IFC

International Food Coalition

Working to Make It Better

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July 8, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852
ATTN: Dockets Nos. 02N-0277 and 02N-0275

Proposed Recordkeeping and Administrative Detention Regulations

Dear Sirs:

The International Food Coalition (IFC) is a coalition of businesses involved in the international food industry, including Customs brokers, food importers of a wide variety of food products, food transporters and domestic food purchasers dependent upon foreign food products to meet customer demands. Because the reputations and commercial viability of IFC members is dependent upon the safety and integrity of imported food products, the Coalition appreciates the need to maintain detailed records identifying all food handlers and understands the potential benefits of an immediate detention method, as is contemplated with the administrative detention procedures. Nevertheless, the specific regulations proposed by the FDA on May 9, 2003, seek to impose uncertain standards, and in some respects, impossible requirements on an industry already experiencing the harsh economic effects of foreign competition and loss of consumer goodwill.

The following comments are, therefore, offered in an attempt to provide the FDA with the perspectives of international food traders --- small and large businesses alike ---who continue to be perplexed by the purported necessity of agency regulations that expand the scope of congressional authority without apparent concern for the resulting domestic economic injury and without a rational relationship to the objective of achieving food safety.

Recordkeeping Requirements

The BioTerrorism Act requires that records be maintained by all food importers, processors, transporters, manufacturers, processors, packers, distributors, receivers or holders "which records are needed by the Secretary for inspection to allow the Secretary to identify the immediate previous sources and the immediate subsequent recipients of food..." The FDA, however, has proposed recordkeeping that requires food *non-transporters* to maintain two

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separate sets of records - one for previous/subsequent food transporters and another for previous/subsequent food non-transporters --- and food *transporters* to maintain records consisting of information presently not provided to food carriers and unlikely to be provided to them in the future. The sole result of such onerous recordkeeping burdens is, like the proposals published earlier this year by the FDA, the elimination of many legitimate and safe food distribution businesses and serious reduction in global food trade.

The records required of food non-transporters must include information beyond that necessary to identify the immediate previous sources and the immediate subsequent recipients of food, including information to identify potentially unidentified lot numbers or other product identifiers, even on food products that may bear no visible manufacturer identification symbols. Food manufacturers may, in fact, place 1 or 10 or 20 or 100 different symbols or markings on a food product's packaging, some of which may not even be visible on cartons, pallets, invoices, etc. If manufacturers do not clearly identify which of their many markings is the "lot number" or the "product identification code" then any person required to identify that data in its records may necessarily fail to comply with the proposed regulations. Such noncompliance will not be the result of intentional or negligent oversight, but, rather, will solely be the result of the FDA providing the food manufacturers with the ability to control product distribution and pricing by permitting – or facilitating - selective dissemination of lot number information.

But perhaps the most onerous of the published recordkeeping requirements are those proposed for food transporters --- who oftentimes have no relationship with the original food manufacturer and who are not made privy to the detailed product or commercial information of interest to the FDA regarding the products being transported, the party from whom the product was received or the party to whom the product will be delivered. Without regard to the Act's clear mandate that food transporters --- and other similar food handlers --- only be required to maintain records sufficient to *identify* immediate previous sources and immediate subsequent recipients, the FDA more extensively suggests that in order to comply with federal regulations and conduct business in the United States related to the transport of food articles, food transporters should be required to learn, verify and maintain records documenting the following details concerning each particular food item being carried among hundreds of pallets in the back of a truck, for example:

- Name, address and phone number of the person who had the food immediately before and immediately after (the transporter's immediate previous source and subsequent recipient);
- Date received product from immediate previous source and immediate subsequent recipient;
- The type of food transported, by brand name and specific variety;
- The lot number or other identifier of the food to the extent it exists (versus is available)

- The quantity and how the food is packaged;
- Identification of each and every mode of transportation used (e.g. company truck, private carrier, ail, air, etc.) from the time Transporter first received the food until the time he/she delivered it;
- Transportation companies that use several modes of transportation within their company must record when the food was put on which kind of vehicle and who was responsible for it during that leg of the trip.

Cargo transportation companies maintain records such as bills of lading and similar documentation which may, very well, identify the product to be transported, the number of loads or boxes to be loaded, the place of pick up and delivery and the date of receipt and drop off. However, details as to specific varieties of food cargo, specific food packaging and brand names are irrelevant and unimportant both for the food transporter to conduct its business and for the FDA to identify that transporter's immediately previous and subsequent customer. In fact, should the FDA insists on creating this type of disclosure in business operations (i.e., requiring a food manufacturers to relay to its unrelated carriers the specific brand names and lot numbers of products the transporter is delivering) many large cargo carriers will suffer severe business reductions as food manufacturers and packers will necessarily only divulge such sensitive information to contracted employees. Moreover, even if food transporters could obtain the required information to comply with the proposed recordkeeping requirements, the sheer volume of the data will require many small businesses and carriers to either invest in larger information databases or storage facilities, increasing the cost of doing business over and above the extraordinary additional costs the first two proposed regulations (Prior Notice and Facility Registration) already threaten to impose.

