Health Canada's Action Plan in Response to Stakeholder Feedback from Consultations on Modernizing Canada's Framework for Health Claims on Food

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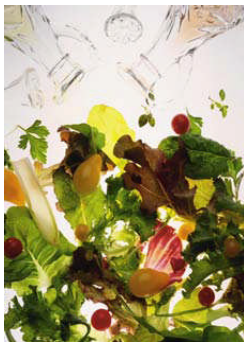


Canada

Food and Nutrition

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Introduction:

A number of pressures and influences have prompted Health Canada to initiate a review of the current system for the management of health claims. In early 2008, the Food Directorate of Health Canada's Health Products and Food Branch (HPFB) undertook consultations in order to solicit stakeholders' opinions with respect to their policy preferences in the area of health claims for food. The process included an online publication of a discussion paper entitled *Managing Health Claims for Foods in Canada: Towards a Modernized Framework* (http://www.hc-sc.gc.ca/fn-an/consultation/init/man-gest_health_claims-allegations_sante-eng.php) November 2007; six face-to-face sessions with 286 stakeholders in 6 cities across Canada; and the solicitation of written feedback using a questionnaire. The *Report on Stakeholder Feedback on Modernizing Canada's Framework for Health Claims on Food* (http://www.hc-sc.gc.ca/fn-an/pubs/label-etiquet/_claims-reclam/2009-feedback-commentaire/index-eng.php) and the *Report of Regional Workshops on Modernizing Canada's Framework for Health Claims on Food* (http://www.hc-sc.gc.ca/fn-an/pubs/label-etiquet/_claims-reclam/2009-atelier-region-wrkshop/index-eng.php) provide a summary and analysis of the stakeholder opinions received by Health Canada in early 2008

Government Response and Action Plan:

This Response and Action Plan summarizes stakeholder opinion very briefly and communicates to stakeholders the government's progress and intended future activities. Health Canada has developed a five year Action Plan of ongoing and planned activities which is already being implemented. Stakeholders' recommendations have been reviewed and some suggestions have already been implemented. Health Canada is committed to continuing to work with its partners and stakeholders in order to determine what additional activities can be undertaken to address the identified issues. The following is an outline of the action plan.

1. Improving the Efficiency and Transparency of Processes:

Overall, stakeholders agreed with Health Canada's proposed improvements in processes identified in the Discussion Paper, such as implementing standard operating procedures for the Health Canada review of submissions, developing an abbreviated process for review of claims recently approved by internationally recognized scientific bodies or competent national authorities, and dedicating additional resources to the review of health claims as well as to regulatory drafting and legal services.

A small group of consumers and health/disease organizations believed that only a finite number of health claims should be permitted and that these claims should be managed as a standardized system by government.

Stakeholders generally supported improved transparency; however, industry did have concerns about the dissemination of any proprietary information. All groups strongly supported the publication of Health Canada's decisions for approved health claims with a majority believing that only a summary of the evidence submitted and Health Canada's scientific evaluation needs to be published.

Actions in progress or completed:

- A Submission Management and Information Unit has been created within the Food Directorate and will provide industry with a single entry point for filing food submissions for pre-market assessment including those for health claims.
- The Nutrition Labelling & Claims Section was created in May of 2005 and will be maintained; evaluators are being hired and trained to review health claims submissions.
- Summary Basis of Decisions documents for food health claims will be posted on the Health Canada website as they are completed.
- The development of an abbreviated review process for the use of claims based on

authoritative statements or claims authorized in other jurisdictions, which will expedite the approval of some health claims, is in progress.

- Health Canada will publish a report summarizing the feedback on the paper entitled "Five US Health Claims Considered for Use in Canada" (http://www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/position_paper-enonce_position-eng.php) and complete the regulatory process for the authorization of the claim linking folate to neural tube defects.
- Health Canada intends to post process maps of the submission review process and the regulatory amendment process for health claims with clarifications regarding their application.

