FOOD MARKETING INSTITUTE

655 15TH STREET, N.W., SEVENTH FLOOR
WASHINGTON, D.C. 20005-5701
TELEPHONE: 202/452-8444
FAX: 202/429-4519
E-MAIL: FMI@FMI.ORG
WEBSITE: WWW.FMI.ORG

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Via Messenger

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

Re: FDA Food Security Guidance Documents; Docket No. 01D-0583

Dear Sir or Madam,

The Food Marketing Institute[1] (FMI) is pleased to respond to the Food and Drug Administration's (FDA's) request for comments regarding the two industry guidance documents that the Agency recently released on food security: "Food Producers, Processors, Transporters, and Retailers: Food Security Preventive Measures Guidance" (Food Producers, et al. Guidance) and "Importers and Filers: Food Security Preventive Measures Guidance" (collectively referred to as FDA's Food Security Guidance Documents). 67 Fed. Reg. 1224 (Jan. 9, 2002).

As discussed more fully below, FMI commends FDA for issuing flexible guidance to the food industry on the important and timely subject of food security. FDA must continue to recognize, however, that the measures identified by the Agency in the guidance are not appropriate for every segment of the food industry or even for every company within a given segment of the food industry and that the guidance should not be used as a basis for regulation, inspection or enforcement action by any federal, state or local governmental entities. Moreover, FDA should continue to work with the food industry and the governmental bodies that regulate food to ensure the development and execution of a seamless food security infrastructure.

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[1] FMI conducts programs in research, education, industry relations and public affairs on behalf of its 2,300 member companies — food retailers and wholesalers — in the United States and around the world. FMI's U.S. members operate approximately 26,000 retail food stores with a combined annual sales volume of $340 billion — three-quarters of all food retail store sales in the United States. FMI's retail membership is composed of large multi-store chains, regional firms and independent supermarkets. Its international membership includes 200 companies from 60 countries.

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FMI and FMI's members are committed to strengthening the food security infrastructure. On February 15, 2002, FMI signed an agreement with the National Infrastructure Protection Center (NIPC), based at the Federal Bureau of Investigations (FBI), to establish the Food Industry Information Sharing and Analysis Center (Food Industry ISAC). The Food Industry ISAC is intended to provide a system through which the food industry can notify the federal government of events that arise from malicious or unknown causes that may impact the food supply infrastructure. NIPC will analyze the incident reports and determine whether to distribute a warning notice to the industry. NIPC includes representatives from a variety of government agencies. All segments of the food industry have been invited to participate in the Food Industry ISAC.

A. FDA Food Security Guidance Documents

FDA's Food Security Guidance Documents are intended to aid operators of food establishments and food importing establishments by identifying preventive measures that the food industry can employ to minimize the risk that food under the operators' control will be subject to tampering or criminal or terrorist actions. 67 Fed. Reg. at 1224. Toward this end, the guidance for food establishment operators, including retailers, is divided into sections that relate to individual elements of a food establishment's operation, including:

1. Management of food security;
2. Physical security;
3. Employees;
4. Computer systems;
5. Raw materials and packaging;
6. Operations; and
7. Finished products

The document also includes advice on establishing security strategies and evaluating existing programs. See, Food Producers, et al. Guidance at 1.

FDA encourages those within the food industry to review their current procedures and controls in light of the potential for tampering or criminal or terrorist actions and to make appropriate improvements. 67 Fed. Reg. at 1224. However, the documents specifically recognize that not all of the guidance contained therein is appropriate or practical for every food establishment. Rather, FDA recommends that individual operators review the guidance that relates to components of their operations and assess which preventive measures are suitable. Food Security Guidance Documents at 1.

B. FMI Supports Flexible FDA Food Security Guidance Documents as Tools To Assist Industry in Evaluating Industry Security Programs, but Not as Regulatory Mechanism

FMI supports FDA's Food Security Guidance Documents, provided that the Agency continues to recognize the proper scope and function of the documents. We appreciate FDA's efforts in preparing a list of measures that may be employed by the food industry to better secure their facilities and that such a list may be useful to operators who may compare their current security measures against those identified by FDA. However, the documents must continue to be considered in this context: that is, as a collection of security measures that individual food establishment operators may wish to consider adding to their own food security programs, if appropriate. FDA must not use the documents as a basis for regulation, facility inspection, or enforcement actions against food industry operators, and should likewise ensure that the State and local regulatory bodies are aware that the guidelines are intended to be used only as guidance for industry.

