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Summary of Comments from the Consultation on the Regulatory Modernization Strategy for Food and Nutrition (RMSFN)



Canada 

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BACKGROUND AND CONTEXT

In April 2007 Health Canada's Health Products and Food Branch (HPFB) released its Blueprint for Renewal II plan, a key initiative that presents a vision and objectives aimed at modernizing Canada's regulatory system for health products and food, as well as proposed actions for moving forward.

The Blueprint for Renewal II recognizes the important challenges facing Canadians and the Canadian food production chain. Health Canada continues to work with industry, other government departments and concerned Canadians to maintain the safety of Canada's food supply and to help Canadians make healthy food and diet choices. To this end, a Regulatory Modernization Strategy for Food and Nutrition is a key feature of the HPFB Blueprint for Renewal and is intended to expand upon Objective #4 of the Blueprint for Renewal II:

“Health Canada will design and implement a modern, efficient, and responsive food regulatory framework that protects and promotes human health, responds to emerging food safety and nutrition challenges, and minimizes unnecessary delays in bringing safe food and food products to the Canadian marketplace.”

The Health Canada document “Towards a Regulatory Modernization Strategy for Food and Nutrition” was published in May 2007 to provide a basis for a discussion among Health Canada, industry, stakeholders, and Canadians about the direction of Health Canada's efforts to modernize its food regulatory system. An on-line consultation was held between May 7th and June 29th, 2007 to solicit comments on the proposed goals and objectives included in the document.

Twenty-one respondents submitted comments during the consultation period. The respondents represented academia, health professionals, members of the public, federal and provincial agencies/departments, individual food companies and organizations representing the food industry including growers, processors, manufacturers, distributors, importers/exporters and retailers.

Many comments and suggestions were received during the consultation which will help to transform the discussion document into a Strategy that will then guide the modernization of Health Canada's regulatory system for food and nutrition and, subsequently, the Food Directorate's Strategic Plan which is targeted for publication in the Spring of 2009. This consultation report provides a summary of the comments that pertained to the goals and objectives of the strategy. Other comments that related more to general approaches taken by the Government of Canada, or to specific food and nutrition issues and not to the strategy *per se*, are not addressed in this report.

WHAT WE HEARD

In general, participants were in agreement with the Strategy, emphasizing that the modernization strategy was timely, and needed to address the evolving challenges around food safety, product innovation, and global markets. Improving predictability, efficiency and

transparency of the system was seen as a key goal.

There was support for Health Canada to continue to meet its responsibilities under the Food and Drugs Act with a modernized toolkit that sustains the strengths of the existing system but employs an appropriate mix of risk based approaches: this would continue to promote and protect health while avoiding unnecessary impediments/burden to industry. At the same time, there was an emphasis on ensuring that modernization efforts remained grounded in science based risk assessments.

Some gaps were noted by participants. In particular, it was noted that the modernization efforts did not appear to reflect appropriately the integration of other departments/agencies and partners who share responsibility in the delivery of the food safety system.

Participants remarked that for this initiative to be successful, sufficient resources would need to be assured to help move improvements beyond the consultation stage.

Scope

About half of the respondents questioned why Health Canada (HC) was not pursuing a strategy in conjunction with all or, at least, some of the other departments/agencies who are, in some capacity, involved in the regulation of food, specifically, the Canadian Food Inspection Agency (CFIA), Agriculture and Agri-Food Canada (AAFC), the Public Health Agency of Canada (PHAC) and provincial and territorial partners (P/Ts).

There was some concern expressed as well that the RMSFN implies that Health Canada, “needs to expand and extend its reach in terms of control over the food chain and that great care must be taken not to have Health Canada duplicating what is already being done (or should be done) by other agencies such as AAFC or CFIA”.

Goal One: Improving Predictability, Effectiveness, Efficiency, and Transparency in Health Canada’s Food Regulatory System

All of the respondents supported the intent of the first goal. They felt that accountability, predictability, effectiveness, efficiency and transparency were key to successful modernization. Several respondents were able to draw on their own experiences to demonstrate the need to address this goal in the strategy, examples where they felt that the limitations of the current processes and regulatory environment had impeded progress.

