Draft Guidance Document on Food Health Claims Related to the Reduction in Post-Prandial Glycaemic Response

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Bureau of Nutritional Sciences
Food Directorate
Health Products and Food Branch
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1.0 Introduction

1.1 Purpose

The purpose of this Guidance Document is to define the acceptable use of health claims related to the reduction in post-prandial glycaemic response, in the labelling and advertising of food products sold in Canada. In doing so, it provides guidance to industry for complying with subsection 5(1) of the Food and Drugs Act by making substantiated health claims that are truthful and not misleading. This Guidance Document is a complement to Health Canada’s *Guidance Documents for Preparing a Submission for Food Health Claims* (2009, 2011).

This Guidance Document applies to products that are manufactured, sold, or represented for use as food, which is defined in section 2 of the Food and Drugs Act. To fully understand the regulations governing the sale and advertising of foods, the document should be read together with applicable provisions of the Food and Drugs Act and its regulations and all other legislation and regulations applicable to foods, as well as their associated policies and guidelines. Food manufacturers are responsible for compliance with all relevant food legislation and regulations and for the accuracy of all information on the labels and in the advertisements of their products.

1.2 Terms

The following descriptions are provided as working definitions for the purpose of this document.

*Available carbohydrates (CHO)* are carbohydrates that are absorbed from the small intestine into the bloodstream.

*Comparative claims* are claims where the food that is the subject of the claim is compared to a reference food.

*Food* refers to a food (whole or processed) or a beverage that is the subject of the claim and that is tested as consumed.

*Function claims* are health claims that describe specific beneficial physiological effects of foods or food constituents on normal functions or biological activities of the body associated with health or performance.

*Post-prandial glycaemic response/Post-prandial glycaemia* is the change in blood glucose concentration following the consumption of available carbohydrate (CHO) containing foods.

*Reference food* is the food used for comparison to a test food. The composition of the reference food is typical for food commonly found in the marketplace.

*Test food* is the food being tested for its potential to exert the claimed effect.
2.0  Context

The growing interest in the health effects of foods among consumers and the food industry has prompted the development of the Food Directorate’s (FD) Health Canada’s Action Plan in Response to Stakeholder Feedback from Consultations on Modernizing Canada’s Framework for Health Claims on Food (2009). Among other objectives, this plan aims to increase industry’s capacity to make function claims for foods while retaining high standards to maintain the credibility of health claims. In Canada, food-related health claims have been classified into three main categories: disease risk reduction claims and therapeutic claims; function claims; and general health claims. While the use of function claims on food does not trigger premarket review by Health Canada, the manufacturer or distributor of the food product carrying such a claim remains responsible for documenting the validity of the claim. As with all claims about the health effects of foods, function claims must be substantiated by scientific evidence obtained through well-designed human studies.

In this context and as a complement to Health Canada’s Guidance Documents for Preparing a Submission for Food Health Claims (2009, 2011), this document sets out the criteria by which the validity of claims related to post-prandial glycaemic response may be assessed, and also clarifies the scope of acceptable function claims related to this health effect. Therefore, it will assist industry to comply with subsection 5(1) of the Food and Drugs Act regarding the use of such claims in the labelling and advertising of food products sold in Canada. This will also help contribute to public confidence in the food health claims system, as well as to promote consumer access to new food products with verified health benefits.

3.0  Claims on the Reduction of Post-Prandial Glycaemic Response and Characterization of Test and Reference Foods

Claims referring to the acute effect of reducing post-prandial blood glucose levels within normal physiological ranges in the context of food consumption would be considered function claims. Claims related to post-prandial glycaemia must not refer, explicitly or implicitly, to the long term control or management of overall glycaemia. Explicit claims about effects on post-prandial glycaemic response should characterize the food or food component(s), taking into consideration the amount likely to be consumed at one eating occasion (Aziz 2009). Many factors, such as the quantity, the physical properties, the nutrient composition (fat, fibre and protein content, starch characteristics) of the food, and the method of processing can affect the digestion rate of foods and thus the post-prandial glycaemic response to such foods (Food and Agriculture Organization 1998; Brouns et al. 2005; Venn and Green 2007; Englyst et al. 2007).
Claims on post-prandial glucose response can be made for:

