



American Bakers Association

Serving the Baking Industry Since 1897

February 25, 1992

Dockets Management Branch (HFA-305)
Food and Drug Administration
Room 1-23
Parklawn Building
12420 Parklawn Drive
Rockville, Maryland 20857

Re: Proposed Definition of "Fresh"
Docket No. 91N-0384
56 Fed. Reg. 60421 (November 27, 1991)

The American Bakers Association (ABA) is a national trade association of 200 companies that manufacture approximately 85 percent of the bakery products sold in retail stores throughout the United States. Because bakery products have long been regarded by the consuming public as a foremost example of "fresh" food available in the retail market, the ABA has a deep interest in the proposal by FDA to define this terminology.

Summary

The ABA supports a definition of "fresh" as found in contemporary dictionaries and as supported by current consumer usage. Regrettably, the FDA proposed definition conflicts

both with the dictionary definition and with common consumer terminology. FDA has offered no dictionary definition, no consumer survey, and no other factual basis to support its unprecedented approach. The FDA proposal would therefore reverse decades of a consistent and well-documented consumer understanding of the term "fresh bread" for no demonstrated reason. For this reason, the ABA is strongly opposed to the proposed FDA approach.

The FDA proposed definition of "fresh" would be applied inconsistently and would blatantly discriminate against the baking industry. A potato that is a year old, or even five years old, could be labeled as "fresh" -- even if it is rotten -- but a five-minute-old loaf of hot bread right out of the oven could not be labeled as "fresh" and usually could not even be labeled as freshly baked. Raw agricultural commodities could be preserved by a wide variety of methods and still be called "fresh" but bread could not. FDA offers no factual basis for these extraordinarily inconsistent and discriminatory rules.

In these comments, the ABA documents the reasons why fresh bread -- as defined in numerous dictionaries and as commonly understood by the consuming public -- should be allowed to continue to be called "fresh" as it has been for decades. The ABA believes that no regulation of this type is required or justified at all in order to prevent consumer

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confusion or product misbranding, but nonetheless offers a revised approach for the proposed regulation -- incorporating contemporary dictionary definitions -- in the event that FDA concludes that it will proceed with this rulemaking.

Finally, it must be underscored that this proposed regulation is not required by the Nutrition Labeling and Education Act of 1990. There is no statutory or other reason why it should be considered at the same time as the other regulations that are required by law to be promulgated by November 8, 1992. The ABA strongly urges that the proposed regulations relating to the definition of "fresh" be separated out from the NL&E Act regulations and deferred for further consideration. FDA should determine whether these regulations are required at all and, if they are, how the term "fresh" can be applied consistently and in a nondiscriminatory way to all food products. The regulations could then be repropoed and, after further public comment, promulgated in final form. We strongly object to the promulgation of these regulations without any factual data or information to support them and on the present abbreviated time schedule. In the interim, FDA can continue to bring regulatory action wherever the term "fresh" is flagrantly misused in a way that is false or misleading.

Comments

The ABA submits the following comments on proposed new Subpart F of Part 101 of the Code of Federal Regulations consisting of proposed Section 101.95, as published in 56 Fed. Reg. 60421, 60477 (November 27, 1991). These comments take into consideration the discussion of the proposed regulations contained in the preamble at pages 60462-60466.

I. Introduction

As the preamble acknowledges at page 60463, the Nutrition Labeling and Education Act of 1990 does not require FDA to define the term "fresh." FDA has chosen to do that on its own initiative. Thus, there is no statutory or other requirement that FDA consider this portion of the proposed regulations at the same time, or within the same statutory time limit (November 8, 1992), as the regulations required to be promulgated under the NL&E Act.

For several reasons, the ABA urges FDA to separate the proposed regulations dealing with the term "fresh" from the NL&E Act proposed regulations. This will allow FDA further time and resources to consider those regulations that are required by the NL&E Act to be promulgated by November 8, 1992. The delay will also permit time for the development of an adequate factual basis for considering an appropriate definition for the term "fresh." FDA could, for the first time, provide the data on which it relies for a proposed

regulation governing this term. It would then be appropriate for FDA to repropose a regulation, if this were thought necessary and appropriate, for which an adequate factual record would exist.

