No Two Twinkies Are Alike: Understanding the "Reasonable Basis" Requirement of Federal Menu Labeling

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Relevant Publications

- *FDA Answers Questions on When and How to Comply With New Restaurant Menu Labeling Law.* Aug. 2010.
- *State and Local Menu Labeling Laws Present Compliance Challenges.* Nov. 2009.
- *House Passes Nationwide Menu Labeling Legislation.* Nov. 2009.
- *California Enacts Nation's First Statewide Menu Labeling Law.* Feb. 2009.

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Jill Marchant holds the position of Associate General Counsel – Litigation & Employment for DineEquity, Inc., parent company for Applebee's Neighborhood Grill & Bar and IHOP Restaurants – a combined system of over 3500 units. Marchant reports to DineEquity's General Counsel and has enterprise-wide responsibility for managing the company's litigation and litigation related matters (attorney demands, third-party subpoenas, agency inquiries, and requests for information) as well as serving as legal advisor to senior management and human resources on litigation & employment law matters arising in restaurant operations and the company's two restaurant support centers – a workforce of over 30,000 employees at the height of company operations.* Marchant also oversees the docket of lawsuits and litigation-related matters in which company entities are named but which arise in franchised operations. Marchant takes an active role in litigation involving real estate, intellectual property, contracts, consumer protection, and employment matters in order to manage and reduce litigation expenses and to direct case strategy. Marchant is also legal advisor on matters relating to nutrition and menu-labeling and is the legal advisor to the company's crisis management, public relations, and guest relations teams. Marchant works closely with senior leaders on strategic business issues that have potential legal risks from a litigation or employment perspective. She also collaborates with senior and front line human resources managers to resolve day-to-day issues relating to performance management, employment practices & processes, and general employment policy. Marchant has conducted internal and public seminars for senior management and human resources professionals on various legal issues relating to labor relations and human resources management. Marchant is the co-founder of the REAL Network – Restaurant Employment Attorneys & Litigators – a network for in-house legal professionals who support litigation and/or employment functions in restaurants that offer sit-down dining.

Prior to joining the Applebee's business unit in January of 2005, Marchant spent twelve years at Honeywell Federal Manufacturing & Technologies. In her position there, Marchant practiced primarily labor and employment law in both the union and non-union context. She represented Honeywell in legal proceedings before federal and state courts, administrative agencies, mediators, and labor arbitrators, litigating numerous cases from the initial investigation through discovery and motion practice on behalf of Honeywell. She has obtained dismissals and summary judgments in various cases without the assistance of outside counsel. Marchant has presented oral argument before the federal district court and Missouri Court of Appeals and briefed appeals before the Eighth Circuit. Marchant also provided counsel to FM&T on environmental issues, intellectual property matters, and workers' compensation cases.

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**The Applebee's business unit is in the process of re-franchising its existing company operations and the number of company employees declines with the sale of company restaurants to new or existing franchisees.*

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I. NUTRITIONAL LABELING REQUIREMENTS FOR RESTAURANT FOODS

The federal Nutritional Labeling and Education Act of 1990 (NLEA) established a federal regulatory regime for foods and beverages sold in the United States, including both packaged foods sold at retail and foods served in restaurants.

For packaged foods, nutritional labeling has been mandatory for the past two decades. This is the origin of the familiar "Nutrition Facts" panel on the back of most packaged foods such as breakfast cereal, potato chips, or frozen pizzas.

But for restaurant foods, nutritional labeling was not required by the NLEA. Instead, the law established the standard for determining the nutritional content for restaurant foods should a restaurant choose to do so. The standard was designed to be flexible and not burdensome in order to encourage restaurants to provide this information.

But fifteen years later, growing attention to health and nutrition prompted various local and state governments to require nutritional information for restaurant foods. The growing patchwork of varying and unworkable requirements prompted the restaurant industry to seek national uniformity legislation, which Congress enacted as part of the healthcare reform legislation in 2010.

The new law makes nutritional labeling of restaurant food mandatory for most restaurants and other similar retail food establishments. It requires calories to be disclosed on menus and menu boards, and it requires other nutritional information to be made available in another written form such as a brochure or poster.

What the new law did not change, however, is the standard by which restaurants are to determine the nutritional information of items they serve. That standard -- known as the "reasonable basis" standard -- is the subject of this paper. It represents a balance struck -- first by FDA and then more recently by Congress -- between the costs and burdens of providing nutrition information to consumers and ensuring that the information is accurate.

II. DEVELOPMENT OF THE STANDARD

A. THE NUTRITION LABELING AND EDUCATION ACT OF 1990

On November 8, 1990, President George H.W. Bush signed the Nutrition Labeling and Education Act ("NLEA") of 1990 into law. This statute was uniformly recognized as the most significant change in food labeling law since the Federal Food, Drug and Cosmetic Act ("FDCA") was adopted in 1938. The NLEA added section 403(q) to the FDCA, which requires that all pre-packaged foods be labeled with certain nutritional information. This is what is known today as the "Nutrition Facts box." Restaurants were exempted from section 403(q) and therefore were not required by the NLEA to provide nutrition information for the food they sold.

Nevertheless, the NLEA also added section 403(r) to the FDCA, which provides that food is misbranded if it is the subject of a claim that characterizes the level of a nutrient, unless

the food conforms to the FDA's definition for that claim. *See* 56 Fed. Reg. 60421, at 422. In other words, FDA regulates how companies are allowed to characterize the nutrient content of the foods they sell. Restaurants are not exempt from section 403(r), and so if a restaurant were to voluntarily make a nutrient content claim about food, then the food that is subject to the claim would need to comply with the definition for that claim set forth in the NLEA. For packaged food companies, the usual application of section 403 (r) is to terms such as "low fat," which (unlike the number of grams of fat) is not required to appear on a food label. But for restaurants, although they are not required to state how many calories are in a given menu item, if they do so then they are characterizing the level of a nutrient and therefore making a nutrient content claim that is regulated by the NLEA and its implementing regulations.

Regardless of whether a given statement is "nutrition information" regulated under section 403(q) (and required for packaged foods but not for restaurant foods) or a "nutrient content claim" regulated under section 403(r), the NLEA preempts any non-identical state or local laws in order to ensure national uniformity in the information presented to consumers.