Actions planned:

- Regulatory proposals will be prepared for claims linking oats, psyllium, and phytosterols and heart disease.
- Regulatory proposals will be prepared for the authorization of health claims linking vegetables and fruit or whole grains and heart disease. The proposals related to the whole grain health claims also involve the regulation of whole grain labelling and regulatory amendments of standards for whole wheat flour and (naming %) whole wheat bread.
- Alternatives are being sought for regulatory or legislative changes that would help to reduce the time required between the scientific review of claims and the time when companies are authorized to go to market with products carrying the claims.
- Health Canada is working towards having 90 % of submissions reviewed within target review times within five years.
- Health Canada will propose criteria for prioritizing health claim submissions waiting for review, for use if a large number of submissions are in the queue.

2. Supporting Good Quality Submissions:

Most stakeholders favoured Health Canada's proposals to improve quality of submissions through clearer submission requirements, but believed that Health Canada should not expend significant resources in assisting industry with submissions and that this role can be undertaken by non-government organizations such as private consultants or academia.

Actions in progress or completed::

- The *Guidance Document on Preparing a Submission for Food Health Claims* (*aka* the Submission Guidance Document) (http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/health-claims_guidance-orientation_allegations-sante-eng.php) has been updated. It provides clearer submission requirements and maintains the principle that disease risk reduction claims and therapeutic claims be based on a high level of certainty.
- A submission completion checklist for use by evaluators and petitioners is posted on the

Health Canada website as part of the updated Submission Guidance Document.

- Supplementary guidance will be developed and posted as it is completed on the Health Canada website, e.g. *Guidance Document: Use of Probiotic Microorganisms in Food*. (http://www.hc-sc.gc.ca/fn-an/legislation/guide-ld/probiotics_guidance-orientation_probiotiques-eng.php)
- Health Canada is undertaking training workshops on submission preparation for all interested parties from time to time. An example is the webcast (http://event.on24.com/eventRegistration/EventLobbyServlet?target=lobby.jsp&eventid=134290&sessionid=1&key=DA4B7F31669D9EAF2B8592909C3B3DA3&eventuserid=22986565) held on March 24, 2009 through the sponsorship of Agriculture and Agri-Food Canada which is available for website viewing until March 24, 2010.
- Health Canada is collaborating with Agriculture and Agri-Food Canada (http://www4.agr.gc.ca/AAFC-AAC/display-afficher.do?id=1244561820163&lang=eng) through the Growing Forward (http://www4.agr.gc.ca/AAFC-AAC/display-afficher.do?id=1200339470715&lang=eng) initiative to provide the food industry with support in the development of research that can be appropriately used to support health claims submissions.

3. Increasing Industry's Capacity to Make Function Claims:

Most stakeholders believed that the same standards of evidence should be applied to all claim types, e.g. disease risk reduction claims, function claims and general health claims. However, others supported a tiered approach and believed that only disease risk reduction claims should be based on a high level of scientific certainty. Generally, stakeholders supported regulatory measures to manage function claims and believed that Health Canada should have the authority to require pre-market assessment or at least justification of information for foods carrying function claims when concerns have been identified. Industry, however, was less supportive of this approach and believed that a mandatory pre-submission review process should only apply to disease risk reduction claims.

Actions in progress or completed:

- Following reviews led by Health Canada or reviews based on voluntary submissions by the industry, function claims for foods that are considered acceptable will continue to be added to the Guide to Food Labelling and Advertising (http://www.inspection.gc.ca/english/fssa/labeti/guide/toce.shtml) of the Canadian Food Inspection Agency (CFIA). The principles outlined in the Submission Guidance Document also apply to the substantiation of function claims.
- For the time being, no additional regulatory measures will be implemented to manage function claims. While it is not mandatory to file a submission with Health Canada for these function claims, the evidence relied on to support the claim should be retained on the company's site and made available to CFIA upon request in case there are concerns

that the claim is false, misleading or deceptive.

4. Enhancing Consumer Confidence in the Regulations of Health Claims

Stakeholders in general would like to see information communicated in simple clear language that would enhance confidence in the regulatory system. They also believe that academia, industry and non-government agencies could play a role in delivering this information. Stakeholders mostly supported the idea of post-market surveillance to determine the market impact of health claims (http://www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/index-eng.php) and they generally agreed that "disclaimers" on products with health claims (such as the "qualified" health claims in the United States) should not be permitted.

