IFDA
international foodservice distributors association

Government Relations / Educational Services

July 8, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
Department of Health and Human Services
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

Dear Sir or Madam:

The International Foodservice Distributors Association (IFDA) appreciates this opportunity to submit comments to the Food and Drug Administration (FDA) regarding the agency's proposed rule on establishment, maintenance, and availability of records under section 306 of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). 68 Fed. Reg. 25,188 (May 9, 2003).

IFDA is a trade organization representing foodservice distributors throughout the United States, Canada, and internationally. IFDA's 145 members include broad line and specialty foodservice distributors that supply food and related products to restaurants and institutions in the "food away from home" business. IFDA members operate more than 550 facilities, and sell more than $64 billion in food and related products to the fastest growing sector in the food industry. Formerly a division of Food Distributors International, IFDA was established as an independent trade association on January 1, 2003.

IFDA strongly supports the purposes of the Bioterrorism Act and of this proposed rule. However, we are deeply concerned that some of the proposed record keeping and records access requirements will place unnecessary burdens on food distributors.[1] We note that compliance is a very serious matter insofar as failure to maintain the required records, or failure to provide access to these records within the required time frame, subjects a company to civil and criminal liability.

[1] Although these comments refer to food distributors, many of our concerns apply to all nontransporters as defined in the proposed rule.

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We urge FDA to make the following changes in the final rule and otherwise clarify certain outstanding issues:

1. FDA should clarify how the record keeping requirements apply to "cash and carry stores."

The proposed rule exempts retail facilities from maintaining records of immediate subsequent recipients (*i.e.*, the consumers who purchase foods at retail). A "retail facility" is defined as a facility that sells food directly to consumers *only*. Thus, a warehouse store or "cash and carry" store that sells food both to consumers and to commercial accounts would not qualify for this exemption.[2] Nevertheless, FDA should clarify that, if an entity conducts both exempt and non-exempt activities at the same location, it would be required to retain records only with respect to its non-exempt activities. Under such a clarification, a "cash and carry" store that sells food to individual consumers but that may also sell to commercial customers, would not be required to maintain records regarding its retail sales to consumers. IFDA requests that the final rule confirm this interpretation.

This clarification will both continue to serve the underlying purposes of the legislation, *i.e.*, to enable FDA to carry out its statutory duties in the event of a need for investigation, yet at the same time will not impose an undue burden on retailers that may also sell to commercial customers. No purpose would be served by requiring "cash and carry" stores to maintain records of sales of food to consumers for their personal use.

2. FDA should clarify that a "nontransporter" that transports food as an incidental part of its business is not thereby a "transporter."

The proposed rule establishes different record keeping requirements for transporters and nontransporters. A "transporter" is defined as a domestic person who has possession, custody, or control of food for the sole purpose of transporting such food. A "nontransporter" is defined as a person who holds, processes, packs, imports, receives, or distributes food for purposes other than transportation. Not surprisingly, many nontransporters own trucks or other vehicles and transport food as an incidental part of their operations. For example, many food distributors deliver food by truck to their customers and also may transport food returns. These entities should not be classified

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[2] As the name implies, a "cash and carry" store sells food products to anyone who wishes to buy bulk quantities in cash transactions (*e.g.*, from an individual consumer planning a party or providing for a large family to intermittent supply to restaurants). Such stores typically do not retain detailed records of cash sales. For cash and carry stores that do engage in regular commercial transactions, or which provide credit to commercial customers, ordinary business practices should normally generate records that could be tailored to serve the requirements of the proposed rule.

as transporters for their distribution practices that are incidental to the nontransporters' holding, processing, packing, importing, or receiving of food.

IFDA requests that the final rule clarify that an entity is either a transporter or a nontransporter, and that FDA will not consider the same entity a transporter for some purposes and a nontransporter for other purposes.

3. The specific information required to be retained should not go beyond what is necessary for FDA to conduct a tracing investigation.

a. A distributor should not be required to retain information regarding the transporter that transports food to it.

