



April 15, 2002

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

NATIONAL  
FOOD  
PROCESSORS  
ASSOCIATION

RE: Docket No. 01D-0583 – Food Security Guidance Notice; 67 FR 1224

Dear Sir or Madam:

The National Food Processors Association (NFPA) submits the following comments concerning the Food and Drug Administration (FDA) guidance documents, “Food Producers, Processors, Transporters, and Retailers: Food Security Prevention Measures Guidance” and “Importers and Filers: Food Security Preventive Measures Guidance”. NFPA also comments on the tamper evident packaging and tracking issues raised in the January 9, 2002 notice of availability (67 FR 1224).

NFPA is the voice of the \$500 billion food processing industry on scientific and public policy issues involving food safety, nutrition, technical and regulatory matters and consumer affairs. NFPA's three scientific centers, its scientists and professional staff represent food industry interests on government and regulatory affairs and provide research, technical services, education, communications and crisis management support for the association's U.S. and international members. NFPA members produce processed and packaged fruit, vegetable, and grain products, meat, poultry, and seafood products, snacks, drinks and juices, or provide supplies and services to food manufacturers.

Scope of the Guidance

NFPA applauds FDA for timely and comprehensive guidance documents on the types of security measures that may be considered by operators of food establishments and importing establishments, storage warehouses, and filers. The FDA guidance documents join other references, including those developed by NFPA, that can greatly assist establishments to evaluate their current security measures. By identifying the various aspects of food establishment operations such as management of food security, physical facility, and employees and offering examples of security issues and measures, the guidance documents provide a useful framework for individual operations to identify and determine what might be appropriate to their particular circumstance. NFPA strongly encourages FDA to continue working with all

1350 I Street, NW  
Suite 300  
Washington, DC 20005  
202-639-5900

WASHINGTON, DC  
DUBLIN, CA  
SEATTLE, WA

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sectors of the food chain to insure appropriate and necessary steps are being taken on a voluntary basis. This should include FDA providing opinions or additional guidance regarding measures that are relevant to addressing specific aspects of producing, holding, transporting, and processing foods.

NFPA supports FDA's effort to clearly describe the documents as guidance and not actual or implied conditions that food establishments must meet. It would be counter productive for any federal, state, or local government entity to apply the guidance documents as mandatory requirements or to mandate use of the guidance or specific security measures through regulatory action. NFPA believes the introduction to the documents establishes that they are offered as aids to food establishments. Of particular importance is the statement, "It [guidance] does not create or confer any rights for or on any person and does not operate to bind FDA or the public." To help avoid misinterpretations, NFPA recommends FDA expand on the discussion presented in the January 9, 2002 notice. FDA could clarify that by "identifying the kinds of preventive measures that operators can take", the Agency recognizes that effective controls dealing with the risk of intentional threats to foods may already be in place, which are not described, and that the actual approach to assessing and managing potential risks utilized by each food establishment will be dictated by the establishment's unique circumstances.

FDA's reference to the Operational Risk Management (ORM) process also provides important direction. While dealing with possible tampering or criminal actions against food products is regrettably not new to the food industry and many of the types of measures identified in the guidance documents are in place, NFPA believes the ORM process can help establishments refine their programs and aid in appropriately focusing efforts on true priorities. FDA is encouraged to provide more detail on the use of the ORM process in order to emphasize the importance of establishments performing individual, tailored assessments as opposed to viewing the examples of security measures provided in the guidance documents as the only options possible in FDA's view.

NFPA does not believe FDA is suggesting the security measures presented in the guidance documents preclude other options, either more or less elaborate in scope. As stated in the guidance for operators of food establishments, "Not all of the guidance contained in this document is appropriate or practical for every food establishment. Operators should review the guidance in each section that relates to a component or their operation, and assess which preventive measures are suitable for their operation." To further encourage creative and appropriate approaches that ensure effective and relevant steps by individual establishments, NFPA recommends FDA augment the guidance documents, as they are refined.

#### Use of Tamper Evident Packaging

NFPA believes it is important to focus on the concept of "package integrity" rather than "tamper evidence" and recommends the use of the former term. FDA views tamper evidence in terms of a barrier and communication to the consumer that points out the barrier. However, our concern is that FDA will view packaging for food the way they do for pharmaceuticals with the result that attention would be inappropriately directed to prescriptive packaging requirements for the food

industry. Therefore, NFPA recommends FDA continue to allow manufacturers to design and package their products in a way to call consumers' attention to a breach in package integrity rather than tamper evidence.

With that said, NFPA recommends against FDA attempting to address package integrity through the current guidance documents. NFPA believes package integrity could not be adequately and meaningfully addressed in the format of the guidance. There are too many factors that must be considered including current voluntary efforts, the current and future state of packaging technology, the huge diversity of food product forms and packaging needs, and the care that must be given to ensure against the perception that the presence or absence of package integrity, in and of itself, is an essential indication of a food's safety. If FDA wishes to convey a general position on the relationship of package integrity and food security, we believe that a statement such as the following would be appropriate: "Package integrity is an approach that may, enhance food security, recognizing that it may not be the same for all products, companies, or packaging technologies, and recognizing also that its implementation for any specific product can be complex and requires careful planning. FDA supports the food industry's voluntary implementation of programs to ensure package integrity as appropriate for their products."

#### Linking Food Ingredients and Final Products

In the January 9 notice, FDA raises the issue of food establishments' ability to identify specific source(s) of ingredients with respect to specific product(s) shipped from an establishment. The ability to establish such a link involves many factors including ingredient and finished product inventory controls, production characteristics such as batch versus continuous processing, ingredient and product forms (i.e., whether products are blends of differing ingredients from multiple sources) and the state of current technologies and management information systems. While NFPA believes most food establishments apply procedures of some form that link ingredients and finished product, there are also extremely diverse levels of complexity, effort and technology throughout. Equally important with respect to meaningful guidance to the industry is the precision and extent of the information that can reasonably be achieved. While NFPA believes the ability to link ingredients and finished products can be a valuable capability for a food establishment, because legislation is currently being considered that may call on FDA to take formal action on this issue, NFPA believes that FDA should defer any action under the current guidance to industry.

NFPA appreciates the opportunity to provide these comments to FDA and extends our desire and willingness to work with the Agency on these important matters.

Regards,



Rhona Applebaum, Ph.D.  
Executive Vice President  
Scientific & Regulatory Affairs



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Washington, DC 20005

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