With respect to the purpose of the Food Security Guidance Documents, the documents are clear: they repeatedly state that they are intended for use by food establishment operators in evaluating their programs. For example, FDA states both in the guidance documents and in the Federal Register notice announcing their availability that, "This guidance is *designed as an aid to operators of food establishments...*" 67 Fed. Reg. at 1224 (emphasis added); see also, Food Producers, et al. Guidance at 1. FDA advises that, "*Operators* should review the guidance in each section that relates to a component of their operation, and assess which preventive measures are suitable for their operation." Id. (emphasis added). FMI supports the stated purpose of the documents.

Moreover, FDA explicitly recognizes that, "Not all of the guidance contained in this document is appropriate or practical for every food establishment." See, e.g., Food Producers, et al. Guidance at 1. We agree: not all of the measures identified will be applicable to all sectors of the food industry or even all establishments within a given sector of the food industry. Obviously, the advice regarding surveillance of salad bars is not appropriate for a food manufacturing plant and access to retail stores and the food within the stores cannot and should not be unnecessarily restricted. Moreover, some measures just may not be necessary if the potential area of concern is addressed by other procedures already in place or by the integrity of the program as a whole.

Nonetheless, despite the documents' clear statements regarding their purpose and the extent of their utility, we are concerned that the documents may be used for regulatory purposes, an exercise that FMI would strongly oppose for the following reasons.

First, FDA has no legal authority to require food facilities to implement food security measures. Some FDA guidance documents express the Agency's interpretation of a particular statutory or regulatory requirement, in which case, enforcement action

against a facility for failing to meet the legal requirements may be appropriate, regardless of whether the facility has followed the advice given in the guidance document. See 21 CFR § 10.115; see also 65 Fed. Reg. 56468, 56471 (Sept.19, 2000) (preamble to good guidance regulations). In this case, however, FDA has no legal mandate nor does it have any legal authority to regulate food security in food establishments. Therefore, the Food Security Guidance should *not* be used by food regulatory officials during inspections or audits of facilities that handle food. Moreover, FDA may not cite failure to follow a guidance document in any observation on Form FDA 483 (List of Inspectional Observations). 65 Fed. Reg. at 56471.

Second, not only does the Agency lack the legal authority to compel food establishments to change their security procedures, the food *safety* inspectors who conduct regular audits and inspections of facilities that handle food are not trained to evaluate the food *security* measures in place at a food establishment. In the absence of proper qualification, the tendency may be for inspectors to view the guidance documents as a checklist of sorts where the inspectors look to see whether each and every measure identified in the document is applied in the facility.

As discussed above, FDA specifically recognizes that the guidance contained in these documents may not be appropriate or practical for every food establishment. However, a food safety inspector will not have the proper training to evaluate whether a measure identified in the guidance document but not implemented in the food establishment is "appropriate or practical" for the facility. Nor will the food safety inspector have adequate knowledge to evaluate the overall effectiveness of the facility's food security system, regardless of whether the operator has chosen to implement all measures identified in the guidance. *Such security evaluations are not within the scope of food safety inspectors' expertise, nor should they be; food safety inspectors should maintain their focus on food safety.*

C. Comments on Specific Food Security Measures

As discussed more fully above, we fully support FDA's statement that not all of the measures identified in the guidance will be appropriate for all sectors of the food industry. Accordingly, we will not comment on those measures that are inappropriate for retailers, as retailers should properly disregard them; however, we would like to call the Agency's attention to concerns that we have regarding some of the specific measures that might be appropriate for some food retailers to use. This section also discusses FDA's request for comments on tamper-evident packaging and records appropriate for traceback/traceforward purposes.

1. Food security audits of suppliers

FDA suggests that food establishment operators consider auditing their suppliers and public warehouses for food security programs. See Food Producers, et al. Guidance to Industry at 6, 7. FDA's suggestion places an unreasonable burden on retailers. In many cases, retailers do not have the resources or the expertise to audit their suppliers' food security programs, even if they are capable of designing food security programs for their immediate facilities. The burden for establishing a sound food security program rests with each operator; FDA should not suggest otherwise. Accordingly, we recommend that FDA delete these two references from the Food Security Guidance Documents.