There was also a clear signal that the regulatory oversight pertaining to innovation should reflect the relative risks, and modernization should look for ways to support innovation:

“A modern system at Health Canada would more effectively contribute to the well-being of consumers by allowing more informed nutritional choices” and,

“A review system that clearly sets out submission requirements for product proponents and thoroughly reviews submissions in a timely and transparent

manner will help to ensure a regulatory climate that protects public health and encourages innovation and product development in the food industry.”

Respondents cautioned that at the same time, that Canada’s food regulatory system should remain grounded in science-based risk assessment.

It was also suggested that the work done under the Chemicals Management Plan be looked at as a concrete example of what can be accomplished and of the ability of Canadian regulators to be bold in developing a modern regulatory framework, with ongoing multi-stakeholder input, and a high level of transparency.

The implementation of service standards (as outlined in the discussion document) was supported and other specific suggestions included looking at progressive licensing, similar to that being developed for drugs.

Objective 1.1 - Improve Health Canada’s processes for pre-market regulatory clearances and notifications

Respondents support Health Canada’s plans to examine ways of triaging or screening submissions (“short track system” was also suggested) to improve review times and adapt best practices from other submission management models. Addressing this goal with timely turn around was noted as being important to allow agri-food industry to maintain a competitive edge.

The critical need to address this goal from a business perspective was emphasized. One respondent noted that, for small business, it is essential that the process for pre-market regulatory clearance be done as quickly as possible to allow the product onto the market as soon as possible:

“This is essential for small business which isn’t as leveraged to play years ahead of time and have long periods of time before a return on product investment has been made”.

Specific approaches to address this goal were suggested, including a greater degree of communication between Health Canada and the food industry, particularly, during the pre-submission stage, where consultations between the two would be very welcome to ensure that the submissions being sent to Health Canada meet all of the requirements. Additionally, several respondents agreed with Health Canada’s suggestion of developing realistic performance standards/service standards:

“Pre-submission consults, stated time lines for the assessment process and closure dates for requests for additional information are examples of concepts which we would like to explore with Health Canada”.

Objective 1.2 – Promote increased transparency throughout Health Canada’s food regulatory risk assessment and risk management deliberations

There was general agreement with this objective and many respondents felt that increased transparency was needed. One respondent noted that “improved transparency of the submission review process would aid smaller food industry players in providing the information necessary to produce high quality product submissions.”

Specific examples of how to address this goal were provided by some respondents. The Trans Fat task force was cited as a model to explore, using working groups to discuss and reach consensus to achieve a workable policy across the sectors. Improved communication and dialogue with industry was another suggestion, particularly in cases where the risk management decisions may not appear to reflect industry concerns. It was suggested that exploring some mechanism of publication of pre-market submissions awaiting approval would increase transparency support as well. In addition, greater transparency and the sharing of food science data across all sectors will make efficient use of Canadian scientific resources.

Objective 1.4 - Reform the regulatory architecture for food additives and develop a regulatory standard for “food grade chemicals” (or “food contact chemicals”) under the *Food and Drug Regulations*

This goal was supported by respondents. The absence of clarity and consistency in the regulation of food additives and food grade chemicals was identified as creating great uncertainty and putting industry at a competitive disadvantage to U.S. industry.

Specific suggestions were received, suggesting “outside” organizations which may be able to assist Health Canada in developing the standards suggested in this objective. They included the Flavour and Extract Manufacturer’s Association and the International Organization of the Flavour Industry.

Objective 1.5 - Improve Health Canada’s regulatory science capacity through expanded and appropriate international regulatory cooperation and work sharing

Respondents were generally in agreement with this objective, but there were a range of perspectives around the goal. Some supported exploring arrangements with leading regulatory counterparts in other jurisdictions, while others suggested caution saying that Health Canada should not “lose sight of defining and delivering standards that are in the Canadian interest first and foremost”. There were some concerns that Health Canada should “retain the decision-making role and not allow international, non-Canadian decisions to automatically apply to Canada”.

