA should extend the exemption to cover food packaging, food contact materials (food wraps, for example), and other items that have traditionally been treated by FDA as covered by the so-called "housewares exemption."

Food packaging sold as such, food contact materials sold for home use, and items such as utensils, pots and pans and the like ("housewares exemption items") present the same low risks to human and animal health as outer food packaging. For many of these items, FDA has long recognized the low risks presented by these items and exempted them from the requirements of the food additive provisions of the Federal Food, Drug, and Cosmetic Act ("FDC Act"). Further, the production processes for these items effectively inoculates them from any substances that could conceivably be used by persons intent on intentionally contaminating the food supply. Thus, for the same reasons that FDA concluded that outer food packaging should be excluded from the record maintenance requirement, so should these other food packaging and food contact materials.

e. Product Descriptions

Under the proposal, records would be required to contain an "adequate description" of the food, including the brand name, specific variety, and how packaged (proposed 1.337, 1.345, and 1.352). Typically, this information is maintained now by the use of company-specific codes and abbreviations. It is unclear whether FDA intends to permit the use of codes and abbreviations to satisfy the proposed requirement. We strongly urge that FDA make clear in the final regulation that codes and abbreviations are acceptable to identify the food with the specificity that FDA expects (that is brand, variety, how packaged). If necessary, the codes and abbreviations can be deciphered for FDA without imposing delay or other impediments to the exercise of FDA's regulatory authority. In short, there would be a burden associated with eliminating the use of codes and abbreviations on existing commercial documents, without commensurate benefit.

Additionally, some products are not packaged in neat containers. For some products (liquids, for example), the raw material may be received in bulk, such as a tanker load. In these situations, it should be made clear in the final regulation that it is sufficient for the records of the distribution of this food to indicate the gross quantity (*e.g.*, 5,000 gallons of X).

f. Time Periods for Records Maintenance

Under section 1.360, FDA proposes a one-year record retention period for records related to perishable foods not intended to be made into nonperishable foods and two years for all other human foods. There are several problems with the proposed requirement.

First, the definition of perishable food is too narrow and limiting. There are many foods with a limited period of shelf life, but which are not strictly speaking "perishable." For example, a bag of chips is not perishable under the proposed FDA definition, but it will not remain on a store shelf for as long as canned soup. FDA should revisit the perishable/nonperishable distinction; perhaps, a third category of semi-perishable should be introduced.

Second, under the proposal, records for perishable foods would have to be maintained for one year, unless the perishable foods were intended to be made into non-perishable foods. This requirement would thus impose an obligation on

the person distributing perishable foods to determine the ultimate intended use of the foods. This is not feasible or routinely possible. How is someone who distributes fresh produce in a position to know what every buyer (direct and indirect) intends to do with the produce purchased? The produce distributor may not even know what the persons who buy directly from him intend to do with the product, much less the intentions of persons several transactions away. Thus, as proposed, persons would have to assume that perishable foods were or might be made into non-perishable foods. They would have no choice but to apply the non-perishable record retention period.

We suggest that FDA adopt an approach to the record retention issue that recognizes that there are three (perishable, semi-perishable, and long shelf life) categories of food products as opposed to two (perishable and everything else). FDA could easily adopt the definitions for "perishable," "semi-perishable," and "long shelf life" that are set forth in the "Uniform Open Dating Regulation" as adopted by The National Conference on Weights and Measures. Sections 2.2, 2.3, and 2.4 set forth definitions for the three terms. Notably, these definitions recognize that there are food products with relatively short shelf life, but which are not typically considered to be perishable. Using these definitions, we suggest the following retention periods:

Perishable Foods:	6 months
Semi-Perishable Foods:	12 months
Long Shelf Life Foods:	18 months

These time periods will be manageable for persons who are required to maintain records, while also covering the likely period in which FDA would need access to records for regulatory purposes.

3. *Records Access*

The proposal fails to include provisions necessary to ensure that the exercise of the records access authority under the Bioterrorism Act is Constitutional and otherwise in accordance with law. Moreover, there are several provisions of the proposal in which records access is addressed (time period for access in proposed 1.361), which are neither feasible nor needed. We address these issues in this section of these comments.

a. *A request for access to records must be accompanied by an explanation of the basis for the request.*

The proposal should be revised to provide that, whenever FDA exercises the records access authority under sections 414 or 704(a) of the FDC Act, it will provide a written statement to the person from whom the records are sought, which contains a summary of the evidence on which FDA relied in concluding that the standard for records access ("reasonable belief that an article of food is adulterated and presents a serious risk of adverse health consequences or death to humans or animals") has been met. Without such a written statement, persons from whom records are sought will have no basis to assess the bona fides of the request itself or to determine whether the requested records are reasonably related to the putative risk that led the FDA to conclude that the high standard for records access had been met.

Under the Bioterrorism Act, access to records requires that FDA possess a "reasonable belief." If FDA does not provide to the person whose records are sought an explanation of the evidence that provided the "reasonable belief," there will be no practical way for anyone to provide a check on the exercise of discretion by the FDA. How will anyone ever determine whether FDA had a "reasonable belief" as opposed to merely a belief or even an unreasonable one? On the other hand, if FDA provides such a statement to persons whose records are sought, there is the ability of such a person to assess the legitimacy of the request and, if unpersuaded, decline to provide the requested access or, alternatively, seek judicial intervention to nullify the request. Without a statement, persons whose records are sought have to choose between: (1) providing the records merely because the agency asked for them; or (2) declining to provide access in order to determine whether the basis for the request is a "reasonable belief" (under the theory that the agency will seek judicial intervention to enforce its access rights). It is only when the agency has a "reasonable belief" that the exercise of its access authority is lawful; providing the suggested statement will thus help to ensure – FDA and the regulated industry – that the authority is being used responsibly.

