



**Food and Drug Administration Public Hearing
Food Labeling: Use of Symbols to Communicate Nutrition Information
September 10, 2007**

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Thank you for the opportunity to present the views of the American Heart Association (AHA) and the American Stroke Association (ASA). I am Dr. Rose Marie Robertson, Chief Science Officer of the American Heart Association.

AHA is the nation's largest voluntary health organization, with over 22.5 million volunteers and supporters. Since 1924, AHA has dedicated itself to reducing disability and death from cardiovascular disease and stroke – the #1 and #3 leading causes of death in the United States.

Let me first convey AHA's support for the Agency's efforts to improve public nutrition. In recent months, the FDA has examined a number of nutrition issues including the regulation of functional foods, the FDA review process for unqualified and qualified health claims, and now, this public hearing on nutrition symbols. All of these activities have a similar focus – how nutrition information is communicated to the public; and we are pleased with the Agency's decision to examine this issue. AHA supports the dissemination of scientifically valid and understandable nutrition information to the public; however, in order for this information to appropriately influence purchasing decisions, there is a need for coordinated and consistent consumer education. I am hopeful that this meeting will help us move in that direction.

My comments today will address four basic areas: the AHA Food Certification Program, consumer education activities, consumer research, and our recommendations for a standardized front-of-package food icon system with uniform criteria.

AHA Food Certification Program

As the public learns more about the relationship between diet and disease, many consumers are trying to adopt a healthier lifestyle and make better food choices. The Nutrition Facts Panel is one method consumers can use to evaluate foods; however, many consumers need and desire additional guidance that is readily available, at a quick glance on the front of food packages.

In recognition of this need, and the fact that FDA had insufficient resources to develop a suitable program at the time, AHA created its Food Certification Program in 1995 to provide consumers with a reliable, easy-to-use method to identify *heart-healthy* products.

2007N-0277

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Note that the heart-check mark (the “mark”) is not a general health promotion program; it specifically addresses heart disease prevention and uses a heart-shaped symbol, and therefore must operate under federal regulation. The mark allows consumers to identify products that meet AHA criteria for heart-healthy foods, which is the most popular diet choice among consumers,¹ and serves as a first step in building a sensible eating plan.

Participation in the AHA Food Certification Program is voluntary, and the program is revenue-neutral to the Association. Food products that meet AHA’s certification criteria are eligible for one of two certification marks, the standard certification and a whole-grain certification.

A wide array of food products are eligible for certification. We do not certify candies or confectionaries, or food products owned by tobacco companies. And we currently do not certify cooking oils. There are approximately 800 products currently certified and carrying the AHA mark. As you can appreciate, this represents a small portion of the products that consumers have to choose from every day and if such a program were mandatory, our ability to impact consumer purchasing behavior and the health of the country would be much broader. Because the AHA mark applies the same criteria to all foods across the board, it cannot reach as many products as an icon system that varies its criteria by product category.

The criteria for AHA’s standard certification program and AHA’s whole-grain products certification program are widely available to the public (See Attachment A). Products must be low in fat, cholesterol, and sodium, and must contain at least 10% of the daily value of vitamin A, vitamin C, iron, calcium, protein, or dietary fiber. Seafood, game meat, meat, and poultry must also meet the standards for “extra lean”. And whole-grain products must be at least 51% whole grain by weight and meet minimum dietary fiber content criteria. And as I mentioned previously, the criteria are not product-specific; all products must meet the same requirements and the criteria are non-negotiable.

For those of you familiar with the program, you’ll notice one small but significant change to our criteria. The standard certification now includes a trans fat criteria of less than 0.5 grams per RACC. As of January 1, 2008, all new products must meet this trans fat criteria in order to qualify for the mark. Existing products must be reformulated by December 31, 2008, to remain in the AHA program. Our whole-grain products certification has included a trans fat threshold since its inception.

AHA selected these certification criteria after careful consideration. The criteria align with select FDA A-level unqualified health claims related to the risk of coronary heart disease,² and are comprised of AHA’s nutrition recommendations.

To ensure that food products continue to meet our certification criteria after they are accepted into the program, AHA maintains a stringent monitoring and enforcement program. For example, AHA requires manufacturers to submit product packaging and promotional materials to

¹ Heart-healthy diets are favored by 52% of all shoppers. Shoppers also favor diets low in fat (38%) and diets high in fiber (38%). National Study of Public Attitudes and Actions Toward Shopping and Eating. HealthFocus International.