### 3.1 Addition of ingredients

The addition of certain food ingredients (for example different types of dietary fibre) to carbohydrate-containing foods can decrease the rate of digestion and/or absorption of available carbohydrate and thus result in a decrease of the post-prandial glycaemic response following the consumption of these foods (EFSA 2012). In this context, the reference food should be the food without the added ingredient.

### 3.2 Substitution of ingredients

The total or partial substitution of non- and low digestible CHO such as resistant starch, high amylose starch, intense sweeteners and sugar alcohols, for highly digestible CHO in foods, can reduce the post-prandial glycaemic response to these foods (EFSA 2012). In this case, the reference food should be the food without substitution. Of particular interest in this case is fructose, a monosaccharide that elicits a much lower glycaemic response than other sweeteners such as glucose and sucrose. The health effects of fructose are a subject of debate within the scientific community (Bray 2008; Dolan et al. 2010a; Dolan et al. 2010b; Livesey and Taylor 2008; Livesey 2009; Stanhope and Havel 2010). It appears that very high intakes (≥100 g/day) of fructose could be associated with adverse metabolic effects, such as increased fasting triglyceride levels (Livesey and Taylor 2008). While the use of pure fructose as a sweetener is uncommon, some sweeteners have high levels of fructose, such as blue agave nectar (>90%), fruit (apple, pear) juice concentrates (≈65%), and some formulations of high fructose corn syrups (>55%). Therefore, in order to mitigate risks of long-term adverse effects associated with increased consumption of fructose, the total fructose content of the food bearing the claim should not exceed that of the reference food.

### 3.3 Foods with multiple compositional changes

The multiple changes to the composition of foods, for example addition of ingredients along with the substitution of one or more ingredients (for example, the addition of fibre and substitution of slowly digestible CHO for highly digestible CHO) can result in a reduction of the post-prandial glycaemic response to these foods. In this context, the reference food would be a similar food with different compositional characteristics. The claim would be comparative where the reference food should be stated as part of the claim (see also section 5.0). If one of the compositional changes involves substitution of fructose for other carbohydrates, the total fructose content of the food bearing the claim should not exceed that of the reference food.

### 3.4 Foods with inherent properties

Inherent properties of foods, such as the rate of digestibility, can explain the lower glycaemic response to such foods compared to reference foods. The test food must be in the same food category or serve a similar dietary role as the reference food with equal or lower amounts of...
available CHO per serving. In this case, the claim would be comparative where the reference food should be named as part of the claim (see also section 5.0).

Examples of acceptable claim wording for each of the above options can be found in Table 1.

4.0 Substantiation of Claims Related to Post-Prandial Glycaemic Response

4.1 General Considerations

While not meant to define precise research protocols, the following guiding principles for substantiating health claims in general are also applicable to substantiating claims about post-prandial glycaemic response.

4.1.1 Evidence should be based on in vivo human studies. In vitro studies can be used as supporting evidence to explain mechanisms of action by which the food or food ingredient exerts the claimed effect. However, in some instances where an acceptable in vitro method (for example starch digestibility) has been shown to correlate well with in vivo studies, the number of in vivo human studies required to support the health claim may be reduced. Also, in vitro data could be used for verification purposes, for example, to support claims for an ingredient in various matrices. If the claimed effect is verified in one matrix using both in vitro and in vivo studies, in vivo testing may not be necessary in another matrix for the same ingredient if the in vitro data for the different matrices are similar.

4.1.2 The studies should be carried out with the food/ingredient for which the claim is made. The amounts of reference and test food given in the study must be consistent with its serving size and intended pattern of consumption (for example, whether the food is consumed as snack or as part of a meal). Also, the food should be given as usually prepared because of the effects that factors such as cooking, physical form (whole versus puréed) and particle size of food can have on the glycaemic response (Pi-Sunyer 2002).

