
NUTRI-NET CANADA HEALTH CLAIMS SYMPOSIUM

“AS IT WAS HEARD” REPORT

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GROUPE INTERSOL GROUP

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A. INTRODUCTION

The following report captures the discussions of a functional food health claims symposium held November 27th and 28th, 2007 at the Holiday Inn Hotel in Toronto.

The meeting was hosted by Nutri-Net Canada and attended by industry sector participants from across Canada as well as by representatives from the research community and Health Canada.

Anne Wilkie welcomed the participants to the symposium and set the context by providing a brief outline of the vision and goals of the Nutri-Net project and progress to date. She also highlighted the objectives of the meeting which were to

- To obtain stakeholder input and to provide a forum for the exchange of ideas related to key aspects of managing health claims for foods in Canada with a particular focus on aspects related to
 - Scientific substantiation of claims;
 - Supporting good-quality submissions;
 - Functional foods and the food/NHP interface; and
 - Managing a broader range of function claims.
- To receive and discuss the international comparative analysis study of regulatory frameworks for health claims on foods prepared by Cantox Health Sciences International;
- To discuss possible options to improve the health claim approval processes; and
- To assess the level of consensus agreement with the proposed Cantox recommendations.

B. PROPOSED REVISIONS TO HEALTH CANADA'S POLICY AND REGULATORY FRAMEWORK FOR HEALTH CLAIMS RELATED TO FOODS

SCIENTIFIC SUBSTANTIATION OF CLAIMS

Q1 a) Should all disease risk reduction and function claims be based on a high level of certainty?

There was a qualified response from participants on this question. Several table groups felt that there is a need to define or clarify what is meant by "risk reduction" and "high level of certainty". Having made this point, some table groups felt that claims should be based on a high level of certainty but also made the point that the degree of certainty should take into consideration a risk-based continuum related to safety, efficacy and effectiveness, whether or not a specific disease is targeted, etc. as well as the potential benefits to consumers. How to operationalize this type of model presents a challenge. Most also felt that the bar could be lowered to some extent for structure-function claims. Many also made the point that there is a high likelihood of confusion in the marketplace among consumers. The differences between risk reduction and structure-function claims are not well understood. Some felt that current U.S. based claims are adding to this confusion and suggested that there is a need to do some consumer research to test understanding followed by consumer education before moving forward. It was suggested

that a set of short standardized statements that are well understood in the marketplace based on good consumer education might be a partial solution. Other points made by participants included

- an assumption that safety and quality of product must be demonstrated;
- that the level of evidence should match the importance of the claim;
- that evidence from other countries should also be considered; and
- that science is evolving and there should be a constant re-evaluation and re-classification of claims.

Q1 b) 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 lower level of certainty?

Most groups felt that there could be circumstances where claims based on a lower level of certainty could be acceptable. The category of structure-function claims were mentioned most often in this discussion. Many groups suggested that first and foremost, safety should be the overriding mandatory criteria that guides whether or not a claim should be allowed – in other words, if there is a safety concern, a claim should not be allowed. Others principles or factors proposed included:

- A core nutrient criterion – i.e. no claims on items with high sodium, high sugar added, etc.
- High dosage effects.
- Being clear about the group for whom this is a benefit (and for whom it might be dangerous).
- Mutual recognition of science & claims of other jurisdictions
 - Standardization of evidence gathering so that a high level of evidence in one jurisdiction could be used in Canada (e.g. Germany or U.S.)
 - Collaboration with other jurisdictions internationally to obtain best available science
 - Take collaborative approach to managing review of science with other government departments.
- Better communication by Health Canada to inform public on science and benefits
- Risk mitigation
 - Foods/ingredients that are highly innocuous/safe should be allowed health claims even with lower level of certainty
 - Specificity of claim – Grading of certainty / confidence e.g. possible / probable / demonstrated
- Importance of claim allowed and level of evidence – must define clearly levels of certainty

SUPPORTING GOOD QUALITY SUBMISSIONS

Q2. Is there capacity and capability in Canada to support good-quality submissions? If yes, where does it reside? Where are the gaps in capacity and capability and how might the gaps be addressed?

There is capability and capacity in Canada however it is important to note that the requirements will differ by interest group i.e. industry, government, experts or researchers. In light of this it will be important to bring expert groups together based on products submitted for review and to perform the evaluation with the rigour appropriate to the type of claim requested. In light of this, the group suggested the following approaches to address gaps:

- External group: External to Health Canada with prescribed service level agreements whose time for review begins as soon as the submission is received.
- Put a structure in place that will enable industry to put “plus value” active nutrients on the market.



