

Trans Fat Industry Coalition
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January 14, 2004

Dr. Fumie Yokota
Desk Officer for FDA
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

RE: [Dockets No. 2003N-0506 and No. 2003N-0507] Agency
Emergency Processing Request Under Office of Management and
Budget Review; Experimental Study of Possible Footnotes and
Cueing Schemes to Help Consumers Interpret Quantitative Trans
Fat Disclosures on the Nutrition Facts Panel (NFP) and
Experimental Study of Trans Fat Claims on Foods

Dear Dr. Yokota:

The Trans Fat Industry Coalition comprised of the undersigned appreciate this opportunity to comment on FDA's planned consumer research on trans fat labeling.

The Federal Register notices of November 10, 2003 announcing the request for OMB did not provide the relevant documentation nor did it indicate how to obtain it. It is our understanding that these documents (i.e., "Supporting Statements" and questionnaires) were not available at the time the Federal Register notices were published. By the time participants in our Coalition were able to obtain this documentation, the holiday season was well underway making it difficult to share these documents for evaluation. Furthermore, we note that an important document related to these research protocols and survey instruments, "a one-page summary of the current state of scientific evidence for the health effects of trans fat in the diet" was not voluntarily provided by FDA in response to requests for relevant documentation until its existence was discovered by the Coalition and specifically requested just prior to the long New Years weekend.

While we are now offering some detailed comments regarding the proposed research, the Coalition may wish to comment further as additional experts review this material. And, we would hope that if FDA has not yet put the research into the field as of that time, it would take any additional Coalition comments under advisement.

The Coalition understands that OMB wants FDA to move forward with this research expeditiously, but it is important to acknowledge that the results of this research will have far reaching impact. Therefore, it is as critical to get this consumer evaluation right as

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well as it is to get it done quickly. We have been advised that FDA will “tweak” the surveys to now include references to the recently published IOM “DRI Uses in Labeling” report recommendation that there be a combined Daily Value for saturated fat and trans fat. While we endorse that inclusion, we have not seen how questions related to that option have been integrated into the questionnaires. The wording and ordering of questions are critical elements of any thorough consumer research.

The far-reaching impact to which we refer likely includes the publication of the results of this research in future Federal Register notices and in FDA documents on trans fats and possibly other nutrients as well as in scientific journals. This then “positions” these results to the health professional community and the media who are significantly influential with consumers. To suggest to consumers that trans has a greater impact on health outcomes than saturated fat or to attempt to link trans fat to overweight through the inclusion and wording of specific survey questions almost assures a misleading outcome. This concern is addressed more specifically in comments below.

Our comments on the proposed research supporting statements and questionnaires follow in four sections:

- 1) Comments on the “one-page summary” noted above
- 2) Comments relating to both proposed research studies
- 3) Comments relating only to the “Experimental Study of Trans Fat Claims on Foods”, referred to below as “Trans Fat Claims”
- 4) Comments relating only to the “Experimental Study of Possible Footnotes and Cueing Schemes to Help Consumers Interpret Quantitative Trans Fat Disclosures on the Nutrition Facts Panel (NFP)”, referred to below as “Possible Footnotes and Cueing Schemes”

One-Page Summary of Scientific Evidence Related to Trans Fat

This summary is characterized on page 8 of the “Trans Fat Claims” supporting statement as follows: “In the Full Information condition, respondents will read a one-page summary of the current state of scientific evidence for the health effects of trans fat in the diet. It will be written at a 6th-8th-grade reading level. Nutrition scientists at FDA will review the summaries for accuracy.”

In general, the Coalition has serious concerns about using this statement in its present form even with only a segment of the overall sample.

FDA plans to introduce information about trans fats to half of the respondents in order to gauge the impact of this knowledge. This approach is unlikely to achieve its objective, as it is impossible to recreate the actual learning experience that health-knowledgeable consumers undergo. Further, by drawing respondents’ attention to the information just prior to asking questions about the healthfulness of the foods to be tested, the results are likely to be biased. In particular, the unbalanced approach used in this summary surely will position trans fat as worse than any other nutrient on the Nutrition Facts Panel.