In addition, FDA should provide that before a request for access may be made, the basis for the request and the scope of records to be examined be approved by the district director for the FDA district in which the records are located. The approval of the district director should be reflected on the written statement provided to the person from whom the records are sought. Together, the written

statement and indication of district director review and approval will provide assurance that the warrantless records access authority is being implemented in a manner that is consistent with the requirements of the Fourth Amendment to the Constitution.

b. *Procedures for Access to and Protection of Confidential Information*

Under the records access provisions of the Bioterrorism Act, FDA may obtain access to the records of food manufacturers where FDA has a "reasonable belief" that food is adulterated and "presents a serious threat of adverse health consequences or death to humans or animals." Excluded from the scope of the records access provisions are "recipes" (Section 414(d)(4) of the FDC Act, as added by section 306 of the Bioterrorism Act). In the proposal, FDA has defined "recipes" to mean only the "quantitative formula" used to make a food product, but not the identity of the individual ingredients (proposed section 1.328). In the brief discussion in the preamble concerning this proposed definition, FDA appears to take the position that because ingredients are required to be disclosed on product labels, there are no issues with regard to the use of its records access authority concerning product ingredients. We suggest that there are major issues and that FDA must address them in the final regulation.

Under the section 403(i) of the FDC Act, 21 U.S.C. § 343(i), flavors and spices are exempt from the requirement of ingredient listing on product labels because flavors and spices are highly proprietary and, in many products, are what distinguishes one manufacturer's product from another. Disclosure on the label, or disclosure through the exercise of FDA's records access authority would be highly damaging to the food manufacturer whose "secret formula" entered the public domain. FDA's procedures for the exercise of its records access authority should, therefore, embody recognition of the special status of these ingredients.

First, FDA should provide that it will not routinely seek access to records that would require the disclosure of confidential ingredient information.

Second, if FDA concludes that it needs access to information about ingredients, it should present a writing to the custodian of the records that sets forth the basis for the agency's conclusion.

Third, FDA should seek records access in an orderly manner, beginning with ingredients other than flavors and spices. It will not be possible for FDA to assess simultaneously each ingredient in a product as the potential source of the problem that is being investigated. Given that flavor and spice information is highly confidential and that the low levels of use of those ingredients make it unlikely that one of them will be the source of the problem investigated, it is reasonable to provide that requesting information on flavors and spices will occur only as a "last resort."

Finally, FDA should provide for special procedures to ensure that when flavor and spice information is obtained, it is properly protected from disclosure, whether advertently or otherwise. Among other things, such information should be shared within FDA only to the limited extent necessary to conduct the particular investigation that resulted in the disclosure. Highly proprietary information about product formulas should not be widely distributed within the agency, and all persons who are made privy to the information should be reminded explicitly of the confidential nature of the information. Moreover, FDA should amend its public information regulations to provide expressly that information obtained under the records access authority is exempt from disclosure pursuant to or more of the exemptions under the Freedom of Information Act, 5 U.S.C. § 552.

c. *The Time to Provide Records Must Be Reasonable*

FDA has proposed entirely unreasonable time periods for providing access to records (proposed 1.361).

Under that section, companies would have only four hours to provide records if the request is made between 8 a.m. and 6 p.m., Monday through Friday. The notion that companies should always be in a position to respond fully to a request for records within four hours has no foundation in either FDA's regulatory needs nor the practices and procedures of other regulatory agencies. The time that will be required to respond fully to a request for records is obviously very much a function of the scope and timing of the request and the timing of the request. There is a difference, for example, between a request made early in the day where the person who maintains the requested records has the bulk of the normal business day to respond and a request made at 5 p.m. (technically within the proposed 4-hour time to respond, but barely in the normal business day).

GMA recognizes FDA's desire for a simple and straightforward rule on records availability. We suggest, however, that such a rule can be adopted only by ignoring the variety of circumstances in which records may be sought and the vast differences in the time required to produce say, three months worth of production records and three days worth.

We suggest that proposed section 1.361 be revised to delete the 4-hour and 8-hour time periods for making records available. Alternatively, FDA could revise that section to provide that the 4 and 8 hour time periods are illustrative only and acknowledge that the actual time to begin making records available will depend on a variety of factors, including the scope of the request. It would certainly be reasonable to provide that persons must begin the process of making records available within 4 hours of a request made during the normal business day. FDA must recognize, however, that in some cases at least it will reasonably take 24 hours or more to collect all of the records responsive to a request.

GMA commends FDA for its outreach program to various stakeholders. In various forums and on countless occasions, FDA personnel have been available to explain the proposal, to respond to questions, and to listen to concerns. GMA urges FDA to remain accessible during the time in which it is evaluating comments and to continue to include the stakeholders in the ongoing process of developing regulations to implement the Bioterrorism Act.

Sincerely yours,

Susan M. Stout

Vice President, Federal Affairs