B. THE PROPOSED REGULATION

The NLEA directed the Secretary of Health and Human Service to promulgate rules implementing the legislation, and the Secretary in turn delegated that authority to the FDA. *See* Section 403(r)(2)(A)(i). On November 27, 1991, FDA issued a proposed rule setting out general principles and procedures governing nutrient content claims, including those made by restaurants. *See* 56 Fed. Reg. 60421 *et seq*.

The proposed rule listed and defined nutrient content claims that could be made about food products. For example, the FDA defined the term "low fat" for meals as meaning that the meal contains less than three grams of fat per 100 grams of food, meaning that a meal bearing the claim "low fat" would be misbranded under the proposed rule if it contained more than three grams of fat per 100 grams of food.

The FDA proposed that compliance with the NLEA for nutrient content claims would be determined by using the compliance standard for nutrition information on pre-packaged foods, meaning that the actual amount of vitamins and minerals must be at least 80 percent of the declared values, and the calorie, fat and sodium values may not exceed the declared value by more than 20 percent, i.e., they may not be more than 120 percent of the declared value. *See* 21 CFR 101.9(g)(4)-(5). This is often referred to as the "80/120" rule. To determine compliance with this standard, FDA would take a sample from each of twelve randomly chosen shipping lots, prepare and analyze a composite from these twelve samples, and compare the mean value of the test results for those composites to the standard. *See* 21 CFR 101.9(g)(2). As a practical matter, this is how packaged food companies assess their compliance with the 80/120 standard.

But the FDA recognized that restaurants could not reasonably be expected to comply with the standards for pre-packaged foods due to variation inherent in the food itself, methods of preparation in restaurants, and customization by the chef and the customer. *See* 56 Fed. Reg. 60421, at 60427. The FDA was concerned that, in order to comply with the standard for pre-packaged foods, restaurants would have to perform frequent nutrient analyses, and the cost of

this would deter restaurants from making any claims at all. *Id*. After all, restaurants are regularly changing their menu offerings -- more often than even breakfast cereal makers -- and they may not operate on the same scale as a food manufacturer. As a result, the FDA proposed that restaurants voluntarily making nutrient content claims show compliance with the NLEA by demonstrating that they have a "reasonable basis" for believing that the food complies with the definition for the claim. *Id*. at 60429.

In addition to having a reasonable basis for the claim, the proposed rule required restaurants to take "reasonable steps" to ensure that the food was prepared in a manner consistent with the reasonable basis. This requirement contemplated controls, for example, on the types and amounts of ingredients used in preparing the food subject to the claim. 21 CFR 101.13(q)(5)(ii). Finally, the proposed rule required restaurants making claims to provide to regulatory officials, upon request, specific information showing both their reasonable basis and reasonable steps to ensure adherence in preparation. *Id*.

The FDA believed that by proposing the reasonable basis standard, it was striking a balance that would encourage restaurants to provide consumers with nutrition information in the form of nutrient content claims, and at the same time ensure that consumers receive reasonably accurate information. The FDA also requested comments on this issue. *See* 56 Fed. Reg. 60421, at 60427.

C. THE FINAL REGULATION

Over the next year, the FDA received numerous comments related to the reasonable basis standard for restaurants. Some comments took the position that restaurants should be held to the same standard as manufacturers of pre-packaged foods, because (particularly for large quick-serve restaurant chains) much of the food is centrally manufactured, and because many restaurants control portion sizes as a method of containing costs. *See* 58 Fed. Reg. 2302, at 2386. On the other hand, some comments pointed out that additional variation is inevitable in the restaurant context due to factors such as the inherent variability of ingredients, preparation methods, and customer preferences. *Id*. at 2387.

After reviewing these comments, FDA issued a final rule governing nutrient content claims on January 6, 1993. In the preamble to the final rule, the FDA stated that the restaurant sector -- constituting 30 percent of the American food dollar at the time but much more today -- was too important to overall public health to be ignored. *See* 58 Fed. Reg. 2302, at 2387. It further found that providing dietary information at the point-of-purchase can help Americans maintain healthy lifestyles. FDA reiterated its belief that the public interest requires that claims made at the point-of-purchase be truthful and not misleading. *Id*. For these reasons, the FDA determined that restaurants making nutrient content claims would be required to show that the food met the definition for the claims under the NLEA. *Id*.

Furthermore, FDA described the question of *how* restaurants demonstrate compliance with the definitions for the claims as "a difficult matter." *Id*. Based on the comments it had received to the proposed rule, FDA determined that factors unique to the preparation of restaurant food, including the differing methods of preparation, consumer customization, and

inherent variation of food itself, would make compliance with the standard for pre-packaged foods extremely burdensome for restaurants. *Id*. Because of these factors, the FDA adopted in the final rule the "reasonable basis" standard it had set out in the proposed rule. *Id*. The rule was codified at 21 C.F.R. 101.13(q)(5)(ii).

The preamble to the final rule provides examples of what might constitute a reasonable basis. For example, the final rule states that a restaurateur claiming a fish dish is "low fat" could demonstrate a reasonable basis by showing that, per FDA's guidelines on seafood (56 FR 60880, Appx. B. (Nov. 27, 1991)), the fish contains less than 3 grams of fat per 100 grams of food, and that the method of cooking would not add fat. *Id*. Alternatively, the preamble explains, the restaurateur could show that he or she relied on a cookbook that gave values for fat in the finished food of less than three grams per 100 grams. *Id*. The preamble emphasizes that these examples are not exhaustive, and states that "certainly, other methods are possible." *Id*. at 2387-88.

FDA also acknowledged the deficiencies in nutrient databases and the inherent variability in food, and stated unequivocally that it would assess a reasonable basis "without regard to the computed variability or to differences between the computed nutrient levels and levels determined by laboratory analyses." *Id*. at 2389. As a result, the regulation stated no preference for laboratory testing over other methods of determining the nutrient content of restaurant food.

D. GUIDANCE DOCUMENTS

After the passage of the final rule, FDA began to receive questions about the various definitions, standards, and requirements set forth in the implementing regulations. In response, FDA staff drafted two "Q& A" documents to provide guidance to companies and consumers about compliance with the NLEA. The latter of these volumes, entitled "Questions and Answers, Volume II, A Guide for Restaurants and Other Retail Establishments (August, 1995)" answered questions about the application of the implementing regulations to restaurants, including questions about compliance with the reasonable basis standard. Excerpts are presented in the appendix.