To prevent egregious abuses of use of the term "fresh," FDA has instituted numerous court actions and warning letters beginning in April 1991. These regulatory actions have clearly stopped improper use of "fresh." Thus, delaying action on the proposed regulations will in no way prevent FDA from continuing to take regulatory action for flagrant misuse of this term.

As these comments point out, there is no factual basis whatever for the current proposed regulations. FDA cites no data or information of any kind to support the proposal. FDA does not even cite a single dictionary definition to support its proposal -- undoubtedly, as is documented below, because current dictionary definitions contradict the proposal.

It is not sufficient for FDA now to attempt to find some kind of factual basis to support the proposal and then to promulgate a final regulation based upon newly-found information. The ABA and other members of the public are entitled to review whatever factual basis is thought by FDA to support the proposal, and to comment on the adequacy of that support, before any final regulation is promulgated. The

support for a regulation must be part of the proposal, not brought forth as a post hoc rationalization after the time for public comment has expired.

This is an extraordinarily important issue to the baking industry. For decades, bakers have been selling fresh bread, doughnuts, and other baked goods, clearly designated as "fresh," without any objection by FDA, the FTC, state governmental agencies, or the consuming public. The term "fresh bread" is a long-used and commonly-understood part of the English language. Now FDA proposes to abolish this term, by administrative fiat, without a single citation to a factual basis. The ABA believes that this constitutes arbitrary and capricious governmental action that cannot withstand public scrutiny.

II. Contemporary Dictionaries Offer a Uniform, Well-Accepted and Long-Understood Definition of the Term "Fresh Bread"

As already noted, FDA cites no dictionary in support of its proposed regulation on the term "fresh." That is undoubtedly because FDA does not purport to accept the current definition of the term, but rather proposes an entirely new, different, and unsubstantiated version of the term that is in direct conflict with contemporary and long-accepted definitions.

Webster's Third New International Dictionary of the English Language (unabridged 1986) contains the following relevant definitions of the word "fresh":

2a: newly produced, gathered, or made:
not altered by processing (as by canning,
pickling in salt or vinegar, or refriger-
ation) (___ vegetables) (___ fruit)
b: having its original qualities
unimpaired: as . . . (2): not stale,
sour, decayed, or deteriorated in any way
(meat kept _____ by refrigeration) (____
bread)

The New College Edition of the American Heritage Dictionary of the English Language (1978 ed.) puts the same two concepts of "fresh" in somewhat simpler prose:

3. Recently made, produced, or harvested;
not stale, spoiled, or withered: fresh
bread. 4. Not preserved, as by canning,
smoking, or freezing: fresh vegetables.

These definitions are illustrative of the definitions found in other dictionaries as well.

Thus, it is clear that the term "fresh" has different meanings in different contexts, and not a single meaning. When referring to raw agricultural commodities, the term means that there has been no fundamental change in the commodity in the form of canning, smoking, freezing, or similar major processing. When referring to bread (and undoubtedly milk as well), it refers to the retention of product quality and the absence of spoilage and staleness. In both of the definitions relevant to bread cited above, the

term "fresh" is explicitly referred to as the opposite of stale (as well as such related terms as spoiled, decayed, or deteriorated). In both definitions, one example of the proper use of the term "fresh" in this context is given: "fresh bread."

III. The FDA Proposed Regulations Conflict with the Dictionary Definition and With Common English Usage

Proposed Section 101.95 would define two terms: "fresh" and "freshly baked." The term "fresh" could be used only for a "raw food," and thus could not be used for any bakery product. The term "freshly baked" could only be used for bakery products that contain no form of preservative and are available for sale less than 24 hours after baking, and thus could not be used for the vast bulk of bakery products marketed in the United States today. The ABA believes that these two definitions, which are blatantly inconsistent with the dictionary definition of the term "fresh," are unsupported by any data or information and cannot be justified on any reasonable ground.

