



American Bakers Association

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August 18, 2000

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

Re: [Docket No. 00N-1351] Food Labeling: Use of the Term "Fresh" For
Foods Processed with Alternative Non-Thermal Technologies, 65
Fed. Reg. 41029 (July 3, 2000)

Comments of the American Bakers Association

These comments are submitted by the American Bakers Association (ABA), the national trade association representing the wholesale baking industry. The Association's membership consists of approximately 300 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 focus on FDA's regulation restricting use of the term "fresh" in food labeling. ABA welcomes the opportunity to voice our concerns regarding new questions surrounding the "fresh" issue. As we have previously advised FDA, allowing use of "fresh" claims for bakery products is consistent with the agency's current approach, which expressly permits "fresh" claims for pasteurized milk and other foods, would not mislead consumers, and is mandated by the First Amendment.

ABA has repeatedly advised FDA of our position that bread and other baked goods should be accorded the same treatment under 21 C.F.R. § 101.95 as milk and produce, because consumers do not misinterpret "fresh" when used in the labeling of bread products. ABA welcomes this opportunity to reiterate our objection to FDA's current policy of "fresh" labeling for baked goods and to advocate amending Section 101.95 to recognize that bakery products are nearly always preserved.

FDA should amend Section 101.95 to expressly permit use of "fresh" claims for foods containing preservatives or processed using other new technologies, both thermal and non-thermal. Currently both fresh milk and fresh produce may be preserved by various methods under the current regulations and still be

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promoted with "fresh" claims. FDA should extend this approach to fresh bread and bakery products.

Specifically, FDA should amend the first paragraph of Section 101.95 to state that, like pasteurized milk, baked goods that are preserved with a safe and suitable preservative may be labeled "fresh." As FDA has recognized, use of the term "fresh" is not misleading when used in the labeling of milk that has been pasteurized, because consumers understand that milk is nearly always pasteurized. Similarly, consumers commonly understand that bread and other baked products are nearly always preserved. Therefore, FDA should amend its regulations to allow use of the term "fresh" for baked goods that have been treated with preservatives. Alternatively, FDA should amend Section 101.95(c) to permit "the addition of safe and suitable preservatives to baked goods" on the same basis.

The bakery industry, from manufacturer to retailer, takes a number of steps to assure that the baked goods purchased by consumers are consistently fresh. It is a common industry practice to rotate shelved bakery products every three days to maintain freshness. The uniform use of "sell by" or "use by" dating helps assure that bakery products purchased by consumers are fresh.

These practices meet consumer expectations. Webster's Dictionary uses "fresh bread" as an example of "fresh," which is defined (in reference to food) to mean "recently made, produced or harvested." During the agency's public hearing in Chicago on July 21, 2000, several witnesses, including an FDA Representative, Christine Lewis, used bread as an example of a food product that is concededly "fresh," even though FDA's current policy prohibits the use of "fresh" in labeling of 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 opposes restrictions based on an alleged risk of such deception and also opposes restrictions that are unduly burdensome or otherwise inappropriate to address deception.

This careful tailoring is mandated by the First Amendment. Since FDA established the basic food labeling requirements authorized by the NLEA, the Supreme Court and lower courts have repeatedly found that food labeling is

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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.

The existing regulation bans use of the term "fresh" for an entire category of food products, despite the truthfulness of the claim and the lack of evidence that consumers would be misled by its use in labeling for those products. To assure that its 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.

ABA appreciates this opportunity to comment on this proposal which 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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