² 21 CFR101.75 – Dietary Saturated Fat and Cholesterol and Risk of Coronary Heart Disease.
Docket 03Q-0547 – Whole Grains with Moderate Fat Content and Risk of Coronary Heart Disease.

the Association for pre-approval; and products must renew each year to assure their formulations continue to meet our criteria. We also conduct annual grocery store audits in which certified products are randomly selected and tested by a contract laboratory to assure compliance with nutrient criteria. Tested products must meet the certification criteria and are not given any leeway such as the 20% variance that the FDA and USDA allow for values displayed on the Nutrition Facts Panel. AHA does not hesitate to enforce our criteria and order the removal of our mark from any product found not to be in compliance. If such action is taken, we monitor the products that have exited the program to ensure that they no longer display the mark. We also monitor in-store product promotional materials bearing the mark to ensure that they meet our standards.

AHA requires food products that meet the certification criteria to display the mark, in its entirety, on the food package. This includes the heart-check mark symbol, the AHA name, and the statement, “Meets American Heart Association food criteria for saturated fat and cholesterol in healthy people over age 2.” The whole grain certification program adds the term “whole grains”.

With the inclusion of this statement and the key criteria the product has been evaluated against – saturated fat, cholesterol, and in some cases, whole grains, the mark clearly tells consumers what the symbol means.

Consumer Education Activities

Consumer education is another significant component of AHA’s Food Certification Program. AHA communicates with consumers through editorial placements in newspapers, national television spots, in-store campaigns, and direct mail. 1.2 million households in 20 metro areas have been reached by direct mail alone. AHA also operates the heart check mark (heartcheckmark.org) website which contains easy-to-understand information about the food certification program, as well as an online grocery list builder and pop-up nutrition tips that help consumers with product selection. Additionally, we provide health care professionals with free “Pro Paks”, a simple tool they can use when counseling patients about their diets.

However, all of these educational activities are just a small part of a much broader consumer education campaign to promote better food choices. The heart-check mark provides us with an opportunity to encourage consumers to seek additional information on building a heart-healthy eating plan whether it is from the AHA website, our call center, or their health care provider.

Consumer Research

So far in my presentation I’ve described the AHA Food Certification Program and our related consumer education activities. But the most important question, at least for this hearing, is how do we know that the heart-check mark works? To answer that question, I will share some AHA proprietary research that was conducted for us by a reputable consumer research firm.

Through our research, we learned that the mark is a recognized and respected symbol. More than 90% of consumers are aware of the mark; 89% find it helpful for AHA to certify products and put our mark on food packaging; and 91% rate the program as good or excellent.

The research also found that consumers understand what the heart-check mark means. When shown the mark, 82% of respondents interpreted the mark to mean that the food product is heart

healthy or “good for my heart”; 60% understood that the product met certain criteria or requirements; and 55% responded that the product is “good or healthy for me.”

A significant number of respondents understood that the product is low in cholesterol (43%) and low in fat (37%) while only a small number of respondents attributed characteristics not indicated by the mark such as reduced or lower sugar content (12%). Consumers did not associate the mark with taste. Only 1% felt the mark conveyed that the food would taste good (1%). The research also found that consumers do not necessarily perceive products bearing the mark to be lower in calories, and understood that selecting products with the mark is just a first step, not the endpoint of a healthy eating plan.

Because our goal is to promote better food choices, we also looked at whether or not the mark influences consumers’ product selection. 92% of shoppers say it influences their decision to purchase a food; 45% are more likely to purchase a product with AHA’s mark than a product bearing a generic heart; and 26% are more likely to purchase a product with the mark than a product bearing a manufacturer’s nutrition symbol.

Consumers also reported finding the heart-check mark more useful when evaluating products (78%) than using manufacturer nutrition symbols (64%); and are significantly more likely to purchase a product bearing the mark than a product only bearing a manufacturer nutrition symbol. 68% of consumers believe that the heart-check mark is backed by very or somewhat strong research, compared to only 29% for manufacturer-run programs. The mark’s connection with strong research provides clear value to the consumer. If a consumer perceives the nutrition symbol is backed by research, they are more likely to purchase the product. However, we did find that a product bearing *any* nutrition symbol is more effective in influencing consumer purchases than a product that only bears a health claim or a generic heart, or that has no claim at all.

