CSPI CENTER FOR SCIENCE IN THE PUBLIC INTEREST
Publisher of **Nutrition Action Healthletter**

Nov. 17, 2000

933 '00 NOV 20 P1:18

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

Re: FDA Docket No. 00N-1351, reopened

Dear Sir or Madam,

The Center for Science in the Public Interest (CSPI) is pleased to submit this comment regarding the use of the designation "fresh" for foods processed with alternative nonthermal technologies. CSPI is a nonprofit consumer group with approximately 850,000 members/subscribers that focuses primarily on nutrition and food safety issues.

CSPI supports safe and effective new technologies to prevent and reduce food contamination. However, FDA should not allow use of "fresh" for foods that have been changed in ways that would undermine either the FDA's current regulatory definition of that word or consumers' expectations based on seven years of experience with foods regulated under that definition. "Fresh" is a quality claim that means the food "*is in its raw state and has not been subjected to any form of thermal processing or any other form of preservation*", 21 CFR §101.95(a). This definition, codified since 1993, accords with what consumers now reasonably expect. The marketplace relies on this and often provides a premium because a food item that is fresh typically offers better taste, smell, appearance, texture, and nutrition. CSPI strongly supports the protections for freshness embodied in 21 CFR § 101.95(a).

Nevertheless, CSPI recognizes the critical problem that fresh and unprocessed foods may contain pathogens, which processing may reduce or eliminate.[1] CSPI supports efforts to develop, test, and approve more effective technologies for contamination prevention and reduction. Those technologies should be applied with attention to the entire farm-to-table supply chain, with the emphasis on preventing contamination in the early stages, not just on sanitizing already-contaminated foods.

Use of these technologies can raise issues as far as fair and adequate consumer notification. CSPI believes that if detectable organoleptic or nutritional changes occur after use of the food

[1] See, *Outbreak Alert! Closing the Gaps in Our Federal Food-Safety Net,* (Washington, DC: Center for Science in the Public Interest, Aug. 2000). This report compiled information on 865 foodborne-illness outbreaks between 1990 and 2000. The vast majority of these outbreaks originated from FDA regulated foods, such as seafood, eggs, fruits, and vegetables.

00N-1351 C49

Tel: (202) 332-9110
Fax: (202) 265-4954
Home Page: www.cspinet.org
E-mail: cspi@cspinet.org

Suite 300
1875 Connecticut Avenue, N.W.
Washington, DC 20009-5728

Michael F. Jacobson, Ph.D.
Executive Director

technologies, then the food should not be labeled as "fresh". If it were so labeled, the label would be false and misleading and the premium paid for freshness would be wrongfully obtained. FDA should define best practices for determining whether such changes are, in fact, detectable and how to describe the nature of the change. For example, FDA should consider developing protocols for food processors to conduct consumer trials of foods to determine whether a change is detectable and for nutritional analysis of any changes.

CSPI does not support a new euphemistic term for foods that are "almost fresh", but have been detectably changed by the processing technology. Creating various levels or grades of freshness has the potential to confuse or mislead consumers.

In general, consumers want to know how their food is produced, including what preservation technologies have been used. Therefore, informative labeling is needed for food products when there are detectable changes. At a minimum, consumers should be informed what technology was used and the nature of the change. Failure to provide this information would mean that the food is misbranded under 21 U.S.C. § 321(n). The labeling requirement also should include adequate consumer information for unpackaged foods and foods sold in restaurants.

Respectfully submitted,

Peter T. Jenkins
Senior Food Safety Attorney