Food Labeling in the United States

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Director, International Trade
Grocery Manufacturers of America

GMA Member Companies

archway Home Style Cookies

Dreyer's

Heinz

Cadbury Schweppes

Kellogg's

HERSHEY'S

Procter&Gamble

KRAFT

ANHEUSER-BUSCH

Bristol-Myers Squibb Company
A global health and personal care company

The Coca-Cola Company

QUAKER

Coors

Heinz

COLEMAN NATURAL PRODUCTS

vlasic

SC Johnson

3M

PEPSICO INC.

DIAMOND OF CALIFORNIA

Hormel

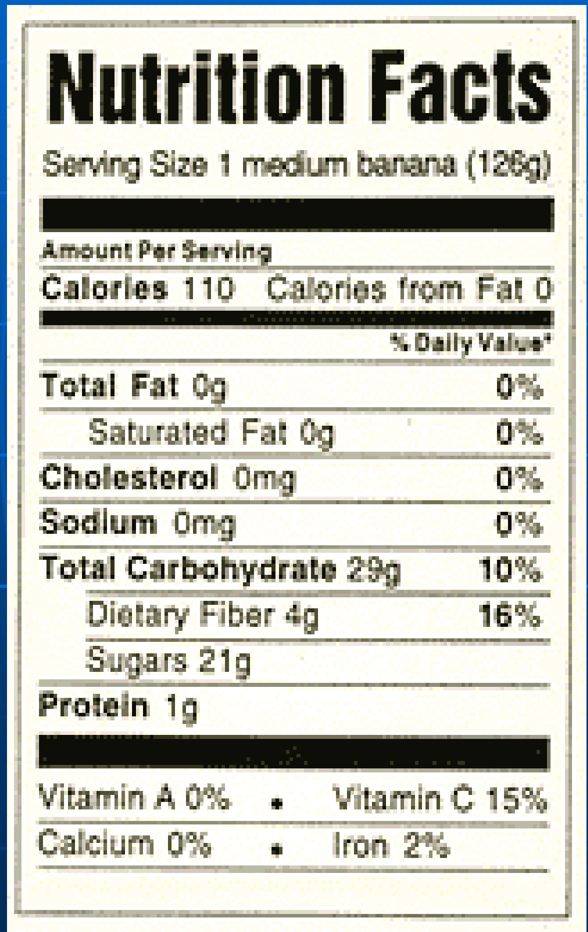
GMA

AJINOMOTO

Introduction

- Consumers receive information from a variety of sources
- Manufacturers are committed to providing truthful non-misleading information about their products
- Label is not always best means to communicate with consumers

Labels and Food Products: Manufacturers View



Nutrition Facts

Serving Size 1 medium banana (126g)

Amount Per Serving

Calories 110 Calories from Fat 0

	% Daily Value*
Total Fat 0g	0%
Saturated Fat 0g	0%
Cholesterol 0mg	0%
Sodium 0mg	0%
Total Carbohydrate 29g	10%
Dietary Fiber 4g	16%
Sugars 21g	
Protein 1g	

Vitamin A 0% • Vitamin C 15%

Calcium 0% • Iron 2%

Mandatory requirements

- Should be used to convey essential information related to product attributes such as:
  - Health (nutrition)
  - Safety (allergens)
  - Quality (brands)
- Sacred space
  - Mandatory requirements must be reserved for legitimate goals

Example: Food Labeling of Trans Fats

November 1999 – Proposed rule for trans fat labeling

September 2002 – Dietary Reference Intake report on macronutrients—NAS/IOM

- Link between trans fats and heart disease
- Recommendation to keep consumption "as low as possible" with caveats

November 2002– Reopening of the comment period

Federal Register / Vol. 67, No. 221 / Friday, November 15, 2002 / Proposed Rules 69171

attorney fees, costs of the lawsuit and (in the court's discretion) punitive damages.

