



March 31, 2008

CIAI Response to the Consultation on Food Health Claims

Note: CIAI responses are shaded in the following text.

Theme 1.1 Business improvement actions for increased efficiency

1. Several business improvements are proposed to address key operational issues:
 - Dedicating additional resources to the review of health claims for foods
 - Implementing standard operating procedures (SOPs) for the Health Canada (HC) review of submitted claims. Finalized SOPs will be shared with stakeholders.
 - Developing the parameters for an abbreviated process for claim review where internationally recognized scientific bodies or competent national authorities have recently completed a review and deemed the claim as valid. Acceptable ways to deal with different decision outcomes would also need to be considered
 - Examining ways to improve efficiency administering the current regulation, where claim specific regulatory amendments are required.

Several options are being considered

 - dedicating more resources in regulatory drafting and legal services
 - exploring when it may be possible to expedite the time taken to proceed to the final amendment of the Regulations in *Canada Gazette Part II*
 - Exploring appropriate triggers and processes for deciding when a second review of an approved claim may be needed. However, this is not considered a priority activity at this time.

Overall, how effective do you feel these actions would be, using a 1–6 rating, with 6 being highly effective and 1 being not effective at all.

1 **X** 2 3 4 5 6

Please **explain your rating:**

We believe that the consultation document puts too much emphasis on helping business to create multiple confusing claims rather than on ensuring that claims are credible and meaningful to consumers. Recent US research has made it clear that the concept of “qualified claims” is not well understood by consumers, who tend to believe that the more is said on a claim, the better the claim is, while the opposite may actually be the case.

CIAI believes that any additional resources should go to monitoring and enforcing current rules, rather than in making it quicker and easier for industry to make more claims. It is difficult to “fix” a system without a clear understanding of where existing problems exist.

Canada's food labelling policies in general and health claims in particular should be based on good public policy and addressed through regulations where required, with appropriate implementation and enforcement strategies and the resources to carry them out. While we recognise the needs of food processors, their marketing imperatives should not be driving this process.

Despite the work that has gone in to making it possible for food processors to make health claims on food, the current system does not appear to address their requirements. A simpler system would seem to be preferable, even if it does not allow them to make all the claims they would like to make. Care must also be taken to ensure that health claims do not move consumers away from healthy fresh fruit, vegetables and meat towards eating even more processed food.

Theme 1.2 Increased openness and transparency

1. Health Canada is exploring the possibility of publishing decision documents related to health claim applications. All proprietary information would be excluded. Please tick the box beside the information that you think should be included in published decision documents from

- the health claim submission:
 - proposed health claim
 - summary of evidence submitted
 - full tabulation of evidence submitted
 - other (please specify)

In addition to the items identified above, CIAI believes that it would be helpful to both Health Canada and consumers for the submission to contain information on how the same claim has been

addressed by our trading partners, particularly the USA, EU and Australia/New Zealand, and for that information to be part of the package that is publicly available.

- Health Canada's assessment:
 - summary of HC scientific evaluation of the submission
 - detailed HC evaluation of the submission
 - results of consultations, if applicable
 - decision and rationale (including conditions of use for an accepted claim and product)
 - other (please specify)

Please **explain your selections:**

This list would seem to be the minimum to enable non-government scientists to review the process and decision adequately.

Please provide a copy of what you consider to be an appropriate format for a decision document in the Canadian context.

There are existing examples within the Canadian government that could be used for this process. CIAI would recommend using an existing model, such as that used by the Pest Management Agency, which is part of Health Canada, rather than re-inventing the wheel and using valuable resources creating a specific framework for publication of this data.

1. A high level of certainty in scientific substantiation of claims is based on the following:
 - structured, comprehensive literature review of all the relevant evidence,
 - human studies of acceptable quality, and
 - consistent cause-and-effect relationship between the consumption of foods or food constituents and the claimed health benefit.

Should all claims be based on a high level of certainty? Please provide the rationale for your response.

This was a discussion item on which there was considerable difference of opinion between stakeholders at some of the consultation meetings. At others, there was more agreement that a distrusted food labelling system would not be in the best interest of any stakeholder group.