For example, one question received by the FDA was whether the FDA would use the compliance standard for packaged foods -- that the actual amount of vitamins and minerals must be at least 80 percent of the declared values, and the calorie, fat and sodium values may not exceed the declared value by more than 20 percent -- to evaluate nutrient content claims made for restaurant foods. *See* Questions and Answers, Volume II, at No. 89. The FDA responded that it would not. The FDA explained that this 20 percent rule was established to account for variation in the nutrient content of commercially manufactured and packaged foods, not restaurant foods. The standard for restaurant foods, the FDA explained, was whether a restaurateur had a "reasonable basis" for believing the information to be valid. The FDA clarified that it would "not subject restaurant foods to chemical analysis to determine whether nutrient levels are properly declared." Instead, to determine compliance with the law, the FDA would look at:

(1) the recipe, calculations, and other methods used to determine the content, and

(2) the steps a restaurant was taking to ensure operational adherence.

Throughout the guidance documents, it is apparent that FDA recognized the inherent variability of the nutrient content of foods. Even foods that, to a consumer, appear to be quite consistent and uniform can vary widely in their nutrient content. Most foods originate in nature, where there are various factors that can affect the nutrient content of a plant or animal. As a result, some variability is to be expected.

For example, the NLEA statute permits the FDA to allow nutrient levels to be stated as a range, but the FDA decided instead to require that they be expressed in the form of an absolute value. 56 Fed. Reg. 60366, at 60373. Although using absolute values results in greater variation between the value declared on the label and the underlying value, the FDA determined that providing a single, absolute amount would be "more informative and less confusing for consumers than are ranges of values, especially where ranges are large." *Id*. FDA anticipated that "requiring a single value may result in under-declaration of some nutrients (e.g. vitamin C) and over-declaration of other (e.g. sodium) when variability is high," but was not deterred by this concern because "the single value will fairly represent the nutrient levels that the consumer can depend upon receiving from the product over time." *Id*. Finally, the FDA determined that use of a single value would permit manufacturers to avoid frequent product analyses and label changes." *Id*. Like the "reasonable basis" standard itself, the use of a definite value instead of a range shows that the FDA was focused on providing consumers with useful benchmarks that would be accurate over time.

The FDA rounding rules also take the inherent variability of food into consideration, particularly as to fat. In 1991, for example, the FDA proposed that claims regarding fat content be rounded to the nearest 0.5 gram. 56 Fed. Reg. 60366, at 60380. The FDA acknowledged that one of the disadvantages to this approach was that "because of natural variability in fat content in some foods, the 0.5 gram increment will convey to the consumer a degree of precision that may not be supported by the analytical measurements and thus the degree of reliability of the value for some foods may be decreased." *Id*. However, the FDA proposed the 0.5 gram rounding rule anyway in order to ensure that the ratio of fat to the Recommended Daily Value would be consistent with the ratios of other nutrients. Thus the rounding rules provide another example of the FDA choosing to provide useful information to consumers instead of requiring complete analytical precision.

Indeed, in proposed guidance implementing the new requirements for nutritional labeling of restaurant foods, FDA has stated that "calorie disclosure should be expressed in the nearest 5-calorie increments for menu items containing up to an including 50 calories, and in 10-calorie increments above 50 calories, except that amounts less than 5 calories may be expressed as zero." Draft Guidance for Industry, Questions and Answers Regarding Implementation of the Menu Labeling Provisions of Section 4205 of the Patient Protection and Affordable Care Act of 2010, announced at 75 Fed. Reg. 52426 *et seq.* (Aug. 25, 2010).

III. ENACTMENT INTO LAW

As noted, the "reasonable basis" standard was developed by the FDA as part of its regulations implementing the NLEA. It originally applied only to statements of nutrient content that restaurants made voluntarily, and there were no mandatory requirements – federal, state, or local – that restaurants state the nutrient content of their food.

A. STATE AND LOCAL REGULATIONS

But beginning in 2008, various local and state governments began requiring nutritional labeling of restaurant food. In the one year from May 2008 to May 2009, local menu labeling requirements were slated to become effective in New York City; San Francisco, California; Santa Clara County, California; King County (Seattle), Washington; Multnomah County (Portland), Oregon; and Westchester County, New York. In addition, at least 14 other jurisdictions – from Vermont to Arkansas, Oklahoma to Hawaii – were considering such laws.

These laws – both enacted and proposed – had differing requirements in such areas as menu placement, font size, disclaimers, and the standard for determining the nutritional information in the first place. They sought to apply varying technical requirements to nationwide and regional restaurant companies that run on consistency and uniformity. Menus could no longer be printed nationwide. Websites either had to be tailored to local jurisdictions or nutritional information had to be disclosed nationwide, even when only one jurisdiction had required such disclosure. Momentum began to build for a uniform, nationwide requirement that would be workable for restaurant companies.

B. CONSUMER CLASS ACTIONS

At about the same time, consumer class actions were filed against two of the largest casual dining brands (Applebee's and Chili's), alleging that their voluntarily provided nutritional information was inaccurate and therefore violated the consumer protection laws of multiple states. Plaintiffs dismissed the one lawsuit against Chili's, reportedly due to procedural issues under Texas law. But they pursued six consumer class actions against Applebee's, each of which alleged that differences between analytical testing and the calorie, fat, fiber, and Weight Watchers POINTS figures provided on the menu justified a finding of false advertising.

Applebee's has defended these cases based on the NLEA and the "reasonable basis" standard that FDA adopted to implement the NLEA for restaurant food. To date, one federal and two state courts have ruled emphatically that this standard preempts any non-identical state law. The federal court dismissed two separate cases on this ground. The two state courts (in Ohio and California) went further to rule that Applebee's met the "reasonable basis" standard. Although appellate activity continues, the two remaining cases have either been dismissed or are inactive.

C. THE PATIENT PROTECTION AND AFFORDABLE CARE ACT OF 2010

Against the backdrop of plaintiffs' lawyers seeking to apply vague standards of false or misleading advertising to restaurants' nutritional information, and attempting to harmonize the

patchwork of varying state and local requirements, the restaurant industry sought national uniformity legislation that would set a workable standard. Bills were proposed in Congress in 2008, and when the healthcare reform legislation began to move forward in 2010, a version of the nationwide menu labeling legislation was incorporated into it, eventually to be enacted on March 23, 2010, as Section 4205 of the Patient Protection and Affordable Care Act of 2010.