There is no basis to require food transporters to maintain this volume or detail of information records related to food cargo. To impose such requirements would be to strike one more nail in the coffin of the global food industry. The larger carriers may refuse to enter into the types of contractual arrangements with the supply chain participants necessary to gain access to the information required to ensure compliance; the smaller carriers may simply be unable to bear yet another increased cost for doing business in these commodities.

Administrative Detention

IFC members understand that the FDA already has the ability to administratively detain any food article it believes is harmful to human or animal health. . Nevertheless it is striking that the proposed regulations published by the FDA on May 9, 2003 setting forth expedited appeal and seizure processes do absolutely nothing to cement or confirm the standard for such a detention. It is even more disturbing that the proposed regulations appear not to take into

account the devastating effect such detentions would have on any business within the relevant supply chain and on potential, future customers of such a supply chain participant.

The proposed regulations indicate that when the FDA has "credible evidence" that a food article poses a threat to human or animal health, it may administratively detain that article. But the regulations do not indicate the standard of "credible evidence". Will it be sufficient for a reputable trader to orally advise an FDA inspector that a competitor's product may cause such harm? Will any proof be required prior to the detention being issued? Further, if such proof is related to the records maintenance regulations summarily discussed above, then will the FDA be required to review records of the accused importer or transporter or manufacturer ALWAYS prior to issuing a detention order? How will this possibility expedite issuance of a detention order on food which is potentially hazardous to human health? Without such clear standards and practices made clear to food traders by federal regulation and mandate, further business operations remain vulnerable to some unknown threat of unsavory competitor activities, unfounded detention and limited rights of appeal.

Perhaps the most frustrating of the proposed rulemaking is the timeline set forth for appeal and seizure of perishable goods. Under the scenario envisioned by the FDA, the owner of a perishable item placed on administrative detention must file an intent to appeal within two calendar days. The FDA must initiate a seizure action within four calendar days of detention, unless such a day falls on a day on which a Court is not in session (in which case the action must be initiated on the last working calendar day before the fourth calendar day after detention). In addition, any detention order is terminated upon the commencement of a seizure action. Accordingly, for example, let's follow the progression of fresh fruit that was detained on Wednesday. As set forth in the proposed rulemaking, the owner is required to file its notice of appeal by Friday. However, the FDA is also obligated to file its seizure action with the Department of Justice on that same day --- Friday, because the actual 4th calendar day after detention is Sunday, when the Court is not in session. Because the detention order automatically terminates when the seizure action is initiated, in truth, the owner of the articles would be robbed of any right to appeal that action --- if it was based on some unproven, unsubstantiated "credible evidence."

Equally frustrating is the ability of the FDA, at is option, to conspicuously label a detained article in a manner identifying it as being so detained and ordering it not to be moved, handled, etc. Because the potential circumstances of where such a detention may occur are limitless, it is certainly possible that a customer could venture into a retail market and see shelves of product conspicuously labeled as potentially hazardous to human health. Substantial harm will be suffered by any business from the visceral reaction of its customers to the sight and news of the marked goods on the store shelves; many customers (and their friends, relatives, etc.) are unlikely to ever purchase any products from that retailer again. This is certain even if the basis

for such detention was unfounded because it was based on some undefined standard of "credible evidence." Amazingly, the proposed regulations go so far as to suggest that no harm could be foreseen as a result of the labeling option.

The foregoing clearly illustrates how the FDA's proposed regulations wield the threat of administrative detention as a weapon to overregulate an industry that is already at peril as a result of the Agency's proposed implementation of the BioTerrorism Act. Without standards of "credible evidence" provided in the federal rulemaking, reputation and goodwill stand to be severely threatened; without more thoughtful timelines for permissible appeals (especially in connection with perishable food items), due process rights and free trade policies are denied, disrupted or destroyed.

CONCLUSIONS

The International Food Coalition remains committed to ensuring the safety of all food items entering the U.S. marketplace and its members are dedicated to maintaining business practices to ensure compliance with federal rulemaking and policy. However, it is imperative that the FDA re-examine its proposed rules to better protect existing businesses and to more effectively enable legitimate and safe trade to flourish. Coupled with the onerous proposed regulations for facility registration and Prior Notice, businesses dependent upon a competitive marketplace founded on a belief in the free flow of goods between countries are understandably distressed and frustrated. It is sincerely hoped that the FDA will reach out to IFC members and others involved in international trade to better reflect the needs of these necessary businesses that are so critical to a productive national marketplace.

If, upon your review of the foregoing comments, you have any questions or wish to schedule a meeting with the IFC members to address their concerns, it is requested that Lauren Perez or the undersigned be contacted immediately.

Respectfully submitted,
The International Food Coalition

By: _____
Gilbert Lee Sandler
General Counsel

GLS/kmb

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PROPOSED RECORDKEEPING AND ADMINISTRATIVE DETENTION REGULATIONS
DOCKETS NOS. 02N-0277 AMD 02N-0275

Attached, please find comments to the above referenced dockets. These have also been submitted to the FDAdockets@oc.fda.gov email address, but we wanted to be certain they were received today as we are unable to attach the document via the internet docketing system. Two hardcopies are being sent via Fedex tonight as well.

Thank you for your attention.