- Provide a market advantage to those who are 1st to make submissions.
- Recognize external groups as an extension of Health Canada
- Recognize that these food ingredients are not covered by a separate category – neither drug or natural health product – therefore there is a need to address this gap.

FUNCTIONAL FOODS AND THE FOOD/NHP INTERFACE

Q3. What principles should guide the addition of bioactive ingredients to foods? How should the level of addition be handled? Which types of bioactive substances should be allowed to be added to foods? Please identify which ones and explain why.

With regard to principles, safety was mentioned as the overriding principle. Several groups suggested that there should be a way to identify the bioactive in the food as well as an indication of daily maximums – perhaps a monogram system that indicates acceptable levels of bioactive ingredients and possible interactions with other foods and a generic warning system (possibly through labelling) to advise consumers not to exceed certain levels. Others suggested a warning system based on toxicological effects – the system would be based on the potential for and severity of possible negative effects as well as whether or not the effect is reversible. Several groups also wondered whether addition of bioactive ingredients to foods that have little nutritional value should be allowed. One group also suggested that Health Canada's Food Directorate should compile a positive list of allowable bioactive ingredients based on the advice of an expert advisory committee. In addition to the list of allowable ingredients, some also suggested that there be a list of the foods that bioactive ingredients could be added to – others felt that there should be no restriction.

Q4 a) What case can be made 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?

Participants suggested that there should be a category of special purpose foods created and labelling used to clearly identify these foods with appropriate warnings.

Q4 b) What steps must be taken to effectively manage risks?

To manage the risks participants proposed a labelling system, identification of conditions for use, a post-market surveillance system and adverse effects reporting system that has web-based, toll-free line and mail-in components. Others also suggested that there be quality risk assessment and stability studies done as well as good quality assurance and quality control processes in place.

MANAGING A BROADER RANGE OF FUNCTION CLAIMS

Q5. Do you see opportunities in present or in future to use function claims that do not bring foods into the definition of drugs and therefore would not require regulatory amendments?

Most felt that there are opportunities for use of function claims however the line between food and drug needs to be clarified. Many suggested that consumers want to take control of their health and in cases where there is evidence of foods that support promotion of good health and prevention of disease claims that highlight the benefits to health should be allowed – one



challenge is to understand where to draw the line between a function claim and a risk reduction claim. Other challenges mentioned by participants included

- How to substantiate the claim – some proposed a market notification system
- Should there be standardized wording – should it be prescribed or done on a case by case basis?
- Lack of market advantage – it was suggested that 1st to market should benefit from some exclusivity.
- Too much focus on regulations and a need for a common sense approach.

How to make things clear to consumers remains a challenge, and any system that promotes the benefits of a functional food should also provide a balanced view of any associated risks.

Q6. What in your view, would be the challenges associated with the use of such claims? What measures should be considered to mitigate the identified challenges?

The key challenges associated with the use of function claims were firstly definitional in nature – what is and can be said in a function claim and what substantiation is required? Secondly, assuming industry is prepared to bear the costs associated with gaining approval, what market advantage can they gain from their efforts? Thirdly, the approval process is also poorly understood and cumbersome. This said, participants suggested some standardization of terminology that is understandable to consumers and the general population would help with the definitional questions. They also suggested that there should be some form of market advantage for those who are 1st to market but realized that this is difficult to do. It was also propose that the approval process be improved. Finally, in order to increase the use of function claims, it was suggested that there be means to encourage more collaborative efforts to develop new submissions.

**C. INTERNATIONAL COMPARATIVE ANALYSIS STUDY
BY CANTOX HEALTH SCIENCES INTERNATIONAL**

Representatives of Cantox Health Sciences International presented a comparative analysis of the regulatory regimes of Canada, Australia, the E.U., Japan and the U.S. They spoke to both the science requirements as well as the regulatory processes in place in each of these countries. Following the presentation, participants engaged in plenary discussions to clarify understanding as well as to further explore questions of interest.

CHARACTERISTICS OF AUTHORITATIVE BODIES

1a) If existing authoritative reviews on the totality of evidence for a health claim of interest were used to simplify the process of health claim substantiation, what are the characteristics of acceptable bodies?

Suggested characteristics included:

- Recognized professional associations;
- Organizations knowledgeable in evaluating the science and acceptable to Health Canada;
- Evidence of acceptable studies and the jurisdictions where studies were carried out;
- Transparency and rigour in their review process;
- Recognized by the scientific community;



- Assembled 3rd party bodies based on international criteria;
 - Scientific committees (multi-disciplinary & multi-sectoral) formed in response to an appropriate set of criteria developed in advance by the regulator;
 - Established reputation and demonstrated capacity;
 - No conflict of interest;
- It was also suggested that the NSIRC model be used for committee evaluation as well as to help establish the validity of research.