The new federal law both preempted non-identical state and local requirements and wrote into a statute the "reasonable basis" standard established by FDA in 1993. Today, therefore, a restaurant making a nutrient content claim must demonstrate that it has a reasonable basis for believing that the nutrient value that is the subject of the claim meets the definition for the claim under the NLEA.

The original regulation reads as follows:

> (ii) In lieu of analytical testing, compliance may be determined using a reasonable basis for concluding that the food that bears the claim meets the definition for the claim. This reasonable basis may derive from recognized data bases for raw and processed foods, recipes, and other means to compute nutrient levels in the foods or meals and may be used provided reasonable steps are taken to ensure that the method of preparation adheres to the factors on which the reasonable basis was determined (e.g., types and amounts of ingredients, cooking temperatures, etc.). Firms making claims on foods based on this reasonable basis criterion are required to provide to appropriate regulatory officials on request the specific information on which their determination is based and reasonable assurance of operational adherence to the preparation methods or other basis for the claim . . . .

21 C.F.R. § 101.13(q)(5)(ii). This was in turn enacted into a statute as section 4205 of the Patient Protection and Affordable Care Act of 2010, which also required restaurants to make nutrient content claims for specified nutrients:

> (iv) REASONABLE BASIS.--For the purposes of this clause, a restaurant or similar retail food establishment shall have a reasonable basis for its nutrient content disclosures, including nutrient databases, cookbooks, laboratory analyses, and other reasonable means, as described in section 101.10 of Title 21, Code of Federal Regulations (or any successor regulation) or in a related guidance of the Food and Drug Administration.

21 U.S.C. § 343(q)(5)(H)(iv). The specific reference (21 C.F.R. § 101.10) cross-references section 101.13 and reads as follows:

> § 101.10. Nutrition labeling of restaurant foods. Nutrition labeling in accordance with §101.9 shall be provided upon request for any restaurant food or meal for which a nutrient content claim (as defined in §101.13 or in subpart D of this part) or a health claim (as defined in §101.14 and permitted by a regulation in subpart E of this part) is made, except that information on the

> nutrient amounts that are the basis for the claim (e.g., "low fat, this meal provides less than 10 grams of fat") may serve as the functional equivalent of complete nutrition information as described in §101.9. Nutrient levels may be determined by nutrient data bases, cookbooks, or analyses or by other reasonable bases that provide assurance that the food or meal meets the nutrient requirements for the claim. Presentation of nutrition labeling may be in various forms, including those provided in §101.45 and other reasonable means.

IV. APPLICATION OF THE STANDARD

FDA has published extensive guidance on the meaning of this standard and its practical application. (Excerpts from that guidance are provided in the Appendix.) Nevertheless, because there does not appear to have ever been an FDA enforcement action brought under the reasonable basis standard, it has been hard to know for sure what procedures will pass muster under the reasonable basis standard.

Rulings in two of the consumer class actions noted above provide additional insight into how an independent party would assess compliance. In the only cases to date in which courts have reviewed a restaurant's compliance with the reasonable basis standard, both the California Superior Court (Alameda County) and the Ohio Court of Common Pleas (Clermont County) found, based on declarations and expert reports provided to the courts following extensive discovery, that Applebee's and its parent company DineEquity had complied with the standard. Applebee's methods are summarized below.

A. INITIAL DETERMINATION

The law therefore calls for the initial determination of the nutritional information to be based on such sources as databases and cookbooks as well as information provided by raw material suppliers, which may include laboratory analyses.

In order to determine the fat, calories, and points values for one set of menu items, Applebee's cooked full plates of the items in its culinary center, and sent them to a laboratory for testing. There is no exclusive method specified for obtaining a reasonable basis, and the FDA has emphasized that many methods are possible. In the opinion of Applebee's expert, sending fully cooked meals to laboratories for analysis is a reasonable means of determining the nutrient levels in the food. In fact, it appears that this is an approach the FDA would have encouraged, although it was neither a required nor anticipated method of complying with the NLEA.

Applebee's also took several precautionary steps that the courts found supported its reasonable basis for these initial items. For example, Applebee's prepared twelve samples of each full plate and averaged their results together, as prescribed by the FDA in the context of packaged foods. Similarly, if there were multiple suppliers for an item, Applebee's cooked twelve samples for each supplier, sent them to a laboratory, and then used for its nutrient content claims the highest value for fat and calories, and the lowest for fiber. This was an attempt to

reduce the chance of under-declaring fat and calories o over-declaring fiber. (Only calories, fat, and fiber were declared on the Applebee's menu before mandatory menu labeling came into effect.)

Applebee's later revised its procedures so that nutrient content for each ingredient for each item was entered into the Genesis database, which computed the values used in the nutrient content claims. The Genesis database is a commonly used, commercially available tool for computing accurate and reliable nutrient amounts. It both allows for specific information to be entered (like a spreadsheet) and also calls on a database that is periodically updated as new information becomes available and averages together a large quantity of data for most common ingredients in restaurant foods. The use of nutrient databases is specifically approved as a method for determining a reasonable basis. 21 C.F.R. 101.13(q)(5)(ii).

Applebee's quality assurance personnel reviewed data from each supplier of each ingredient and entered into the Genesis database the highest values for fat and calories, and lowest values for fiber. Applebee's experts opined that this reinforces the reasonable basis for these items because it reduces the risk of under-declaring fat and calorie information, and over-declaring fiber information.

Applebee's experts further advised the courts that the fact that Applebee's used laboratory testing to determine nutrient amounts for some items, but subsequently used nutrient databases for other items, is also consistent with FDA requirements. In fact, the FDA was concerned, as described above, that requiring restaurants to perform repeated analytical tests would be so burdensome that it would deter them from making nutrient content claims at all. The experts view was that Applebee's approach not only complied with the "reasonable basis" standard but went beyond the FDA's expectation for restaurants to comply with the standard.

B. OPERATIONAL ADHERENCE

A restaurant making a nutrient content claim must also demonstrate that it took reasonable steps to ensure that the method of preparing the food adhered to the basis for the claim. The courts reviewing Applebee's compliance also agreed that it had complied with this prong of the standard.