(b) We will not file a civil action against your employer before we terminate collection action against you, unless earlier filing is necessary to avoid expiration of any applicable statute of limitations period. For purposes of this section, "terminate collection action" means that we have terminated collection action in accordance with the Federal Claims Collection Standards (31 CFR 903.3) or other applicable standards. In any event, we will consider that collection action has been terminated if we have not received any payments to satisfy the debt for a period of one year.

[FR Doc. 02–28856 Filed 11–14–02; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 101

[Docket No. 94P–0036]

RIN 0910–AB66

Food Labeling: Trans Fatty Acids in Nutrition Labeling, Nutrient Content Claims, and Health Claims; Reopening of the Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening to December 16, 2002, the comment period for a proposed rule published in the **Federal Register** of November 17, 1999 (64 FR 62746), in which FDA proposed to amend its regulations on nutrition labeling to include the amount of trans fatty acids present in a food in the amount and percent Daily Value declared for saturated fatty acids. Since publication of the proposed rule, the National Academy of Sciences issued a report entitled "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids" that did not provide a dietary reference intake value for *trans* fat. In response to this report, FDA intends to take a more incremental approach and provide for mandatory declaration of *trans* fat content on a separate line within the Nutrition Facts panel. FDA is reopening the comment period to receive comment on a footnote statement that it is proposing be required on the label when *trans* fat is listed. Lastly, FDA is outlining conditions for when it would consider exercising enforcement discretion for manufacturers who wish to begin labeling the *trans* fat content of food products prior to publication of a final rule.

DATES: Submit written or electronic comments on the proposed footnote by December 16, 2002.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Joyce Saltsman, Center for Food Safety and Applied Nutrition (HFS–306), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1641.

SUPPLEMENTARY INFORMATION:

I. Reopening of Comment Period

In the **Federal Register** of November 17, 1999 (64 FR 62746) (the November 1999 proposal), FDA (we) proposed to amend our regulations on nutrition labeling to require that the amount of trans fatty acids (*trans* fats) present in a food, including dietary supplements, be included in the amount and percent of Daily Value (% DV) declared for saturated fatty acids. We also proposed that, wherever saturated fat limits are placed on nutrient content claims, health claims, or disclosure or disqualifying levels, the amount of *trans* fatty acids be limited as well. Finally, we proposed to define the nutrient content claim "*trans* fat free." In that document, we requested comments on the proposal by February 15, 2000. In the **Federal Register** of February 16, 2000 (65 FR 7806), we reopened the comment period to April 17, 2000, in response to requests for more time to submit comments. In the **Federal Register** of December 5, 2000 (65 FR 75887), we again reopened the comment period to January 19, 2001, in response to comments regarding nutrient content claims.

Subsequent to FDA's November 1999 proposal, the Institute of Medicine of the National Academy of Sciences (IOM/NAS) issued a report entitled "Dietary Reference Intakes for Energy, Carbohydrate, Fiber, Fat, Fatty Acids, Cholesterol, Protein and Amino Acids" (the IOM/NAS macronutrient report) and found "a positive linear trend" between *trans* fatty acid intake and total and low density lipoprotein-cholesterol (LDL–C) concentration, and therefore increased risk of coronary heart disease (Ref. 1).

The report summarized that the scientific evidence would suggest a tolerable upper intake level (UL) of zero, but because *trans* fats are unavoidable in ordinary diets and achieving such a UL would require extraordinary changes in dietary intake patterns that might introduce other undesirable effects and unknown health risks, a UL was not proposed. Instead, the report recommended "that *trans* fat consumption be as low as possible while consuming a nutritionally adequate diet." Likewise, the conclusions in the Dietary Guidelines for Americans, 2000 (Ref. 2) and recent guidelines from the National Cholesterol Education Program (NCEP) (Ref. 3) are similar with recommendations to limit *trans* fat intake in the diet.

The IOM/NAS report (Ref. 1) underscores the relationship between the intake of *trans* fat and the increased risk for heart disease and emphasizes that consumers need to limit *trans* fat in their diets. FDA recognizes that, to accomplish this, information on the *trans* fat content of foods needs to be available on food labels. But the IOM/NAS report did not provide a dietary reference intake (DRI) value for *trans* fat or information that the agency believes is sufficient to support its establishing a daily reference value (DRV) to assist the agency in providing other information on the label, such as a % DV for *trans* fat.