Rather than include an “information treatment” as part of the design, we would recommend asking objective questions (toward the end of the questionnaire, so as not to bias response to key questions) that determine the respondents’ true level of awareness about not only trans fats, but also health and nutrition information in general. Respondents could then be divided into groups and analyzed according to their actual knowledge level, not an artificial imposed knowledge level.

More specific to the proposed scientific summary, the Coalition notes that the second sentence of that summary says, “There are three main types of fatty acids: saturated, monounsaturated, and polyunsaturated”. In the context of nomenclature used for other fats on the Nutrition Facts Panel (NFP), “fatty acids” is inappropriate. In its July 11, 2003 final rule on trans fat labeling, FDA states that the term fatty acids is not to be used on the NFP. It should not be used for purposes of this study either, especially if this summary is written as a 6th-8th-grade reading level. Trans fats is the more appropriate term.

Sentence number 3 states, “Trans fat (also known as trans fatty acids) is a specific type of fat formed when food manufacturers turn liquid oils into solid fats like shortening and hard margarines.” The parenthetical expression, again, is unnecessary. Because margarine is one of the test products used in the “Possible Footnotes and Cueing Schemes” research, introduction of margarine to the respondent with respect to this technical effect that may not be fully understood biases the respondent to be more critical of margarine with any level of trans fat. Placing a period after solid fats would cure this problem, particularly since margarine is included in the enumeration of products in sentence number 6. Inclusion of the “food manufacturers” in this sentence suggests that food manufacturers purposefully add trans fats to their products. We recommend the entire sentence be reworded to read: “Trans fat is a specific type of fat formed when vegetable oils are processed and made more solid or into a more stable liquid for the purpose of producing food products that stay fresh longer and have a more desirable texture.”

Sentence number 5, states; “Trans fat behaves in the body like saturated fat by raising low-density lipoprotein (LDL or “bad”) cholesterol that increases your risk of coronary heart disease”. Although this statement compares trans fat to saturated fat, the question could be phrased differently. For example, a statement such as, “Like saturated fat, trans fat raises low-density lipoprotein (LDL or “bad”) cholesterol that increases your risk of coronary heart diseases” puts more emphasis on the similarity in the dietary impact of saturated and trans fat and is likely to yield a different result than the language currently proposed.

Sentence number 6 says, “Trans fat can be found in some of the same foods as saturated fats, such as vegetable shortenings, some margarines, crackers, candies, cookies, snack foods, fried foods, baked goods, salad dressings, and other processed foods made with partially hydrogenated vegetable oils”. This statement implies these products are the most likely sources of trans fats. Various FDA personnel have been advised that almost

none of the salad dressings in the marketplace contain trans fat. In fact, in past Federal Register notices, FDA has clarified this point¹. To include salad dressings is misleading and raises questions as to whether FDA nutrition scientists did, indeed, review this summary statement for accuracy. Furthermore, if this statement is to be used it should be qualified to reflect that not all of these products contribute trans fat to the diet at the same level. We suggest: ““Trans fat, *at varying levels from trivial to some* [emphasis added], can be found in some of the same foods as saturated fats, such as vegetable shortenings, some margarines, crackers, candies, cookies, snack foods, fried foods, baked goods, and other processed foods made with partially hydrogenated vegetable oils”.

If the purpose of the summary is to convey a truly objective assessment of the presence of trans fat in the diet, additional points should be added to the summary for balance. More specifically, trans fats make up a small percentage, between 2 and 3 percent, of the total fat intake in the average American diet. And, trans fats from all sources provide 2-4 percent of total calories compared with 12 percent from saturated fat and 34 percent from total fat in the American diet. The majority of trans fats come from processed foods, but about one-fifth of trans fats in the diet come from animal sources such as meats and dairy products.