For example, Applebee's distributes to each of its locations detailed plate presentations for each menu item. These include step-by-step preparation instructions, pictures and diagrams showing how the item should appear, and lists of "critical ingredients" for use in the items, and "critical controls" that must be followed to ensure that the item is properly prepared. These are provided in both Spanish and English because a number of the relevant employees are native Spanish speakers. In the opinion of Applebee's experts, the use of these plate presentations is a "reasonable step" to ensure that the method of preparation of the items supports the reasonable basis for the nutrient content claims.

In addition, some ingredients for the specific menu items at issue in the litigation were pre-portioned and pre-packaged before the menu items were cooked or assembled. There were also unique pink kitchen implements such as tongs, ladles and other measuring instruments that

were used to prepare these special menu items (which were part of Applebee's Weight Watchers-branded offerings). Applebee's also undertook periodic trainings dedicated to ensuring proper preparation of these menu items. Training videos were also sent to store locations for the use of employees. Applebee's experts believed that these steps show adherence to Applebee's reasonable basis for the items at issue, because they tend to minimize variance in preparation methods.

Applebee's also conducted regular audits to monitor its adherence to standards for preparation, training, and facilities management. These audits included a specific section for the menu items at issue in the lawsuits. Furthermore, Applebee's sends new updates to its stores, which have periodically reminded individual stores of the importance of adhering to specific preparation procedures for Menu Items. Applebee's experts also believe that these processes were reasonable steps taken by Applebee's to promote adherence to the reasonable basis underlying the nutrient content claims.

APPENDIX:
EXCERPTS FROM REGULATORY HISTORY AND FDA GUIDANCE

THE REGULATION

> (5) A nutrient content claim used on food that is served in restaurants . . . shall comply with the requirements of this section and the appropriate definition . . . except that: . . .
>
> (ii) In lieu of analytical testing, compliance may be determined using a reasonable basis for concluding that the food that bears the claim meets the definition for the claim. This reasonable basis may derive from recognized data bases for raw and processed foods, recipes, and other means to compute nutrient levels in the foods or meals and may be used provided reasonable steps are taken to ensure that the method of preparation adheres to the factors on which the reasonable basis was determined (e.g., types and amounts of ingredients, cooking temperatures, etc.). Firms making claims on foods based on this reasonable basis criterion are required to provide to appropriate regulatory officials on request the specific information on which their determination is based and reasonable assurance of operational adherence to the preparation methods or other basis for the claim . . . .

21 C.F.R. § 101.13(q)(5)(ii).

THE REGULATORY HISTORY

56 Fed. Reg. 60421, 60427 (November 27, 1991) (emphasis added)

. . . .

The applicability of current regulations to restaurant foods was discussed in rulemaking promulgating § 101.10 Nutrition labeling of restaurant foods (39 FR 42375, December 5, 1974 and 41 FR 51002, November 19, 1976). In the preamble to the proposed rule, the agency discussed its belief that nutrition education is of prime importance and stated that it will take every opportunity to foster the dissemination of such information to the consumer, including the use of nutrition labeling in restaurants. However, the agency acknowledged that if nutrition information provided in restaurants necessitates the expense of nutrition labeling, the restaurant "may choose not to provide any nutrition information in advertising or labeling, on the basis that the added cost of providing detailed information * * * might cause the project of providing nutrition information not to be worth the expense" (39 FR 42375). Therefore, to encourage the dissemination of nutrition information in the food service industry, FDA proposed to exempt ready-to-eat foods from the requirement of bearing nutrition labeling on food labels if the required nutrition labeling was displayed prominently on the premises by other means, e.g.,

counter cards or wall posters, where the information would be readily available to the consumer when he is making a menu selection.

Subsequent action on this proposal led to the issuance of a statement of policy in § 3.207 (recodified as 21 CFR 101.10 in the Federal Register of March 15, 1977 (42 FR 14302)) that if any advertising or labeling (other than labels) includes a claim or information about the total nutritional value of a combination of two or more foods (e.g., a combination consisting of a hamburger, french fries, and milkshake), then, as an alternative to providing nutrition information about each separate food on the food label, the restaurant may instead provide information about the total nutritional value of the combination of foods, provided that the statement of total nutritional value follows the nutrition labeling format and provided that the nutrition information is effectively displayed to the consumer both when he/she orders the food, and when he/she consumes the food.

As discussed in the supplementary nutrition labeling proposal published elsewhere in this issue of the Federal Register, the 1990 amendments specifically exclude restaurant foods and foods sold in other establishments in which food that is ready for human consumption is sold (hereafter "restaurant food") from the requirement for nutrition labeling. However, as stated above, the agency believes that it has the authority to issue regulations requiring restaurants that choose to make nutrient content claims to adhere to the requirements for such claims, including nutrition labeling.

FDA is not, at this time, making any specific provisions for the nutrition labeling of restaurant foods. FDA specifically seeks comment on how it should handle this issue. On one hand, many believe that it is important that consumers be given useful and meaningful nutrition information. On the other hand, many continue to be concerned, as FDA was in 1974, that the cost of compliance not be so high that restaurants will not be willing to offer and identify through nutrient content claims those foods that will assist consumers in selecting diets that provide health benefits. Therefore, the agency is requesting comments on whether and to what extent it has a basis for nutrition labeling when nutrient content claims are made on restaurant foods, or whether a requirement for such labeling would discourage restaurants from making nutrient content claims because of the cost associated with nutrition labeling.

If, based on comments received, FDA were to require nutrition labeling of restaurant foods, should the requirement apply only to large restaurant chains with fixed menu items. Additionally, should the content or format of nutrition labeling be different for the food service industry than for packaged foods. If so, how and why.

FDA recognized in its July 19, 1990 reproposal on mandatory nutrition labeling (55 FR 29504) that certain restaurant-type food service facilities cannot reasonably be expected to provide information concerning nutrient profiles, and that exempting provisions should be established for such situations. The proposal advised that comments pointed out that nutrition labeling for foods served in restaurant-type facilities present significant feasibility problems in a number of situations. The comments made the following points: These facilities may not be able to develop consistent nutrient information on the foods that they sell because of frequent menu changes and variations in how the consumer wants the food prepared and served. Without nutrient

consistency, frequent nutrient analyses would have to be performed to provide consumers with accurate nutrition labeling information. These analyses could become very burdensome. The cumulative costs of these analyses could place undue restrictions on some establishments. Firms could be inhibited from making frequent menu changes or forced to limit the options that consumers have in ordering a food.

