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September 2, 2005

Division of Dockets Management
Food and Drug Administration
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Re: Docket No. 2005P-0278

The International Foodservice Distributors Association (IFDA) appreciates the opportunity to submit these comments in support of a citizen's petition submitted by the National Institute of Oilseed Products (NIOP) requesting that food samples for quality assurance, research, or analysis purposes be exempt from the Food and Drug Administration (FDA) regulations on establishment, maintenance, and availability of records (21 C.F.R. part 1, subpart J).

IFDA is a Washington, D.C. based trade organization representing foodservice distributors throughout the U.S., Canada, and internationally. IFDA's 130+ members include broadline, systems, and specialty foodservice distributors that supply food and related products to restaurants, institutions, and other food away from home foodservice operations. IFDA members operate more than 550 facilities, and sell more than \$75 billion in food and related products to the fastest growing sector in the food industry.

IFDA requests that FDA exempt all food samples that are for quality assurance, research, or analysis purposes and not for commercial sale or distribution from the recordkeeping provisions of 21 C.F.R. part 1, subpart J. This exemption may be made in an informal policy document and does not require amendment of existing regulations.

1. Current FDA Policy

FDA's regulation requiring establishment, maintenance, and availability of records does not distinguish between food samples and other foods. However, FDA has announced that a sample of food for quality assurance, research, and analysis purposes only is exempt from the requirement to retain records identifying the immediate previous sources and immediate subsequent recipients of such food, provided the sample is not consumed by humans or animals. In determining whether a food sample qualifies for this exemption, FDA will consider the sample's size, whether it is used up by the analysis or destroyed after analysis, and whether the shipping documents indicate that the sample is for quality assurance, research, and/or analysis only. This exemption is set forth in the preamble to the final rule. 69 Fed. Reg. 71562, 71574 (Dec. 9, 2004). Because this exemption is a matter of agency policy, FDA may expand the scope of the exemption in a policy document.

As explained by FDA, this exemption does not apply to samples that are consumed by humans or animals. If a sample is consumed by humans or animals, it is not exempt and the nontransporter source, transporter, and nontransporter recipient of the sample all must establish and maintain records with respect to the sample. However, a sample that is used for sensory examination (e.g., organoleptic examination for tea quality or detection of histamines) is exempt from recordkeeping.

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2. Requiring records of samples that are consumed only by company employees imposes a substantial new burden on many segments of the food industry to achieve a minimal public health benefit.

Large companies routinely receive many food samples everyday. These samples may be received at corporate offices, processing plants, warehouses, and other facilities. For example, it is not unusual for a distribution center to receive 150 to 200 food samples a week. Some of these samples are for laboratory (e.g., nutritional, chemical, toxicological) analysis only, but many are tasted and/or consumed by company employees.

Food distributors and restaurants, in particular, may regularly receive a large number of unsolicited samples from potential suppliers that want the distributor or restaurant to carry their products. Many of these samples may come from persons with whom the distributor or restaurant has no existing commercial relationship. Samples may be shipped via the U.S. postal service, private courier services (e.g., FedEx, UPS), or local messenger services, or they may be personally delivered by a manufacturer or broker. Consequently, they may arrive with little or no documentation. At present, we believe most companies retain few, if any, records about such samples.

Whatever documentation does accompany food samples typically does not contain the detailed information required by FDA's regulation. For example, a sample that is shipped by a private courier service such as FedEx arrives with an airway bill that contains the following information: the name, address, and telephone number of the sender (which may or may not be the nontransporter immediate previous source of the food sample); the name, address, and telephone number of the transporter (e.g., FedEx); and the date of shipment. (See copy of FedEx USA Airbill attached to this petition). The same is true of UPS Shipping documents. Neither necessarily contains the following required information: a description of the food (including the brand name and specific variety); the quantity of food; information on how the food is packaged; or the food's lot number or other identifier. Shipping documents, if any, that accompany samples arriving by mail, local messenger service, or personal delivery by a manufacturer or broker are likely to have even less information. In the case of unsolicited samples, the firm receiving the sample may have no existing commercial relationship with the source of the sample, and therefore cannot request that the source modify the shipping documents to add the required information.

Under FDA's current policy, the source that sends a food sample, the transporter that delivers the food sample, and the recipient of the food sample will each be required to maintain records with respect to that food sample.¹ Each of these companies (i.e., source, transporter, and recipient) will need to create an entirely new category of record and new

¹ The exemption that FDA has announced for food samples for quality assurance, research, or analysis purposes that are not consumed will likely be of little value to most companies. The source and transporter of the sample typically have no way of knowing whether the recipient will consume the sample. Even the recipient of the sample may not know whether the sample will be consumed, because in large companies the mail room may not know whether the individual buyer for whom the sample is intended plans to consume it. Therefore, most companies will need to assume that all samples will be consumed and maintain the required records for all samples.

