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GAO

Report to the Chairman, Subcommittee on Nutrition and Investigations, Committee on Agriculture, Nutrition, and Forestry, U.S. Senate

December 1994

NUTRITION LABELING

FDA and USDA Need a Coordinated Assessment of Food Label Accuracy

GAO/RCED-95-19

GAO

United States
General Accounting Office
Washington, D.C. 20548

Resources, Community, and
Economic Development Division

B-258079

December 29, 1994

The Honorable Tom Harkin
Chairman, Subcommittee on Nutrition
and Investigations
Committee on Agriculture, Nutrition,
and Forestry
United States Senate

Dear Mr. Chairman:

Scientific evidence demonstrating a direct relationship between nutrition and health increasingly has focused consumers' attention on the nutritional content of the foods they purchase. Responding to this interest, the food industry provided more nutrition information about its products. However, this information was at times inconsistent and misleading. To address public concerns and problems with food labels, the Congress enacted the Nutrition Labeling and Education Act of 1990 to provide consumers with accurate nutrition information on food labels.

The Food Safety and Inspection Service (FSIS) of the U.S. Department of Agriculture (USDA) is responsible for nutrition labels on meat and poultry products, and the Food and Drug Administration (FDA) in the Department of Health and Human Services is responsible for labels on all other food products. The agencies' regulations became effective on May 8, 1994. The Congress enacted a 3-month extension for certain products until August 8, 1994. The regulations require food companies to follow specific requirements relating to the labels' format, nutrient values, nutrient content claims, and health claims. Nutrient values are the amounts or quantities of specific nutrients, such as fat, protein, and sodium, contained in a serving—defined in the regulations as the amount customarily consumed. Nutrient content claims cover terms such as "light" and "low fat," and health claims characterize the relationship of a specific nutrient to a disease or health-related condition, such as sodium and high blood pressure.

You asked us to describe (1) what the new nutrition labeling regulations require food companies to do to develop accurate nutrient values for labels, (2) what enforcement steps FDA and FSIS are taking to help ensure the accuracy of nutrition information on food labels, and (3) what plans the agencies have for evaluating the overall effectiveness of their nutrition

labeling policies and procedures. You also asked that we provide suggestions for improvement on the basis of the observations we made.

Results in Brief

FDA's and FSIS' regulations clearly specify the level of accuracy necessary for the nutrient values provided on the new labels, but the agencies give companies a great deal of flexibility in how they develop the values.

To help ensure the accuracy of the nutrition information on food labels, the agencies will (1) perform laboratory analyses to independently verify the accuracy of the nutrition information on labels; (2) conduct visual reviews of labels to determine compliance with the requirements for format, nutrient content claims, and health claims; (3) work with companies to correct any inaccurate labels identified; and (4) where appropriate, pursue legal action against manufacturers of products with violative labels. However, the sheer number of nutrition labels—about 500,000—and the limited resources the agencies have at their disposal could limit the effectiveness of the enforcement steps the agencies are taking.

Plans by FDA to evaluate the effectiveness of its policies and procedures for nutrition labels include an assessment of industry's compliance obtained through a periodic statistical survey of food products and the nutrition information on their labels. FSIS does not plan to conduct such a statistical assessment because of resource constraints. Without a statistical approach for meat and poultry products, the federal government may not be able to evaluate the effectiveness of its nutrition labeling program for all nutrition labels in the marketplace.

Background

The 1990 act required FDA to issue new nutrition labeling regulations for all foods except meat and poultry products. Under FDA's regulations, food companies must provide more nutrition information in a uniform format on more food products than ever before. About 250,000 food product labels are under FDA's jurisdiction. Although the 1990 act did not apply to meat and poultry products, the Secretary of Agriculture decided to issue new nutrition labeling regulations for these products that are very similar to FDA's. About 247,000 labels come under FSIS' jurisdiction.