Under the proposed rule, a nontransporter is required to retain records sufficient to identify both the immediate nontransporter source of food and the transporter that transported the food to it. For example, if a distributor receives food from nontransporter A via transporter X, the distributor must keep detailed records about both nontransporter A and transporter X. In the preamble to the proposed rule, FDA acknowledges that "requiring nontransporters to keep records on both previous and subsequent transporters and nontransporters is potentially burdensome" and that "there could be other interpretations" of section 306 of the Bioterrorism Act. 68 Fed. Reg. at 25,195. The agency said it is open to "alternative record keeping arrangements that would allow for the complete and efficient investigation of food-related emergencies." *Id.*

Requiring a distributor to keep records about the transporter that delivers food to it is unnecessary and unreasonable. Such records are not currently maintained by most distributors, and we suspect the same would be true of other types of nontransporters. Therefore, an entire new category of records would need to be created at considerable expense to industry. When that information already exists elsewhere (*i.e.*, at the immediate nontransporter previous source), requiring a distributor to likewise create such records is an unnecessary redundancy. Thus, in the example above, if it is necessary for FDA to identify transporter X, it would be far simpler for FDA to go to nontransporter A who already retains that information. Nontransporter A will be easily identifiable from the records of the subsequent nontranporter to which nontransporter A distributed the food products.

While it is reasonable for FDA to want information sufficient to reconstruct the entire chain of custody of a food product, it is unnecessary to create duplicative records of the same information at different stages of the chain.

b. Intra-corporate transfers should require only one set of records.

Under the proposed rule, the information contained in records must pertain to the facility where the covered activities occurred, and the records must be accessible at the location where the covered activities occurred. This is true even in the case of intra-corporate transfers of food between facilities owned by the same corporation. For example, if food is transferred between warehouse A and warehouse B, both of which are owned by the same company, warehouse A must retain records regarding warehouse B (as the nontransporter immediate subsequent recipient of the food) and warehouse B must retain records regarding warehouse A (as the nontransporter immediate previous source of the food). The records required to be retained by warehouse A must be accessible at warehouse A, and the records required to be retained by warehouse B must be accessible at warehouse B.

IFDA believes that, in the case of intra-corporate transfers, companies should be permitted to make all required records accessible at one location. We do not think that such "one-stop shopping" would delay a tracing investigation by FDA. Therefore, in the example above, the company should be able to choose whether to make the required records accessible at warehouse A or warehouse B.

c. A distributor should not be required to retain the name of a "responsible individual" at the immediate nontransporter previous source, the transporter that transports the food to it, the immediate nontransporter subsequent recipient, or the transporter that transports the food from it.

Under the proposed rule, a nontransporter is required to retain the name of a "responsible individual" at the immediate nontransporter previous source, the transporter that delivered the food to it, the immediate nontransporter subsequent recipient, and the transporter that received the food from it. The term "responsible individual" is not defined.

IFDA requests that the requirement to retain the name of a "responsible individual" be deleted from the final rule. Instead of requiring an individual's name, FDA should require identification of a responsible individual *or* department (*e.g.*, QA department). Individuals change frequently, especially in large companies. Requiring the name of a specific individual increases the likelihood of errors. Having the name of a department rather than an individual should serve FDA's tracing purpose. Moreover, FDA will have the name of an emergency contact person at every food facility in the country in its registration system.

d. FDA should clarify the requirement to retain "the lot or code number or other identifier of the food (to the extent this information exists)."

Under the proposed rule, a nontransporter must retain the "lot or code number or other identifier" of each article of food it receives or sends "to the extent this information exists." It is not clear what "other identifiers" FDA would consider sufficient to satisfy this requirement, and it is not clear under what circumstances such information will be deemed to "exist." IFDA believes it is essential that these questions be clarified in the final rule.

By requiring retention of a lot number "or other identifier," IFDA assumes that FDA intended to give distributors and other nontransporters considerable leeway in determining what is an appropriate identifier for a particular shipment of food. We request that the final rule confirm this interpretation. Lot numbers are difficult to work with for a variety of reasons. First, it is not clear that food contact products such as film and foil wrap, which are within the definition of "food" under the proposed rule, bear lot numbers or other identifiers. Second, because there is no industry standard for lot numbers, they vary tremendously in form, whether they are embedded in the UPC code or stand alone, and whether and where they appear on product packaging. If the lot number is not provided by the manufacturer to the distributor in documentation and is not on the outer cases of product, the distributor would need to break open cases of product to find the lot number. Third, a given shipment or pallet may contain food from multiple lots. Most distributors therefore track food by purchase order number, a far simpler and more efficient method. All foods have a purchase order and purchase order number. If a manufacturer recalls a product, it is an easy matter to translate lot numbers into a purchase order number and remove the recalled product. IFDA urges FDA to permit the purchase order number to serve as an acceptable identifier.