Because of these problems, FDA proposed an exemption under section 201(n), 403(a), and 701(a) of the act for restaurant-type foods in the mandatory nutrition labeling proposal (see proposed § 101.9(h)(2), 55 FR 29516). Although the agency wanted to limit the exemptions to only those situations in which it is needed, FDA did not, and still does not, have sufficient indepth knowledge of the food service industry to develop adequate criteria to fairly impose such a limitation. The agency therefore requests comments on this issue.

A related question is what is to be done with § 101.10. Because § 101.10 was adopted under section 403(a) of the act, it is not subject to State enforcement under section 307 of the act. For this reason, and because § 101.10 has not been enforced by FDA, the agency believes that it is appropriate to make an affirmative statement about the continuing need for this provision. Thus, if FDA elects not to make restaurant labeling part of the Nutritional Labeling Education Act implementation, the agency will, in the final rule, delete § 101.10.

58 Fed. Reg. 2302, 2387-89 (January 6, 1993) (emphasis added)

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How the restaurant demonstrates compliance with those definitions is a difficult matter. FDA recognizes that, as detailed in the comments, there are variations in the nutrient values for restaurant foods. Some of these variations are not unique to restaurants. Manufacturers of packaged foods also have to deal with differences in nutrient levels as a result of seasonal, regional, and supplier variations. FDA has been able to develop workable criteria that take into account these variations. However, the agency acknowledges that there are variations unique to restaurant foods (e.g., methods of preparation). Moreover, FDA recognizes that there are difficult questions, as demonstrated by the comments, as to how exactly to analyze restaurant foods in a reasonable and cost effective manner.

While there are difficulties associated with restaurant foods, FDA concludes that the difficulties are not so great as to preclude restaurants from making claims or to prevent the agency from being able to assure consumers that the nutrient content claims that appear on restaurant foods reasonably reflect the nutrient content of the food. Thus, FDA is providing in new § 101.13(q)(5)(ii) that, except if a claim is made on a menu, a restaurant food may bear a nutrient content claim if the restaurateur has a reasonable basis on which to believe that the food that bears the claim meets the definition for the claim that FDA has established under section 403(r)(2)(A)(i) of the act. Thus, if a restaurateur labels a fish dish as “low fat,” on a sign or a placard he or she must have a reasonable basis for believing that the dish complies with FDA's definition for “low fat,” that is it contains less than 3 g of fat per 100 g. The reasonable basis can be provided in a number of ways. The restaurateur can show, for example, that FDA’s guideline

on nutrient levels in seafood (56 FR 60880, Appendix B, November 27, 1991) shows that the fish contains less than 3 g of fat per 100 g, and that the method of cooking and other foods used in the dish would not add fat. In addition, the restaurateur could show that he or she relied on a reliable cookbook that gave values for fat in the finished food that were less than 3 g per 100 g. Certainly other methods are possible. If a restaurateur uses recognized data bases for raw and processed foods to compute nutrient levels in the foods or meals and then does not use methods of preparation that violate the appropriate use of data bases (e.g., uncontrolled addition of ingredients or inappropriate substitutions of ingredients), FDA will [*beginning of pg. 2388]* find that there is a reasonable basis for believing that the food meets the criteria for a defined nutrient content claim.

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As an additional measure of flexibility, which will especially benefit small restaurants, it was decided not to include claims on menus within the coverage of these regulations. FDA has considerable discretion in regulating nutrient content claims in restaurants. As the comments have indicated, there are unique problems and concerns associated with regulating such claims. The 1990 amendments do not specify precisely how such claims are to be regulated. These regulations will apply to nutrient content claims made in restaurants except on menus. The agency's efforts will focus on signs, placards, and posters, which are increasingly used in fast food and other restaurants to bring nutrition information and claims about food to consumer's particular attention. The comments pointed out that menus are subject to frequent, even daily, change. This additional measure of flexibility for menus will help assure that restaurants, especially small restaurants, will not be deterred by the 1990 amendments from providing useful nutrition-related information to their customers. States remain free, however, to ensure under their own consumer protection laws that menus do not provide false or misleading information.

Although it has arrived at an approach that will provide for nutrient content claims on restaurant foods, other than the exclusion of menus, FDA does not consider the problem of assuring the useful and reliable provision of nutrient related information in restaurants to be solved. It is possible that there are other definitional criteria that are more appropriate for restaurant foods than those that FDA has developed based largely on packaged foods. Also, it may be that consumers have completely different expectations for, and understanding of, terms used for restaurant foods as compared to the same terms used on packaged foods. If this is the case, a different glossary of terms for use in restaurants may be appropriate. However, at this time, the agency simply does not have the data or knowledge on which to base such determinations. FDA is working, and will continue to work, with the restaurant industry to determine how terms are used on restaurant foods and whether such terms are appropriate. For example, with FDA's cooperation, the National Restaurant Association is planning to undertake a survey of industry use of nutrition information and of consumer knowledge, practices, expectations, and understanding of various terms and symbols in restaurants. FDA is open to petitions for different criteria for nutrient content [*beginning of pg. 2389*] claims for restaurant foods, and if data warrant, the agency will consider establishing regulations specifically for restaurant foods.

FDA also recognizes that there are a number of significant issues concerning the adequacy of existing data bases for use to compute nutrient levels in restaurant meals. However, the agency is

working, and will continue to work, with the restaurant industry to assess the adequacy of these data bases and to encourage the development of additional or newer data where those data bases are found to be lacking.

In developing more specific policies, FDA will also consider whether restaurant foods should be afforded greater latitude in the compliance criteria than the criteria that are currently applied to nutrient variations in processed foods. FDA regulations state that for naturally occurring vitamins, minerals, and protein, the nutrient content must be at least 80 percent of the value declared, and that for calories, carbohydrate, fat, and sodium, the level must not exceed the declared value by more than 20 percent. The agency recognizes that all data bases have inherent variabilities, and that a computed nutrient level for a food with several ingredients may have an accumulated variability that exceeds the agency's criteria for packaged foods. FDA is concerned about the accuracy of nutrient level estimations, but pending the development of better data, the agency will accept, as a reasonable basis, claims based on nutrient levels drawn from recognized nutrient data bases, without regard to the computed variability or to differences between the computed nutrient levels and levels determined by laboratory analyses. The agency is open to comments and suggestions on how nutrient variability issues should be addressed for restaurant foods and will continue to work with the industry on this issue.