1b) How should the reviews be incorporated into the health claim substantiation process – e.g. if the review's quality is deemed acceptable and findings relevant to Canadian population/dietary patterns, should evidence published since the review be evaluated in detail to evaluate whether findings of a review continue to be valid?

Participants suggested that this is dependent upon asking the right questions – has anything changed since the review? If so should we be reviewing just what is new or should a total review be undertaken and how do we decide? Participants also felt that there should be a mechanism to reject a permitted claim if warranted based on re-evaluation of evidence.

SEPARATING SAFETY EVALUATION AND EFFICACY EVALUATION

2) Is there support for a process that would separate evaluation of safety from evaluation of efficacy, assuming evaluation of safety could either precede or occur concurrently to evaluation of efficacy and assuming safety would be evaluated with a novel food submission?

Participant were supporting of separating the safety evaluation from the evaluation of efficacy as long as the same rigour is applied and the criteria use are consistent with what is used in the current evaluation process. One participant noted that in the event that a claim caused increased consumption, the potential for excessive intake causing adverse effect should also be considered in the safety evaluation. Another participant questioned whether the same evaluation body must assess both safety and efficacy.

LEVELS OF NUTRIENTS AS A CRITERION FOR ELIGIBILITY

3a) Should a system of profiling foods based on the levels of nutrients they contain be incorporated into the eligibility criteria for use of health claims?

3b) If so, what type of nutrient profiling system should be applied – e.g. a nutrient score based on levels of nutrients encouraged and discouraged for consumption or disqualifying criteria based on levels of nutrients discouraged for consumption?

Participants raised a cautionary note that a potential health claim could be disqualified on the basis of 1 nutrient – the example of trans fat in dairy products was raised. Others suggested that the focus shift from one of disqualifying criteria to qualifying criteria. Most preferred positive

listings and a move to nutrient density – “naturally nutrient rich”. There is also a need to define qualifying and disqualifying criteria (criteria should be reflective of what the claim should be) and to set standards.

MARKET ADVANTAGES FOR HEALTH CLAIM APPLICANTS

4) Should there be market advantages to health claim applicants? How would that be accomplished?

Participants felt that there should be a benefit in the form of market advantage to applicants who invest in the application process however there was some concern that the cost of food could rise. It was suggested that the pharmaceutical model be examined to determine if there was something that could be learned from that experience. Some of the suggested ways to provide market advantage included:

- Inclusion of economics as part of the application process;
- A licensing process to protect exclusivity of the market;
- Increased cost at the front end as well as a reward system for companies that put the science and application process together – e.g. to incent a rebate on life insurance if you show receipts for use of the product;
- An investment fund to assist small innovative organizations that don't have the necessary resources in-house.

MANDATORY TIMEPOINTS FOR COMMUNICATION BETWEEN GOVERNMENT AND APPLICANT

5. Once a health claim application is received by government, what are the preferred time points at which communication should be mandatory between a health claim applicant and the government?

Several suggestions were made by participants with regard to communication points – at minimum, upon receipt of an application, notice of completeness of application and notification of decision – however it was also made clear that fundamental to any effective regulatory approval process is clear definition of each step in the process and communication with the proponent as the application moves through each of the steps “there must be certainty in the regulatory approval process and a reasonable expectation of a return on investment otherwise there will be no appetite to proceed”. It was suggested that the process adopted by the Natural Health Products be examined as a possible model as well as the pre-market submission process for novel foods and food additives. Participants also suggested that an applicant should have an option to withdraw an application at any time in the process. A web based system to track the progress of an application as well as a score card system to provide information on review performance were also proposed.

OUTSOURCING EXPERTISE FOR HEALTH CLAIM EVALUATION

6. If there was a consideration given to outsourcing expertise for health claim evaluations, how would the process proceed? Who would decide on the expertise (government and health claim applicant)?

Several recommendations to identify suitable evaluators were put forth by participants. These included:

- The use of NCERC or NRC to help identify suitable outsource bodies;
- The establishment of a database of accredited experts;
- Applicants or authors of papers could suggest external reviewers;
- Professional associations knowledgeable in the aspects particular to the application.