The new regulations require food companies to provide information for certain nutrients and to follow specific criteria when making a nutrient content claim or health claim on a food product's label. For example, for

most foods, the regulations require companies to provide information on the amount of 14 nutrients in a serving in a label's "Nutrition Facts" panel. (See app. I for an example of the new food label.) These "nutrient values" must appear in a uniform format for ease of comparison among food products. The nutrient values serve as the basis for a variety of nutrient content and health claims. (See app. II for examples of labels' nutrient content and health claims.) The regulations specify the general requirements for the use of these content and health claims.

The two agencies are also responsible for (1) reviewing food labels to determine industry's compliance with their nutrition labeling regulations and (2) monitoring overall program operations to identify problems and take corrective action.

Food Companies Have a Great Deal of Flexibility in Developing Nutrient Values for Labels

FDA's and FSIS' regulations give food companies a great deal of flexibility in choosing the procedures they use to develop the nutrient values reported on food labels. The agencies' regulations clearly specify the acceptable range for accuracy of the nutrient information provided on the new labels. The regulations also lay out the procedures and analytical methods the agencies will use to verify label information to determine compliance with the accuracy provisions of the regulations. However, the agencies' regulations do not require companies to use specific procedures to develop the nutrient values.

For FDA, the flexibility afforded food companies is a continuation of past practices. FDA officials told us that FDA never required food companies to use specified procedures to determine the nutrient values for labels under its prior nutrition labeling regulations.

For FSIS, however, not requiring food companies to use particular procedures is a change from past requirements. Before FSIS issued its nutrition labeling regulations in January 1993, it had required companies seeking approval for nutrition labels to conduct laboratory analyses of their products using FSIS-specified analytical methods and to submit analytical data that substantiated the nutrient values listed on the labels. In addition, to ensure that this nutritional information continued to be accurate over time, companies had to periodically submit the results of new laboratory analyses to FSIS. According to FSIS, it did not retain these requirements because the move from voluntary to mandatory nutrition labeling placed an additional burden on companies in terms of the number of products requiring nutrition information as well as the amount of

nutrient information required on individual labels. Because of this increased burden, the agency wanted to enable companies to develop nutrition information for labels in the most cost-effective manner possible. In addition, the agency believed that food companies should be responsible for the accuracy of the information on the labels.

FDA and FSIS Are Taking Steps to Ensure Accurate Nutrition Information on Labels, but Limitations Exist

FDA and FSIS are taking some steps—laboratory analysis of food products, visual reviews of product labels, and cooperation with food companies to get inaccurate labels corrected—aimed at ensuring that consumers get accurate nutrition information on food labels. However, the sheer number of nutrition labels—about 500,000—and the limited resources the agencies have at their disposal, coupled with FDA's lack of explicit authority to demand company records on how the nutrient values on labels were established could limit the effectiveness of the enforcement steps the agencies are taking.

Relatively Few Labels Will Be Verified by Laboratory Analyses

FDA and FSIS perform independent laboratory analyses of food products to verify the accuracy of nutrient values and related nutrient content or health claims on labels. However, because of limited resources, the agencies will only verify annually about 500 out of the 500,000 food labels for which they are responsible. FDA and FSIS officials indicated that while the number of products selected for laboratory verification is relatively small, these efforts play an important part in their enforcement strategy by demonstrating an agency presence to the industry.

In selecting foods for laboratory analysis, FDA will generally target food items that FDA inspectors believe, based on past experience, have labeling problems. This practice has the benefit of enabling FDA to efficiently use its limited laboratory resources to correct specific problem areas.

According to FDA officials, the agency plans to analyze up to 415 food samples annually for compliance with the nutrition labeling requirements. However, FDA may not achieve this number. Historically, the number of samples actually analyzed has fallen short of agency goals because of competing demands for laboratory resources for higher-priority programs such as medical foods[1] and infant formula. In addition, laboratory officials told us that existing laboratory resources could be strained because the types of analyses required to verify some of the information contained on

[1]A medical food is a specially formulated food that is used under medical supervision for dietary management of a medical disorder.

the new labels were more complex and time-consuming than previous analyses.

