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QUALITY MANAGEMENT

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Subject: Carbohydrate Nutrient Content Claims

Nestlé USA, Inc. ("Nestlé") would like to comment on the GMA and Kraft petitions (Docket # 2004P-0110 and #2004P-0105, respectively) filed with FDA regarding nutrient content claims for carbohydrates, and offer alternatives. Nestlé disagrees with several of the criteria recommended in those petitions, and would like the agency to have our viewpoint as it develops its proposed regulation on this topic.

Nestlé actively participated in the discussions leading to submission of the GMA petition. Because the issues surrounding carbohydrate claims are so complex, it was a very difficult process. As a result, there was not a consensus from the membership and the final GMA petition represented more of a majority view of GMA's membership.

Nestlé does not agree with what GMA (or Kraft) suggested as criteria for the nutrient content claims "low", "good source", or "excellent source". However, we do agree with the suggested criteria for "free", "reduced", and "modified" carbohydrate claims.

The issue that makes carbohydrate claims so confounding is that it would be the only nutrient for which there would be both high and low claims. The result is a potentially confusing message to consumers: Should they consume less carbohydrate or more? Are carbohydrates good for us or bad for us? Also, would "low" claims encourage reduced fiber intake? Although low-carb dieters would seek products labeled as "low carbohydrate", would it send an unintended signal to non-dieters that carbohydrate is to be minimized, which in turn could encourage high fat, high calorie diets? Will there be a sufficient spread between a "low" carb food and one that is considered a "good source of carbohydrates"? Should the "good source" and "high" claims have a sugar criterion? How would compliance of the declared carbohydrate amount be handled – 80% of label, 120% of label?

The agency should be aware of the struggles that industry faced in trying to recommend meaningful and responsible criteria for such claims. One very significant area where Nestlé differs from the GMA petition is that we believe their criteria for "low

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carbohydrate” are too low to allow consumers to construct a healthful diet. Therefore, our suggestions to the agency are to propose higher values for “low”, “good source”, and “excellent source”, and, to introduce other suggestions and qualifying criteria to help make such claims meaningful.

“Low” carbohydrate should be 15 g or less per RACC

Kraft suggested 6 g and GMA suggested 9 g to define “low” carbohydrate. We think both of these values are unrealistically low. Even the higher of these two, 9 g, means that the diets of consumers following “low carb” diets would likely be too low in carbohydrate (i.e., too high in fat and protein), and too low in fiber, to be healthy.

GMA based its 9-g recommendation on 3% of the DRV, which in turn was based on how ubiquitous carbohydrate is in the food supply. We do not agree that the “ubiquitous” basis is convincing for carbohydrates. Although calories are ubiquitous, its contributors are not. In addition, when applied to actual diets, and given the “conflicting” situation that results from having both “low” and “high” criteria, we think carbohydrate claims need a different basis. Thus, we believe it is more valid and consistent to base the “low” criterion on 5% of the DV, which is the basis used to determine “low” for fat, saturated fat, and sodium (5.8%).

We also believe that a 9-g criterion for “low” would lead to unhealthful diets. If one assumes 16 servings of food per day, as the GMA petition did, then a consumer wanting to achieve a low carbohydrate diet would get about 144 g carbohydrate per day. For a 2000-calorie diet, that represents only 28% of calories. Since the IOM recommended that healthy diets should range in carbohydrate between 45% and 65% of calories, we conclude that 9 g is too low. This would likely limit the consumption of fiber, important vitamins and minerals, and foods like fruits, vegetables, and whole grains.

When the agency implemented the Nutrition and Labeling Education Act (NLEA), a fundamental goal was to create criteria for nutrient content claims that would provide meaningful information to assist consumers in selecting foods that could lead to healthier diets. Therefore, we submit that a more reasonable criterion for “low” is 15 g of carbohydrate per RAAC. This amount corresponds to 48% of calories using the analysis described above (i.e., 16 servings/day in a 2000-calorie diet), which is only slightly above the minimum recommended by the IOM report. Also, again, it is consistent with other “low” nutrient content claims that are based on 5% of the DV (i.e., fat, saturated fat, and sodium).

