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NATIONAL
FOOD
PROCESSORS
ASSOCIATION

March 14, 2003

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

RE: [Docket No. 02D-0137] Regulatory Procedures Manual; Chapter 9, Imports, Subchapter: Guidance Concerning Recommending Customs' Seizure and Destruction of Imported Human and Animal Food That Has Not Been Reconditioned.

Dear Sir or Madam:

The National Food Processors Association (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, food security 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.

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NFPA submits the following comments on the guidance document (Customs Guidance) referenced above.

NFPA supports the Food and Drug Administration's (FDA) objective to prevent the distribution and/or possible export for re-importation of imported foods that are found to pose a significant risk to public health. The use of procedural guidance for FDA field staff can be useful element in the overall effort to meet this objective. While NFPA agrees there may be instances in which the severity and certainty of significant risk to public health calls for destruction of the relevant imported food, the draft guidance raises several issues that NFPA believes should be addressed in the final guidance.

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<u>The Customs Guidance does not follow existing statutory authority.</u>

The draft guidance makes no reference to methods for FDA to deal with the importation of food that may or does violate the Federal Food, Drug and Cosmetic Act (Act). Under Sections 334 and 381 of the Act FDA has operated under

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established procedural and evidentiary requirements. However, the draft guidance proposes a method for FDA to circumvent the statutory obligations and remedies established by the Act. Specifically, FDA would eliminate the importers right to re-export under Section 381, while freeing the Agency from the requirements in a Section 334 proceeding.

Similarly, the draft guidance is consistent with Customs law. Under 19 U.S.C. Section 1595a(c)(2) Customs is permitted to seize an article on health or safety grounds if the article "is not in compliance with applicable, rule, regulation, or statute". Under the Draft Guidance neither FDA nor Customs is required to satisfy this evidentiary requirement. FDA would be permitted to recommend destruction to Customs if the product "may" be adulterated and has a "reasonable probability" of harm. There is no requirement that FDA or Customs actually prove the adulteration and the harm the product poses to public health.

The economic, legal, and public relations implications associated with FDA calling for the destruction of imported product are such that districts should be required to have a level of verifiable evidence of a significant risk to public health that is consistent with existing statutory authorities before initiating the destruction recommendation process. Discussion of what evidence is necessary to justify initiation of the destruction recommendation process must be included in the Customs Guidance. Similarly, what administrative or judicial remedies are available to the importer for demonstrating a districts finding is not valid must be included in the Draft Guidance.

"Criteria" for determining when destruction is recommended should be more precisely described.

In comments of March 3, 2000 on the FDA and US Customs Service (Customs) plan to address problem importers and unsafe imported foods, NFPA called for the criteria used for determining if food poses a serious public health threat be defined and communicated in a transparent manner. We urged the agencies not to rely solely on FDA's Class I recall criteria. The current Customs Guidance, however, does not go beyond referencing the Class I recall criteria as the basis for determining if a product violation is such that destruction of product is warranted. NFPA does not believe the selected examples of Class I recall situations given provide an adequate basis for field personnel to judge when destruction of product should be recommended. NFPA believes the guidance should include a more detailed discussion of decision criteria and evidentiary requirements.

The Customs Guidance should be clear when a violation calls for the application of existing procedures as currently provided under Sections 334 and 381 of the Federal Food, Drug and Cosmetic Act and in the Regulatory Procedures Manual (Manual). Neither the November 5 Federal Register notice of the draft guidance nor the Customs Guidance itself discuss when other established statutory authority and/or procedures, such as those described in the Subchapter Import Procedures and Subchapter Notice of Refusal of Admission of the Manual, should be applied. How the draft guidance relates to existing

guidance concerning product detention, reconditioning, and re-export and current statutory authority must be made clear. As indicated in our March 3, 2000 comments to FDA, we urge the Agency to provide an appeal process when it is determined that an imported food poses a health hazard serious enough to warrant destruction.

NFPA appreciates the opportunity to comment on this important Agency guidance.

Sincerely,

Richard N. Jarman

Richard N. Jarman
Vice President Food and Environmental Policy