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INDEPENDENT BAKERS ASSOCIATION

P.O. Box 3731 • Washington, DC 20007 • (202) 333-8190 • Fax (202) 337-3809

January 19, 2001

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

Re: [Docket No. 94P-0036] Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims; Reopening of Comment Period (65 Fed. Reg. 75888, December 5, 2000).

Dear Sir or Madam:

The Independent Bakers Association (IBA) is a Washington, DC based international trade association. Founded in 1968 to represent the independent wholesale baker, the association has grown to over 420 members, including many family owned wholesale bakeries and allied industry trades.

IBA previously submitted comments on the trans fat rulemaking initiative in April 2000 (comment #2146). Today, IBA is responding to FDA's request for comments on the proposed nutrient content claim "reduced saturated and trans fats."

The "reduced saturated and trans fats" claim is of concern to IBA because we believe that saturated fat and trans fat should not be combined in labeling. The principal criterion for the proposed claim apparently would be a 25% reduction in the combined quantity of saturated fat and trans fat, compared to a reference food. Since FDA's policy is nutrient content claims should be verifiable by reference in the nutrition label, we assume saturated fat and trans fat would be combined on the nutrition label.

As discussed in our April 2000 comments, IBA believes that if labeling of trans fat is required, FDA should not require that the amount of trans fat be included in the amount and percent Daily Value declared for saturated fat. Combining saturated fat and trans fat on the nutrition label would not be consistent with scientific principles because saturated fats and trans fats are chemically and biologically distinct. Such labeling would suggest to consumers that saturated fat and trans fat are equivalent – a premise that is not supported by the data in the record. IBA therefore opposes labeling formats and claims that would treat these two nutrients as one.

IBA is also concerned that the "reduced saturated and trans fats" claim itself—like the proposal to combine saturated fat and trans fat on the nutrition label—may confuse and mislead consumers. While the proposed claim presumably is intended to characterize a reduction (of at least 25%) in the combined amount of saturated fat and trans fat, many consumers may assume the claim means that saturated fat has been reduced by at least 25% and trans fat has been reduced by at least that same percentage.

For these reasons, IBA cannot support authorization of the claim "reduced saturated and trans fats."

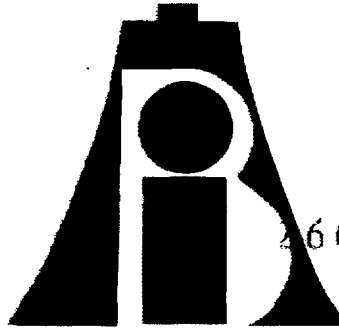
IBA appreciates the opportunity to comment on these issues, which are of critical importance to the baking industry.

Sincerely,


Robert N. Pyle, President
Independent Bakers Association

94P-0036

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INDEPENDENT BAKERS ASSOCIATION

P.O. Box 3731 • Washington, DC 20007 • (202) 333-8190 • Fax (202) 337-3809

April 14, 2000

The Honorable Jane E. Henney, M.D, Commissioner
United States Food and Drug Administration
Attn: Dockets Management Branch (HFA-305)
5600 Fishers Lane – Room 1061
Rockville, Maryland 20852

RE: Proposed Food Labeling Rule: Trans Fatty Acids in Nutrition Labeling,
Nutrient Content Claims and Health Claims –
64 Federal Register 62746, November 17, 1999
Docket No 94P-0036

Dear Madam Commissioner:

The Independent Bakers Association is a Washington, DC based international trade association. Founded in 1968 to represent the independent wholesale baker, the association has grown to over 400 members, including many family owned wholesale bakeries and allied industry trades. Today we offer the FDA the consensus opinion of our Trans Fatty Acid Labeling Working Group.

Summary Statement

Twenty-four bakeries participated in with IBA working group. IBA's labeling comments reflect the view of the independent segment of the baking industry. One overall concern of the group is why FDA pushed the proposed rule so rapidly. The following comments explain why Trans Fat should not be combined with saturated fat; provides alternative label formats for FDA consideration; suggests that trans fat labeling should be optional unless claims are made and gives the groups thoughts on "threshold" disclosure. Finally we also provide some thoughts on FDA implementation of the rule.

94P-0036

Independent Bakers Association
FDA Docket No 94P-0036
Trans Fatty Acids Nutrition Labeling
4/14/00

C 2146

FDA Should Not Combine Trans and Saturated Fat in Labeling

FDA's proposal to combine saturated fat and trans fat on the nutrition label is not consistent with scientific principles, and may not be in the best interests of consumers or the food industry. Specific concerns include the following:

- FDA's proposed format for labeling would require that trans fat be included in the declared amount of saturated fat, despite the fact that trans fats are not saturated. This format is not consistent with scientific principles and may set an undesirable regulatory precedent for the future.
- The proposed format may cause significant consumer confusion because its terminology would not match the terminology used in books and articles that provide scientifically accurate information regarding trans fat and saturated fat.
- Additional consumer confusion may result from the fact that under the proposed format the saturated fat amount declared on many products would increase, although the products' formulations would be unchanged. Under the current FDA proposal consumers will find a sudden and unexplained change in the declared amount of saturated fat. This may erode consumer confidence in the food label and in food manufacturers.
- The proposed format suggests to the consumer that the physiological effects of trans fat and saturated fat are equivalent. However, the data cited by FDA in support of the proposal does not indicate that trans fats have an effect on serum cholesterol or coronary heart disease (CHD) that is equivalent to that of saturated fat. Thus, the proposed labeling format is misleading.
- The data cited by FDA in support of the proposal indicates that the adverse impact of saturated fat, with respect to LDL-cholesterol (LDL-C), is greater than that of trans fat. The proposal, however, equates the two nutrients on a gram-for-gram basis.
- Scientific research regarding trans fat will continue in the coming years. There is no reason to expect that such research will establish that trans fat and saturated fat should be equated in the Nutrition Facts panel, in the criteria for making claims, or for any other purpose.

Trans Fat Labeling Should Be Voluntary Except When Claims Are Made

There may be evidence sufficient to warrant labeling of trans fat to prevent consumer deception with respect to products which make claims regarding saturated fat, cholesterol or trans fat content. However, it is not clear that FDA has made a sufficient case for mandatory labeling of products that do not make those types of claims. Attachment 1 provides reasoning that trans fat labeling should be voluntary except in the case of products which make claims related to saturated fat, cholesterol or trans fat content.

Alternative Labeling Formats

FDA should not adopt its proposed labeling format. Attachment 2 describes two alternative formats, which do not imply that trans fat and saturated fat are the same. We believe these alternatives would be preferable to FDA's proposed format if trans fat labeling is required.

Threshold Disclosure Levels

IBA's Attachment 3 shows our group's conclusions as to whether FDA regulations should only require trans fat labeling for foods exceeding certain "threshold" levels of trans fat, as some trade groups have suggested. IBA generally opposes establishment of any new fat labeling threshold disclosure levels or "triggers."

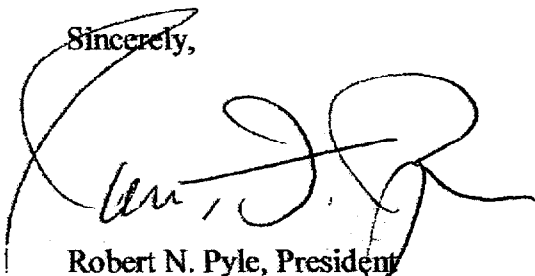
Implementation

If a final rule results from the proposal, industry should be given a minimum of two years following adoption of the rule before compliance is required. Any shorter period of time would cause substantial adverse economic impact on industry.

Conclusion

Thank you for the opportunity to comment on this critical labeling issue.

Sincerely,



Robert N. Pyle, President
Independent Bakers Association

CC: IBA Executive Committee
IBA Board of Directors

**Attachment 1: Trans Fat Labeling Should be
Voluntary Unless a Product Makes Certain Claims**

Declaration of trans fat should be voluntary unless a product bears a claim regarding saturated fat, trans fat, or cholesterol, or the product declares polyunsaturated fat or monounsaturated fat. This approach would be consistent with the approach currently taken in §101.9(c)(2)(ii) and (iii) for declaration of polyunsaturated fat and monounsaturated fat. This regulation provides that polyunsaturated fat [§101.9(c)(2)(ii)] may be declared voluntarily except when monounsaturated fat is declared or when a claim about fatty acids or cholesterol is made; the regulation is similar for monounsaturated fat [§101.9(c)(2)(iii)].

In view of the First Amendment limitations on FDA's authority, it appears that the agency has not made a sufficient case for mandatory labeling of products that do not make such claims and do not declare polyunsaturated or monounsaturated fat. Under the First Amendment, regulations that compel speech (such as mandatory labeling requirements) are permitted only if the regulations are narrowly tailored to serve a "substantial government interest" (such as preventing consumer deception). Such regulations also must be supported by evidence demonstrating that the harm sought to be remedied is genuine.

FDA has not shown that mandatory declaration of trans fat is necessary to prevent consumer deception with respect to product labels that do not make the specified claims and do not declare polyunsaturated or monounsaturated fat. Nor has the agency provided any other justification that would satisfy First Amendment standards.

It is important to keep in mind that under the current regulations, trans fat is included in the amount of total fat declared on the label. And, the American Heart Association has indicated that concerns regarding trans fat consumption should be addressed by focusing on the total amount of fat consumed.

Further, most of the studies cited by FDA in support of its proposal involved trans fat consumption levels that were substantially higher than those found in a typical diet. It is unclear that trans fat has those same adverse effects on serum cholesterol at more typical consumption levels.

FDA anticipates that mandatory declaration of trans fat for all products will result in reformulation by manufacturers. FDA expects that manufacturers who reformulate will likely add 0.5 grams of saturated fat for each gram of trans fat removed. Our information indicates that to lower trans fat and achieve an equivalent baked product quality, a one for one replacement of saturated for trans fat would be required. At present functional, unsaturated replacements for trans fat are simply unavailable. Since the data cited by FDA indicates that saturated fat's adverse physiological effects are greater than those of trans fat, it is highly questionable whether such reformulation would benefit consumers.