CIAI believes that simple is better – set one bar and set it high. We do not support the concept of less scientific support for different claims, it is just confusing for consumers and leads to more “qualified” claims that are misunderstood.

Also, substantiation of claims must be of an acceptable quality, based on an appropriate population group of consumers, and not a convenience sample (2nd bullet).

1a. If there is a role for claims based on a lower level of certainty,

- what principles should determine which claims could be based on a lowest level of certainty?
- should consumers be informed of the level of certainty that supports a claim?
- what type of information about the level of certainty should be conveyed?

1b. How should this be communicated? Please provide evidence (if available) to show that what you suggest would not be misleading to consumers.

CIAI does not support the use of claims with a lower level of certainty. In the event that Health Canada continues to consider allowing food producers to make such claims, they should be required to invest in consumer education on their existing claims prior to any expansion of the current system or any lessening of evidentiary support for claims. This education effort should be monitored and approved by Health Canada to ensure that it is provision of accurate information rather than more advertising.

CIAI is aware of economic studies indicating that the wide range and variety of claims – like the qualified claims at issue – add noise that impedes the successful interpretation of truthful messages from sellers with superior offerings.

Theme 2.2 Supporting good-quality submissions

1. Health Canada is proposing several ways in which it could support industry in drafting good quality submissions:

- encouraging pre-submission consultations;
- updating the 2002 *Interim Guidance Document* to include specific guidance on the preparation of a structured, systematic review with the knowledge gained from the work done by the PFSNRA and Health Canada;
- supporting in principle the efforts of third parties to coordinate and assist small and medium-sized industry members that are willing to collaborate in making joint submissions on ingredients or food constituents of common interest;
- exploring ways to address gaps in the scientific evidence associated with the health-related benefits of food ingredients at a pre-submission stage with interested parties (e.g., Agriculture and Agri-Food Canada); and
- participating in third-party forums organized to sustain domestic infrastructure for basic and applied research in food and nutritional science needed to support the development of safe, innovative food products with substantiated health benefits.

Overall, how effective would these proposals be, using a 1–6 rating, with 6 being highly effective and 1 being not effective at all.

1 2 3 4 5 6

Please explain your rating:

CIAI would not want to see scarce resources being used to help large food processing companies through the process of making advertising type health claims. However, we do support the concept of systems that enable Canadian small and medium enterprises (SMEs) to compete more effectively in the value added food and agrifood system. We would encourage Health Canada to examine systems already in place in other parts of the department that may facilitate SMEs competitive market entrance (a process similar to user requested registrations under PMAC) in order to find effective models.

A critical pre-submission requirement of any health claim should be that the food product itself is “healthy” and we believe this is an area where third parties can play an effective role. Not only is additional research needed in this area but also increased monitoring by Health Canada of general “healthy” claims already in the marketplace and enforcement of misleading advertising rules.

We support basic and applied research in food and nutritional science but care must be taken to ensure that government funds are not being applied to normal business development in existing competitive companies. We do support business assistance to SMEs that would result in increased competition in the food-processing sector.

2. What should be industry's role in preparing good quality submissions?

2a. Which organizations could support applicants in preparing good quality submissions? How?

CIAI believes that if industry wishes to make a health claim, which we believe is a marketing tool, they should be responsible for preparing high quality submissions and the only role of Health Canada should be to refuse to accept submissions that are not of a high enough quality to warrant review.

3. In managing health claims for foods, there is a need for long-term research to substantiate potential health benefits and to identify health risks. Which organizations can help strengthen or support research in these areas? How?

A great deal of research is currently underway in these areas, particularly in the food and agriculture research “clusters” at the universities of Guelph, Manitoba and Saskatoon. CIAI believes that Universities and the private sector are forming partnerships to perform this research and, given the current reduced scientific capacity within Health Canada, these should be used to oversee and review rather than being engaged in primary research. We do support an increase in the number of scientists employed at Health Canada.