4.1.3 The test food and the reference food should be sufficiently characterised in terms of physical properties and nutrient composition to allow for evaluation and for a comparison to be made.

4.1.4 The quality of studies is assessed against applicable standards such as clearly defined objectives, and appropriate outcome measures, participant selection, methods and procedures and statistical analyses. Researchers may find it helpful to review and use recognized guidelines such as the CONSORT (Consolidated Standards of Reporting Trials) Statement in documenting their studies. Furthermore, Welch et al. (2011) provide additional guidance to assist with designing studies to support nutrition science and to substantiate health claims for foods.
4.2 Study Population

4.2.1 To substantiate a function claim such as those related to post-prandial glycaemia, the study population should be adult individuals who are generally healthy and should be clearly defined in terms of subject inclusion/exclusion criteria. These criteria should provide assurance that the subjects are suitable for the purpose of the study and are representative of the general population.

4.2.2 Individuals with clinically diagnosed impaired glucose tolerance who are not treated with medications that could interfere with glycaemic response may be included in addition to healthy individuals. However, the study should be powered to allow for subgroup analysis in order to determine whether the health effect is equally applicable to healthy individuals and individuals with the problem. Nevertheless, the claim on the food must be directed at the general population.

4.3 Outcome Measures for Post-Prandial Glycaemic Response

4.3.1 Substantiation of health claims for the reduction of post-prandial glycaemic response is obtained from acute (single meal) human intervention studies.

4.3.2 Glycaemia and insulinaemia are affected by the meal consumed just prior to testing (the pre-test meal), and the duration between the pre-test and the test meals. Therefore, if the test is done in a non-fasting condition, it is recommended that the composition of the pre-test meal and the time lapse between pre-test meal and the test meal be controlled and standardized.

4.3.3 Effects on the reduction of post-prandial glycaemic response could be demonstrated by a decrease in blood glucose concentrations measured at different time points after the consumption of the test food. Measurements should be taken for an appropriate period of time. Generally, measurements should be taken for at least 2 hours, with higher frequency (for example, at 15-minute intervals) in the first hour, and 30 minutes thereafter.

4.3.4 The insulin response to a food should be proportional to the post-prandial glycaemic response. Therefore, data on insulin concentrations following the consumption of the test food should be provided to show that the decrease in blood glucose concentrations is not accompanied by disproportionately increased levels of insulin, in comparison to the reference food. Data on insulin response is particularly important in the presence of large differences in protein between the test and the reference food.

4.3.5 The glycaemic and insulinaemic responses should be measured as the incremental area under the response curves (iAUC) above the baseline, according to the trapezoidal method (Wolever et al. 1991; Wolever 2004). Peak level (highest level) and time to peak for blood glucose or insulin are not sufficient to measure response, but can be used as supportive data, when correlating with area under the curve.
4.3.6 In order to support a claim related to the reduction of glycaemic response, a minimum 20% decrease in the average incremental area under the glucose curve in comparison to the reference food is generally considered a physiologically relevant change (Health and Welfare Canada 1985). This magnitude of change must also be statistically significant.

5.0 Claim Wording

While it is not meant to be an exhaustive list, Table 1 provides examples of acceptable and unacceptable claims on post-prandial glycaemia. Although the claim wording may be modified to reflect the evidence available, the following criteria are to be applied.

5.1 As with all health claims, the potential benefit to the consumer is clearly articulated in the claim in a manner that is well understood by the average consumer, as supported by consumer research.

5.2 As a function claim, the claim wording for post-prandial glycaemic response states the specific effect that has been demonstrated in the studies in support of the claim.

5.3 A claim about post-prandial glycaemic response based on human acute studies does not state or imply long-term maintenance or control of blood glucose.