Mandatory labeling of all products will also impose enormous costs on industry. It appears unlikely that benefits gained from such labeling would justify those costs. Thus, it seems appropriate to limit mandatory labeling of trans fat to those products that make the specified claims or that declare polyunsaturated fat or monounsaturated fat. This approach does have a sound consumer deception rationale – if a label suggests that the product may be “heart-healthy,” then the label should disclose the trans fat content.

Attachment 2: Alternative Labeling Formats

If FDA decides to mandate trans fat labeling, it should not adopt the format in its proposal. For reasons discussed previously, that approach is inappropriate. Both of the following options would be preferable to FDA's proposed format, if trans fat labeling is required.

Option 1: Asterisk Beside "Total Fat"

Under this option, an asterisk beside "total fat" would reference a footnote at the bottom of the Nutrition Facts box. The footnote would state "Includes ___ g trans fat." This approach, unlike FDA's proposal, would employ scientifically accurate terminology and would recognize that trans fat is already included in the label definition of total fat.

This option would not involve establishing a Daily Value for trans fat. As FDA stated in its proposal, there is no scientific basis for establishing such a value. There is precedent for not establishing a trans fat Daily Value; there is no Daily Value for polyunsaturated fat, monounsaturated fat or sugars. There is a Daily Value for protein; however, it is not required to be labeled unless a protein claim is made.

This approach would not characterize trans fat as saturated fat and can be readily defended on scientific grounds. Further, because the "total fat" listing in the Nutrition Facts box is more prominent than the saturated fat listing, an asterisk beside "total fat" might be more readily seen by consumers.

One of FDA's objectives was to leverage consumer education as to the heart-unhealthy effects of saturated fat. To achieve that goal, FDA has proposed a shortcut methodology that is scientifically flawed and may result in consumer confusion as described previously. We believe that the goal of consumer education is best achieved by applying sound science and providing consumers with accurate information.

Another variation would be to include a parenthetical "(incl. ___ g trans fat)" on the same line as the "total fat" declaration.

Option 2: Separate Line for Trans Fat

FDA could add a separate line for trans fat, in the same format that is used for monounsaturated and polyunsaturated fatty acids when they are labeled.

This option would be preferable to the format proposed by FDA. Like Option 1, it would employ terminology which is scientifically accurate. From a manufacturer's perspective, this option may be less desirable than placing an asterisk beside "total fat," because of higher relabeling costs that would be incurred with adding another line.

For the reasons discussed previously, FDA should not establish a Daily Value for trans fat under this option or under any labeling format, until sufficient supporting scientific evidence is available.

There is precedent for not establishing a trans fat Daily Value; there is no Daily Value for polyunsaturated fat, monounsaturated fat or sugars. There is a Daily Value for protein; however, it is not required to be labeled unless a protein claim is made.

FDA cited 3 problems with this option (counterpoints in parenthesis):

- 1) expense involved for manufacturers of foods with no trans fat (there is a simple answer to this concern – don't require such foods to add a line for trans fat),
- 2) lack of publicized information about trans fat may confuse consumers (in their proposal, FDA states that consumers are likely to purchase foods with claims about trans fats for the same reason they would purchase a food with claims about saturated fats, which contradicts the premise that consumers are not informed about trans fat), and
- 3) since there is no recommended Daily Value, this format may not provide consumers information they can use to plan their diet (again there is precedent for not establishing a Daily Value).

Attachment 3: Trans Fat Labeling Threshold Disclosure Levels

Opposition:

We have given consideration as to whether FDA regulations should only require trans fat labeling for foods exceeding certain "threshold" levels of trans fat, as some trade groups have suggested. This concept uses "trigger" disclosure levels. This approach presents numerous problems, including the following:

- There is no precedent for these types of thresholds in nutrition labeling, and there is no reason to treat trans fat differently from other nutrients in the Nutrition Facts panel.
- Such thresholds may well mislead and confuse consumers. It seems likely that consumers will assume that products which are under the threshold contain no trans fat.
- Threshold levels would create a bad regulatory precedent with respect to the "good food/bad food" issue. In our view the baking industry should not support a proposal under which "bad" foods would be subjected to heightened labeling requirements.

However, it seems that a one-gram trans fat or a three-gram total fat threshold for mandatory trans fat labeling may have a sound policy basis and could be justified to FDA. At the same time, these levels would exempt a substantial number of bread products from the trans fat labeling requirement, while keeping the labeling playing field level for cake and cookies.

A threshold level of one gram of trans fat is defensible on the grounds that a product which contains one gram or less of trans fat is "low" in that nutrient. Consequently, declaration of trans fat content would not be material to consumers. A similar argument can be made on behalf of a three-gram total fat threshold.

One gram of trans fat and three grams of total fat are arguably de minimus levels of those nutrients. Therefore, mandatory labeling of foods that exceed those levels would not necessarily characterize those foods as "bad."