2. Labeling and packaging authentication

FDA's Food Security Guidance Documents suggest that food establishment operators consider "authenticating labeling and packaging configuration in advance of receipt of shipment" of incoming supplies. Food Producers, et al. Guidance at 6. We understand FDA to be recommending that facilities that receive food supplies obtain from their suppliers labeling and packaging information in advance so that the recipient can check the supplies received to ensure that the labeling and packaging conforms with the information provided by the bona fide supplier.

Although this measure may be appropriate for a food manufacturer that receives a limited number and type of supplies, food retailers typically receive 40,000 to 60,000 different types of products. Expecting retailers to obtain labeling and packaging information for tens of thousands of products and then to authenticate each of those products is unrealistic. Accordingly, we recommend that FDA amend the identified measure by adding "if practicable" to the end of the phrase.

3. Locked and sealed vehicles

FDA suggests requesting "locked and sealed vehicles" for supplies that are delivered to the food establishment. Food Producers, et al. Guidance at 6. Presumably the purpose of this suggestion is to minimize the possibility that food-related cargo will be tampered with when, for example, the cargo is transported over substantial distances and may be unattended by the driver for portions of the transportation period.

Some of our members have expressed concern about this provision because it is not feasible to perform in the food retail context. For example, many of our members operate their own distribution centers where food is received and then distributed by their own trucks to individual retail locations, often within a few miles of the distribution center. The trucks distributing product from the distribution centers to the retail stores usually stop and deliver items at multiple stores. Locking and sealing the vehicle between each store would be prohibitively complicated and would provide minimal, if

any, security benefit because the vehicles are under the constant control of the food establishment operator and are usually used to transport food over short distances where the driver rarely leaves the vehicle unattended.

Additionally, some products, such as breads and soft drinks, are often delivered to stores via "direct store delivery," where the vendor brings the products directly to the store and often stocks them on the shelves. With direct store delivery, one truck may bring products to ten different stores in a day. To lock and seal the truck between each retail store would be extremely time-consuming and would not provide any meaningful food security benefits. Accordingly, we recommend that FDA change the recommendation in the guidance to reflect its applicability to long-haul transportation of finished food products and by adding "if feasible."

4. Testing water for potability

FDA recommends that food establishments regularly test the potability of their water. Food Producers, et al. Guidance at 7. Many food retailers rely on municipal water sources and should not be asked to bear the responsibility for its potability. The Food Code sets forth standards for water from nonpublic water systems. See Food Code, Part 5-1 (1999). Accordingly, we recommend that FDA delete the suggestion that food establishments should be responsible for the potability of the municipal water supplied to their facilities.

5. Identifying customer contacts

As one of the recall strategies, FDA suggests that food establishment operators identify their customer contacts, addresses and phone numbers. Food Producers, et al. Guidance at 8. Retailers should not be asked to provide information on the consumers who shop in their stores, although it may be helpful for retailers to maintain supplier information. Accordingly, we recommend that FDA amend this provision to provide as follows: "identifying customer *or supplier* contacts, address and phone numbers *as appropriate*."

6. Investigating missing stock

FDA recommends that food establishments consider investigating missing stock. Food Producers, et al. Guidance at 6. We agree that such investigation may be a worthwhile food security measure for a variety of reasons. In the retail context, missing stock may be the result of organized retail theft (ORT), which involves theft rings that move quickly from community to community and across state lines to pilfer large amounts of merchandise that is then repackaged and sold back into the marketplace.

ORT has implications for bioterrorism and terrorist activities generally for two reasons. First, it is our understanding that the profits from ORT rings have been used to support terrorist activity. Second, and more directly relevant to bioterrorism, the goods

stolen may be tampered with before they are returned to the marketplace through fencing operations, flea markets, or swap meets.

FMI is a member of the Coalition Against Retail Theft, which has developed draft legislation to make ORT crimes federal offenses. In brief, the coalition's draft bill would amend Title 18 of the United States Criminal Code, establishing monetary thresholds for goods stolen from a retail establishment that would allow for prosecution under federal law. We urge FDA to support the Coalition's efforts.