Comments to the November 1999 proposal stressed the importance of helping consumers understand the relevance of the quantitative amount of *trans* fat in relation to recommended dietary intake patterns. In addition, Section 2(b) of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) (Public Law 101–535) states that the Secretary of Health and Human Services, and by delegation FDA, shall require the declaration of nutrients "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." The % DV has been added to nutrition labeling for most nutrients to achieve this purpose. However, we do not have a basis on which to establish a DV for *trans* fat at this time. Therefore, in light of the public health recommendations to reduce *trans* fat intake in the American diet, FDA is proposing to require an asterisk (or other symbol) in the % DV column for *trans* fat when it is listed, that is tied to a similar symbol at the bottom of the Nutrition Facts box and

Example: Trans Fats

- FDA proposed change to nutrition facts label
- Addition of trans fat information
  - Asterisk added under % Daily Value for trans fats
  - Footnote saying "intake of trans fats should be as low as possible"

Question: How will consumers respond to the proposed footnote?

Consumer Study:
Butter vs. Margarine: Label Set 1

Spread A

Nutrition Facts

Serving Size 1 Tbsp (14 g)

Amount Per Serving

Calories 100 Calories from Fat 100

	%Daily Value *
Total Fat 11g	**17**%
Saturated Fat 7g	**36**%
Cholesterol 30mg	**10**%
Sodium 90mg	**4**%
Tot…	**0**%
Pro…	
Vit…	8%

*Per… …alorie
diet. … …r
depe…

14%

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less th an	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Spread B

Nutrition Facts

Serving Size 1 Tbsp (14 g)

Amount Per Serving

Calories 100 Calories from Fat 100

	%Daily Value *
Total Fat 11g	**17**%
Saturated Fat 2g	**11**%
Cholesterol 0mg	**0**%
Sodium 105mg	**4**%
Total C…	**0**%
Protein	
Vitamin …	10%

*Percent …
diet. Your …
depending …

86%

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Consumer Study:
Butter vs. Margarine: Label Set 2

Spread A

Nutrition Facts

Serving Size 1 Tbsp (14 g)

Amount Per Serving

Calories 100	Calories from Fat 100
	%Daily Value *
Total Fat 11g	**17**%
Saturated Fat 7g	**36**%
Trans Fat 0 g	
Cholesterol 30mg	**10**%
Sodium 90mg	**4**%
T	**0**%
P	
V	8%

*P...) calorie
di... wer
d...

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

53%

Spread B

Nutrition Facts

Serving Size 1 Tbsp (14 g)

Amount Per Serving

Calories 100	Calories from Fat 100
	%Daily Value *
Total Fat 11g	**17**%
Saturated Fat 2g	**11**%
Trans Fat 2g	
Cholesterol 0mg	**0**%
Sodium 105mg	**4**%
Total C	**0**%
Protein	
Vitamin	10%

*Percent ... e
diet. You
depending

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

47%

Consumer Study:
Butter vs. Margarine: Label Set 3

Spread A

Nutrition Facts

Serving Size 1 Tbsp (14 g)

Amount Per Serving

Calories 100	Calories from Fat 100
	%Daily Value **
Total Fat 11g	**17**%
Saturated Fat 7g	**36**%
Trans Fat 0g	*
Cholesterol 30mg	**10**%
Sodium 90mg	**4**%
Total Carbohydrate 0g	**0**%
Protein 0g	
Vitamin A	8%

* Intake of trans fat should be as low as possible

**Percent Daily Values are based on a 2000 calorie diet. Your daily values may be higher or lower dep

		500
Total Fat		g
Sat Fat		g
Cholester		0mg
Sodium		400mg
Total Car		5g
Dietary Fiber	25g	30g

70%

Spread B

Nutrition Facts

Serving Size 1 Tbsp (14 g)

