The Use of Post-prandial Glycaemic Health Claims on Dry and Canned Whole Pulse Food Products for the Canadian Market.

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# Table of Contents

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Background</td>
<td>3</td>
</tr>
<tr>
<td>Scientific Evidence Supporting the Claim for Whole Pulses and Reduced Post-prandial Glycaemia</td>
<td>4</td>
</tr>
<tr>
<td>Consistency and Strength of Evidence for Whole Lentils</td>
<td>4</td>
</tr>
<tr>
<td>Consistency and Strength of Evidence for Whole Beans</td>
<td>4</td>
</tr>
<tr>
<td>Consistency and Strength of Evidence for Whole Peas</td>
<td>5</td>
</tr>
<tr>
<td>Consistency and Strength of Evidence Whole Chickpeas</td>
<td>5</td>
</tr>
<tr>
<td>Summary and Conclusions</td>
<td>5</td>
</tr>
<tr>
<td>Suggested Health Claim that Communicates Reduced Post-prandial Glycaemic Response with Whole Lentils, Beans, Peas and Chickpeas</td>
<td>6</td>
</tr>
<tr>
<td>References</td>
<td>7</td>
</tr>
</tbody>
</table>
Background

Acute post-prandial glycaemia health claims are considered to be function health claims in Canada and thus, prior to their use, do not require pre-market approval. However, as per Section 5 of the Canadian Food and Drug Act and the Canadian Food Inspection Agency’s Food Labeling for Industry, health claims should not be misleading and are required to be supported by scientific evidence, respectively. (1, 2) A systematic review of the scientific literature related to pulses and post-prandial glycaemia was commissioned by Pulse Canada in 2013 to determine if current data would support the use of this health claim on Canadian foods that contain whole dry and canned pulses. Released in 2013, Health Canada’s Draft Guidance Document on Food Health Claims Related to the Reduction in Post-Prandial Glycaemic Response (3) outlined proposed rationale and stipulations for using post-prandial glycaemia health claims on foods within the Canadian marketplace. At the time of the systematic review, a finalised version of Health Canada’s guidance specific to post-prandial glycaemia claims was not available. Therefore, Health Canada’s, Guidance Document for Preparing a Submission for Food Health Claims (4) was used to ensure results and conclusions from the systematic review were aligned with Health Canada’s standards of evidence.

The purpose of this briefing document is to summarize the results from the above mentioned systematic review and demonstrate that, at the present time, the current science supports the use of post-prandial glycaemic response health claims on whole dry and canned pulses.
Scientific Evidence Supporting the Claim for Whole Pulses and Reduced Post-prandial Glycaemia

To ensure that recent data were included in the review, only studies published between 1980 and 2012 were included in the literature search. Hand-searching was also included as a search strategy. Unpublished data were excluded from the literature search. After the removal of duplicate studies, established inclusion/exclusion criteria was used to further filter for relevant studies. Based on the predefined inclusion criteria and after full-text review, the number of studies remaining was 11 whole lentils, 7 for whole peas, 7 for whole beans and 4 for whole chickpeas.

Scientific Evidence Low Glycaemic Response Claim for Whole Pulses

Consistency and Strength of Evidence for Whole Lentils

For Lentils, 11 studies met the predefined inclusion criteria. Ten studies, which encompassed 12 treatment arms, were of high quality. When statistical significance was considered, 10 of the 12 treatments (83.3%) demonstrated a significant decrease in post-prandial glycaemic response with whole lentils. With the exception of one study, all of the studies included in the analysis used at least one cup (250 ml or ~200 g) cooked whole lentils. Compared to controls, statistically significant reductions in post-prandial glycaemic response ranged from 32% to 73%; which surpasses Health Canada’s threshold response of -20%. The total study population was comprised of healthy individuals and individuals with type two diabetes.