A. The Definition of "Fresh"

It is apparent that FDA selectively took one of the two dictionary definitions of the word "fresh" and has pretended that the other one does not exist, thus purporting to abolish it from the English language. Under the FDA proposal, the one definition -- "Not preserved, as by canning,

smoking, or freezing: fresh vegetables" -- would be elevated by FDA to the status of the sole definition of the term "fresh." The other definition -- "Recently made, produced, or harvested; not stale, spoiled, or withered: fresh bread" -- would be abolished. The ABA believes that FDA has no authority under the Federal Food, Drug, and Cosmetic Act to rewrite dictionaries and repeal common usage of the English language.

To support its narrow and unprecedented definition of the term "fresh," FDA has cited absolutely nothing. No dictionary, no consumer survey, no factual information of any kind. The preamble consists of a series of recitations that FDA "believes" that its definitions are appropriate. Neither in the preamble nor in the list of references is there any attempt at a factual basis for those beliefs. The unsupported beliefs of FDA employees, however sincere and well-intended, are simply not enough to disregard long-established and well-recognized consumer use of the term "fresh," as documented by contemporary dictionaries.

Under the proposed FDA definition, only "raw food" is eligible to use the word "fresh." This directly conflicts with the dictionary definitions cited above. The ABA submits that the consuming public is not stupid, and that people fully understand that bread does not grow on trees or in the ground. Bread is obviously not a raw agricultural commodity. It is

well-recognized as a processed food. It is one of the oldest forms of processed food known to humans. Its use goes back to earliest records, and undoubtedly began long before recorded time. Consumers understand that a product can be "fresh" even though it is not a raw agricultural commodity. If this were not true, the dictionaries would not use "fresh bread" as a universal example of the proper use of the term "fresh" when it refers to the fresh quality of a food.

Under the FDA definition, as explained in the preamble at page 60465, any use of any type of chemical preservative, such as a mold growth inhibitor, would preclude use of any form of the word "fresh" (although, as will be discussed below, extraordinary exceptions are made for raw agricultural commodities that are not permitted for bakery products). It is common practice in the bakery industry to include mold inhibitors in products in order to promote the public health and to extend the useful life of bakery products in the home. None of the dictionary definitions that we have found state, or even imply, that preservation of this type would preclude fresh bread from being regarded as "fresh." Let us again reiterate the definition of "fresh" that, according to the dictionary, applies to bread:

Recently made, produced, or harvested; not stale, spoiled, or withered: fresh bread.

There is no reference in this definition to the matter of preservation. Indeed, this definition implicitly includes preservation, to avoid the bread from becoming stale or spoiled. It is only in the definition of "fresh" as it applies to "fresh vegetables" (and similar raw food) that the dictionary definitions refer to the absence of preservation, and then only such major forms of preservation as canning, smoking, or freezing, which change the fundamental nature of the food itself.

It must also be recognized that the use of mold inhibitors in bread, such as calcium propionate, is not to preserve the bread while it remains in its retail package, but rather to prevent the growth of mold once the package has been opened. The purpose is not to preserve the food in the store and in transit, but to prevent the loaf from developing mold while it is in use by the consumer in the home. This, in itself, distinguishes the "preservation" of bakery products from the common practice of preserving food products in order to prevent deterioration throughout the life of the product, from production through consumption.

It would be perverse indeed if the nation's leading food safety agency -- the Food and Drug Administration -- were to promulgate a regulation that encouraged reduction in food preservation. The use of mold inhibitors in bread has vastly increased the quality and safety of bakery products. The

proposed definition of "fresh" could encourage the bakery industry, as well as the rest of the food industry, to take chances with preservation in order to continue to justify use of the word "fresh." For this reason alone, the proposed definition is contrary to sound public policy.