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procedures to capture and maintain this information. For large companies, new recordkeeping procedures would have to be instituted throughout the entire organization. We question whether the burden of creating and maintaining these records is justified by the marginal public health benefit that would be realized by such records.

3. As applied to samples, the costs of recordkeeping outweigh the benefits.

FDA's regulatory impact analysis did not adequately address the issue of samples. It did not consider the option of excluding food samples. In fact, there appears to be no discussion whatsoever of samples in FDA's analysis. In addition, many of the assumptions that FDA made in estimating the costs and benefits of the rule are not valid when applied to samples. In estimating costs, FDA assumed that "one set of records can serve as source, transportation, and recipient records" so that the burden will be shared among more than one facility. 68 Fed. Reg. 25188, 25207 (May 9, 2003). FDA also assumed that "all required information provided for in the regulation represented only small deviations from current business practice." 69 Fed. Reg. 71562, 71634 (Dec. 9, 2004).²

FDA apparently assumed that compliance would only entail modification of standard shipping documents. However, as noted above, samples typically are transported by a variety of means and may not be accompanied by any standard shipping documentation. If the source and recipient of the sample do not have an existing commercial relationship (as is often the case with unsolicited samples), there is no way for them to coordinate to ensure that the shipping documents contain all required information. Moreover, the modification of standard shipping documents the agency envisions would have to be carried out by entities such as FedEx and UPS (and other smaller, less sophisticated services) that are not otherwise regulated by FDA at all.

Similarly, FDA's model for estimating the food safety benefits of the rule does not work well when applied to samples. In its regulatory impact analysis, FDA estimated that the rule would avert approximately 1,204 illnesses a year for an estimated annual benefit of \$7 million to \$25 million. The benefit estimated by FDA comes primarily from accelerating the tracing investigation that would be done in the event of a foodborne illness outbreak associated with an article of food, and thereby reducing the duration and scope of the outbreak. None of the outbreaks cited in FDA's regulatory impact analysis, however, involved samples.

Thus, the costs of recordkeeping are probably higher with respect to samples, and the benefits lower, than FDA's analysis suggested. Nor would samples make a tempting target for bioterrorists, since samples generally reach few people and a bioterrorist would have no guarantee that the contaminated sample would be consumed.

4. Sample recipients stand in the same position as other persons exempt from recordkeeping.

² See also 69 Fed. Reg. at 71639 (".... we assumed that persons subject to this final rule may be required to add a limited amount of new information to existing transaction records, such as bills of lading, commercial invoices, and other shipping documents.")

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A policy that would exempt sample recipients from recordkeeping should be established for the same reasons that other persons are exempt from recordkeeping. Under the current regulation, restaurants are exempt from recordkeeping, and retailers are exempt from retaining records of recipients of food (*i.e.*, consumers). The restaurant exemption itself is statutory. *See* § 306, Pub. L. 107-188, *adding* § 414 to the Food, Drug, and Cosmetic Act, *codified at* 21 U.S.C. § 350c. In addition to the statutory exemption, however, FDA also provided reasoning that restaurants, as entities that distribute food directly to consumers, would be unduly burdened by recordkeeping and that this burden was “not necessary to help address credible threats of serious adverse health consequences or death to humans or animals. If a traceback or trace forward is necessary, FDA can learn from sickened consumers the sources of the food they purchased, or notify consumers generally about food that presents a threat.” 69 Fed. Reg. at 71,575.

The same reasoning applies to recipients of food samples. The recipient of a product sample stands in precisely the same posture as a restaurant. The recipient provides the sample to the ultimate consumer, in this case the recipient’s employees. In the event of a traceback or trace forward, FDA can obtain the identity of the source of the sample from the recipient employee that was made ill by it. If the sample was taken from a food in commercial distribution, FDA can notify consumers generally about the food. The agency has acknowledged that in certain limited circumstances such as these, the burden of recordkeeping may outweigh any potential benefit.

For all of these reasons, IFDA requests that FDA revise its current policy to provide that food samples intended for quality assurance, research, or analysis purposes and not intended for sale or distribution are exempt from the recordkeeping requirements at 21 C.F.R. part 1, subpart J.

IFDA appreciates FDA’s consideration of these comments.

Respectfully submitted,



David French
Senior Vice President – Government Relations