Initially, FDA plans to analyze only food products that have health claims or nutrient content claims that FDA inspectors believe are inaccurate. For these food products, FDA will analyze only the nutrients that are the basis for the questionable claims on labels. The agency will phase in more complete laboratory analyses for surveillance purposes.

FSIS has begun to select a limited number of food items for laboratory analysis. Unlike FDA, FSIS did not verify nutrient values through laboratory analyses before the new regulations were enacted. To conduct such analyses, FSIS launched its Nutrition Labeling Compliance Pilot Program in February 1994. Under this pilot program, FSIS selected about 40 food products for analysis by September 1994 in order to test and refine systems to collect, handle, and analyze samples and to report laboratory results. During fiscal year 1995, FSIS plans to verify nutrient values through laboratory analysis on about 100 food products. FSIS is limiting its analyses to 100 samples, according to agency officials, because of limited resources. Like FDA, FSIS intends to target its verification efforts at products with potential problems. FSIS plans to adjust its laboratory verification procedures in response to its first year's experience.

Visual Label Reviews Will Provide Some Accuracy Checks

While the accuracy of nutrient values reported on labels can be verified only through laboratory analysis, FDA and FSIS will make some limited accuracy checks on other information on labels as part of their reviews of labels. These reviews, which involve a visual check of all nutrition elements on labels, are intended to determine compliance with the rules for format, nutrient content claims, and health claims. However, the accuracy checks will be limited to certain types of errors, such as inconsistencies between nutrient values and related nutrient content claims made on the label. The reviews will not verify the accuracy of the nutrient values on the labels.

For example, FDA's regulations state that in order to make a "fat-free" claim, a product must contain less than 0.5 grams of fat per "reference amount customarily consumed." If a label shows that a product contains more than 0.5 grams—say 1 gram—of fat per reference amount customarily consumed and also makes a fat-free claim, a review of the label could indicate a problem with the label's accuracy. The reviewer would need to obtain additional information from the company or have the

food analyzed to determine whether the fat-free claim, the amount of fat, or both were in error.

FDA and FSIS differ in how they will conduct their reviews and in their authority to demand company records, such as data from laboratory analyses to support the nutrient values on labels. Since food companies subject to FDA's regulations are permitted to use food labels without obtaining FDA's prior approval, FDA's reviews of labels will occur after food products have already entered the marketplace. In performing their label reviews, FDA inspectors can request, but not require, companies to provide supporting documentation for nutrient values. According to an FDA official, food companies frequently refuse requests for supporting documentation because no provision of the Food, Drug, and Cosmetic Act explicitly grants FDA access to food production records, other than those records concerning infant formula. In recent years, legislation has been proposed to give FDA additional inspection authority, including the authority to inspect company records for enforcement purposes. However, none of the proposals have been enacted.

In August 1994, FDA initiated a major effort to identify food products that should have contained the new nutrition facts panel on their labels but did not. (See app. I.) In the effort, FDA employees visited retail grocery stores throughout the United States to identify companies that did not have the required nutrition facts panel on the labels of their food products. Then, FDA inspectors visited the plants of each of those companies to check whether the labels being placed on their food products had the required nutrition facts panel.

In contrast, FSIS requires meat and poultry companies to obtain approval of their labels before using them. FSIS headquarters staff review nutrition information as part of the agency's preapproval process for labels. These reviews are intended to determine compliance with requirements for format and nutrient content claims, not to determine whether the nutrient values are accurate. In performing these visual reviews, FSIS' staff rely on the unverified nutrient values that appear on the label. The staff do not have company data supporting the nutrient values nor the results of agency laboratory analyses available for use in reviewing the labels. While FSIS requires companies to have documentation supporting the nutrient values on labels at their processing plants, this information is not forwarded to headquarters staff for use in verifying the information on the labels. To aid in label reviews, FSIS has developed an automated system that compares nutrient content claims with the nutrient values appearing

on a label. This system enables staff to determine if the nutrient content claims are consistent with the regulations.