It is common knowledge that, with modern food technology, "preservation" of food can occur not just with "chemical" additives but also with common food ingredients, such as vinegar. If FDA were to promulgate a definition of "fresh" that discriminated against chemical preservatives, the food industry would undoubtedly be forced to experiment with new formulations that "preserve" the food through the use of common "food" ingredients. Promulgating a regulation that could easily be avoided, and that could not conceivably be enforced fairly and consistently, serves no public purpose. The net result would be large changes in food formulation, resulting in increased consumer prices, simply to solve a problem created by an FDA regulation.

FDA itself recognizes, in two places in the preamble to the proposed regulations, that common forms of current food preservation should not preclude use of the term "fresh." On page 60465, FDA cites, with approval, the current USDA policy that permits use of the term "fresh" when it describes a recently prepared food consisting of ingredients that could not meet its policy criteria (e.g., a ham salad containing

cured ham). Cured ham is, of course, a preserved food. Thus, FDA agrees with USDA that it is perfectly appropriate to say that a product containing a preserved ingredient is commonly understood as "fresh" when it has been recently prepared. Second, on page 60466 FDA notes the common use of extended shelf life packaging and recognizes that such products may be of a degree of quality similar to that of traditional prepared foods that could appropriately be labeled "fresh." Extended shelf life packaging is, of course, a form of preservation. It is one alternative to the use of chemical or other preservative ingredients in food. Certainly preservation by packaging cannot properly be given an exalted status over preservation by ingredients.

For all of these reasons, ABA urges FDA simply to adopt the two long-standing definitions of the term "fresh" commonly found in standard dictionaries. Because the American Heritage version is set forth in simpler terms, we would particularly recommend that version, although there is no substantive difference between that formulation and the formulation found in other dictionaries. To repeat, the two definitions would be:

Recently made, produced, or harvested; not stale, spoiled, or withered: fresh bread.

Not preserved, as by canning, smoking, or freezing: fresh vegetables.

FDA would then be entirely consistent with common English usage and on strong ground for support of its definitions.

FDA has recognized, in the preamble, that definitions of the term "fresh" cannot be reduced to mathematical precision, and may vary depending upon the type of food to which reference is made. In 28 Fed. Reg. 10900 (October 11, 1963), quoted on page 60463 of the preamble, for example, FDA stated that:

The term "fresh" is ambiguous in that it is difficult to determine and to draw the line when a product is fresh and when it is no longer fresh.

Similarly, FDA acknowledges on page 60465 of the preamble that:

The term "recently" as used in this proposal is a qualitative term whose meaning depends in large degree on the food in question.

Nonetheless, FDA proposes to establish an arbitrary limit, for which no factual justification is even offered, that bakery products have only been "freshly baked" if they are available for sale less than 24 hours after baking. This limitation is arbitrary, wholly inconsistent with common baking industry practice, and entirely unenforceable because records are not kept showing the precise time that a product is baked. The ABA urges that it be withdrawn and replaced by the more general criterion used in all of the dictionary definitions,

that to be "fresh" a bakery product must be recently made, produced, or harvested, and must not be stale, spoiled, or withered.

Bread that is baked on one day is seldom distributed on the same day. In most instances it is distributed on the following day. Thus, the vast bulk of the bread marketed in the United States could not meet the 24-hour limit set forth in the proposed regulation. This would mean that bread that consumers have long regarded as "fresh bread" could no longer be labeled as such. Without doubt, consumers would continue to call it "fresh bread." And without doubt, retail grocery store and bakery store owners in every part of the country would also legitimately continue to call it "fresh bread." Dictionaries would also continue to define it as "fresh bread." Only bread companies would be precluded from using the terminology that everyone else in the country would continue to use. FDA would thus be engaging in an arbitrary exercise in futility, attempting to force a change in consumer terminology that has been an accepted part of our language for decades.

B. The Definition of "Freshly Baked"

As already noted, dictionaries and consumers routinely use the term "fresh bread." FDA's proposal to ban contemporary dictionary definitions and consumer usage can find no support and no justification.

"Fresh bread" is, of course, recently baked and therefore can also properly be referred to as "fresh baked" or "freshly baked." This use of the adverb "fresh" (or "freshly") is in addition to, and not in lieu of, use of the adjective "fresh."

