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DATE OF CORRESPONDENCE: 08/14/02

DATE INTO FDA: 08/21/02

TO: LESTER M CRAWFORD HF-1

FROM: MICHAEL F JACOBSON, CSPI, CENTER FOR SCIENCE IN THE PUBLIC INTEREST
BRUCE SILVERGLADE, CSPI, CENTER FOR SCIENCE IN THE PUBLIC INTEREST
(PUBLISHER OF NUTRITION ACTION HEALTHLETTER)

SYNOPSIS: COMMENTS ON TRANS FAT DOCKET # 98N-0644 - FDA'S PROPOSAL "TO AMEND ITS REGULATIONS ON NUTRITION LABELING TO REQUIRE THAT THE AMOUNT OF TRANS FAT PRESENT IN A FOOD BE INCLUDED IN THE AMOUNT AND PERCENT DAILY VALUE (%DV) FOR SATURATED FAT."

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ASSIGNED TO	ACTION	DUE DATE
----- HFA-305 BUTLERJ	----- NECESSARY ACTION	-----

August 14, 2002

Lester M. Crawford, D.V.M., Ph.D.
Deputy Commissioner
Food and Drug Administration
5600 Fishers Lane, Room 14-71
Rockville, MD 20857

Docket Number: 94P-0036

Dear Dr. Crawford:

Almost three years ago the Food and Drug Administration (FDA) invited public comment on its proposal "to amend its regulations on nutrition labeling to require that the amount of *trans* fat present in a food be included in the amount and percent Daily Value (%DV) for saturated fat."¹ As the petitioner in this matter, we write to emphasize that:

- The recent report of the Institute of Medicine (IOM) on *trans* fat "recommended that *trans* fatty acid consumption be as low as possible while consuming a nutritionally adequate diet."²
- Those findings, together with a consumer survey we recently commissioned in response to that report, strongly support the FDA's initial proposal to include *trans* fat in the %DV for saturated fat;
- The FDA is obligated to finalize its proposed rule in a manner consistent with the Administrative Procedure Act and the Food, Drug, and Cosmetic Act.

The FDA explained in 1999 that it had tentatively concluded that it would require *trans* fat to be included in the %DV for saturated fat because "Evidence has accumulated that *trans* fatty acids have physiologic effects similar to saturated fats and *trans* fatty acids in food are used functionally to replace saturated fat....If *trans* fatty acids are not considered, consumers who make food choices on the basis of saturated fat content with the intention of reducing their risk of CHD [coronary heart disease] may be misled by the declared %DV [for saturated fat]....FDA will consider amending its approach if the public health and scientific organizations that are the source

¹ 64 Fed. Reg. 62746 (November 17, 1999).

² Letter Report on Dietary Reference Intakes for *Trans* Fatty Acids (Food and Nutrition Board of Institute of Medicine, July 10, 2002) (IOM Report) at 14.

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of current dietary recommendations arrive at different conclusions.”³

The IOM’s July 2002 report, which concluded that *trans* fat are at least as harmful to health as saturated fat, supports the FDA’s 1999 conclusion.⁴ People making food choices on the basis of the %DV for saturated fat could be misled, because that %DV ignores the presence of *trans* fat. Listing only the amount of *trans* fat is only marginally useful, because consumers would have no idea of the significance of that amount compared to the amount of saturated fat in a serving of food. Nor would consumers know whether the amount of *trans* fat in a serving of food is a small, moderate, or large amount. Nor would consumers know how the total amount of saturated plus *trans* fat compares to the amount they should limit themselves to in a day.

To understand better Americans’ attitudes about *trans*-fat labeling, earlier this month CSPI commissioned TNS Intersearch, which is headquartered in Horsham, Pennsylvania, to conduct a nationally representative survey of more than 600 consumers (see attachment A). The results of the survey indicate that many consumers want to follow the IOM’s recommendation and that they support the FDA’s 1999 proposal to include *trans* fat in the %DV for saturated fat.

* 81 percent said that food labels should list *trans* fat in addition to saturated fat.

* When asked whether four grams of *trans* fat per serving was a small, moderate, or large amount of what one should eat in a day or whether they didn’t know, 70 percent said they did not know. Only 15 percent answered correctly that 4 grams is a large amount, with 7 percent answering “small” and 8 percent answering “moderate.” That indicates the importance of providing *trans* fat information in a way that enables consumers “to understand its relative significance in the context of a total daily diet.”⁵

* 79 percent said that the label should indicate the percentage of a maximum daily intake of *trans* fat a serving of that food supplies.