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61 Fed. Reg. 40320, 40324, 40326 (Aug. 2, 1996) (emphasis added)

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Criteria for claims on meals and main dishes (as defined in §101.13(l) and (m)) are generally based on the level of a nutrient in 100 g of the food. For example, a "low fat" meal weighing 333 g can contain up to 10 g of fat (333 g serving /100 g = 3.3; 3 g of fat per 100 g of food x 3.3 = 10 g of fat). Again, a restaurant serving a larger portion of a meal or main dish item is not at a disadvantage compared to other food sources when making a "low fat" claim. FDA advises, however, that some claims, e.g., "free" claims and cholesterol claims, have additional criteria based on the labeled or actual serving size. The criteria for specific nutrient content and health claims are set out in part 101 (21 CFR part 101).

FDA advises that it is not necessary for restaurants to produce and market a reference food in order to sell a food that bears a claim. Reference foods are necessary only for comparative nutrient content claims, i.e., claims about the level of a nutrient in one food compared to another, such as "reduced sodium" or "less fat." Provisions for the use of data bases and other means to determine nutrient values for an appropriate reference food are set out in § 101.13(j)(1)(ii). FDA also advises that, while restaurants are required to provide nutrition information on request for foods that make a claim, FDA is providing considerable flexibility in §101.10 as to the type of nutrition information that must be provided and on how this information can be provided. For example, in a restaurant situation, nutrition information may be presented in various forms, including those provided in §101.45 and by other reasonable means (e.g., using posters, fliers, brochures, notebooks, or communicated orally by restaurant staff). In sum, FDA notes that the

types of misconceptions presented by these comments have resulted in a perception of burdens that do not in fact exist.

Given the flexible provisions, such as the "reasonable basis" criterion that the agency set out in the claims final rules, FDA concludes that most restaurants that wish to make claims will be able to do so. Further, as stated in several comments, many resources, including Federal, State, and local governments; professional health organizations; and dietary professionals, are available to aid restaurants in their efforts to comply with FDA's requirements. Moreover, as stated above, FDA has made available the labeling guidance document to assist restaurants and other retail establishments in developing or revising their labeling to comply with the new requirements.

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[*Start 40326*]
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7. One comment argued that compliance would be more difficult for small firms compared to large restaurant chains because of limited resources. The comment did not, however, provide any information that the agency had not previously considered. Another comment maintained that an extension for small restaurants is justified by the "lack of real harm" to the public from such a delay.

Conversely, the majority of letters that addressed the proposed modification in effective dates supported the agency's proposal to establish uniform effective dates for all restaurants. These comments maintained that there is no appropriate basis for differentiating among restaurants based on size when establishing a date by which each must comply with FDA's requirements. Thus, the comments stated, the agency should enforce its labeling requirements for large and small restaurants, at the same time. However, the comments contained numerous and varied suggestions as to when the new effective dates should be.

Having considered the comments, FDA concludes that, although there are some areas where small restaurants may be at a disadvantage compared to large restaurants, e.g., the cost of a one-time menu change relative to more limited resources, in most respects, the distinction between small restaurants and larger restaurants is not as great as the agency had believed when it issued the January 6, 1993, final rules. For example, not all restaurant firms with greater than 10 establishments are familiar with the new requirements or have established nutrition support personnel. Further, in establishing the requirements for restaurant labeling in the claims final rules, the agency worked with restaurant industry representatives to make its requirements feasible for both large and small restaurants. FDA advises that the flexibility built into these requirements, e.g., the "reasonable basis" criterion, provides a wide range of options for how a restaurant may determine the nutrient content of its food, and how it communicates this information to consumers. FDA finds that this flexible approach will allow most restaurants, including small restaurants, to choose options that fit their own needs and resources. Thus, FDA finds nothing in the comments that would provide a basis for differentiating among restaurants based on size when establishing a date by which restaurants must comply with these requirements.

THE FDA GUIDANCE DOCUMENTS

FDA, QUESTIONS AND ANSWERS, VOLUME II, A GUIDE FOR RESTAURANTS AND OTHER RETAIL ESTABLISHMENTS (AUG. 1995)

Question No. 89

R89.

Question: For packaged foods, the actual amount of naturally occurring vitamins, minerals, and protein must be at least 80 percent of the values that are declared on the label, whereas the actual calorie, carbohydrate, and sodium contents may not exceed the labeled values by more than 20 percent. Will FDA apply these same compliance criteria to the nutrient content information declared on labeling for restaurant foods?

Answer: No. The above compliance criteria (#101.9(g)) were established to account for natural variations in the nutrient content of commercially manufactured and packaged foods that are subject to chemical analysis to determine compliance. These criteria ensure that values declared in the Nutrition Facts panel for nutrients such as vitamins and minerals are not over-declared, and that nutrients such as calories and fat are not under-declared, compared to actual amounts that are determined by chemical analyses. The standard that restaurant foods must meet is that a restaurateur have a "reasonable basis" for believing a claim or other nutrition information is valid. Thus, FDA will not subject restaurant food to chemical analysis to determine whether nutrient levels are properly declared. Rather, FDA will be assessing whether the restaurant's basis for a claim or other nutrition information is, or is not, reasonable. For example, if a restaurant claims a meal is "low fat," FDA would look at the recipe, calculations, and any other information used by the restaurant in determining whether the meal meets the definition of "low fat," i.e., that it contains no more than 3 g fat per 100 g of food.

Question Nos. 138 to 145

R138.

Question: Many food service items are partially or wholly processed when they are purchased for use in a restaurant or similar establishment. Thus, it may be difficult for the restaurant to keep track of the sodium content of foods. It may also be difficult for a restaurant to monitor the use of sodium in the cooking process and to develop recipes for "low sodium" foods that taste good. How will these problems be addressed in implementing the new requirements?

Answer: FDA does not intend to impose an unrealistic regime (e.g., to require exacting measurements or strict portion controls) in restaurants. However, the agency is requiring that a restaurant have a reasonable basis for believing that a food meets the nutrient requirements for a claim, and that it be able to provide reasonable assurance that the

preparation of the food adheres to the basis for the claim. If a restaurateur has no knowledge of, or control over, the sodium content of a food, or some other aspect of its nutrient content, he/she should not attempt to make a sodium content or other claim about the nutrient levels in that food.

R139.

Question: Many restaurants do not have, or do not use, scales. Consequently, wouldn't a criterion such as "no more than 30 percent of calories from fat" be more appropriate for a low fat claim on a restaurant food compared to weight based criteria?