In addition, the 15 g criterion for “low” is preferred in that it more realistically allows for product innovation to meet this claim. We have consumer data showing, not surprisingly, that the foods missed most by those following a “low carb” diet are bread, potatoes, pasta, candy/chocolate, and crackers. A 15-g criterion for “low” would allow many bread and cereal products, with some innovation, to achieve “low”, whereas a 9-g criterion would not. This approach would allow for incremental improvements for the benefit of consumers who choose to lower their carbohydrate intake.

In fact, currently on the market are several carbohydrate-type foods (e.g., breads, pastas, etc.) promoted as “low carb” that contain approximately 14-17 g carbohydrate per RACC. The additional dietary fiber is a positive attribute for health. If “low” were to be defined as 9 g, many such foods would be absent from the marketplace because they simply would not be palatable, and this would remove excellent sources of fiber for the “low carb” dieter. Thus, a 9-g criterion would, we believe, lead such dieters to low-fiber diets whereas a 15-g criterion, because carbohydrate foods could achieve it, would actually allow for moderate-to-high-fiber diets.

The GMA petition made a point against setting the criterion higher than 9 g by relating daily carbohydrate totals to the DV of 300 grams. For example, they felt that 9 g times 16 daily servings of “low” carbohydrate foods would be only 48% of the DV, while a 12-g or 15-g criterion would be 64% or 80% of the DV, respectively. However, we view this as a flawed argument because a high percentage of the DV does not mean it is too high an amount. In fact, 80% of the DV is only 240 g of carbohydrate – again, only 48% of calories on a 2000-calorie diet, a level that is low in carbohydrate. The “low” criterion for fat (i.e., 3 g), when analyzed this same way, is 48 g fat, or 74% of the DV. Yet this amount of fat is only 22% of calories which is clearly a low-fat diet.

In sum, 15 g to define “low” is the most reasonable criterion because it allows for healthy low carb diets, and encourages innovation of carbohydrate foods and products (many as good sources of fiber).

Regarding the “small serving size” provision, Nestlé supports the criterion proposed by GMA, which is no more than 50% of calories from carbohydrate for foods with a RACC of 30 g/2 tablespoons or less.

For meal-type products, Nestlé also supports the maximum value proposed by GMA of 25 grams. Meal-type products use an approach of applying the “low” criterion for single foods on a per-100-g basis. Since we are recommending 15 g as the “low” criterion for single foods, if applied even to the minimum weight for a meal-type product (6 oz, or 170 g), one would get a value already exceeding the 25-g recommended maximum (25.5 g). We agree with GMA that any amount above 25 grams is inconsistent with what consumers would expect as being low, even for meal-type products. Nestlé’s recommended criterion for single foods would eliminate the need for a per-100-g criterion, and instead would simply set an absolute criterion of 25 grams or less to define “low” for all meal-type products.

#### “Good Source” and “High” should have two qualifying criteria

The GMA petition recommends 15 g and 30 g for “good source” and “high” carbohydrate claims, respectively. Not only will we demonstrate that these values are too low to define truly carbohydrate-rich foods, we also believe that the small difference between “low” and “good source” – only 6 g – would potentially be confusing for consumers. For

example, only two-thirds of a second serving of a “low carb” food enters the realm of a “good source” of carbohydrate.

To be consistent with the existing criteria for currently authorized “good source” and “high” claims, we recommend using the 10% DV and 20% DV standards. However, another qualifying criterion for each claim is clearly needed since 30 g and 60 g, respectively, would not be achievable by very many foods. This is especially true given that many foods have RACCs of 50 grams or less. It turns out that even using GMA’s proposed levels of 15 g and 30 g, similar problems arise whereby foods generally considered as carbohydrate-rich would not qualify for these claims if their serving sizes are relative small (this is demonstrated in a table of examples below).

The need for another qualifying criterion is also illustrated by products marketed by Nestlé’s sports nutrition business. We market PowerBar energy bar, the leading, and original, sports-nutrition bar for athletes needing high carbohydrate foods before, during, and after exercising. This product has always been regarded by athletes as a “high carbohydrate” food, yet with a RACC of 40 g, its 28 g of carbohydrate would fall below not only GMA’s proposed 30-g criterion for “high”, but also Nestlé’s proposed 30-g criterion for “good source”.