While we would not expect the FDA to rely solely on our survey when deciding how *trans* fat should be labeled, we do think that our survey provides critically important information and demonstrates the near-worthlessness of listing the number of grams of *trans* fat per serving without a %DV. If the FDA – prior to issuing its final rule – believes it would be worth assessing consumer understanding of different label formats, the FDA should supplement our survey with its own consumer research to ascertain what label information would be most helpful to

³ 64 Fed. Reg. at 62756-62757.

⁴ IOM Report at 14. The IOM did not propose a UL for *trans* fatty acid intake because the suggested level of zero would imply such an extraordinary change in patterns of dietary intake that there might be unknown and unquantifiable health risks. *Id.*

⁵ 21 U.S.C. section 343, note.

consumers who want to follow the IOM's recommendation.⁶

In particular, we think a labeling format similar to that proposed by Canada – that is, displaying the amounts of saturated fat and *trans* fat separately, but including both in one %DV – is a useful approach to consider in light of the IOM report (see attachment B). We urge that it be adopted. At the very least, it should be one of the alternatives considered by the FDA if it conducts its own consumer research. We believe that format would best inform consumers. In addition, it would help harmonize the United States' nutrition labeling regulations with those of Canada.

The Canadian approach makes sense for several reasons.⁷ If the number of grams of *trans* fat per serving were listed without any contextual information, such as a %DV, the great majority of consumers, as our survey showed, would not know what to make of that information. The IOM concluded that a Tolerable Upper Intake Level (UL) for *trans* fat should be zero and, therefore, that people should consume as little *trans* fat as possible.⁸ The IOM's conclusion makes it difficult for the FDA to set a separate DV for *trans* fat. However, *not* setting a DV for *trans* fat would fail to convey the IOM's conclusion that people should consume as little *trans* as possible. *That leaves the FDA with only one reasonable option, an option it recommended in 1999: The label should indicate the percentage of the saturated-fat DV (20 grams) supplied by the sum of the saturated and trans fats in a serving of the food.* (Even if the FDA could and did set a separate DV for *trans* fat, consumers still would not be well served, because they would have to add up the %DVs for saturated fat and *trans* fat to determine the total percentage of a day's recommended limit of artery-clogging fat in servings of different foods. What's more, the label would not enable them to compare the merits of a food that contained more *trans* fat, but less saturated fat, than another food.)

One option that is clearly unacceptable is merely listing the number of grams of *trans* fat on the Nutrition Facts label. Some may argue that if just the number of grams of *trans* fat were listed on labels, consumers could simply look for the lowest number of grams when comparing different products. Yet the FDA has no effective means of teaching consumers that *trans* fat is something to be avoided. Furthermore, consumers who want to minimize their *trans*-fat intake may mistakenly believe that they are doing so by choosing foods that contain only one to four

⁶ The IOM's recommendation to minimize consumption of *trans* fat did not recommend how the FDA should amend its labeling regulations so as to communicate to consumers its recommendation.

⁷ See CSPI's April 17, 2000, comments on FDA's Nov. 17, 1999, and February 16, 2000, *Federal Register* notices for a more complete discussion of different label formats.

⁸ The IOM committee said that there are no data available to indicate a health benefit from consuming *trans* fat and so it could not establish an Adequate Intake, Estimated Average Requirement, or Recommended Dietary Allowance.

grams of *trans* fat per serving. Such quantities appear small, but are actually associated with a significant increased risk of heart disease.⁹ For example, many consumers might see that a serving of Oreos has two grams of *trans* fat and simply assume that the quantity is too small to worry about.