There was also some divergence on Health Canada’s relationship with the Codex Alimentarius Commission. On the one hand respondents noted that the pace at which some international organizations, such as Codex, are moving is too slow, and they are not able to meet the marketplace and industry needs in Canada. On the other hand, others commended Health Canada for “continuing to promote Canadian interests and approaches internationally by

participating in standards development in world standard-setting organizations such as the Codex Alimentarius Commission”.

Goal Two - Promoting Regulatory Responsiveness to Food Innovation and Promoting Consumer Access to Foods with Assessed Health Benefits

Respondents strongly supported this goal. Several stressed the need for Health Canada to move quickly in the areas identified under this goal to address challenges the current system poses to innovation and that “if a responsive environment is not fostered, there would be a resulting lack of consumer choices, not to mention economic losses due to discouragement of investment in Canada’s food industry.”

It was suggested that to achieve this goal, processes and policies regarding the introduction of new innovations must be streamlined and better coordinated between all of the government partners and the regulated community.

It was also encouraged under this goal to develop systems/processes “flexible enough to adapt to future innovation in the agri-food industry, for example, a system which would allow for concurrent submissions of a novel food item and health claim as this is the way food development will work in the future”.

Objective 2.1 - Developing a comprehensive framework for the management of food with health claims

All comments received on this goal addressed the proposed comprehensive framework for health claims. As these pertain specifically to elements that the respondents feel should be considered in the development of the regulatory framework for the management of food with health claims, they have been forwarded for inclusion in the consultation on health claims. Additional information regarding this consultation can be found on the Food and Nutrition Consultation web page.

Objective 2.2 - Complete the development of, and implement, a comprehensive policy on the discretionary fortification of foods

There was interest in this as a goal, though all comments received on this goal pertained to details of the specific initiative, “Proposed Policy on the Addition of Vitamins and Minerals to Foods”, rather than the merits of goal itself. The comments will be forwarded to the policy team managing that file.

Objective 2.3 - Increase Health Canada’s science and research capacity for health claims and food innovation by increasing strategic partnerships

Few comments were received on this objective. All responders agreed that this was an important element to the Strategy, and that decision-making and changes to the regulatory framework must remain based on sound science.

Goal Three - Modernizing the Regulatory Toolkit to Address “Food Contributors” to Chronic Disease

Relatively few comments were received on this objective. The model of trans fat was noted again as a model where regulatory action may not always be needed, as “natural market forces and advances in product formulation are taking hold”.

Health Canada was encouraged under this goal to focus not solely on potential negative contributors to chronic disease. It was noted that the industry is able and willing to provide more beneficial products for consumers and the consumer is ready and accepting of these products. The time is more than right to put forward policy that will encourage the development of even more healthy food.

Goal Four - Improving Health Canada’s Responsiveness to Acute Food Safety Health Risks - Responding to New Threats while Managing Ongoing Risks

There was strong support for this goal and the objectives outlined in the discussion document.

Increased collaboration between the food industry and government was noted by some as a critical component for the success of this goal. Some specific examples were given where stronger collaboration was needed to “further refine cost effective risk-based food safety systems and to promote consumer education”. This would also allow industry and government to come together for education opportunities about each other – to stay abreast together in terms of the evolution of new technologies, discovery of new contaminants in foods and/or new by-products of processing, challenge both the food industry and government regulators. Other examples were suggested for exploration under this goal which could improve industry capacity to respond to acute food safety risks.

Respondents encouraged considering under this goal enabling mechanisms for “home grown” technologies, such as those being developed to combat food-borne illnesses for example, bacteriophage technologies and vaccines designed to fight food-borne pathogens as they would benefit not only the Canadian marketplace but also Canadian consumer.

As well, it was recommended that Health Canada continue to support the Public Health Agency of Canada’s surveillance activities regarding microbial and chemical contaminants in foods and integrated surveillance of antimicrobial use and resistance to animals, foods and humans.

The importance of working with and learning from other respected organizations in the international community was also identified as a key means of addressing the issues outlined in this section in a timely manner. International collaboration would allow the sharing of expertise, knowledge and best practices, all of which were noted by one respondent as “vital to staying abreast.”