Theme 3.1 Functional foods and the food/NHP interface

1. What are the expected areas of development of functional foods or bioactive ingredients in the next 1–3, and 3–10 years? Why?

2. Considering the addition of bioactives to foods in general,

- are there some types of bioactive substances that should not be added to foods at any level? Please identify and explain.

- should the addition of bioactive ingredients be allowed in foods at levels that, while safe, are too low to claim any health benefit? Please explain.

Bioactives are being used and promoted with little regard as to whether consumers know or understand what they are, how they work in the human system, whether they can be consumed in amounts that pose risk and whether or not they are actually needed as part of a healthy diet. There is a need for a massive consumer education movement on these substances with close oversight by Health Canada to ensure accuracy.

If bioactives are to be added at a level that is too low to make a health claim, there is still a requirement to inform consumers that they has been added to their food if there is any possible risk from over-consumption. If there is scientific evidence that there is no risk, there is still a need for consumers to know and understand more about bioactives. This does not necessarily mean mandatory labelling.

3. Is there a case for adding bioactive substances to foods at levels that would benefit some, but be risky to that same group if improperly consumed, or risky to other segments of the population?

3a. If these types of bioactive substances were to be considered, what type of risk management options would be appropriate

- to ensure that the untargeted population is not put at risk, and
- to ensure the safe use of the product by the target population.

Examples used for managing this type of risk in Natural Health Products (NHPs) and drugs include the following:

- claim wording
- packaging to target specific user groups
- restricting distribution channels
- directions for use
- cautionary statements
- warnings

Given the current level of consumer understanding of these substances, CIAI could only support restricted distribution channels at this time. It is clear from the US research that claim wording and additional qualifications are misunderstood. Our own research in Canada has shown that the

readability of food labels is so poor that none of the other alternatives would be effective at this time.

If any other alternatives are considered by Health Canada, they must be accompanied by rules on the presentation of the information similar to those applied to the nutrition facts panel. These rules must be enforced and must not include exceptions to the rules, such as those allowed for “meal replacements” in the nutritional panel rules.

3b. If possible, explain how the risk management measures you suggest would be effective when applied to products sold as foods.

It is likely that restricted distribution channels would make it difficult for these products to be sold as “food”. Should these products be sold through unrestricted channels, the only effective risk management measure would be increased monitoring and enforcement by Health Canada. CIAI believes that an increase in the capacity for administrative penalties would enable this activity.

Theme 3.2 Managing a broader range of function claims

1. Some measures are proposed in the document to help ensure credibility of a broader range of function claims:

- clarifying the nature of acceptable function claims that would not be considered drug claims,
- encouraging industry to submit, voluntarily, new function claims for review by the Food Directorate, and
- maintaining an up-to-date list of function claims that are deemed “not misleading” in the CFIA Guide to Food Labelling and Advertising.

Overall, do you feel these non-regulatory measures would be sufficient to manage an expanding range of function claims, using a 1–6 rating, with 6 being completely sufficient and 1 being not sufficient at all.

1 2 3 4 5 6

Please explain your rating:

CIAI does not support an increase in the range of function claims at this time. We do not believe that consumer information is adequate to handle the existing claims nor is the government capacity for oversight able to enforce the existing legal requirements of food labelling. Adding options at this time will just add to consumer confusion and will not help us move to a better-nourished population. Focus group research we performed recently led us to believe that food labels are leading to Canadians being overfed and undernourished and we would like to see health claims reversing that situation, not adding to it.

CIAI is particularly concerned that this consultation, which will affect food labels, appears to be proceeding in isolation of other labelling issues: highlighted ingredients, QUID, and allergen labelling come to mind. All of these issues will affect the use of space on the label and, unless regulations on readability of labels is tightened up and enforced, consumer use of label information will be reduced.

We also believe that it would be simpler for the processing industry to deal with implementation of new labelling regulations if all of these items were addressed together and presentation rules that dealt with the readability issues were applied at the same time. That makes the playing field level between competitive products in the Canadian marketplace, whether they are domestic or imported products.