During fiscal year 1995, FDA plans to have its field inspectors review about 10,000 domestic food product labels and about 10,000 imported food product labels. FSIS expects to review about 100,000 meat and poultry product labels with nutrition information under its preapproval process.

Agencies Will Work With Companies to Correct Inaccuracies

Once label violations are detected, the agencies have indicated that, in general, they plan to work with food companies to correct inaccurate labels rather than impose sanctions in all cases.

For example, FDA does not intend to take compliance action against any product for which it determines the company made a "good faith" effort to appropriately provide nutrition labeling. Rather, FDA will work with companies cooperatively to effect the necessary changes. In FDA's experience, such cooperation usually brings about the desired result—that is, accurately labeled food products at lower resource expenditures.

FSIS has said that it is not its intent to proceed in a punitive manner against companies when problems surface during compliance monitoring. FSIS expects the company to locate the source of any discrepancy and rectify the problem, such as changing the values on the label and correcting the cause of the problem.

Both agencies have the authority to exercise a variety of sanctions for label violations. For example, FDA can (1) issue written warnings to violators, (2) seize products that violate the regulations, (3) seek a court injunction prohibiting a company from introducing an improperly labeled product into interstate commerce, and (4) seek criminal prosecutions and penalties. FSIS sanctions include (1) withholding permission to use the label, which in effect precludes further production of the product; (2) detaining the product in commerce; and (3) prosecuting the violator if the company intentionally misbranded the product.

Overall Evaluation of New Label Policies Is Not Planned

Both agencies plan to use information obtained from their enforcement activities—including laboratory verifications and label reviews—to monitor the industry's response to the new regulations. Such information, however, cannot be used to evaluate the overall effectiveness of the new

label policies because it cannot provide an assessment of the level of industry compliance with the new regulations.

Recognizing this, FDA plans to evaluate the overall effectiveness of its label requirements by assessing information obtained from both its (1) enforcement activities and (2) periodic survey of a statistical sample of food products, known as the Food Label and Package Survey.[2] In the 1995 cycle of this biennial survey, FDA plans to resume laboratory verifications of the nutrient values on labels for a statistically valid sample of products.[3] The sample of products collected and analyzed for this survey is separate and in addition to those targeted for the laboratory verification described earlier. According to FDA officials, any product sampled as part of the biennial survey that has an inaccurate label would be targeted for verification under the compliance sampling program. Only food products that are FDA's responsibility will be included in the survey.

In contrast, according to FSIS officials, resource constraints will prevent the agency from periodically assessing the overall accuracy of nutrition information on labels by analyzing a statistical sample of meat and poultry products. Without such statistical assessments, FSIS will not be able to evaluate the overall effectiveness of its policies and procedures.

Conclusions

The Nutrition Labeling and Education Act of 1990 is intended to provide consumers with uniform and accurate nutrition information about the foods they eat. The new nutrition labeling regulations provide the framework for more uniform and informative food labels. To help ensure the accuracy of the nutrition information on labels, the agencies will perform laboratory analyses of food products and visual reviews of food labels. However, relatively few labels will be verified by laboratory analyses, and the visual reviews will not verify the accuracy of the nutrient values. Because of these limitations and the flexibility afforded food companies in developing the nutrient values on labels, the accuracy of the nutrition information provided on about 500,000 labels will depend largely on the food industry.

[2]FDA conducts the Food Label and Package Survey to monitor the labeling practices of U.S. food manufacturers.

[3]FDA contracted for laboratory verification of nutrient values of a sample of 300 products in May 1994. However, because of methodological limitations in that analysis, FDA believes that the 1995 survey will provide the first assessment of industry compliance with the new regulations.