Therefore, the solution Nestlé recommends is to include an alternative criterion for these claims based on a “percentage of calories from carbohydrate” approach. This same approach was used for GMA’s and our recommended second criterion in the “low” definition for small-serving-size foods described above (< 50% of carb calories). We recommend that products would qualify for “good source” or “excellent source” if they provide 60% or 75% of calories from carbohydrate, respectively.

The 300-g DV for carbohydrate represents 60% of calories from carbohydrate. This is clearly a “good source” approach to achieve a balanced diet. Thus, we think 60% of carb calories will identify foods that are good sources of carbohydrate.

We think that the corresponding criterion for “excellent source” should be 75% of calories.

#### Include a disclosure of percentage of calories from carbohydrate

We note, however, that our suggested approach above of using percentage of calories from carbohydrate to define “high” and “good” source claims presents a potential complication. As serving size decreases, the grams of carbohydrate per serving of a product making these claims get smaller to the point they approach or even fall below the grams that qualify for “low”. Again, these are the kinds of complex issues one faces when dealing with a nutrient that has both “low” and “high” claims.

Our proposed solution, to minimize confusion, would be to require that “good source” or “excellent source” of carbohydrate claims that qualify on this basis of percentage of calories include, as part of the claim, the percentage of calories from carbohydrate. Thus,

this would communicate to consumers a clear demonstration that the product, even one with a small serving size, is “moderately high” (i.e., a good source) or high in carbohydrates relative to fat and protein. For example, “Good source of carbohydrate – 68% of calories”.

Here are some examples of products that would qualify for one, both, or neither claims using this approach. It gives the calories/serving, carbs/serving, and the amounts to qualify for “good source” (60% of carb calories) or “excellent source” (75% of carb calories). The Yes/No in parentheses indicates whether the product’s carbohydrate amount per serving exceeds the claim criteria and therefore would qualify for the claim:

	<u>Carbs/serving</u>	<u>Good Source</u>	<u>High</u>
2 oz pasta, 200 calories	41 g	30 g (yes)	37.5 g (yes)
PowerBar, 65 g, 230 calories	45 g	34.5 g (yes)	43 g (yes)
per 40-g RACC, 142 cal	27.7 g	21.3 g (yes)	26.6 g (yes)
Endurance sports drink, 70 cal	18 g	10.5 g (yes)	13 g (yes)
Honey Nut Cheerios, 120 cal	24 g	18 g (yes)	22.5 g (yes)
Whole wheat bread, 2 slices, 110 cal	22 g	16.5 g (yes)	21 g (yes)
Crackers, 120 cal	23 g	18 g (yes)	22.5 g (yes)
Dried fruit, 100 cal	24 g	15 g (yes)	19 g (yes)
Mexican style rice and sauce, 210 cal	44 g	31.5 g (yes)	39 g (yes)
Corn tortillas, 80 cal	14 g	12 g (yes)	15 g (no)
Nature Valley trail mix bar, 140 cal	25 g	21 g (yes)	26 g (no)
Tortilla chips, 140 cal	18 g	21 g (no)	26 g (no)
Biscuits, 190 calories	23 g	28 g (no)	36 g (no)*
Croutons with cheese, 30 calories	5 g	4.5 g (yes)	5.6 g (no)
“Carb Counting” bread, 2 (54 g), 120 cal	18 g	18 g (yes)	22.5 g (no)
per 50-g RACC, 111 cal	16.7 g	16.7 g (yes)	20.8 g (no)

\* However, would qualify as “good source” since it has 30 g/RACC

These examples show that foods thought of as carbohydrate-rich foods would qualify for one or both claims regardless of serving size. It also demonstrates that using the 15 g and 30 g proposals from GMA (which are only 5% and 10% of the DV), many of these same carbohydrate-rich foods would NOT qualify simply because of their serving sizes.

For example, the breakfast cereal, breads, crackers, dried fruit, and sports drink would not be “excellent sources” of carbohydrate using GMA’s 30-g criterion. The sports beverage would not even qualify as a “good source”, even though 97% of its calories are from carbohydrate. Likewise, the tortillas and croutons (which are not over 75% of carbohydrate calories due to their fat contents), would not even be “good sources” if using GMA’s 15-g criterion.