In addition to the identification of evaluators, participants also proposed a set of rules that should govern the way the outsourced evaluation process should proceed – these included:

- A requirement that the 3rd party evaluator be completely impartial;
- The choice of external evaluator be made by government (some proposed that the applicant should have the opportunity to oppose a selected reviewer while others suggested that the identity of the reviewer should not be disclosed);
- The reviewers would be required to adhere to a set of review criteria and review methodology standards

Finally, participants also suggested that an expert advisory committee could play a role in the recommendation of outsource review or could be a source of reviewers as well.

REVIEW / ASSESSMENT OF RECOMMENDATIONS

Prior to adjourning the meeting, participants provided an indication of their level of support for the recommendations put forward by Cantox. The notes below are a reflection of the level of the group's support for each recommendation as well as the comments advanced by individual participants to explain a low score.

Recommendation 1:

Document Revision – Strong support for this recommendation

Recommendation 2:

Document Development – Strong support for this recommendation with the exception of one participant – it was felt that others could do this work.

Recommendation 3:

Authoritative Reviews – Strong support for this recommendation

Recommendation 4:

Approval Process – Consider a “step-up” or “tiered” process for the approval of different types of health claims - Strong support with one exception. It was suggested that this type of system may create consumer confusion and the participant proposed that the same level of evidence should apply and that the strength of evidence should be equal.

Recommendation 5:

Transparency / Communications – Most participants expressed strong support for this recommendation. It was further suggested by some that this should be an integral part of everything that Health Canada does while others felt that this recommendation was of questionable benefit.

With regard to the 3rd bullet related to accessibility of information, it was suggested that the name of the applicant be kept confidential.

Recommendation 6:

Accountability to Timelines – There was strong support for this recommendation however many wondered what the repercussions could be for poor performance. There was support for targeted timelines but it was felt that mandating timelines was probably going too far. There was concern by some that resources may be re-directed away from food safety efforts an attempt to deliver on mandated timelines.

Recommendations 7, 8 & 9:

Outsourcing Expertise, Market Advantage and Website – Strong support for all of these recommendations

Recommendations 10:

Research – There was strong support for this recommendation however there was some question of who should do the research - some

APPENDIX A

Scientific Substantiation of Claims – Table Report Notes

Question 1 a)

Should all disease risk reduction and function claims be based on a high level of certainty? Please provide the rationale for your response

Table 1 Answers

- Yes it should remain the way it is. People find it difficult to differentiate between types of claims already. Allowing claims with lower certainty will make it difficult for consumers.
- To measure risk reduction is difficult – you may miss something that can have an effect even if it is minor when relying only on “high level of certainty” evidence – you can re-phrase the claim by implying the claim is based on a lower level of certainty, however the food item still may reduce the risk of The claim should be qualified accordingly.
- Should have different claims for the level of risk reduction.

Table 2 Answers

- No – what is a “high level of certainty”?
- Science continues to change
- More flexibility on certainty with function claims vs. disease reduction claims with a similar tolerance for opposing evidence but a higher tolerance for “neutral” evidence with function claims.
- Profiling foods for their nutrients can serve as a mechanism to decrease consumer misperceptions regarding claims.
- Implement eligibility criteria for all claims.
- Supporting a “greater good” for health
- Enabling product innovation and competitiveness but without risk to consumers
- Aiming for a high level of certainty may be an unrealistic expectation
- High level of certainty a policy decision to prohibit claims to protect consumers
- Positive list of bioactives with levels and indices
- Nutrient profiling protective mechanism for not a high level of certainty

Table 3 Answers

- Yes – need a high level of certainty. How does one determine what qualifies as high certainty? What should be the source of the science?
- How many studies necessary? Newer ingredients owned by a company vs. something like DHA where thousands of studies are done.
- Do the regulations select against innovation?
- Countries that require a new set of studies on their native population is anti-competitive.
- Perhaps we should pursue additional types of claims i.e. no place for claims like “helps improve absorption of calcium”. Like structure-function but no real place in Canada. Low risk.
- For certainty, we need to be similar to US, otherwise it is anti-competitive.
- By limiting claims such as structure-function, the Canadian consumer loses. Nutritional science is still fairly young. Need more room for promoting overall health as opposed to specific drug claims. i.e. improve digestion; absorption; etc.
- We have limited our scientific resources for efficacy due to our reliance on trials similar to those used for drugs. How do you design a study for overall health? Can't rely on double-blind placebo controlled studies for overall

Question 1 a)

Should all disease risk reduction and function claims be based on a high level of certainty? Please provide the rationale for your response

health. Doesn't work.