2. What other types of non-regulatory measures would you suggest?

A suggestion made at the Winnipeg consultation outlined a process similar to the Environment Canada led eco-logo programme where a multi-stakeholder third party process would manage the system for development and use of criteria for health claims with Health Canada “owning” and overseeing the process. This would enable full transparency, credibility, reliability, consistency, a level playing field, access to all sizes of industry and increased consumer education while Health Canada would still be the final authority. It would also facilitate the process of only allowing the claims to be applied to products that meet a “healthy food” standard and could lead to the removal of the multiplicity of private, meaningless logos from the food market. CIAI would be supportive of this type of non-regulatory measure.

Any non-regulatory measure must involve a range of stakeholders that includes a specific representative of the consumer interest.

3. Health Canada could also rely on regulatory measures for more rigorous control of claims.

Please indicate whether Health Canada should explore the following measures:

3a. requirement for the submission of supporting evidence when there are concerns about the credibility of a health claim being used on foods already in the marketplace.

Yes No

Please explain:

CIAI is concerned about many of the claims and logos already in the marketplace. The criteria used for these are not transparent and there appears to be no regulatory oversight of the science to support their use or application.

Health Canada needs to define “healthy” food. We have the “Canada’s Food Guide” and the nutrition panel but there are a lot of food products that contribute little to our nutrition, add a lot of “empty” discretionary calories to a daily diet and are leading to the obesity crisis. All food carries the nutritional panel that, since it is poorly understood, may lead some consumers to believe there is nutritional value in some products where there is none. The non-use of the nutrition panel on many fresh foods and the use of private label “healthy” logos on highly processed products can add to this misunderstanding. If we are to have health claims on healthy food, we need Health Canada to lead the way with a “healthy food” definition.

3b. mandatory pre-market review of function claims

Yes No

Please explain:

We do not believe that the many consumers actually recognize the difference between the different levels of claims. US research shows that consumers actually believe that claims with more qualifications suggest that products are better because they say more rather than recognizing that the reverse may be true. Whether the system continues to be totally regulatory or some non-regulatory system is introduced, there is a need for pre-market review of all claims, how they are

made and the science that supports them. Additionally, they should not be allowed on food that does not meet a basic requirement of being a healthy part of the diet.

4. Are there other regulatory measures that Health Canada should consider? If so, please identify the measure(s) and explain your rationale.

There is no value in additional regulatory measures if they are not accompanied by the resources necessary for adequate monitoring and enforcement. CIAI would prefer to see additional resources applied to monitoring and enforcement of existing rules relating to food nutritional requirements and labelling requirements rather than to more regulatory rules that are not enforced.

Theme 3.3 Managing diverse front of package claims

1. Several measures are proposed to ease confusion by consumers over the proliferation of health-related claims on the front of food (FOP) packages:

- educating consumers on the Nutrition Facts table and ingredient listings in conjunction with FOP symbols and claims,
- providing guidance to industry on conditions and wording that would help ensure that claims are not misleading,
- improving nutrition labelling regulations as needed, and
- monitoring the marketplace to ensure that activities related to consumer education, industry guidance, and regulatory changes are evidence-based.

Would these measures be sufficient to reduce the confusion arising from proliferation of health-related claims on the front of food packages?

Yes No

Please explain:

While CIAI believes that these measures would be sufficient, we are not convinced that the current system has the capacity to implement these measures. Recent CIAI research on the readability of food labels demonstrated that, while the nutrition facts panel is the only part of the label that is

clear and readable on most products, it is poorly understood and educational efforts have, to date, been ineffective. The nutrition facts panel labelling regulations are generally adequate, although we do not support exceptions such as those in place for “meal replacements” but enforcement of the “readability” requirements of the rest of the label are definitely not. Health claims definitely require rules on print style, size, contrast, etc. but along with that, information already required on labels must be made more readable and proportional to claims made purely for the purpose of increasing sales.

2. Prohibiting implied claims of a health benefit, unless the health effect is clearly stated, could also reduce consumer confusion. How worthwhile would it be to explore this measure, using a 1–6 rating, with 6 being highly worthwhile and 1 being not worthwhile at all.