The last two examples with croutons and “carb counting” bread point out interesting situations:

- 1) **Croutons:** Because this is a bread-based product, one thinks of it as a carbohydrate food. Due to its small RACC, it has only 5 g carbohydrate per serving, which is lower than either the 9-g or 15-g criterion for “low”. However, it wouldn’t qualify for “low” based on the second criterion of < 50% of carb calories (it has 67% carb cal). This is as it should be. However, under the GMA proposal it would not qualify as Good Source, while under Nestlé’s proposal it would qualify for “Good source of carbohydrate – 67% of calories”. Would this confuse consumers, to have a product with fewer than 15 g of carbohydrate claiming to be a good source of carbohydrate? We believe it would not be confusing or misleading because of the added requirement to disclose its percentage of carbohydrate calories.
  
- 2) **“Carb-Counting” bread:** Although this bread was labeled to attract the “low carb” dieter, it did not quite meet even Nestlé’s recommended “low carb” criterion of 15 g per RACC. However, interestingly, it did meet both GMA’s and Nestlé’s recommended criteria for “good source”. This example points out the inherent “conflict” when dealing with a nutrient with both “high” and “low” criteria. With Nestlé’s recommended “low” criterion of 15 g, this bread could likely be reformulated with a little more fiber and less wheat flour to achieve the “low” claim, which would also put it below the amount necessary for “good source” (so that it would not qualify for both at the same time). Still, no matter what criteria are chosen, we will see products that are close to meeting both the “low” and “good source” criteria. With Nestlé’s recommended approach, at least these “good source” claims would be accompanied by a disclosure of the calories from carbohydrate to help minimize confusion.

In addition, the marketplace will certainly contain numerous “reduced carb” products that will still be good or excellent sources of carbohydrate. We saw one “reduced carb” pasta with 25% less carbohydrate, but still 31 g/serving! Incidentally, that would be an “excellent source” using GMA’s criterion, but with its 200 calories, it would not have met Nestlé’s criterion (75% of carb calories) for “excellent”.

We must accept that there will be examples of such dichotomies when dealing with carbohydrate claims. However, with Nestlé’s approach, it would be far less confusing than with the GMA or Kraft approaches.

#### Include a disclosure requirement for sugars

The Kraft petition proposed a maximum of 6 g sugars per RACC for the Good Source and High definitions (within their 15-g and 30-g qualifying suggestion). GMA was silent on this issue because there was no agreement among members on how to deal with this.

A sugars maximum does not necessarily make sense because sports nutrition products, to cite one category of foods, rely on both complex carbohydrates and sugars to provide the energy delivery needed for athletes during performance. Fruit and vegetable juices, and

even *certain* sweet snacks, also provide valuable energy via sugars in nutrient-rich foods. Therefore, we do not feel it is correct to disqualify foods with some level of sugars just to prevent sugary sweets and soft drinks from making a “good source” or “high” claim. Although we doubt that a company would ever attempt to make such a claim for a sugary, low-nutrition food in the first place, we realize that consumers would probably like to protect against this possibility.

Therefore, Nestlé suggests that a *disclosure* requirement be incorporated into the regulations for Good Source and High. As with the current disclosure regulation in 101.13 (h)(1), if a product exceeded the disclosure level for sugar per RACC, a statement in immediate proximity to the claim would direct consumers to the sugar content in the nutrition information panel. We do not have an amount we are ready to suggest at this time, but as an example, if 10 g/RACC were chosen, then a claim example might be:

“Good source of carbohydrate – 64% of calories... see nutrition information for sugar content.”

#### Change in Compliance Rule

The compliance rule in 101.9(g) should be changed slightly. Currently, a carbohydrate value in the Nutrition Facts panel is considered in compliance if it is within 80% of the amount declared. This is not valid, however, when carbohydrate would be claimed as “low”. Therefore, Nestlé recommends that this rule state that if a “low carbohydrate” claim is made on a product, the carbohydrate value must be within 120% of that declared.

Nestlé appreciates the opportunity to provide suggestions to the agency on this issue.

Sincerely,



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