Both Proposed Research Studies

The per-cell sample size, particularly for this “Trans Fat Claims” research is too small. According to study descriptions, the “Possible Footnotes and Cueing Schemes” research will consist of 60 subjects per cell, while the claims study will consist of 20 subjects per cell. In both cases, these cell sizes are described as able to provide “adequate power to identify small to medium size effects.” In the latter case (“Trans Fat Claims” research), we disagree and would recommend at least 60 subjects per cell, or 180 subjects when combining across products. In the “Trans Fat Claims” research as it is presently designed, even if results were to be combined across three products, each combined cell would contain 60 subjects (20 x 3). This carries with it a ± 12.7 percentage point sampling error (at 95% confidence); more importantly, comparisons between claims would be subject to a sampling error of ± 17.9 . In contrast, a combined cell of 180 respondents (60 x 3) is subject to a ± 7.3 percentage point sampling error, and ± 10.3 for comparison purposes (180 vs. 180). Fewer experimental conditions would solve this problem.

The “Trans Fat Claims” research includes three product types: margarine, crackers, and pound cake. The “Possible Footnotes and Cueing Schemes” research includes three product types: cookies, margarine and frozen dinners. There is no rationale provided for not testing the same products in both surveys, nor is there any justification offered for including margarine as the only product category included in both surveys. The Coalition would like to know why and how these specific products were selected for each survey.

¹ It is the Coalition’s understanding that the Association of Dressings and Sauces is providing further detail to OMB and FDA on this Federal Register clarification.

Both questionnaires included questions on health outcomes related to specific product labels, all of which pertain more or less to trans fat. They include:

- Reduce your risk of having a heart attack
- Reduce your risk of blood cholesterol
- Reduce your risk of becoming overweight

A heart attack is an acute event typically resulting from coronary heart disease. The “Trans Fat Claims” supporting statement (Product Perception Questions, p. 8), describes questions that “Will be asked for three health conditions (heart disease, high blood cholesterol and overweight).” And, both questionnaires ask about family health history, in which the question is worded, “Had heart disease”. The question related to this outcome in this section should be reworded to read, “Reduce your risk of heart disease”, which is the more appropriate description of the health outcome concern.

Everyone has blood cholesterol. The question relating to cholesterol should read, “Reduce your risk of having high blood cholesterol.”

The relationship of trans fat and overweight has not been established. It has not even been the primary objective of any research of which we are aware. In its July 11, 2003 Federal Register notice on trans fat labeling, FDA provides an extensive review of the science on trans fat and health. Nowhere in this review is overweight or obesity addressed or even mentioned. We recognize that the “Possible Footnotes and Cueing Schemes” research questionnaire addresses calories in question A.7; however, there should be additional questions added to this survey if FDA wants to tease out consumer beliefs of the cause of being overweight. The basis upon which to test a perception correlation between trans fat and obesity is groundless. Yet, the chances that this questionnaire will bias a response to support that contention are high.

Finally, the Coalition believes that neither questionnaire will yield a complete picture of the impact on consumer behavior of the various label options offered. Because the survey results are likely to be used in the consideration of any policy changes in nutrition or ingredient labeling, we believe FDA should have an understanding of not only what consumers say they want but an indication of what action they will take with additional or different information on food labels. Nowhere in these surveys is the consumer asked what she/he will do with any of these labeling options, even after some respondents reach the “full information condition” as FDA puts it. Consumers frequently say they want more or different information, but often do nothing with the additional or enhanced information they receive. The cost of label changes is very significant. To make the appropriate cost/benefit evaluation, the coalition believes consumer behavior should be thoroughly probed in this research.

“Trans Fat Claims” Research

No description of product labels with respect to nutrient content is provided in the supporting statement or the proposed survey for this research. Thus, the Coalition cannot

determine what FDA considers to be “good”, “medium” and “poor” profiles with respect to saturated fat, cholesterol and trans fat with respect to the margarine, cracker and pound cake products selected.