In addition, because the food with the least amount of *trans* fat may contain more saturated fat than competing brands, consumers would have to understand that saturated and *trans* fats are roughly equally harmful to arteries and then add up the number of grams of those two types of fat before deciding which product to buy. For instance, a consumer who sees a package of Mrs. Smith's Apple Pie would not know whether its 3 1/2 grams of saturated fat and 4 grams of *trans* fat is worse or better than a package of Entenmann's All Butter Coffee Cake, which has 5 grams of saturated fat and no *trans*. The pie is better for saturated fat, while the coffee cake is better for *trans*. The only way a consumer would know that the coffee cake is a better choice is to compare its 5 grams of saturated fat to the 7 1/2 of saturated-plus-*trans* fat in the pie. Yet the label being suggested by the FDA would provide no clue that consumers should add saturated and *trans* fat to compare one product to another. (See attachment C, *Nutrition Action Healthletter*, "Trans Fat: Still Under Cover," July-August 2002, pages 9-11.) The confusion that would result from displaying only grams of *trans* fat without including that amount in the %DV for saturated fat goes against the letter and spirit of the NLEA, the goal of which was to provide clear, informative labels for busy shoppers – rather than require shoppers to become nutritionists and mathematicians. The obvious solution is a Nutrition Facts label based on the Canadian proposal.

Merely listing grams of *trans* fat would not be acceptable as a legal matter. In an announcement concerning the IOM report, FDA stated that the report:

did not provide a Daily Reference Intake value for *trans* fat that would be needed to assist the agency in providing other information on the label, such as a Daily Value for *trans* fat. Therefore, FDA intends to scale back its proposal and take a more incremental approach to provide for *trans* fat labeling that is consistent with the available science.¹⁰

The "available science," however, makes it clear that people should consume as little *trans* fat as possible. FDA's new "scaled back" approach ignores that science by failing to give consumers any guidance about minimizing *trans*-fat intake. Such labeling would violate the Nutrition Labeling and Education Act of 1990 (NLEA). Section 2(b)(1)(A) of the NLEA provides that regulations issued by the FDA "shall require the required [nutrition] information to

⁹ Hu FB, Stampfer MJ, Manson JE, Rimm E, Colditz GA, Rosner BA, Hennekens CH, Willett WC. Dietary fat intake and the risk of coronary heart disease in women. *N Engl J Med* 1997; 337(21):1491-9.

¹⁰ Statement of the U.S. Food and Drug Administration, National Academy of Sciences, Institute of Medicine, Letter Report on *Trans* Fatty Acids: FDA's Next Steps, July 10, 2002.

be conveyed to the public in a manner which enables the public to readily observe and comprehend such information and *to understand its relative significance in the context of a total daily diet.*¹¹ [Emphasis added].

The legislative history of the NLEA explains that the FDA:

may choose among a variety of options. For example, one way that this could be accomplished would be to include information about the recommended daily intake on the label. This could include the use of descriptive terms such as “high,” “medium,” and “low” or use of universal symbols to indicate desirable or undesirable levels of particular nutrients. *While the bill does not mandate any particular approach, it does require the Secretary to specify requirements that would permit the consumer to understand the nutrition information pertaining to a particular food in relation to recommended dietary information.*” [Emphasis added].¹²

Given this requirement, and the public health risk posed by consuming *trans* fat as identified by the IOM, simply omitting a DV for *trans* fat is not a legally permissible option. We are aware that the FDA stated in its announcement concerning issuance of the IOM report that:

similar to declarations for mono- and polyunsaturated fats, no % Daily Value will be listed on the label.¹³

However, labeling of mono- and polyunsaturated fats is generally voluntary, not mandatory.¹⁴ The labeling of those fats is voluntary because the FDA concluded that:

These fat do not meet the criteria for mandatory declaration set forth in the mandatory nutrition labeling proposal [citations omitted] that the nutrient or food component be of

¹¹ 21 U.S.C. section 343 note. It is reasonable to presume that Congress expected this requirement to be met both for the original nutrients specified in the statute, as well as new nutrients to be added to the label. The legislative history of the NLEA states that Section 403(q)(2) of the act gives the agency “the ability to require that the nutrition label of foods be consistent with new research and other information.” H.R. Report 101-538, 101st Cong., 2d Sess. (1990) at 14.

¹² H.R. Report 101-538, 101st Cong., 2d Sess. (1990) at 18.