7. Visitors

FDA sets forth several measures that food establishment operators may take with respect to visitors to the physical facility. Food Producers, et al. Guidance at 2. Although consumers must be able to enter retail stores without inspection or restriction, retailers (and some other food establishment operators) might consider reserving the right to check vendor briefcases when the vendor enters and leaves the store. We recommend that the Agency add this measure to the Food Security Guidance Documents.

8. Background checks on employees

FDA recommends that food establishment operators screen employees prior to hiring them and specifically refers to checking their immigration status with the Immigration and Naturalization Service (INS) and performing criminal background checks through the FBI's Watchlist. See, e.g., Food Producers, et al. Guidance at 4. Although we recognize the value of conducting pre-hiring employee screening, neither of these governmental services is apparently available to the public. FDA should remove these recommendations from the guidance documents.

9. Tamper-evident packaging

The notice announcing the availability of FDA's Food Security Guidance Documents specifically asks for comments from the public on the issue of tamper-evident packaging. 67 Fed. Reg. at 1224. In particular, FDA asks for information on the (1) utility of various methods of tamper-evident packaging in minimizing risk and (2) the practicality of applying tamper-evident packaging to the broad spectrum of foods in commerce. Id.

Tamper-evident packaging should be employed where its use can be accomplished reasonably and effectively. That is, if tamper-evident packaging can reasonably be applied to a product in such a way that the consumer can readily identify if a product has been tampered with, manufacturers should consider using such packaging. However, if tamper-evident packaging would involve excessive cost or difficulty (e.g., wrapping apples individually) or would affect the quality or safety of the product (e.g., crusty french bread or leafy green vegetables enclosed in air-tight packaging), its use would be unreasonable. To the extent possible, the evidence of tampering provided by

the packaging should be as immediately identifiable as possible to facilitate recognition of damaged products by both consumers and retailers, who generally monitor the products on their shelves before consumers purchase them.

10. Records for traceback/forward of products

FDA's Federal Register notice also seeks comments on the use of procedures and/or records that enable shipments of food from a food establishment to be traced to shipments of food received by the food establishment, such as the procedures and records that are practical and effective in facilitating trace-back of incoming shipments, trace-forward of outgoing shipments, and linkages between the two. 67 Fed. Reg. at 1224.

As the Agency knows, the food industry generally keeps records now regarding incoming and outgoing products for commercial reasons. These records are also used by industry and sometimes regulators when products are recalled or withdrawn for food safety or labeling reasons. In general, the current recordkeeping system is effective and the records kept by industry have been helpful in facilitating numerous recalls.

If FDA is considering issuing guidance to industry on recordkeeping, we recommend that the Agency undertake this endeavor as a discrete project, rather than as an adjunct to the Food Security Guidance Documents. The issues associated with recordkeeping are complex and it will be necessary to ensure that the entire food production and distribution continuum is involved and focused on the issue for a comprehensive system to be represented in guidance. Future technology such as new bar codes, scanners, and measures of identifying products should also be considered.

D. All Government Entities Must Work Together and with Industry To Ensure Clear, Consistent National Food Security Program

Finally, we strongly urge FDA to work with the other federal agencies that regulate food, such as the U.S. Department of Agriculture (USDA) and the U.S. Customs Service, as well as the state food regulating entities and all segments of the food industry in continuing to develop a clear, consistent national food security program. Apparently the FDA Food Security Guidance Documents were developed without input from USDA or other agencies within the Department of Health and Human Services (HHS), nor did FDA consult with the INS or FBI on the employee background checking services actually available to the public. Working with the other agencies collaboratively would have produced stronger and more consistent guidance.

As the process continues to move forward, we recommend that FDA work actively with the other relevant government agencies. For example, notices in the press suggest that USDA is working on a guidance document for the meat industry. FDA and USDA should work together to ensure that the resulting guidance documents for the food industry are consistent. It is imperative that the government harmonize their

recommendations to produce a single, clear message; failure to harmonize fully will produce a food security infrastructure that is vulnerable to the very forces against which it seeks to protect the food supply.

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We appreciate the opportunity to provide FDA with our comments on the Agency's Food Security Guidance Documents and look forward to working with all relevant parties to continue to strengthen the security of the food industry infrastructure. Please do not hesitate to call on us if we may be of assistance in any way.

Sincerely,

Tim Hammonds
President and CEO