Actions in progress or completed:

- Consumer research will be conducted as needed, in order to understand consumer interpretation of the proposed health claim statements on foods ensuring that claims are not misleading.
- Disclaimers related to the degree of scientific support for health claims on food labels (qualified health claims) will not be accepted in Canada.
- The CFIA will continue to monitor industry compliance with the *Food and Drugs Act* and its regulations.
- Health Canada has posted a new Health Claims webpage with convenient links to relevant Guidance Documents as well as an update of the Qs and As on Health Claims.

  (http://www.hc-sc.gc.ca/fn-an/label-etiquet/claims-reclam/qa-qr_claims-allegations-eng.php)
- CFIA is amending Chapter 8 on Health Claims of its Guide to Food Labelling and Advertising to reflect the new approach to the management of health claims on food.

Actions planned:

- Health Canada intends to seek involvement from outside organizations to help improve consumer understanding and public health relevance of food health claims. For example, Agriculture and Agri-Food Canada has conducted some consumer research in 2009 that will be used to help refine the regulatory proposal for whole grain claims.
- Additional consumer research will also be conducted to determine what impact health claims have on consumer food choices and on offerings in the market place.

5. Clarifying the Overlap at the Food-Natural Health Product Interface

On the subject of addition of bioactive substances to foods, responses were divided; industry stakeholders generally supported the addition of bioactive substances to foods, indicating that both the potential associated risks and the types of claims for the products vary and the standard

of evidence should vary accordingly; also, proper labelling could be used to help control risk. On the other hand, the focus of non industry stakeholders was more on educating the public and providing clearer messaging on healthy eating.

Actions in progress or completed:

- Health Canada has posted the guidance document entitled *Classification of Products at the Food-Natural Health Product Interface: Products in Food Formats* (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/docs/food-nhp-aliments-psn-guide-eng.php) to assist in the determination of product classification for products falling at the Food-Natural Health Product interface. Determining a product's classification is a necessary first step in identifying which set of regulatory requirements a given product must follow. In the case of these products, either the *Natural Health Products Regulations* (http://www.hc-sc.gc.ca/dhp-mps/prodnatur/legislation/acts-lois/prodnatur/index-eng.php) or the food sections, Parts A, B and D, of the *Food and Drug Regulations* (http://laws.justice.gc.ca/en/F-27/C.R.C.-c.870/index.html) would apply.
- A Classification Committee has been set up which will be responsible for applying the classification principles and criteria for making final classification decisions for products at the food/NHP interface.
- The Food Directorate (FD) is participating with the Natural Health Products Directorate (NHPD) as they develop natural health product (NHP) monographs that overlap with matters relevant to foods.
- A workshop on the labelling and overall representations, including advertising of NHPs in food format was held on April 23, 2009 to identify potential mechanisms, approaches, tools and strategies for reducing the potential risks of NHPs in food format.
- Consumer research will be used to confirm the outcomes of the workshop and better understand consumer perception of NHPs in food format and expectations regarding their composition and labelling.
- Results will serve to guide the work of an established NHPD-FD working group to address these issues.

Actions planned:

- In the medium term, Health Canada will be developing a policy proposal for the management of NHPs in food format and therapeutic foods, and if required, will move forward with the promulgation of regulations for these products under the appropriate regulatory frameworks e.g., NHP and/or Food.

6. Increased Standardization of Front of Package Claims, Logos and Symbols

On the issue of Front of Package (FOP) labelling and implied claims, there was some support for Health Canada's proposals to undertake consumer research on the interpretation of FOP labelling

in concert with the Nutrition Facts table and to examine the standardization of the nutritional criteria underlying FOP symbols and claims. However, on the issues related to setting core nutritional criteria before health claims would be permitted, stakeholders in general felt they were unable, at this stage, to offer informed points of views.

Actions in progress or completed:

- An environmental scan is being undertaken with respect to the use of nutritional criteria in policies and programs such as FOP symbols and health claims and will include an overview of what is being done internationally to define "healthy foods", the challenges encountered as well as the potential implications for population health.
- A similar exercise will be completed at the national level.

Actions planned:

- Following the above analysis, a specific action plan for targeted consultations will be developed. Following this, pending sufficient feedback and support, Health Canada will articulate a policy proposal for nutrition eligibility criteria and possible applications of these criteria within a Canadian context.