



American Bakers Association

Serving the Baking Industry Since 1897

September 11, 2002

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

Re: Docket No. 02N-0209; Request for First Amendment Issues
67 Fed. Reg. 34942 (May 16, 2002)

Dear Sir/Madam:

These comments are submitted on behalf of the members of the American Bakers Association (ABA), the national trade association representing the wholesale baking industry. ABA membership consists of bakers and bakery suppliers who together are responsible for the manufacture of approximately 80 percent of the baked goods sold in the United States. These comments provide information to FDA on first amendment issues, specifically addressing why FDA should change their regulations which currently restrict use of the term "fresh" in food labeling.

ABA welcomes the opportunity to voice the baking industry's opinion regarding first amendment questions surrounding use of the term "fresh" for baked goods. In these comments, ABA will also reiterate our objection to FDA's current policy of "fresh" labeling for baked goods and advocate amending Section 101.95 to recognize that bakery products are nearly always preserved.

First Amendment Considerations for Use of the Term "Fresh" for Baked Goods

FDA should carefully consider the First Amendment implications of restricting the use of a truthful labeling claim in the absence of evidence of consumer deception and assurance that the restriction will address the deception. ABA and its members have a well-established commitment to ensuring that food labeling is truthful, not misleading, and substantiated by sound scientific evidence. ABA has already advised FDA of its general policy of supporting FDA requirements that are carefully tailored to address demonstrable consumer deception. ABA strongly opposes restrictions based on an alleged risk of such deception and also opposes restrictions that are unduly burdensome or otherwise inappropriate to address deception.

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This careful tailoring is mandated by the First Amendment. Since FDA established the basic food labeling requirements authorized by the Nutrition Labeling and Education Act (NLEA), the Supreme Court and lower courts have repeatedly found that food labeling is subject to the same protections granted to other forms of commercial speech. As the D.C. Circuit made clear in Pearson v. Shalala, 164 F.3d 650 (D.C. Cir. 1999), FDA must assure that its food labeling policies do not unduly burden speech and are justified with reference to a defined harm that will be addressed by any speech restriction.

Further, as FDA stated in its request for comments, the Supreme Court has increasingly recognized the first amendment right to free commercial speech, given that the statements are truthful and not misleading. Why then does FDA continue to ban the use of the term fresh in labeling for baked goods?

The existing regulation bans use of the term "fresh" for the entire category of food products, baked goods, despite the truthfulness of the claim and the lack of evidence that consumers would be misled by its use in labeling for those products. There is a lack of any evidentiary basis for the FDA determination that "fresh bread" is misleading and upon the discriminatory handling of other preserved products. In the case of Ibanez versus Florida Department of Business and Professional Regulation the Supreme Court ruled that government cannot restrict commercial speech on the mere assertion that it is "potentially" misleading. The government must bear the burden of proving that the speech it objects to is actually/inherently misleading.

On February 25, 1992, ABA submitted a citizens' petition addressing this very issue and proposed a definition of "fresh" as it applied to baked goods (Docket No. 91N-0384; 56 Fed. Reg. 60421; November 27, 1991). This document provides detailed information on why the definition of "fresh" should be expanded. Those comments have been attached for your reference. Since that time, on many occasions ABA has corresponded and had discussions with FDA on this issue.

To assure that FDA's policy meets the requirements imposed by the First Amendment, FDA should immediately authorize use of the term "fresh" in the labeling of bakery products, or produce evidence that the ban is necessary to prevent consumer deception.

Use of the Term "Fresh" for Foods Processed with Alternative Non-Thermal Technologies

Additionally, ABA previously advised FDA in our comments on August 18, 2000 (Docket No. 00N-1351; 65 Fed. Reg. 41029; July 2, 2000), ABA maintains its prior position calling for redefinition of the term fresh, and we argue it would be unfair to discriminate against the use of preservatives, or other new technologies, thermal and non-thermal, since currently both fresh milk and fresh produce may be preserved by various methods under the current regulations and still be deemed "fresh". ABA has repeatedly advised FDA of our position and reiterates that the situation be remedied in one of two ways. Either the first paragraph of Section 101.95 should be amended to state that, like pasteurized milk, baked goods that are preserved with a safe and suitable preservative, may also be called "fresh" because consumers commonly understand they are nearly always preserved. A second suggested alternative is to amend Section 101.95 (c) specifically to permit "the addition of safe and suitable preservatives to baked goods."

For an industry that serves consumers fresh products on a daily basis, it seems illogical that the result of NLEA was to preclude freshly baked goods from being called "fresh". It should also be noted that it is a common industry practice to rotate products on the grocery shelf every three days to maintain freshness, before it becomes stale, as is the same practice with other fresh food items in retail facilities. This practice has served the industry well and meets the needs and demands of the consumer. Perhaps that is why Webster's Dictionary uses "fresh bread" as an example of fresh, to illustrate "recently made, produced or harvested" foods. ABA also found it noteworthy that during the agency's public hearing in Chicago, July 2000, many who offered testimony on the subject of "fresh", including an FDA representative, Christine Lewis, used "fresh bread" as an example of fresh, even though under current agency regulations, this term is disallowed on packaging.

ABA believes that since the current regulation does not specify a time period during which pasteurized milk remains fresh or which preserved raw agricultural commodities remain fresh, it only logically follows that there is no need to establish a specific time period during which bread would remain "fresh" after baking. As discussed previously, current retail practices ensure proper rotation so that the freshest products are offered to consumers. "Use by" or "sell by" dating on bakery products provides additional label information for consumers.

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ABA appreciates this opportunity to comment on FDA's request for information regarding first amendment issues, and we are hopeful that the above information will assist the agency in its review of "fresh" policy for bakery products. This issue is of great interest to the wholesale baking industry. The technical contact for these comments is Lee Sanders, ABA Vice President, Regulatory and Technical Services, American Bakers Association, 1350 I Street, N.W., Suite 1290 Washington, D.C. 20005-3305 (telephone) 202-789-0300, (fax) 202-898-1164.

Respectfully submitted,



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Attachment