5.4 Where the subject of the claim is an added food ingredient, the amount of the food ingredient that is the subject of the claim (per serving of stated size) must be stated as part of the claim.

5.5 Where a significant difference in post-prandial glycaemic response results from the replacement of one ingredient by another ingredient, both ingredients and amounts, if those are not equal, must be stated as part of the claim.

5.6 When the claim is made for a food as described in 3.3 or 3.4, and for which a decrease in post-prandial glycaemic response has been demonstrated compared to a reference food, the latter must be named as part of the claim.
6.0 Summary

6.1 Claims regarding the reduction in post-prandial glycaemic response are considered function claims and are to be substantiated using methodologically valid human studies.

6.2 Health claims regarding the reduction of post-prandial glucose response may be made for added food ingredients, food ingredients used as replacements for other food ingredients, and for foods used as substitutes for other foods.

6.3 The reduction in post-prandial glycaemic response is to be demonstrated by a decrease in blood glucose concentrations at specific (or various) time points for a period of at least 2 hours, after the consumption of the test food in comparison to the reference food. The claimed effect must be achieved by a serving of the food as customarily prepared and consumed. The decrease in blood glucose concentrations must not be accompanied by disproportionately increased levels of insulin. Incremental area under the curve values should be used for both blood glucose and insulin response.

6.4 To support a claim related to the reduction of postprandial glycaemic response, a minimum of a 20%, statistically significant decrease in the glucose concentrations, in comparison to the reference food, is considered a physiologically relevant change in the target population.

6.5 Claims related to post-prandial glycaemic response must be properly worded to reflect the effect of the food that is being supported by the experimental data. Such claims are not to create the impression that the food carrying the claim would help in the long term control or maintenance of overall glycaemia or in the management or risk reduction of diabetes.
### Table 1: Examples of acceptable and unacceptable claims

<table>
<thead>
<tr>
<th>Acceptable Claims</th>
<th>Unacceptable Claims</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acceptable claims are related to the glycaemic response to one food and limited to the time shortly following its consumption.</td>
<td>The following claims are misleading because they are not sufficiently specific or imply a broader or more long term effect:</td>
</tr>
<tr>
<td><strong>Addition of ingredients</strong></td>
<td></td>
</tr>
<tr>
<td>➢ [A serving of stated size] of [name of product X] contains n grams of [name of ingredient Y]. This ingredient reduces the glycaemic response to this food.</td>
<td>➢ “Low glycaemic index” or “reduced glycaemic index”.</td>
</tr>
<tr>
<td><strong>Substitution of ingredients</strong></td>
<td></td>
</tr>
<tr>
<td>➢ [Ingredient A] is replaced with [ingredient B] in [name of product]. This substitution results in a lower blood glucose/blood sugar rise.</td>
<td>➢ “Helps control blood sugar for up to x hours”.</td>
</tr>
<tr>
<td><strong>Foods with multiple compositional changes</strong></td>
<td></td>
</tr>
<tr>
<td>➢ (A serving of stated size*) of [name of product] results in a lower glycaemic response compared to (a serving of stated size*) of [name of reference food].</td>
<td>➢ “Promotes healthy/consistent blood sugar levels”.</td>
</tr>
<tr>
<td><strong>Foods with inherent properties</strong></td>
<td></td>
</tr>
<tr>
<td>(A serving of stated size*) of [name of food A] results in a lower glycaemic response compared to (a serving of stated size*) of [name of food B].</td>
<td></td>
</tr>
</tbody>
</table>

[ ] = mandatory; ( ) = optional; / = or
*Serving sizes may be omitted from the wording of the claim where they are equal and stated as part of the Nutrition Facts table.
Consultation

Comments on this document may be submitted electronically, between June 13 and September 10, 2013, to healthclaims-allegationsante@hc-sc.gc.ca. Please use the words “Comments Glycaemic Response Guidance” in the subject line of your e-mail. Comments must be received by 11:59 p.m. EST, September 10, 2013.

References


