

July 7, 2003



Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852
Submitted electronically: <http://www.fda.gov/dockets/ecomments>, 7/7/03

Re: Docket No. 02N-0277 (Recordkeeping)

Dear Sir or Madam:

The Northwest Food Processors Association is privileged to comment on the Food and Drug Administration's proposed rules for implementing the records establishment and maintenance provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. The association is comprised of food processors in Idaho, Oregon and Washington, representing the \$10 billion Northwest food industry. These rules will significantly affect the business of this industry.

The purpose of this letter is to endorse the comments made by the American Frozen Food Institute (AFFI), submitted in their letter of July 8, 2003. NWFPFA has reviewed AFFI's evaluation of the impact of these rules and concurs with their comments.

In particular, NWFPFA underscores the following points:

1. The Northwest food industry takes very seriously its role as a partner in the process of protecting the food supply against terrorist attack while providing wholesome high-value products to consumers. NWFPFA supports the goal of developing effective rules with minimum disruption to the efficiency of business systems.
2. To this end, NWFPFA supports the FDA's flexibility in formatting of records. Further, NWFPFA appreciates the FDA's recognition of the difficulty some processors may have in identifying specific sources of ingredients, and supports the concept of "reasonably available" information for sourcing. In discussing these proposed rules, NWFPFA encourages companies to track product flow one back/one up as specifically as possible, believing that it makes good business sense. However, in many cases, it is not cost-effective to segregate product components to specific suppliers, as AFFI ably points out in their comments. NWFPFA underscores AFFI's recommendation that FDA work with industry to develop guidelines on the application of "reasonably available" terminology for the benefit of industry and FDA field investigators alike.

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In conclusion, NWFPA advocates the FDA approach to recordkeeping requirements which incorporates existing industry systems to the fullest extent possible, and to the open and transparent communication of FDA expectations about those requirements. Thank you for your consideration of these comments. A hard copy of this letter follows by US mail.

Sincerely,

A handwritten signature in black ink, appearing to read "David Zepponi". The signature is fluid and cursive, with a large initial "D" and "Z".

David Zepponi
President
Northwest Food Processors Association