- Some companies would prefer words like "reduce risk" vs. more drug-like claims. It should be risk-based. What is the harm in highlighting lycopene in one type of ketchup and putting effort into educating consumers as long as it is not misleading or false? Increases consumer choice.
- Could Health Canada put resources into educating consumers?
- Overall – comfortable with high certainty, but need more leeway for low-risk function claims.
- Qualified claims as in the U.S. are too confusing.

Table 4 Answers

- No – it is difficult to achieve high level of certainty because of all factors impacting health.
- Science is evolving so it makes sense to have different approaches to substantiate different level/types of claims. (biomarkers differ, commodities differ and population differ, type of consumption of particular food products differ)
- Companies don't have significant funding to conduct clinical trials in Canada.
- If the objective is to prevent misleading consumers with claims, there are ways to educate consumers to understand claims.
- Companies currently don't have confidence that if they were to invest in clinical trials to substantiate a claim that Health Canada (Food Directorate) would follow through and approve a claim.

Table 5 Answers

- Canadian Diabetes Association feels very strongly that there should be a high level of certainty because they have so many complications.
- For risk reduction, there should be a high level of certainty; for function claims there could be more lenience to allow latest research to be on the market.
- If people would take it instead of a drug – more certainty is required.
- Claims must be evaluated with a clear definition – what is adequate certainty? What is proper procedure? What does totality of evidence mean? – It must be clearly defined.
- The quality of the study must be weighed, not just the totality.
- If you want consumers to trust the claims, then there must be a high level of certainty. The consumer is not necessarily concerned about the quality of evidence but health professionals must be.
- Consumers don't understand many claims – people should have a sense of how good the evidence is.
- Enforcement – claims that are not sanctioned are on many labels – there should be more consequences for label "violative" labels.
- The message is NB – disease vs. function – do consumers really understand the difference?
- Use commonality in claims – phrases, words etc. for consistency to consumer; short and succinct
 - Problem for people of low literacy levels
- Claims should be consistent with different countries – traditional is not defined the same in different countries – it should be harmonized.
- Canada is a small scientific community – if we could come up with common definitions among Western countries it would save a lot of research and work.
- There are some products that are helpful to disease and harmful to others.
- You can't patent food products – therefore there is little incentive to do research on natural products.
- Simple and accurate health claims have higher benefit for consumers.
- There is a proliferation of "violative" claims because it's so frustrating to get permission to use claims.
- What are the results of "violative" claims? The civil penalties are far greater than any government action – if

Question 1 a)

Should all disease risk reduction and function claims be based on a high level of certainty? Please provide the rationale for your response

consumers saw that there were strict repercussions they might know that not all claims should be believed, but is that what we want? Probably not.

- How do we define the level of a nutrient needed to separate risk reduction vs. structure-function?

Table 6 Answers

- “Exemple de la vitamine D – Non
- Notion du risque a considérer
- Niveau de certitude assez élevé pour ne pas « bruler » le marche mais latitude pour utiliser
- Données « graduées » en acceptant différents éléments de certitude
- If only high level of proof is required – limits too much and prevents consumer access to potentially beneficial products.
- For disease risk reduction – Yes only high level of certainty
- For function claims – No
- Level of evidence based on the “importance of claim”
- Open the door to non-Canadian evidence

Table 7 Answers

- Define “high level of certainty”
- Define “high-risk”
- Consumer research (average consumer)
- Disease risk-reduction
- Re-evaluation and re-classification – continuum dynamic
- Education campaign
- Continuum of claims increasing if specific to a disease.

Question 1 b)

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 lower level of certainty?

Table 1 Answers

- Items should have a core nutrient criteria i.e. no claims on items with high sodium, high sugar added, etc.
- Allow lower level of certainty claims based on the function of foods. The claim would be re-phrased to dictate what the “functional ingredient” may provide.

Table 2 Answers

- Function claims should have a lower level of certainty

Table 3 Answers

No data

Table 4 Answers

- Claims that relate to structure-function are less likely to cause harm to the consumer.
- Levels for NHP and food-related claims should be the same
- Principles:
 - Safety

Question 1 b)

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 lower level of certainty?

- High dosage effects.
- Being clear about the group for whom this is a benefit (and for whom it might be dangerous).
- Standardization of evidence gathering so that a high level of evidence in one jurisdiction could be used in Canada (e.g. Germany or U.S.).

Table 5 Answers

- Mutual recognition of science & claims of other jurisdictions.
- Collaboration with other jurisdictions internationally to obtain best available science
- Better communication by Health Canada to inform public on science and benefits and stand their ground when challenged by consumer interest groups – provide medium to present all parties' positions to counter one-sided media coverage.
- Take collaborative approach to managing review of science with other government departments.
- Focus on preventative health of consumer rather than only risks.