1 2 3 4 5 6

Please explain your rating:

CIAI supports any measure to reduce marketplace confusion. As stated previously, we would like to see a prohibition on implied health claims and logos on products that are not clearly identified as a healthy part of the diet. We are also concerned that health claims and use of the nutrition fact panel on processed food, rather than on fresh fruit, vegetables and meat are leading consumers to eat more processed and/or fortified food products that are not only less healthy than fresh products but are also more expensive and involve more packaging.

Theme 3.4 Eligibility criteria for foods to carry claims

1. Health Canada could also create a set of core nutritional criteria that all implied or explicit health claims should meet, and could apply that system through either a voluntary or a mandatory approach. If such measures were pursued, further consultations would be held on the development of the core nutritional criteria.

Please use a 1–6 rating, with 6 indicating that you consider it highly worthwhile to evaluate the following possible measures, and 1 indicating that you do not consider it worthwhile at all:

1a. Voluntary: foods carrying a health-related claim would have the option of being evaluated against core nutritional criteria, and if they fulfill those criteria, their packaging would be allowed to carry an agreed upon symbol

1 2 3 4 5 6

Please explain your rating:

This option is not explained clearly enough to rank.

To which types of claim should this measure apply?

CIAI believes that ALL food should have to meet a basic set of healthy criteria in order to carry a health claim. While we would support an eco-logo type system, as outlined above, the “voluntary” nature of the programme would only be on whether or not a company wished to participate. No health claim could be made without the pre-requirement of applying for a “healthy food” logo. The specific health claims would only be an extension of a “healthy food” logo.

All types of claims Disease risk reduction claims Function claims

Other health-related claims or symbols

Please explain your selection:

CIAI does not believe that consumer differentiation between claims is based on a clear enough understanding of the differences to warrant different treatment of different types of claims.

1b. Mandatory, option 1: foods carrying a health-related claim that do not meet standardized nutritional criteria would be required to highlight or disclose on their packaging where they fail to do so.

1 2 3 4 5 6

Please explain your rating:

We believe this would not be clear to consumers and would lead to increased marketplace confusion and blatantly misleading claims.

To which types of claim should this measure apply?

All types of claims Disease risk reduction claims Function claims Other health-related claims or symbols

Please explain your selection:

We could not support this option for ANY claims.

1c. Mandatory, option 2: foods carrying a health-related claim or symbol must meet standardized nutritional criteria.

1 2 3 4 5 6 **X**

Please explain your rating:

CIAI has been monitoring the increase of private logos currently in the marketplace and we are very concerned about the implications for consumers of some of these logos – such as the “PepsiCo” one. These are on processed food products that do not meet any of the Food Guide requirements and may add a lot to the “discretionary calories” section without in any way improving nutritional intake. In addition, the misleading logos currently on the market are undermining the credibility of programmes that are transparent, monitored and enforced. There must be a base line of nutrition in any product bearing a “health” claim or logo. This must be a regulatory requirement without exceptions.

To which types of claim should this measure apply?

All types of claims **X** Disease risk reduction claims Function claims

Other health-related claims or symbols

Please explain your selection:

See above.

2. If any of the approaches identified above was to be pursued, how could it be implemented effectively?

Due to the lack of resources within Health Canada, CIAI would support some creative approaches to effective implementation. Examination of other transparent and effective models should be examined. The possibilities of a publicly owned logo scheme managed and implemented by a private body, like the Environment Canada Ecologo would be one example. Existing effective models should be examined, although it may be hard to find an existing model in Canada that has not already been tainted with lack of credibility due to the many private label schemes currently in existence.

2a. Which organizations could play a role in implementation?

An existing organization involved in this process could be used in an implementation role. However, CIAI is concerned that implementation not be allocated to those who lack appropriate credentials or whose present schemes are neither credible nor transparent, such as the Loblaws private label for “healthy food” marketing.