Objective 4.1 - Expand Health Canada’s Food program coverage of new and emerging pathogenic/contaminant agents

There was general agreement with this objective. Some respondents pointed to specific projects or issues that should be included in the Strategy. These included: an updated food allergen labelling policy which “has long been promised and is urgently needed” and allergen thresholds as their absence “has hindered the effective implementation of Food Safety Enhancement Programs”.

Another respondent indicated that obtaining this objective would be helpful in identifying and understanding pathogens that could originate in other parts of the world but are brought into Canada through imported ingredients or products.

Objective 4.2 - Enhance the effectiveness of risk communications for food safety and nutrition risks, consumer-level education, and retail-level food labelling for improved public health and consumer protection.

Few comments were received on the substance of this goal. Some feedback was provided on the wording of this objective and a suggestion to add “ingredient list” to the last bullet under this objective as “it is essential for those with a chronic disease to which food contributes” (such as celiac disease).

Objective 4.3 - Improve Health Canada’s emergency preparedness and the department’s capacity to provide emergency response assistance vis-a-vis food defence and food safety.

Respondents to this objective identified the absence of the Public Health Agency of Canada in the bullet which talks about “strengthening HC/CFIA emergency management collaboration” as a gap in the Strategy. There was also some question on the clarity of the wording of the second bullet.

Objective 4.4 - Improve Health Canada’s ability to produce, analyze, and use health/medical intelligence and surveillance information

Some of the comments received for this section pertained to specific initiatives/projects that should be undertaken by Health Canada and thus are not captured here. There were, however, suggestions from a couple of respondents regarding the wording of the objective itself to more explicitly define how Health Canada would respond to food safety risks, new and ongoing.

Goal Five - Promote a Sustainable and Integrated System for Food Safety and Nutrition in Canada

Overwhelming support was given to the goals and objectives as they were outlined in the discussion document, although, respondents emphasized the importance that all government stakeholders (HC, CFIA, PHAC, AAFC and P/Ts) needed to support the strategy and its objectives. They also emphasized that to have a sustainable and integrated system as described in the discussion document, it must be straightforward, based on high standards that all parties respect and lack duplication of effort in processes/requirements between government agencies.

The increasing importance of coordination of efforts was highlighted “as the economic prosperity of the agri-food sector becomes increasingly linked to health and wellness (and environmental) objectives, it is more important than ever that the economic, scientific and regulatory communities at both levels of government coordinate their efforts against common objectives and performance standards”.

Specific suggestions to help meet this goal establishing a bi-lateral meeting process for those involved in the food regulatory system similar to one that has been developed by the Biologics and Genetic Therapies Directorate (BGTD) in Health Canada so that a regular exchange of information between the regulators and industry partners can take place.

Objective 5.1 - Improve the alignment of food safety and nutrition priorities and risk management approaches within Canada’s food safety system.

Respondents felt that this objective did not appropriately reflect other Departments, and the need to strengthen and deepen collaboration among them. Specific recommendations were made to increase and improve communication and co-ordination of food related activities of PHAC, AAFC and Health Canada.

Implementation of the Strategy

Several respondents also commented on implementation aspects for the strategy.

There was an observation that in conjunction with the modernized Health Canada processes and regulatory strategies, the government could consider reviewing the related compliance and implementation processes that impact other government departments such as CFIA.

There were concerns about how the strategy would be implemented given the breadth of issues captured. Health Canada was encouraged to establish short and long term goals with specified time line and it was recommended that Health Canada report regularly on the progress of these goals.

CONCLUSIONS AND NEXT STEPS

The consultation received feedback from a variety of sectors, representing a range of perspectives and mandates. In general, the modernization goals were supported, and reinforced the need to address efficiencies, timeliness, responsiveness, and better coordination and collaboration with partners in the larger food and nutrition system.

The suggestions offered by the consultation participants will be incorporated into the revised version of the Strategy which will be a part of the Food Directorate’s Strategic Plan. This plan will also include implementation details which will address the questions raised by the

consultation respondents regarding the Regulatory Modernization Strategy for Food and Nutrition. The Food Directorate’s Strategic Plan is targeted for publication in the Spring of 2009.