AHA also examined what effect the mark has on consumers’ perception of a product. We found that consumers are more likely to view a product, or an advertisement for a product bearing the mark, as healthier than a product without the mark, even if the products are otherwise identical. However, consumers are less likely to be affected by the heart-check mark on products that they already believe to be very healthy such as fruits and vegetables and more likely to be affected by the mark on products they initially perceive as “less healthy.”

Our focus is on helping consumers make better food choices, so one area that we have not conducted independent research on is the effect of the heart-check mark on product sales. However, food companies that participate in the program have reported that products that display the heart-check mark and do some type of promotion generally experience a 4 to over 20% growth in sales over the first 18 months. The manufacturer’s research also appears to confirm our own findings that products viewed as inherently healthy such as fresh produce are less affected by the heart-check mark (with a 4% increase in sales), than a product such as lean pork which consumers may initially view as less healthy (with a 40% increase in sales).

Again, the effect of the mark on product sales is not the focus and concern of AHA; however, anecdotal product sales data suggests that consumers are influenced by the mark.

Because the mark is a third-party nutrition symbol program, we do not have any additional information or data on the other areas of interest to the FDA, including product development or reformulation costs. However, we are proud of the fact that the program has encouraged a number of manufacturers to offer better food choices. Each year, AHA works with manufacturers on between 20 to 40 products that require formula modifications during the application process in order to qualify for the Food Certification Program. And, many more reformulate before applying for certification as we make our criteria available to them in advance. When you consider the impact the program has had in the 12 years it has been operating, AHA has also indirectly improved the nutrition quality of a significant number of products.

Recommendations

Before I conclude my presentation, I'd like to offer AHA's thoughts on the future of nutrition symbols on food labels. We firmly believe that icons or symbols can be a good method to communicate important nutrition information to consumers and encourage them to make better food choices. However, we are concerned that there are now at least 25 different icon systems in the marketplace and the criteria used to substantiate these systems varies dramatically across the systems, and over one-third of these systems do not publish their criteria.

AHA supports and encourages the FDA to establish a directed, standardized, comprehensive front-of-package food labeling program and icon system with unified criteria based upon the best available science, featuring consumer education as the ultimate goal (See Attachment B). The system should not be disease-specific, but generalized to the entire U.S. population, highlighting foods and nutrients that are "good for you" and those that should be avoided. All foods and beverages should be required to display the icon, with manufacturers responsible for specified testing and review necessary for use of the icon system.

There are a number of additional elements that have been critical to the success of AHA's program that we'd like to see in a standardized icon system. These elements include use of a self-explanatory nutrition symbol, consumer testing, a nutrition education campaign, and a robust enforcement and monitoring program that includes random sampling in the marketplace. Finally, the program should be evaluated every five years to ensure its standards are consistent with current Dietary Guidelines for Americans and the Dietary Reference Intakes.

Competing health-related icons are going to continue to proliferate until the FDA establishes a standardized, comprehensive system. Amid this growing confusion and until such time that the FDA takes this action, AHA will continue to make every effort to objectively inform and educate the consumer and to certify food products that comply with FDA A level unqualified health claim requirements in a manner that is transparent to the public.

In closing, I thank you again for the opportunity to present the views of AHA at this meeting and reiterate our support for the Agency's efforts to examine the use of nutrition symbols to communicate nutrition information to consumers. I would be happy to answer any questions you might have.

**American Heart Association
Food Certification Program**

Criteria for Certified Food Products

	Standard Certification Criteria	Whole-Grain Products Certification Criteria
Total Fat	3 g or less	Less than 6.5 g
Saturated Fat	1 g or less	1 g or less
Trans Fat	0.5 g or less ¹	0.5 g or less
Cholesterol	20 mg or less	20 mg or less
Sodium	480 mg or less	480 mg or less
“Jelly Bean” Rule²	Yes	Yes
Whole Grain	N/A	51% by weight/RACC ³
Minimum Dietary Fiber (from whole grain only)	N/A	1.7 g/RACC of 30 g 2.5 g/RACC of 45 g 2.8 g/RACC of 50 g 3.0 g/RACC of 55 g

Seafood, game meat, meat, and poultry must also meet the standards for “extra lean”.