Consistency and Strength of Evidence for Whole Beans

Seven studies comprised of 15 treatment arms that used whole beans were examined. Of the seven studies assessed, six (14 treatment arms) were considered high quality, where eight treatments arms (57.1%) significantly decreased glycaemic response by 37% to 78%. Six of the seven studies included in the analysis recruited healthy subjects, while the study by Krezowski et al. evaluated the effects of whole beans on post-prandial glycaemic response in individuals with type 2 diabetes. Efficacious dosages of whole beans ranged from 196 to 338 g (approximately 250 ml to 500 ml).
Consistency and Strength of Evidence for Whole Peas

Eight treatment arms from seven clinical trials were included in the analysis. Eight treatment arms from seven clinical trials were included in the analysis. $^8$ Subgroup analysis of six high quality studies $^{12; 13; 14; 15; 18; 19}$ revealed that, of the seven treatment arms, four (57.1%) demonstrated a significant effect of whole peas on post-prandial glycaemia. $^{15; 18; 19}$ Compared to controls, 143-491 g (approximately 250 ml to 625 ml) whole cooked peas decreased glycaemic response by 24% to 69%. Furthermore, similar to lentils, beneficial effects of whole cooked peas on acute post-prandial glycaemia was shown in healthy subjects as well as those with type 2 diabetes.

Consistency and Strength of Evidence Whole Chickpeas

All four studies (four treatment arms) included in the analysis were considered high quality. $^{12; 13; 14; 15}$ Compared to controls, three of the four treatments (75%) demonstrated that whole chickpeas significantly decreased post prandial glycaemic response by 35% to 47%. $^{13; 14; 15}$ All subjects included in the analysis were considered healthy and efficacious dosages of whole cooked chickpeas ranged from 222 to 341 g (approximately 325 ml to 500 ml). $^{13; 14; 15}$

Summary and Conclusions

The systematic review of high quality studies demonstrated that, when used to replace highly digestible carbohydrates, whole pulses, regardless of type, elicited a significant decrease in post-prandial glycemic response at a magnitude that meets or exceeds Health Canada’s 20% threshold. $^4$ Therefore, at this time, the evidence supports a health claim that communicates the low glycemic response of canned or conventionally prepared dried whole pulses.
Suggested Health Claim that Communicates Reduced Post-prandial Glycaemic Response with Whole Lentils, Beans, Peas and Chickpeas.

Following the systematic review of the scientific literature, Pulse Canada initiated communication with Health Canada regarding the appropriate wording that should encompass a post-prandial health claim for whole lentils; with the understanding that the wording could also be applied to whole cooked beans, peas and chickpeas. Overall, evidence demonstrated an effect of whole pulses on post-prandial glycaemic response when pulses replaced available carbohydrate in comparable and standardized foods, as well as ingredients; including glucose, white bread and pasta. After discussion with Health Canada, the following claim reflects the current body of evidence for the attenuation of glycaemic response with pulses.

“One cup (250 ml) of cooked (type of whole pulse) in place of [instead of] low fibre starchy foods results in a reduced blood sugar [glucose] rise after a meal.”

Currently, evidence supports 250 ml as the minimum effective dose for lowering post-prandial glycaemia. Furthermore, given that a 250 ml serving size for pulses was part of the amended regulations for food that were proposed in Gazette 1 in June 2015, Health Canada has designated that 250 ml be included in the claim statement. This also aligns with Schedule K and Schedule M of the Canadian Food and Drug Regulations where the Reasonable Daily Intake and Reference Amount for cooked whole pulses and legumes is 250 g and 250 ml (one cup), respectively. (20; 21) As ongoing research delineates the minimum effective dose of whole pulses needed to attenuate post-prandial glycaemic response, there will be opportunities to lower the 250 ml threshold that is currently included in the abovementioned claim.

While the health claim outlined in this document is reserved for whole pulses that are sold as dry, canned, or used to replace low fibre and starchy ingredients in multi-ingredient foods, research is currently underway to further decipher the effects of processed pulse ingredients on glycaemic response in various food matrices. Accordingly, as more data that defines the effects of processed pulse-based ingredients on post-prandial glycaemia become available, opportunities to expand the abovementioned health claim to include such products will be critically reviewed and considered.

Please do not hesitate to contact Pulse Canada if there any questions regarding the nature and scope of this summary document and assessment, as well as for any support that might be required to implement the health claim.

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References