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July 5, 2003

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

Re: Docket No. 02N-0277

Dear Madam/Sir:

Please find enclosed the comments of the National Association for the Specialty Food Trade, Inc. in the above referenced docket (Establishment and Maintenance of Records under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002).

You may contact me with any question. Please use mechols@earthlink.net as the email address.

Thank you.

Sincerely,



Marsha A. Echols

Enclosure: 2 pages

02N-0277

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National Association for the Specialty Food Trade, Inc. (NASFT)

Comments Regarding Docket No. 02N-0277

**Establishment and Maintenance of Records under the Public Health Security and
Bioterrorism Preparedness and Response Act of 2002**

July 8, 2003

The National Association for the Specialty Food Trade, Inc. (NASFT) is pleased to submit the following comments in response to the Notice of Proposed Rulemaking in the above Docket. NASFT is the trade association for all segments of the specialty food industry, which includes small and family-owned businesses manufacturing, selling, importing and distributing high-value, processed foods and beverages. The 2,300 members of the NASFT are located throughout the United States.

Stage Implementation The proposal to stage the implementation dates – giving extra time to small businesses (§1.368) - must be maintained. The extra twelve months allowed to small businesses (more than 10, fewer than 500 employees) and the eighteen months accorded very small businesses (10 or fewer employees) will ensure that these businesses have adequate time to understand the new rules, re-organize their administrative recordkeeping and spread the costs of the new rules over a greater volume of their (limited) production. In addition, within the first year of implementation the larger companies and FDA will resolve many of the problems that will arise with the new rules. They are better able to adjust to the problems than are small businesses.

Exempt Retailers NASFT also believes strongly that the proposed retail exemption (§1.327(d)(1)) must be a complete exemption, including an exemption from recordkeeping regarding suppliers, identical to the exemption given to restaurants. Today retailers and restaurants compete in the burgeoning take-home and carry-out market. The FDA proposal gives an unfair and unnecessary advantage to restaurants, which are expanding out of in-restaurant dining into areas formerly served by retailers and carry-out establishments. A full exemption for retailers presents no lessening of food safety safeguards.

The competition between restaurants and retailers has been described by USDA's Economic Research Service, which commented, "[a]n additional challenge for established food service providers [e.g., restaurants] will be competing with other retailers who are entering the food-away-from-home market. For instance, supermarkets and convenience stores are offering more convenient meal solutions including ready-to-eat entrees." *Food market structures: food service*

NASFT Comments

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Needless to say, NASFT agrees that retailers should not be required to identify their customers or to maintain records regarding their individual sales transactions. NASFT congratulates FDA on the wisdom of this aspect of the proposed rule but repeats that this limited exemption is too narrow an approach and creates a competitive imbalance within the food industry.

Limit Scope of New Rules In general, NASFT believes that FDA has been overzealous in its proposals to implement the Bioterrorism Act. The new requirements regarding plant registration, prior notification and recordkeeping go well beyond what is needed to implement the Bioterrorism Act and to protect the nation's food supply. For example, current shipping records identify the transporter. No more and nothing new should be required. FDA only needs access to follow up on an initial incident after it occurs, then only to broadcast to the public and other companies any suspect ingredient or process.

As a consequence of the FDA proposals, a new consulting industry is being established. Persons are distributing solicitations for clients using company names like "FDARegistrar Corp." to take advantage of the alarm about the impending bioterrorism rules. The "FDARegistrar" letter gives the appearance that the letter is from the government or that the company is linked to the FDA. With or without these new consultancies, small businesses will have many added (non-productive) expenses to bear.

Conclusion NASFT urges FDA to stage the implementation of the final rule, to exempt retailers in full just as restaurants are exempted and to limit the scope of your final bioterrorism rules to the minimum necessary to implement the Bioterrorism Act.

NASFT will provide any information in support of the above comments that might be helpful to the FDA. This offer applies in particular to data about the market for take-home and carry-out meals and to competition between restaurants and retailers.