¹ Trans Fat – The standard certification now includes a trans fat criteria of less than 0.5 grams per RACC. As of January 1, 2008, all new products must meet this trans fat criteria in order to qualify for the mark. Existing products must be reformulated by December 31, 2008, to remain in the AHA program. The whole-grain products certification has included a trans fat threshold since its inception.

² Jelly Bean Rule – A product must contain at least 10% of the daily value of vitamin A, vitamin C, iron, calcium, protein, or dietary fiber.

³ RACC – Reference Amount Customarily Consumed

Heart Disease and Stroke. You're the Cure.



Policy Position Statement Front-of-Package Food Icon Systems
July, 2007

Background:

Consumers, manufacturers, third party organizations such as the American Heart Association, and retailers realize the benefit of informing purchasers how to facilitate healthy purchasing by providing symbols and other messaging on the front of food packaging. In consequence, health-related icons have proliferated in the marketplace. Currently, there are at least 25 icon systems in the U.S. marketplace, with more emerging, and several in Europe, including the Swedish Green Keyhole System, the United Kingdom Nutrition Signpost Labeling, and the IKB Foundation “I Choose Consciously.”

There are 15 third-party organizations, retail outlets and manufacturers in the United States that publicize the criteria used by their systems. These criteria vary dramatically across the systems, while some do not specify any criteria at all. As a result, consumers are confused as to what these symbols mean and experts question whether the icons currently in use are of any value in helping people make healthy food choices at point-of-purchase.

Current Landscape:

In response to the plethora of symbols in the marketplace, Senator Tom Harkin (D-IA) recently included language in his HELP America Act (S. 1342) directing the Secretary of Health and Human Services to solicit public comments regarding whether American consumers would be better served by establishing a single, standardized, retail front-label food guidance system regulated by the Food and Drug Administration.

Additionally, the Keystone Center has convened a Food and Nutrition Roundtable to address nutrition labeling. This forum brings together leaders from government, industry, non-profit organizations and the research community to identify and apply comprehensive, science-based strategies to develop high value food labeling and nutrition education systems. The intent of this group is to publish recommendations for a food icon system by Fall 2007. The American Heart Association is participating in this roundtable. The Keystone Center is keeping Senator Harkin abreast of its work.

Finally, the Center for Science in the Public Interest (CSPI) has petitioned the FDA to develop a standardized system of symbols or at least guidance on a standard set of criteria.

AHA Position:

The American Heart Association created its Food Certification program because it recognized the value of this type of consumer education program in adopting heart-healthy dietary guidelines at the time and place that consumers make selection decisions and because the FDA had insufficient resources to develop a suitable program at the time. The public had made it clear that it desired this type of guidance from the AHA.

The American Heart Association favors establishment by the FDA of a directed, standardized, comprehensive front-of-package food labeling program and icon system with unified criteria based upon the best available science, featuring consumer education as the ultimate goal. Sufficient resources must be committed to the program. The system should be generalized to the entire U.S. population, (it should not be disease-specific) highlighting foods and nutrients that are “good for you” and those that should be avoided. All foods and beverages should be required to display the icon, with manufacturers responsible for specified testing and review necessary for use of the icon system. This process should be objective and specific, transparent, adaptable to accommodate a wide range of foods and beverages, easily understandable to the general public and financed in a fashion that eliminates even the hint of appearance of conflict of interest. The process for implementing such a system, monitoring and updating needs to be streamlined, timely, and efficient. The AHA is concerned that until such a comprehensive program is established by the FDA, competing health-related icons will continue to proliferate in the marketplace. Until such a comprehensive program is established by the FDA, the AHA will continue its current efforts to inform and educate the consumer and to certify food products that comply with FDA “A” level unqualified health claim requirements.

The FDA’s program should reference the Dietary Guidelines for Americans and the National Academy of Sciences Dietary Reference Intakes Reports. There should be an effective, tested, and proven accompanying nutrition education campaign focused on calories, saturated fat, trans fat, sodium, “nutrient quality per bite,” and portion control. Consumer testing should be conducted in advance of establishing any system to assure it will be relevant and useful to consumers. Importantly, the program must include appropriate and robust enforcement and monitoring, including components such as random sampling in the marketplace. There is also a need for additional research to determine the impact of icon systems on consumer behavior and healthful choices. Funding should be established where it does not already exist. Finally, the program should be evaluated every five years to ensure its standards are consistent with current Dietary Guidelines for Americans and the Dietary Reference Intakes and if not, the standards should be modified to comply.