Use of the adverb in addition to the adjective is illustrated in both of the dictionaries quoted above. Webster's Third New International Dictionary of the English Language (unabridged 1986) contains the following definitions of "fresh" and "freshly" when used as adverbs:

fresh . . . adv. . . .: just recently:
just now: FRESHLY. . . freshly adv. . . .:
in a fresh manner: as a: NEWLY, RECENTLY
(a _____ cleaned floor) (a _____ acquired
egg). . .

The New College Edition of the American Heritage Dictionary of the English Language (1978 ed.) contains only a single and simpler entry for "fresh" that includes within it both the adjectival use (already quoted above) and the following adverbial use:

fresh. . . adv. Recently; newly. Usually
used in combination: fresh-baked
bread. . . . freshly adv. . . .

Thus, this entry in the American Heritage Dictionary explicitly recognizes that "fresh bread" is "fresh-baked" as well. It also gives preference to the term "fresh" over the term "freshly" when both are used as adverbs.

We in the industry have never heard a consumer ask for "freshly baked bread." People ask for "fresh bread" as the dictionary definitions readily demonstrate. If customers want to know how recently bread was baked, they may ask if it is "fresh baked." We challenge FDA to find any significant number of people who commonly use the term "freshly baked bread" in everyday conversation. It is undoubtedly grammatically correct, but it is not a phrase used by consumers. We therefore strongly urge that the term "fresh baked" be recognized as synonymous with "freshly baked" and that both be recognized as ways to describe "fresh bread."

IV. The FDA Proposed Regulation Conflicts with Prior FDA Precedent

The term "fresh bread" has been used by consumers and the food industry alike for longer than FDA has existed. For more than 200 years, state and local government authorities in the United States have had the power to prohibit false or misleading labeling and advertising. For 86 years, FDA has had the authority to prohibit false or misleading labeling. For 78 years, the FTC has had the authority to prohibit false or misleading advertising. At no time in the history of our country has any government agency prohibited the term "fresh bread" on the ground that the term "fresh" can be applied only to a raw agricultural commodity or to a product sold more than 24 hours after it was prepared.

At no time has any of these agencies contended that such a phrase was in any way misleading, much less false. At no time have consumers risen up to protest the use of the term "fresh bread" when applied to products that were not stale or deteriorated. Just because the term "fresh" has recently been misused in a few instances in other parts of the food industry provides no excuse for FDA to ban a commonly-used term under circumstances that are well-understood by the consuming public.

The only relevant precedent cited by FDA in the preamble fully supports the ABA position on this matter. On page 60463, FDA cited TC-99 (February 21, 1940). In that trade correspondence, FDA stated that the word "fresh" is generally understood by consumers to mean an article of recent origin, and that for butter the word would be appropriate only if the butter had been recently churned. FDA stated that "fresh" would not be applicable to butter which has been kept for a length of time, such as in the usual commercial practice of storing butter in cold storage warehouses until it is placed on the market.

The ABA agrees completely with this precedent. At the time of this trade correspondence (as well as now), butter was defined in 21 U.S.C. § 321a in a way that permits the use of salt, which is a well-known preservative. The trade correspondence did not limit the term "fresh" to unsalted

butter. Obviously, butter that is stored for weeks, months, or even years in cold storage warehouses is not "fresh" under any definition. But butter preserved with salt that was marketed promptly could, under that 1940 FDA precedent, properly be characterized as "fresh."

Moreover, FDA made no attempt to define, in this precedent, the speed with which butter must be rushed to retail sale in order to retain use of the word "fresh." No time or age constraint was imposed. Common commercial practice in the dairy industry is not significantly different than it is in the bakery industry. Butter churned on one day is not marketed on the same day, within 24 hours of churning. Because butter remains unspoiled for longer than bakery products, indeed, it is highly probable that butter labeled as "fresh" in accordance with this trade correspondence would be made available to the consuming public days later than bakery products that were made at precisely the same time.