Table 6 Answers

- Safety
 - If there is a safety concern, this does not equate to a lower level of certainty
 - New molecules / ingredients
 - High dosage effects
- Risk mitigation
 - Foods/ingredients that are highly innocuous/safe should be allowed health claims even with lower level of certainty
- Specificity of claim – Grading of certainty / confidence e.g. possible / probable / demonstrated
- Importance of claim allowed and level of evidence – must define clearly levels of certainty

Table 7 Answers

- No data

APPENDIX B

Supporting Good Quality Submissions – Table Report Notes

Question 2:

Possède-t-on, au Canada, la capacité et la faisabilité de soutenir la présentation de demandes de qualité?

Table Answer

Oui, toutefois il est important de comprendre que les demandes ne sont pas les mêmes si on est de l'industrie, gouvernement, experts ou chercheurs.

Quelles sont les lacunes à combler en matière de capacité et de faisabilité?

Table Answer

Ainsi, il faudrait reconnaître et mettre en place des groupes d'experts selon les éléments soumis. Différents si action d'un produit pas une drogue et pas une action de « claim related to disease » mais un sentiment de bien-être.

Comment arriver à les combler?

Table Answer

- Groupe externe : externe à Santé Canada avec un délai prescrit et suivi par le group dès le début de la soumission
- Mettre en place une structure pour l'industrie pour mettre les facteurs actifs sur le marché avec une « plus value »
- Reconnaître un privilège pour les 1^{er} à soumettre de façon sérieuse avec « file »
- Reconnaître les groupes externes comme étant le prolongement en autorité de Santé Canada.
- Réaliser que l'ajout de ces ingrédients « aliments » n'ont pas une catégorie claire et précise. Actuellement on suit les drogues ou aliments naturel – il faut combler le « gap »

APPENDIX C

Functional Foods and the Food/NHP Interface – Table Report Notes

Question 3:

What principles should guide the addition of bioactive ingredients to foods? How should the level of addition be handled? Which types of bioactive substances should be allowed to be added to foods? Please identify which ones and explain why.

Table 1 Answers

- Consider grape fruit juice / tea (bioactives already present in the product). No food-like NHP will ever meet the food. So in effect we will be getting rid of food additive.
- Principles
 - Safety is most important
 - Approved for use in Canada (must be an approved food additive in Canada)
 - Level – perhaps different level for different types of bioactives – similar to DRI. Upper level – decide on what will be a safe upper level for the population.
- The types of bioactives that should be allowed are all those that are not drugs and are safe.

Table 2 Answers

- Safety is guiding principle for addition to food with safety assessment based on pre-clinical studies / toxicological studies in animals and intake data. Intake should not have contraindications with food, nutrients.
- Efficacy should exist for bioactive addition if claim is made.
- Where do you draw the line for types of foods that include bioactives?
- Warnings and dose frequency described.
- Generic indications on foods (E.U.) to be included on the same place on the label e.g. do not exceed 3g/d of plant sterols (based on efficacy) – applies to all foods containing that bioactive.
- Reversibility of adverse effect.
- Educating consumers – warnings contingent on adverse side effects i.e. toxicological data – heart rate increase vs. liver damage
- Limits – e.g. allergens exist in food supply (nuts)
- Is population ready to integrate food warnings into their lifestyle?
- Low toxicological profile guiding bioactive addition.
- Can consumers understand labels and warnings?
- Nutrient profiling an issue – should bioactives be added to “unhealthy foods”?
- Monographs – lists acceptable levels of for addition to foods and lists of acceptable food vehicles.
- Warnings included.
 - Warning statements won't help people that don't know if they have susceptibility.
 - If a genetic susceptibility is rare, most regulatory authorities don't require acknowledging it for functional foods in warning statements.
 - Keeping in mind definition of “food”
- Source of bioactive – interest to some consumers to know.
 - Keep public health in mind. Balancing information provision of what is in a product with degree of interpretation / consumer understanding required – want information but don't want to spend too much time / effort – information provision vs. time / effort to develop consumer understanding.
- Warning contingent on severity and prevalence of adverse effect

Question 3:

What principles should guide the addition of bioactive ingredients to foods? How should the level of addition be handled? Which types of bioactive substances should be allowed to be added to foods? Please identify which ones and explain why.

- Reversibility of adverse effect, children, pregnant and nursing women.
- Nuts – “contains nuts” written not “nuts may cause an allergy”.
- Nut allergies, salt, vaccinations, fish (BMA vs. toxins) – risks and benefits.
- Recommended daily intake – having a % daily value for a bioactive.