Because food companies have been obligated to label their products in accordance with the new nutrition labeling requirements only since August 8, 1994, it is too early to evaluate the agencies' policies and procedures to ensure the accuracy of the nutrition information on labels. Although FSIS will use information obtained from its enforcement program to evaluate the effectiveness of its policies and programs, unlike FDA, it does not plan to statistically assess the overall accuracy of the nutrition information on labels for meat and poultry products. Without such a statistical assessment of meat and poultry products, which account for about half of all labels, the federal government may not be able to evaluate the effectiveness of its nutrition labeling program for all products in the marketplace.

Recommendation

We recommend that the Secretary of Agriculture and the Secretary of Health and Human Services develop a coordinated evaluation strategy that will provide for an overall assessment of the accuracy of the nutrition information provided on all food labels.

Agency Comments and Our Evaluation

USDA and FDA provided written comments on a draft of this report; these comments are presented in appendixes III and IV, respectively. The agencies generally agreed with the report's findings, conclusions, and recommendation.

USDA said that it supports our recommendation and looks forward to working with FDA in developing an assessment strategy that will ensure the credibility of the nutrition information on all food labels.

FDA commented that it would coordinate with FSIS to the extent possible but added that given the resource constraints FDA and FSIS are experiencing, a coordinated effort may be difficult to achieve without undue delays to FDA's regulatory activities. We believe that a coordinated evaluation strategy will be more cost-effective to the federal government as a whole and may possibly save FDA resources if it can share certain evaluation costs with FSIS. FDA also made a number of specific technical comments on the draft. We made changes to the report to incorporate these comments where appropriate.

Scope and Methodology

To identify FDA's and FSIS' policies and procedures for ensuring that the nutrition information presented on the new food labels is accurate, we reviewed and analyzed the agencies' regulations, interviewed food labeling officials at the two agencies, and reviewed documentation provided by agency officials. We also visited FDA's Atlanta Center for Nutrient Analysis to observe and discuss the procedures the Center used to perform independent laboratory analysis of food products to verify the information on the labels.

To obtain industry's perspective on the matters included in our review, we contacted officials of the American Meat Institute and the National Food Processors Association.

We performed our work from January through September 1994 in accordance with generally accepted government auditing standards.

As arranged with your office, unless you publicly announce its content earlier, we plan no further distribution of this report until 7 days after the date of this letter. At that time, we will send copies of this report to the Secretary of Agriculture; the Secretary of Health and Human Services; the Director, Office of Management and Budget; and other interested parties. We will also make copies available to others upon request.

If you or your staff have any questions concerning the report, you can reach me on (202) 512-5138. Major contributors to this report are listed in appendix V.

Sincerely yours,

John W. Harman
Director, Food and
Agriculture Issues

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Abbreviations

FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
GAO	General Accounting Office
USDA	United States Department of Agriculture

Example of the New Food Label

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%**
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

Source: Food and Drug Administration.

Examples of Label Nutrient Content and Health Claims

The new nutrition labeling regulations, in the standard format, require companies to provide information on the amount of 14 nutrients in a serving in a label's "Nutrition Facts" panel. These nutrient values serve as the basis for a variety of nutrient content and health claims. The regulations specify the general requirements for the use of these content and health claims.

Nutrient content claims (1) expressly or implicitly characterize the level of a nutrient in a food product or (2) suggest that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices. The following are examples of nutrient content claims:

- Free of calories, cholesterol, fat, saturated fat, or sodium.
- Very low in sodium.
- Lean and extra lean in fat for meat, poultry, or seafood.
- High and good source of a beneficial nutrient.
- Reduced and less in calories, cholesterol, fat, saturated fat, or sodium.
- Light in calories, fat, or sodium.

Health claims characterize the relationship of a specific nutrient to a disease or health-related condition. The following are examples of health claims:

- A diet with enough calcium may reduce the risk of osteoporosis later in life.
- A diet low in total fat may reduce the risk of some cancers.
- A diet low in saturated fat and cholesterol and high in fruits, vegetables, and fiber-containing grain products may reduce coronary heart disease.
- A diet low in sodium may reduce the risk of high blood pressure.