Beginning on page 6 of the supporting statement for this research, FDA proposes “to include a label with no trans content claims, and trans content claims with accompanying labeling information that might help improve judgement accuracy”. These labels include:

- 3) No [trans fat] Content Claim
- 4) Trans Fat Claim w. front panel disclosure of saturated fat and cholesterol content
- 5) Trans Fat Claim w. “see back panel for important information about saturated fat and cholesterol content”
- 6) Trans Fat Claim w. selected nutrition guidance message, e.g., “keep your intake of saturated fat and trans fat as low as possible”.
- 7) Trans Fat Claim w. front panel disclosure of saturated fat and cholesterol content w. selected nutrition guidance message.

We would like to assume and, would strongly endorse, that the Nutrition Facts Panel used in these research surveys include the quantitative labeling of trans fat as set forth in the July 11, 2003 final rule for trans fat labeling. However, this point is not specifically clarified in either supporting statement, nor is it suggested in the label descriptions in labels 4 and 7 above.

The example nutrition guidance message in label number 6 does not mention cholesterol. Both the “Macronutrient” and “DRI Uses in Labeling” report from the National Academies as well as the supporting statements for both surveys discuss the reduction of saturated fat, cholesterol and trans fat. The Coalition believes any nutrition guidance message related to fats should include cholesterol.

Label number 6 offers an example of a nutrition guidance message that the Coalition believes does not adequately reflect the recommendation on trans fat in the National Academies, IOM report, “Dietary Reference Intakes for Energy, Carbohydrates, Fiber, Fat, Fatty Acids, Cholesterol, Protein, and Amino Acids”. The recommendation stated, “saturated fatty acids (SFA), trans fatty acids (TFA) and cholesterol intakes should be as low as possible *while consuming a nutritionally adequate diet*” [emphasis added].

While the Coalition acknowledges that the addition of “while consuming a nutritionally adequate diet” is likely not desirable for labeling purposes, it does provide the consumer with appropriate context for evaluating “as low as possible”. Using previous consumer research as a guide, we believe that most consumers will interpret the phrase “as low as possible” to mean zero, and the survey is likely to get a different response to proposed label 6 with this label compared to one that reads, “keep your intake of saturated fat, trans fat and cholesterol low”. The Coalition feels strongly that the phrase, “as low as possible” should not be used.

Asking respondents if they noticed any “health benefits” on the label *prior to* asking key outcome questions (e.g., health impact of food) may bias results. We believe a cleaner approach would be to immediately ask key outcome questions without first drawing attention to the label. FDA’s observation of the International Food Information Council (IFIC) Foundation study in the supporting statement is based on a similar principle: that the design is not truly “experimental” after the respondent is directed to recognize and recall the label content. An important difference, however, is that the IFIC Foundation study included a “clean read” prior to the focusing instructions while the FDA study does not.

“Possible Footnotes and Cueing Schemes” Research

There is no rationale provided in the supporting statement for this research as to how the nutrient content values for fat for each of the products featured were determined. We understand the values may be hypothetical but consumers are asked in the questionnaire to compare products A and B to typical products in the respective product categories. These values are very important to comparisons that consumers will make in responding to this questionnaire and will better represent how consumers may compare labels in “real life” situations.

The Coalition is also concerned about the level of existing consumer knowledge about the fat content of product categories being evaluated. Question 3 in this survey asks, “Thinking about the product you just chose as healthier, how would you rate it compared to the typical product in the [margarine, cookie, frozen dinner] category. This presumes consumers are familiar with the fat, sodium and saturated fat content of these categories, but the questionnaire makes no attempt to determine even a self-evaluation of this knowledge level. This question needs considerable improvement. The “typical product” for a health-conscious consumer is very different from the “typical product” for someone whose diet is poor. Further, it is possible that many consumers have no idea of the nutritional composition of the “typical product” (and nowhere does the questionnaire allow for such a response). Finally, given their higher knowledge levels, health-conscious consumers are better equipped to answer these questions, and may not be representative in terms of what their “typical product” is.