3. Are there other approaches that you would suggest to link core nutritional criteria with health claims?

CIAI is not aware of any other approaches in the Canadian marketplace that do this. However, we do not believe that this should be a barrier to Health Canada leading the way and insisting that products making a health claim must be inherently healthy. There some examples we are aware of in the US, including a healthy food rating scheme, developed by Harvard and Yale university faculty, called the “Overall Nutritional Quality Index” (ONQI).

Theme 4.1 Improving consumer understanding of health claims

1. What could be done to help consumers better understand and appraise health claims?

Consumers do not understand the nutrition facts panel; they are a long way from fully understanding the different levels of health claims. The resources are not available within Health Canada to do this; however, Health Canada does have a role to play in ensuring the credibility and transparency of the private sectors “educational” materials to ensure that they do not represent misleading facts.

2. What role could different organizations or networks play in developing partnerships to build health literacy?

Many organizations such as nutritionists, dieticians, consumer groups and “disease” groups could be effectively involved in networks and partnerships on healthy eating literacy. Unfortunately, resources are always a problem within these groups and they would need financial support to participate effectively.

3. Do you have any suggestions for how we could ensure that the information we provide to consumers is readily understood?

Use of plain language experts and review by those involved in communicating with consumers at the required literacy level for the average Canadian (grade 5 – 6) would be useful. It is also important to recognize that the “one size fits all” system does not work. Different types of communication are needed for different groups of Canadians. Some are offended by simplicity of plain language, new Canadians may need materials in a selection of languages and directed to the type of food they include in their diets, etc. Basically, there will always be a need for at least 3 levels of information – the “readers digest” level, the “financial times” level and the “encyclopaedic” level.

There is also a need to vary the media in which information is delivered – obviously electronic media, particularly the internet is now more effective than print for most Canadians.

4. Food Directorate welcomes research on consumer understanding of health claims and the impact of these claims on consumer decision-making. Please let us know if you are aware of any such research, and if possible attach reports.

CIAI has produced two research reports recently. One, produced for the Dairy Farmers of Canada examined consumer understanding and support for compositional standards for cheese in Canada. The other, funded by the Office of Consumer Affairs of Industry Canada examined the readability of food labels. These reports are available on request from CIAI.

Theme 4.2 Monitoring impact of health claims on food supply and consumer choice

1. What organizations and networks could play a supporting role in the monitoring of the impact of health claims on the food supply and consumer choice?

Post market surveillance is effective but a resource-intensive operation. While consumer groups and other NGOs would be ideally positioned to use their networks to perform this task, they would have to consider it worthy of a high enough priority rating. Also resource support would be needed.

2. Do you see a role for you or your organization?

CIAI will be watching the effect of any new food health claim rules on the marketplace, however effective monitoring or measuring of consumer reaction will be dependent on our ability to propose a fundable research project as our current resources do not enable us to perform this work effectively on a totally volunteer basis.

General Questions

Finally, considering the themes discussed in the document,

1. Have these themes adequately captured the critical issues?

CIAI believes that there was inadequate linkage to the work of the Natural Health Products sector.

2. Are there other themes or issues that should have been included?

The consultation meetings were full and intense so there was probably little opportunity to include more issues in this process. However, there is a need to link the work relating to Health Claims to the work being done on natural health products AND to the movement to “buy local” with its implication that direct buy food is healthier. Other issues such as highlighted ingredient, QUID, allergen identification, etc. could have been included in the consultation, as they will all impact the label.

3. Any other comments?

Consumer information and education on nutrition and healthy eating is grossly inadequate and this has opened the door for the misunderstanding of and misleading nature of a lot of health claims. It encourages the food-processing sector to seek the opportunity to make a lot of claims that might increase their sales, regardless of the credibility of these claims because they know they are dealing with a susceptible market. At a time when the marketplace is becoming increasingly complex and confusing, particularly in the area of food products with the introduction of biotechnology, nanotechnology and functional foods, Canada has been continually reducing the resources put into ensuring that consumers have the background they need to make informed decisions. This is a costly exercise for the health system in the long term.

Submitted by the Consumer Interest Alliance Inc.

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