Comments From the U.S. Department of Agriculture

DEPARTMENT OF AGRICULTURE
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20250

DEC 19 1994

Mr. John W. Harman
Director, Food and Agriculture Issues,
Resources, Community, and Economic
Development Division
U.S. General Accounting Office
Washington, DC 20548

Dear Mr. Harman:

Thank you for the opportunity to comment on your draft report RCED-95-19, NUTRITION LABELING: Federal Efforts to Ensure Accurate Information on Food Labels.

The U. S. Department of Agriculture (USDA) agrees with the General Accounting Office's (GAO) recommendation that USDA and the Department of Health and Human Services (HHS) develop a coordinated evaluation strategy to assess the accuracy of nutrition information on food labels. This recommendation is consistent with the emphasis that USDA and HHS placed on harmonization during the development and implementation of the nutrition labeling regulations. USDA is committed to continued coordination with HHS on matters related to nutrition labeling of foods.

The nutrition labeling regulations issued on January 6, 1993, were jointly developed by USDA and the Food and Drug Administration (FDA) to provide uniform nutrition information that will help consumers to make dietary selections for more healthful diets. Reliable information on food labels is essential to achieve this goal. The Department believes consumers will benefit if USDA and HHS develop a coordinated strategy to assess the accuracy of nutrition labeling information which ensures consistent and accurate information on all food labels. The regulations went into effect in August. Pilot sampling for label verification has started and samples are being analyzed by our laboratories. USDA will continue to explore, in conjunction with FDA, the feasibility of statistically assessing the overall effectiveness of its regulations and procedures.

USDA supports GAO's recommendation and looks forward to working closely with HHS in developing an assessment strategy that will ensure the credibility of nutrition information on all food labels.

Sincerely,

Michael R. Taylor
Acting Under Secretary
Food Safety

AN EQUAL OPPORTUNITY EMPLOYER

Comments From the Food and Drug Administration

Note: GAO comments supplementing those in the report text appear at the end of this appendix.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

DEC 0 6 1994

Mr. John Harman
Director, Food and Agriculture Issues
Resources, Community and Economic
Development Division
U. S. General Accounting Office
441 G Street, N.W.
Washington, D. C. 10548

Dear Mr. Harman:

Attached are FDA's comments on the draft report entitled: Nutrition Monitoring: Federal Efforts to Ensure Accurate Information on Food Labels.

Sincerely,

Dennis T. Strickland
Deputy Associate Commissioner
for Legislative Affairs

Enclosure

Comments of the U. S. Food and Drug Administration on the General Accounting Office (GAO) Draft Report: "NUTRITION LABELING: Federal Efforts to Ensure Accurate Information on Food Labels"

We have reviewed the report and have the following comments:

GAO RECOMMENDATION

We recommend that the Secretary of Agriculture and the Secretary of Health and Human Services develop a coordinated evaluation strategy that will provide for an overall assessment of the accuracy of nutrition information provided on all food labels.

HHS COMMENT

See comment

We concur. FDA will coordinate with FSIS to the extent possible. As the report states, FDA already has plans to evaluate the overall effectiveness of the labeling requirements. The agency has worked consistently with USDA throughout the food labeling initiative and would be interested in continuing to do so during the assessment phase of implementation. However, given resource constraints being experienced by FDA and FSIS, a coordinated effort may be difficult to achieve without undue delays to FDA's regulatory activities.

The following are GAO's comments on the letter from the Food and Drug Administration's (FDA) Deputy Associate Commissioner for Legislative Affairs dated December 6, 1994.

GAO's Comments

FDA agreed with our recommendation and stated that it would coordinate with FSIS to the extent possible. However, FDA cautioned that given the resource constraints both agencies are experiencing, a coordinated effort may be difficult to achieve without undue delays to the agency's regulatory activities. We believe that a coordinated evaluation strategy will be more cost-effective to the federal government as a whole and may possibly save FDA resources if it can share certain evaluation costs with FSIS.

Major Contributors to This Report

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