Table 3 Answers

Principles

- Safety, non-toxic, efficacy
- Food should have some merit – minimum level of nutrients?
- Is it wrong to make unhealthy foods better? Perpetuating the problem of obesity etc. by adding nutrients / bioactives to non-nutritious foods.
- Different socioeconomic groups eat differently (e.g. Kool-aid is cheap compare to juice)

Level of Addition

- For those substances that just get excreted if in excess, no limits / max?
- Level – risk assessment, don’t know enough about – don’t add or add at lowest level
- High-risk substances – e.g. fat soluble (accumulation) due to widespread addition to foods – should not be added.
- Bioactive substances as effective as drugs – should they be allowed to be added to foods?

Table 4 Answers

Principles

- Food Directorate to compile a list of bioactives (via steering / advisory committee)
- Each should be characterized by specs detailing
 - Minimum and maximum permitted levels in foods;
 - Categories of foods;
 - Qualifying / disqualifying nutritional criteria;
 - Ensuring global QC / QA (stability, shelf life);
 - Thorough risk-benefit assessments;
 - Distinguishing feature;
 - Interactions with foods (St. John’s Wart);
 - German monographs, NHP monographs;
 - Most popular bioactive ingredients.

Question 4 a)

What case can be made 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?

Table 1 Answers

- There are already products / food that could be risky but eaten by many (grapefruit, nuts).
- Consumers have the right to have choice.
- Allergen labelling / precautionary labelling helps inform consumer of risk & effectiveness.

Table 2 Answers

- No data

Question 4 a)

What case can be made 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?

Table 3 Answers

- If significant positive effect to a subpopulation (e.g. phytosterols in margarine) – should be allowed.
- What level of risk is too much to allow a product with a benefit to one sub-population but harm to another?
- What about stability for bioactives in food? GMP? Not just putting a component in but stability over shelf life.
- Not a best before but a matter of what is present at the end (e.g. average of 300% for probiotics) 6 billion at beginning and 2 million at end (label claim)

Table 4 Answers

- Special purpose foods

Question 4 b)

What steps must be taken to effectively manage risks?

Table 1 Answers

- Conditions for use.
- Post-market surveillance

Table 2 Answers

Not data

Table 3 Answers

- Labelling
- Stability studies

Table 4 Answers

- Risk assessment
- QC & QA
- Post-market safety surveillance & adverse effects reporting system
 - Web site
 - Toll-free line
 - Mailing

APPENDIX D

Managing a Broader Range of Function Claims – Table Report Notes

Question 5:

Do you see opportunities in present or in future to use function claims that do not bring foods into the definition of drugs and therefore would not require regulatory amendments?

Table 1 Answers

- Yes – to promote healthy behaviour. A drug is a treatment. This is prevention and promotion of good health. This segues into the health care costs issue.
- When science is sufficient that it becomes “mainstream” the tendency is to remove it from the regulatory approach.
- Consumers want to take control of their own health therefore they look to food to help them manage their own health.

Table 2 Answers

- Causes of under utilization: perhaps the required level of evidence is too high / extensive – difficult to demonstrate the “maintenance” of a function in a clinical trial (what markers to look at?).
- Defining the evidence that is required for making a function claim will determine if it is possible to make such claims without going into drug definition. Some function claims are suggested by epidemiological studies (e.g. lutein or lycopene) but will this be sufficient or acceptable?
- The “interesting” function claims are also associated with drug-like effects (e.g. cholesterol)
- Regulatory amendments would be necessary to allow cautionary statements when required.
- When modulation of a “normal range” effect is involved, there should be a possibility to make a health claim (versus switching to drug definition) e.g. “promotes normal bowel movements”. A better definition of function claims would be necessary to avoid falling under drugs. * Also considering “Schedule A” diseases.
- It is still confusing to know what a function claim could be... But, promotion of a normal function should be acceptable to let people know what a product can do even if it is getting close to a drug. Safety would guide what is correct to say.

Table 3 Answers

- Yes – the line that divides a food and a drug is not clear.
 - Clear criteria need to be established;
 - Clarify drug claim;
 - Separating out food from NHP will help define the definition;
 - If a functional food has been proven to do something, it should be allowed to say it.
- Will give consumers more options
 - Help treat a disease not solely treat it
- Cannot identify an example that is not a drug or not affected by Schedule A.
- Clarify what makes a food a drug.
- Definition of a drug.
 - Food can alter or modify functions within physiological range

Table 4 Answers

- Yes

Table 5 Answers

Question 5:

Do you see opportunities in present or in future to use function claims that do not bring foods into the definition of drugs and therefore would not require regulatory amendments?