And, why is FDA probing for a comparison on sodium rather than cholesterol in this question? This focus of this research is fat and should, for reasons stated above, include cholesterol when perceptions about saturated fat and trans fat are surveyed. We suggest substituting cholesterol for sodium.

The supporting statement for this research, unlike that for the “Trans Fat Claim” research, provides detail on the fatty acid profiles of the products to be surveyed:

	Cookies		Margarine		Frozen Dinner	
	Prod A	Prod B	Prod A	Prod B	Prod A	Prod B
Tfat	14g	12g	10g	12g	22g	22g
Sfat	10g	6g	2g	4g	11g	5g
Trfat	0g	2g	3g	0g	0g	7g
Poly F			3g	5g		
MonoF			2g	4g		
Chol	0g	0g	0g	0g	150mg	0g

Much like the approach take in the research submitted to FDA by the IFIC Foundation, the labels for cookies and margarine set up the possibility that less informed consumers who are looking only at trans fats may choose product A as the more healthy choice even though product B is lower in combined saturated and trans fat. This is not the case in the way the Frozen Dinner is presented. We suspect that the reason for the fact that product A has less combined saturated fat and trans fat than Product B is because cholesterol is introduced on this label in Product A, and that FDA is attempting to evaluate the impact of adding cholesterol to the mix. The Coalition hopes that is the reason for treating Frozen Dinners different than the other two categories.

This product comparison is the only attempt in this entire research project to evaluate consumer reaction to cholesterol labeling, which the Coalition believes is important. In general, given the approach taken in the National Academies Institute of Medicine “Macronutrient” and “DRI Uses in Labeling” reports to consider saturated fat, cholesterol and trans fats, the Coalition believes the FDA research protocols do not adequately address consumer perception/response to all three nutrients. And more specifically with respect to cholesterol, all the values shown in the chart above should be expressed in milligrams, not grams.

It should also be pointed out that the individual values in the chart for the different fats do not add correctly, in some cases, to the Total Fat number (e.g., Margarine Product B would be 13g of Total Fat rather than 12g.)

It is the Coalition’s observation that these nutrient values in these products do not reflect those found in the marketplace today. We recognize that some of these values may have been selected in order to present a significant range between products A and B in these three categories, but the extremes in some cases are too high. For example, we know of no margarine products that have more than 11 g of Total Fat, and 4 g. of Saturated Fat is very extreme. A typical chocolate chip cookie found in the supermarket will have 9 g of Total Fat, and 3 g of Saturated Fat. The values in the chart of 14g and 12 g Total Fat for Cookie Products A and B and 10 g of Saturated Fat for Cookie Product A are unrealistic. The Coalition believes that FDA can find enough labels in the marketplace in each of these categories to, particularly with respect to Total Fat and Saturated Fat, to not only

represent real products, but to create a significant difference in the healthfulness of the products being evaluated.

The supporting statement for this research offers a range of footnote options to be tested. The Coalition believes that just as footnote 6 offers the inclusion of “cholesterol” as another variable for evaluation in comparison to footnote 5, this additional “cholesterol” inclusion variation should be offered as respective options to footnote 3 and 4 as well.

We appreciate the opportunity to provide these comments to you and FDA and would welcome the opportunity to discuss them further should you have questions.

Sincerely,

American Bakers Association
American Soybean Association
Grocery Manufacturers of America
Institute of Shortening and Edible Oils
National Association of Margarine Manufacturers
National Food Processors Association
Snack Food Association

cc: Dockets Management Branch, Food and Drug Administration, Dockets No. 2003N-0506 and No. 2003N-0507
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