Answer: No. First, the "no more than 30 percent of calories from fat" criterion does not, by itself, ensure that a food is low in fat. Second, in order to have a reasonable basis for believing that a food derives no more than 30 percent of its calories from fat, a restaurateur needs to have sufficient information on the types and quantities of ingredients used in the food to determine both its fat and calorie content. The same information used to calculate percent calories from fat (a criterion for a low fat claim on meals and main dishes) can be used to calculate the amount of fat per reference amount or, in the case of meals and main dishes, per 100 g of food.

R140.

Question: To support its basis for a claim, does a restaurant need to weigh every serving of a food and calculate the amount of a nutrient in each serving every time it prepares the food?

Answer: No. A reasonable basis determination only needs to be done once provided portion size is reasonably constant, the restaurant follows a standardized recipe, and the method of preparation adheres to the basis for the claim.

R141.

Question: What types of actions would invalidate a restaurant's "reasonable basis," and what should a restaurateur do to help ensure this does not happen?

Answer: Restaurateurs will need to employ preparation methods that are sufficiently consistent, including weight and volume measurements, to provide reasonable assurance that the preparation method adheres to the basis for the claim. They must also consider the effects of any addition or substitution of ingredients, or of any change in preparation method, on the level of a nutrient that is the subject of a claim. For example, the nutrient content values that FDA published in conjunction with the voluntary nutrition labeling program for baked fish would no longer apply to fish that is breaded or fried.

It may be necessary for some restaurateurs to develop written standard operating procedures or other kitchen instructions for use by staff to guard against uncontrolled addition or substitution of ingredients. For example, if a "low fat" claim depends on the

use of skim milk rather than whole milk, staff should be aware that the food bearing a "low fat" claim may not be made with whole milk. Further, if a food bears a "low sodium" claim based on its containing a limited amount of salt, allowing staff to "salt-to-taste" instead of using measured amounts would contravene the reasonable basis for believing that the food meets the requirements for the claim.

R142.

Question: How will compliance with the claims requirements be evaluated in a restaurant situation?

Answer: For compliance purposes, FDA will look at the recipe, nutrient information source, and any calculations used by a restaurant as its "reasonable basis" for believing that a food meets the requirements for a claim or other nutrition information. FDA will evaluate whether this information, and the nutrition information provided to consumers, are consistent with FDA's definition for the claim that is used. FDA may also request that a restaurant provide reasonable assurance that the method of preparation used adheres to the restaurant's basis for the claim.

R143.

Question: Data base analysis reveals that a restaurant food contains 3.3 grams of fat per reference amount. Can the food bear a "low fat" claim?

Answer: No. The definition for a "low fat" claim is that the food contains no more than 3 grams of fat per reference amount (3.3 g of fat per reference amount would be declared as 3.5 g). If the restaurant's reasonable basis determination shows that a food contains more than 3 grams of fat per reference amount, the restaurateur would not have a reasonable basis for believing the food meets the definition of the claim.

R144.

Question: What are the record keeping requirements for a restaurant that make claims?

Answer: The restaurant must keep sufficient records to provide appropriate regulatory officials, upon request, with information on its "reasonable basis" and with reasonable assurance that the preparation method adheres to that basis. The type and amount of information necessary to support a claim will vary with the type of establishment, the types of food sold, preparation methods, and the types of claims being made. However, the following check list may be helpful:

1. Standardized recipe, including ingredients used and their quantities,

2. Nutrient content data for each ingredient (may include information from the ingredient manufacturer, a reliable data base, or other nutrient information source,

or a combination of these; information must include data for the nutrients that are the basis for the claim and may include data for other nutrients,

3. The source of the above data (e.g., the name of the data base, cookbook, etc.),

4. Any assumptions made by the restaurateur or any calculations that were performed that may affect the reliability of the data (e.g., combining data sources, assumed nutrient values, replacing generic or average data base values with values for brands specifically used in the restaurant, etc.),

5. Serving size (total weight) of the finished food or meal,

6. Total amount of nutrient present per reference amount, actual serving, or per 100 g of food, as appropriate for the definition of the claim,

7. Evidence of staff awareness that reasonably consistent ingredient measurement and portion control are necessary for foods bearing a claim (e.g., training materials, observation of food preparation methods),

8. Presence and use of a standard operating procedure identifying essential parameters in the preparation of a food bearing a claim (e.g., the use of skim milk instead of whole milk, broiling instead of frying, or the need to measure salt instead of salting to taste), when the method of preparation could affect the basis for a claim.

R145.

Question: If a restaurant makes a fat claim for a food based on the use of skim milk, for example, does it have to save records to prove that it purchased, and used, an appropriate quantity of skim milk?

Answer: Not necessarily. The requirements in # 101.13(q)(5)(ii) require that a restaurant provide reasonable assurances that it adhered to its basis for making a claim. Examples of the types of information that may be useful for a restaurant to provide in support of its basis for a claim are discussed in response to the preceding question. It is unlikely that a regulatory official would require information like the records of ingredient purchases unless he/she had reasonable cause to doubt a restaurant's stated basis.

GUIDANCE FOR INDUSTRY: A LABELING GUIDE FOR RESTAURANTS AND OTHER RETAIL ESTABLISHMENTS SELLING AWAY-FROM-HOME FOODS (FDA APRIL 2008)

Available at: http://www.fda.gov/food/guidancecomplianceregulatoryinformation/%20guidancedocuments/

65. When making a claim, do I have to have my food analyzed by a lab to determine its nutrient content?

    Answer: No. A restaurant food, including restaurant-type foods described in 21 CFR 101.9(j)(3), may bear a nutrient content claim or health claim provided the restaurateur has a "reasonable basis" for believing that the food meets the definition for the claim. If a restaurateur labels a food "low fat," for example, he or she must have a reasonable basis for believing that the food complies with FDA's definition for "low fat" (i.e., that it contains no more than 3 g of fat per RACC or, in the case of meals and main dishes, no more than 3 g of fat per 100 g) (see question 25).

73. To support its basis for a claim, does a restaurant need to weigh every serving of a food and calculate the amount of a nutrient in each serving every time it prepares the food?
    Answer: No. A reasonable basis determination only needs to be done once provided portion size is reasonably constant, the restaurant follows a standardized recipe, and the method of preparation adheres to the basis for the claim.