Amount Per Serving

Calories 100	Calories from Fat 100
	%Daily Value **
Total Fat 11g	**17**%
Saturated Fat 2g	**11**%
Trans Fat 2g	*
Cholesterol 0mg	**0**%
Sodium 105mg	**4**%
Total Carbohydrate 0g	**0**%
Protein 0g	
Vitamin A	10%

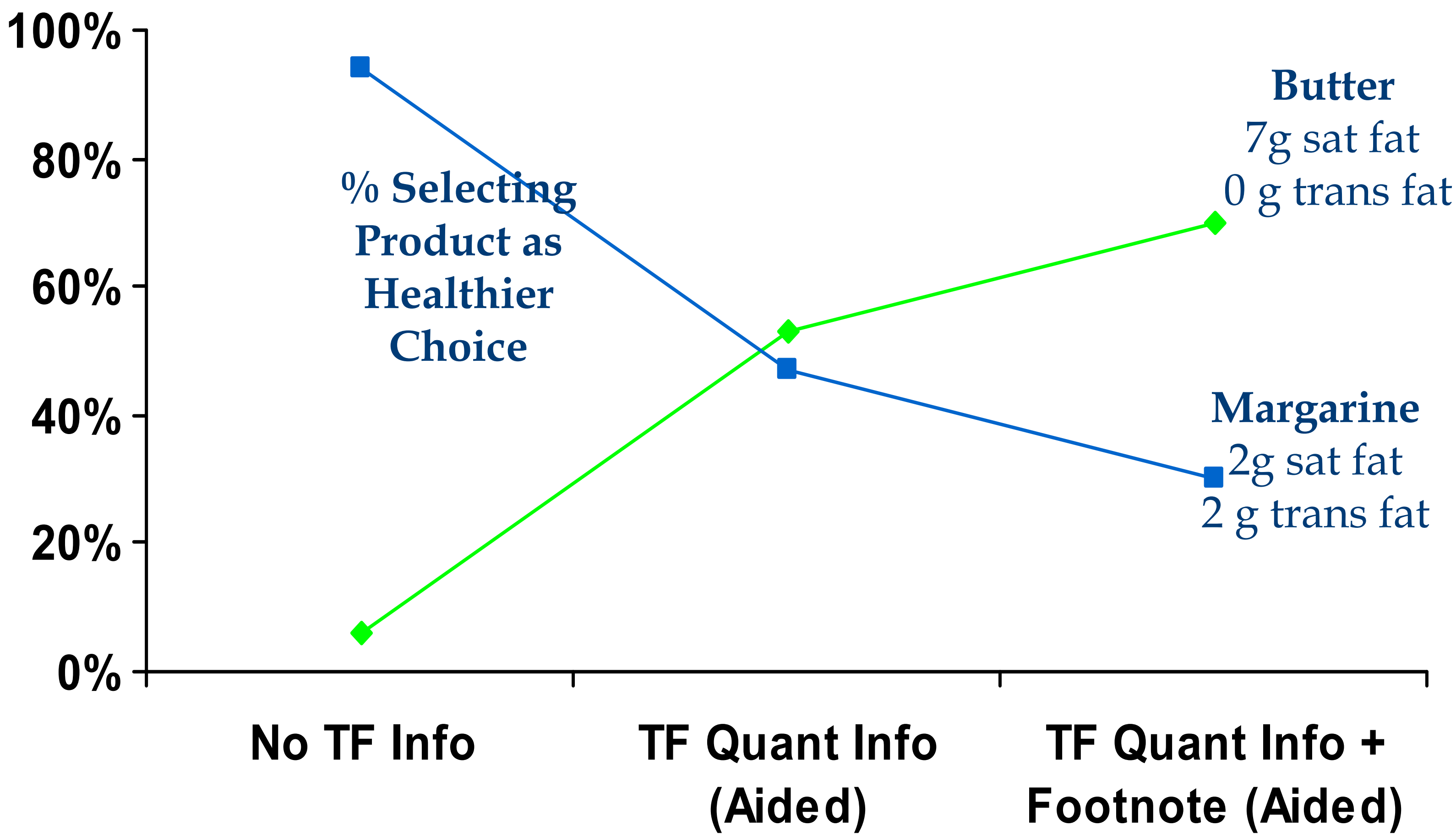
* Intake of trans fat should be as low as possible