The 1940 trade correspondence relating to "fresh butter" thus fully supports the ABA comments on this matter. FDA has provided no reason for overruling this precedent or for making it inapplicable to bakery products.

V. The Very Liberal FDA Proposed Regulation for Raw Agricultural Commodities is Inconsistent with the Proposed Regulation for Bakery Products and Unfairly Discriminates Against the Bakery Industry

The ABA finds no justification, either in the dictionary definitions cited above or in common English usage, for distinguishing between the freshness of raw agricultural commodities and other food products. Yet FDA has proposed regulations that would preclude any bakery product from being characterized as "fresh" because it is not a "raw food," while permitting any raw agricultural commodity, however old and deteriorated, to be called "fresh." A five-year-old rotten potato is "fresh" but a five-minute-old loaf of hot bread straight out of the oven is not "fresh," according to FDA. That is simply nonsense. We challenge FDA to put that to the test of a consumer survey. We doubt that FDA could find any person who believes that is an intelligent approach to the matter.

In the proposed regulations, raw agricultural commodities are permitted to be preserved in three ways: waxes and coatings, pesticides, and preservative washes. Yet bakery products are not permitted to be preserved even by mold inhibitors that serve an important public health purpose and that are used primarily to prevent mold growth after the product is opened. Preservation is thus permitted for agricultural commodities, in direct defiance of all of the

dictionary definitions, but is not permitted for bakery products even though the dictionary definitions implicitly include it. Thus, the proposed FDA regulations directly flaunt the dictionary definitions in both respects, ignoring the limitation placed upon fresh vegetables and improperly adding a limitation for bakery products. The result is unfair discrimination against the bakery industry.

FDA has a statutory and moral obligation to be fair and consistent to all food products, not to give an unfair advantage to some and to penalize others. If bakery products are required to be available for sale to consumers within a specified time period in order to be regarded as "fresh," and to have no form of preservation, then the same types of limitation should also be placed on raw agricultural commodities. The fact that a food is "raw" does not mean that it is also "fresh." Many raw agricultural commodities come from overseas by boat. Many are shipped and stored for months prior to retail sale. Numerous forms of preservation are used. These commodities therefore cannot be regarded as "fresh" under the FDA meaning of that term.

As we have pointed out above, a requirement that bread must be available for sale to consumers within 24 hours in order to be "fresh" would mean that the vast bulk of bread sold in the United States could not be regarded as "fresh." Only bread baked on the premises and sold immediately would

come within this limitation. If this type of limitation is applied to bakery products, it should also be applied to raw agricultural commodities. Only raw produce that is harvested and sold at retail within 24 hours of harvesting -- and raw milk that is sold at retail within 24 hours of milking the cow -- and raw fish that is sold at retail within 24 hours of being caught -- should lawfully be regarded as "fresh" if FDA applies the same requirements to produce as it has proposed for bakery products.

As we have already explained, the ABA does not support these types of arbitrary and unjustified limitation for any food product. But if they are going to be applied to bakery products, the baking industry will insist that they be applied to all food products on a consistent, uniform, and fair basis.

VI. Conclusion

The ABA reiterates that it believes that the proper way for FDA to proceed is to withdraw this proposal, conduct adequate research, and then determine whether there is sufficient justification to continue this rulemaking proceeding. The ABA believes that inappropriate use of the term "fresh" has already been abandoned by the food industry because of the well-publicized FDA regulatory action cited on page 60463 of the preamble. In light of its scarce resources, FDA should consider directing its efforts to issues that are

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of far greater importance. If FDA concludes to proceed, however, it must repropose new regulations that are -- unlike the current proposals -- based upon sound data and information that are cited in the preamble and available for public review and public comment.

The comments set forth above state, in detail, the ABA objections to the current proposed regulations. The ABA would have no objection to FDA adopting contemporary dictionary definitions of the term "fresh" that accurately reflect common English usage and common consumer understanding. ABA strongly opposes the proposed regulations, however, because they conflict with dictionary definitions, abandon the language uniformly used by consumers, and are unsupported by any available data and information.

Respectfully submitted,



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