- Bioactives do support healthy tissues and immune system – antioxidants for maintenance, phytosterols to maintain healthy cholesterol levels – maintenance of a healthy immune system
- We agreed that this area was more difficult to discuss because of the terminology and greying of the line between food benefits and drug category.
- At present there is opportunity to introduce a product into the marketplace in the health category and to make consumers aware of it as something of benefit to their health before / while or instead of undertaking the high costs associated with making risk-reduction health claims.

Table 6 Answers

- There are some opportunities but don't allow companies to differentiate.
- Require some regulatory changes.
- Some issues with the wording of the questions.
- Yes, but we want to be able to differentiate, market forces will prevail.
- Opportunities will be identified by the marketing departments and new opportunities will be driven by consumer demand. RxD will respond and try to find solutions / compounds to get the match between consumer demand and the food product.

Question 6:

What in your view, would be the challenges associated with the use of such claims? What measures should be considered to mitigate the identified challenges?

Table 1 Answers

- Less claims associated with good health. We have no "DRI" like requirements, so we don't have criteria to measure it by in maintenance of good health.
- Benefit / risk equation.

Table 2 Answers

- Challenges:
 - Definition
 - Schedule A
 - Market advantage
 - Safety
 - Process unclear
- Take food out of NHP.
- Drug related claim on food
 - Remove "modifying or restoring a function"
 - Cholesterol – indication for disease – not necessarily disease related. If claim mentions modifying... should be exempt from the definition of a drug.
- Differentiate who the message is for "promotes heart health".
- Increase public education to improve health.
- Allow certain drug related claims.
- Form, delivery e.g. Omega 3, garlic.
- Differentiate between drug vs. naturally occurring functional food
 - Dose

Question 6:

What in your view, would be the challenges associated with the use of such claims? What measures should be considered to mitigate the identified challenges?

- Quantity
- Market advantage
- Identify component (i.e. calcium) which helps maintain – general nutrients
- Schedule A – should be able to make maintenance claims
 - Maintain overall health
- Difficult to define definition
- If modification is inside the level of physiological range e.g. sterol – outside the range
- Reducing cholesterol – stronger claim than maintaining.
- If you need an extremely high level of nutrient to have a health claim, it is considered a drug.
- Cardiovascular is required for health.

Table 3 Answers

- Making the claims understandable for the general population (so the consumer really understands the benefits of the product) will be a challenge. Consistency between the different claims will help the consumers differentiate between different levels of benefits.
- Safety should always be in mind in establishing the phrasing of a claim.
- Would a consumer really understand the difference between a function claim and risk reduction?
- Government could determine types of claims that are acceptable for a food that matches X and Y requirements.

Table 4 Answers

- Challenges:
 - Niche markets
 - Standardization of wording (with some alternatives)
 - Criteria – meeting
 - Substantiation – pre-market ratification (instead of approval for low risk non specific claims)
 - Lack of market advantage
 - Retain a compliant marketplace
- Measures to mitigate the challenges:
 - Joint submissions
 - Exclusive licensing

Table 5 Answers

- Challenge:
 - Definitions of functions and markers – what is measured to demonstrate / understand the function?
 - Terminology – definition of HC terms in order to clearly submit for a function claim.
- Suggestion:
 - More precise requirements for Health Canada for claim submissions and meeting function substantiation
 - What's the claim?
 - How do we get there?
 - When will it be responded to?
 - What will it cost?
 - How long will it take?
- Challenge:
 - Competitive advantage

Question 6:

What in your view, would be the challenges associated with the use of such claims? What measures should be considered to mitigate the identified challenges?

- Suggestion:
 - Opportunity for associations / organizations to make submissions for function claims that industry can use.

Table 6 Answers

- Research is a challenge – real specific skills sets to put a proposal together.
- Very difficult for Canadian companies because of size as well as the size of the Canadian market with is not appealing enough to develop.
- If requirements are too stringent, it is a missed opportunity
- Measures – find a way to help a funding source
- Globalization – competitive advantage of smaller companies
- Information is not shared on submissions
- Measures to mitigate:
 - Collaborative effort to help industry (ingredient, food) to put the claims proposals forward.
 - Lacto bacillus – specific to the species. Using prior claims to document the same studies e.g. master file – public access to master files of approved claims and research trials. Companies could openly access it and use the data.
 - Resources from mentoring, consultation service from Health Canada to help validate that they are on the right track i.e. dose ranging issues.