¹³ *Supra*, n. 8

¹⁴ The only time a manufacturer must disclose mono- or polyunsaturated fat content is when a nutrition claim is made. In such cases, the amount of mono and polyunsaturated fats per serving must be declared, 21 C.F.R. section 101.9(c)(2)(ii)(iii) in order to prevent consumer deception, but no DV is required for the reasons set forth above.

particular public health significance and that quantitative intake recommendations for the nutrient be given in major scientific consensus reports.¹⁵

Thus, the situation that the agency confronted in deciding whether to establish a Daily Value for mono- and polyunsaturated fats is quite different from the instant case. Unlike mono and polyunsaturated fats, the FDA is proposing to make *trans* fatty acid labeling mandatory – and for good reason, given the findings in the IOM consensus report that *trans* fat consumption should be as low as possible within the confines of a nutritionally adequate diet. In this situation, the FDA must require that the amount of *trans* fat in a portion of a food be disclosed in a manner that will allow consumers to understand its relative significance in the context of a total daily diet.¹⁶

Issuing a final nutrition labeling regulation for *trans* fat without complying with this statutory requirement would violate the Administrative Procedure Act because it would constitute final agency action that is arbitrary, capricious, an abuse of discretion and “not in accordance with law.”¹⁷ If the FDA cannot determine a DV for *trans* fat, then it must devise some other labeling mechanism to enable the public to understand the relative significance of the amount of *trans* fat in a portion of a food in the context of a total daily diet. We have suggested such a mechanism here.

As we have noted, both the FDA in 1999 and the IOM in 2002 found that the effects of *trans* fat and saturated fats on low-density lipoprotein (LDL) cholesterol are similar even though they are chemically different. The FDA focused on physiologic effects rather than chemical equivalency when in 1993 it barred *trans* fat from being included with labeled monounsaturated

¹⁵ 58 Fed. Reg. 2079, 2092 (January 6, 1993). The FDA’s statement here specifically referred to polyunsaturated fats. However, in conjunction with that statement, the FDA later noted on the same page of the *Federal Register* that the “declaration of “both poly- and mono-unsaturated is voluntary.” The agency’s statement cited in the text above can thus reasonably be construed to apply to both mono- and polyunsaturated fats.

¹⁶ We note that in 1993, the FDA also did not mandate that a DV for protein be declared on the label (except if a nutrition claim is made) and did not establish a DV for sugars. The FDA stated at the time that it was not necessary to establish a DV for protein because that nutrient was not of significant public health concern, 58 Fed. Reg. 2079, 2102 (1993). The case with *trans* fats is obviously very different. Similarly in 1993, the agency did not establish a DV for sugars. That policy is reasonable as long as added and naturally occurring sugars are combined. CSPI has since petitioned the agency to establish a DV for added sugars and list the number of grams of added sugars and the %DV in all Nutrition Facts labels. Our arguments for requiring a DV are set out fully in that petition.

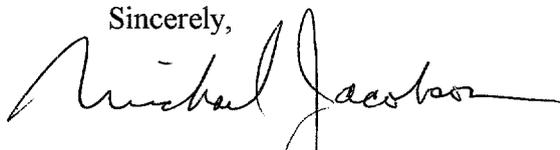
¹⁷ 5. U.S.C. section 706 (2)(A).

fats – even though they are all monounsaturated – because of their cholesterol-raising potential.¹⁸ The FDA should now extend this logic by including *trans* fat in the %DV for saturated fat.

We lastly note that in response to the IOM's report, the FDA announced last month that it "hopes to publish the final [*trans* fat] rule early in 2003."¹⁹ This final rule apparently will not amend the FDA's regulations to cover nutrition and health claims involving *trans* fat content, as it proposed to do in 1999. As demonstrated in our original petition, and by comments on the administrative record, such claims may be misleading. In light of the recent IOM report, which found that no level of *trans* fat can be considered safe to consume, we urge the FDA to finalize the portion of its 1999 proposal dealing with nutrition and health claims as soon as possible.

Thank you for considering our views on this important public health matter. We trust that it can be satisfactorily and promptly resolved by issuance of a final rule specifying the format we have suggested (there would be no need to request public comments, because the recommended label format is similar to what the FDA has already described in the *Federal Register* and proposed).

Sincerely,



Michael F. Jacobson, Ph.D.
Executive Director



Bruce Silverglade
Director of Legal Affairs

cc: Joseph A. Levitt, Director, Center for Food Safety and Applied Nutrition
Daniel E. Troy, Chief Counsel
Bill Hubbard, Office of Policy, Planning and Legislation
Christine Lewis Taylor, Director, Office of Nutritional Products, Labeling and Dietary Supplements

Attachments

¹⁸ 58 Fed. Reg. 2092 (January 6, 1993).