FDA should be aware that the food industry is moving rapidly to adopt a new technology that would make it possible to trace food throughout the chain of distribution. Radio frequency identification technology (RFID) involves tagging pallets or cartons of food with a chip containing an electronic product code (EPC) that can be read by a scanner. According to recent press reports, Wal-Mart is pushing for widespread adoption of RFID technology throughout the retail industry, and other major retailers such as CVS and Target are following its lead. Analysts are predicting the technology will be widespread in a few years. Given the fact that tracing of foods electronically is likely to be common practice in a few years' time, it does not make sense for FDA to invent an elaborate system of paper record keeping that will only be necessary for a short period of time.

e. Correspondence and complaints should be added to the list of records specifically excluded from the proposed rule.

There are indications in the legislative history of the Bioterrorism Act that Congress intended to exclude correspondence.[3] However, the proposed rule does not specifically list correspondence or complaints as excluded records. IFDA requests that the final rule make clear that correspondence and complaints are excluded from both the record keeping and records access requirements.

4. Distributors have no way of knowing whether a perishable food will be processed into a nonperishable food by other parties.

Under the proposed rule, there would be a shorter one-year retention period for records regarding perishable foods that are not intended to be processed into nonperishable foods. FDA requested comments on whether persons subject to the proposed rule always or usually know at the time a perishable food is released whether or not it is intended to be processed into nonperishable food.

IFDA's members are distributors that sell food to the hotel, restaurant, and institution (HRI) trade. Therefore, the perishable foods sold by IFDA members are prepared by their HRI customers for immediate consumption. Under these circumstances, we believe that IFDA distributors can be confident that the perishable foods they sell will not be processed into nonperishable foods. IFDA requests that the final rule confirm this interpretation.

5. FDA should allow more time to produce records in response to a request.

The proposed rule sets very short time frames within which companies are required to make records available to FDA in response to an official request. Moreover, it is not entirely clear from the proposed rule when the clock begins to run.

Given that section 306 of the Bioterrorism Act makes it a prohibited act to fail to comply with the records access regulations proposed here, imposition of a hard-and-fast four-hour timeframe is patently unreasonable. Under applicable case law, violation of the prohibited acts sections of the Food, Drug, and Cosmetic (FD&C) Act is a strict liability misdemeanor. Moreover, company executives can be held personally criminally liable for violation of the FD&C Act's prohibited acts. *See United States v. Park*, 421 U.S. 658 (1975); *United States v. Dotterweich*, 320 U.S. 277 (1943). Imposition of such criminal liability is unworkable and unfair. Currently, many distributors house their records offsite at records storage companies, many of which are not open on weekends and

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[3] "Clearly, the authority would not permit . . . access to information such as correspondence . . .. The managers intend for limitations on records access to be strictly observed." *Congressional Record* H2858 (May 22, 2002) (managers' report).

holidays. Some distributors move records to offsite storage every few weeks. While these records can be retrieved quickly in an emergency, a 4-hour deadline during normal business hours (or an 8-hour deadline outside of normal business hours) is not feasible. IFDA wholeheartedly agrees that FDA must have quick access to records in the event of an emergency. Imposition of criminal liability for violation of a given timeframe, however, is inappropriate. We strongly urge FDA to provide that companies must provide records access in a reasonable period of time. As the courts have been able to determine what constitutes reasonable times and places for inspection under FD&C Act section 704, so too can reasonable records access be required without unfairly imposing criminal liability. If FDA nevertheless determines that a maximum time frame is necessary, we request that the final rule give companies, both transporters and nontransporters, 24 hours to make records available to FDA in response to an official request. The final rule also should clarify that the time frame for production of records begins to run from receipt of a written notice from FDA.

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IFDA thanks FDA for this opportunity to comment on the proposed rule.

Sincerely,

David French

David French
Senior Vice President, Government Relations