**Percent Daily Values are based on a 2000 calorie diet. Your daily values may be higher or lower d

		2,500
Total F		80g
Sat F		25g
Cholest		300mg
Sodium		2,400mg
Total C		375g
Dietary Fiber	25g	30g

30%

Consumer Choices Due to Label Information



Trans Fat Result

Nutrition Facts

Serving Size 1 cup (228g)
Servings Per Container 2

Amount Per Serving

Calories 260	Calories from Fat 120
	% Daily Value*
Total Fat 13g	**20%**
Saturated Fat 5g	**25%**
Trans Fat 2g	
Cholesterol 30mg	**10%**
Sodium 660mg	**28%**
Total Carbohydrate 31g	**10%**
Dietary Fiber 0g	**0%**
Sugars 5g	
Protein 5g	

Vitamin A 4%	•	Vitamin C 2%
Calcium 15%	•	Iron 4%

* Percent Daily Values are based on a 2,000 calorie diet. Your Daily Values may be higher or lower depending on your calorie needs:

	Calories:	2,000	2,500
Total Fat	Less than	65g	80g
Sat Fat	Less than	20g	25g
Cholesterol	Less than	300mg	300mg
Sodium	Less than	2,400mg	2,400mg
Total Carbohydrate		300g	375g
Dietary Fiber		25g	30g

Calories per gram:
Fat 9 • Carbohydrate 4 • Protein 4

- FDA issued final rule requiring a quantitative declaration of trans fats in the information facts panel
- New ANPR for more broad footnote on all fats
- Industry continues to believe that the label is not the appropriate venue for dietary guidance

Example: Labeling of Biotech Products

Biotech Labeling: Market Environment

Activists Campaigns

National Media "Frankenfoods"

Consumer Concern

Demand for label to avoid biotech foods

Biotech Labeling: Consumer Impact

- Consumer right to know
  - Mandatory process based labeling
  - Perceived as a warning label
  - Inappropriate forum for risk communication
  - Restricts trade by discriminating against like products

Biotech Labeling: Manufacturing Impact

Changes in production

- Shift lines abroad for local production

Changes in product composition

- Reformulate products at significant cost
  - EC Ag Directorate Report
    - 6-17% Consumer Price Increase
    - 6-50% Agri-foodchain Cost Increase
  - GMA/KPMG Study
    - 5-10% Consumer Price Increase
    - 32-63% Agri-foodchain Cost Increase

Biotech Labeling: Trade Impact

- Discriminates against like products
- Significant impact on food and agriculture exports
- Alternative, less restrictive approaches available to meet goal

US Snack Food Exports to the EU

Codex and Biotech

Codex Committee on Food Labeling

- Work on guidelines for international harmonization of biotech labeling since 1993
- Deep divisions in group based on preference to replicate national laws
- Friends of the Chair Group to discuss how to proceed

codex alimentarius commission

Example: Organic Labeling

- Strong consumer demand but divergent standards
- 2002 Final Rule
  - Production, labeling and certification standards
  - Labeling standards based on percent of organic ingredients
    - 100 Percent Organic
    - "Made with Organic Ingredients"

Organic Standards: Consumer Response

- Voluntary Standards
  - Market based approach
  - Consumers who want particular qualities pay for those attributes
  - Allows for niche markets to develop
  - Allows for future harmonization of voluntary standards and less trade disruption

Voluntary Organic Standards: Market Impact

- **Significant US growth**
  - U.S. sales in 2001: $9.5 Billion
  - 10-20% growth rate
  - Available in 73% of conventional grocery stores
- **Major world markets growth:**

1997	2001
$11 Billion	$21 Billion

- **Substantial price premiums**

Conclusion

- Need to recognize that mandatory labeling requirements can lead to technical barriers to trade
- Every mandatory label has a cost to consumers and manufacturers. We need to balance benefits and costs and choose most appropriate policy to meet objectives.
- Need to emphasize good regulatory practices towards labeling policy