¹⁹ *Supra*, n. 8.

EXPRESS

TNS Intersearch - CSPI Survey on Trans Fat in Food
 August 12, 2002
 EX-19226

fat1. There's a kind of fat in foods like french fries, crackers, and margarine that causes heart disease. It's called trans fat, and most medical experts agree that it's as bad for your heart as saturated fat. Food packages have to tell you how much saturated fat is in a serving of the food. But they don't tell you how much trans fat the food contains. Should food labels have to list trans fat in addition to saturated fat?

Base: Total Sampled Respondents ** Express Week 32 **

	Sex		Age										Income				Region				Race				Internet																			
			18-34		35-44		45-54		55-64		65+		<\$25k		\$25k- \$35k		\$35k- \$50k		\$50k+		North- west		Mid- east		South west		White		Black		Other		Yes		No									
	(A)	(B)	(C)	(D)	(E)	(F)	(G)	(H)	(I)	(J)	(K)	(L)	(M)	(N)	(O)	(P)	(Q)	(R)	(S)	(T)	(U)	(V)	(W)	(X)	(Y)	(Z)	(AA)	(AB)	(AC)	(AD)	(AE)	(AF)	(AG)	(AH)										
Total Unweighted	616	302	314	181	103	125	96	102	112	94	106	110	58	107	149	206	154	473	49	77	416	200	100	100	100	100	100	100	100	100	100	100	100	100	100	100								
Total Weighted	615	296	319	190	105*	141*	95*	79*	97*	95*	114*	109*	69*	98*	148	215	154	496	47*	59*	418	196	100	100	100	100	100	100	100	100	100	100	100	100	100	100	100							
Yes	501	229	271	151	89	113	80	62	79	80	101	91	45	83	123	176	120	408	38	49	340	160	81.4	77.5	85.0B	79.8	85.0	80.2	84.5	78.4	81.2m	83.8M	88.7M	83.3M	64.7	84.5	82.9	81.6	77.8	82.2	79.6	83.7	81.3	81.7
No	92	53	38	37	13	20	10	11	10	12	13	15	24	13	19	37	23	69	10	8	64	28	14.9	18.0c	12.0	19.7	12.8	14.1	11.0	13.6	10.4	12.5	11.3	14.1	34.7I	13.1	12.7	17.1	15.2	13.9	20.4	14.2	15.3	14.0
Don't know	16	7	9	1	2	2	4	6	4	3	-	2	*	2	5	3	7	13	-	1	9	7	2.7	2.3	3.0	0.5	2.2	1.3	4.5D	8.1DeF	4.1k	3.6k	-	2.0	0.6	1.7	3.6	1.3	4.3	2.7	-	2.1	2.2	3.6
Refused	6	6	-	-	-	6	-	-	4	-	-	1	-	1	-	1	-	4	6	-	-	5	1	1.0	2.1C	-	-	4.4D	degh	-	4.2jk	-	0.6	-	0.7	0.9	-	2.7P	1.2	-	-	1.1	0.7	

Proportions/Mean: Columns Tested (5%, 10% risk level) - B/C - D/E/F/G/H - I/J/K/L/M - N/O/P/Q - R/S/T - U/V
 * small base

Appendix to TNS Intersearch Survey

An initial pilot survey used different language in one (the third) question – notwithstanding advice from the survey-research firm that the question was extremely complicated for a telephone survey. The pilot third question asked:

Labels now list the amount of saturated fat in a serving of food as a percent of the ‘Daily Value.’ For example, a food with 10 grams of saturated fat provides 50 percent of the Daily Value, that is, half as much saturated fat as you should consume in a day. Do you think that the amount of *trans* fat (a) should be added to the amount of saturated fat so that the percentage of the Daily Value includes all fats that might promote heart disease, or (b) should the number of grams of *trans* fat be listed separately from saturated fat without any indication of how that amount fits into a daily diet?

That question found that about equal percentages of people (43% +/- 2%, with a sampling error of +/-4%) supported each of the two choices. Fifteen percent said they didn’t know or refused to answer. Suspecting that many respondents were confused by the complicated question and response choices, CSPI then commissioned the final survey with a briefer, clearer third question, with the results indicated in the previous pages (responses to the first two questions were virtually identical to those in the pilot survey).