

# HEALTH PRODUCTS AND FOOD BRANCH

## PUBLIC ADVISORY COMMITTEE

### 2004 ANNUAL REPORT



## 1. LETTER FROM THE CHAIR

On behalf of the Health Products and Food Branch (HPFB) Public Advisory Committee (PAC), I am pleased to present the second PAC Annual Report to you, Ms. Diane Gorman, Assistant Deputy Minister of the Health Products and Food Branch.

This Report highlights the PAC's achievements and advice in 2004. It also identifies how the Committee's contributions have demonstrated value to the Branch and the tangible actions the Branch is taking to address the PAC's input throughout the year and in the years to come.

The Public Advisory Committee would like to express its sincere appreciation and gratitude for the organizational skills and support provided by the PAC Secretariat and Office of Consumer and Public Involvement.

This Report is ultimately dedicated to all Canadians. PAC members have been contributing feedback to HPFB with diverse public/consumer opinions, values and concerns in mind. The Committee looks forward to the upcoming opportunities you and your Branch Executive Committee will seek from the PAC in addressing future priority issues.

Best wishes for a happy and healthy year ahead.

Sincerely,

Wayne Busch  
Chair, Health Products and Food Branch Public Advisory Committee

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### 3. Introduction

Launched in November 2002, the Public Advisory Committee (PAC) is a forum that provides advice from the consumer/public perspective on priority issues and initiatives as requested by the Health Products and Food Branch (HPFB) of Health Canada. The Committee is an innovative component of the Branch's strategy to increase transparency and public involvement.

The PAC's mandate is threefold:

- to provide the Assistant Deputy Minister and the Branch Executive Committee with advice from a public perspective on Branch issues and initiatives;
- to provide guidance to the Office of Consumer and Public Involvement (OCAPI) and the HPFB related to planning and management for public involvement activities; and
- to advise on increasing the effectiveness of OCAPI and HPFB communications to Canadians.

The PAC's newest member, Ms. Tina Martin, joined the Committee in February 2004. There are now 17 members of the general public from across Canada, including men and women of various ages and diverse academic, cultural and linguistic backgrounds.

### 4. Key Achievements: Highlights of Activities and Advice Provided by the PAC

#### 4. a) February 2004

The PAC met for the fifth time in February, launching its second year of providing advice to the Branch. In the context of striving to improve openness and transparency within the Branch, the PAC addressed three topics related to this theme at the February meeting: Dispute Resolution, the Public Involvement Strategy for the Branch and the Advertising of Health Products.

The PAC's input on the definitions of transparency and openness helped to shape and ultimately define the terms and principles for the Branch - no small achievement. This resulted in much clearer and precise commitments in the form of activities and projects on the part of the Branch. The definitions for transparency and openness adopted by the Branch in February 2004 are:

- *transparency* refers to how easily the public can access and understand information about how HPFB do our (its) business and how decisions are made
- and *openness* refers to the Branch's willingness to hear and consider the public's input in the conduct of its business through the exchange of information and/or more direct participation.

#### 4. a. i) Dispute Resolution

The Committee provided advice on the possible services that could be offered to the public through the Ombudsman's Office as part of the Dispute Resolution initiative.

- The cautions expressed by PAC members about the concept of an Info Centre were duly noted and following the review of existing services as well as a review of input from the PAC, the Info Centre has been renamed the “Special Issues Function”.
- Many of the key functions that the PAC highlighted as useful to the public have been included in the “Special Issues Function” of the ombudsman.
- This function is essentially reactive and deals with groups or individuals that have a special issue or problem and need information about the Branch.
- The primary users of the Special Issues Function would be external associations, disease groups, patient groups, community activists, advocacy groups, patients and health care providers.

#### 4. a. ii) Public Involvement Strategy

The advice that PAC provided on the Public Involvement (P.I.) Strategy for the Branch resulted in a deeper understanding of how to improve trust through better relationships with stakeholders. Committee members emphasized the importance of reaching citizens when communicating the strategy, including clarifying what is being committed to and how it will be achieved.

Since the February meeting, the P.I. Strategy was renamed as the Public Involvement (P.I.) Framework. Based on the PAC’s advice, another objective was added to the P.I. Framework. This objective has now been included as Goal #8, and incorporates the concept of public communication:

- Goal #8 reads as: Improve public awareness, through better exposure to and delivery of clear and understandable information about the Branch.

The vision of the Framework was revised to focus on integrating transparency and openness and increasing trust and confidence among Health Products and Food Branch stakeholders. The *vision* now reads as:

- “The Health Products and Food Branch will have mutually beneficial relationships with the public. While respecting our regulatory responsibilities, the Branch will be open, transparent and accountable in our work, and integrate stakeholder input into our decisions. The Branch will improve stakeholder trust and confidence in the regulatory system.”

The Public Involvement Framework attempts to reach a balance between consulting with the traditional national organizations and implementing innovative approaches, which will increase access to the Branch by regions, communities and citizens.

In November, 2004, public consultations were held in regions across Canada on the Public Involvement Framework. Plans are underway for Branch-wide implementation of the Framework, including pilot projects to be undertaken in the coming year.

#### 4. a. iii) Legislative Renewal – The Advertising of Health Products

Building on previous consultations, the Committee advised the branch on how the advertising of health products might be better controlled. Their input will be combined with other perspectives to assist Health Canada and stakeholders to arrive at a better understanding of different perspectives.

- PAC input has been shared with the Legislative Renewal Secretariat and the Marketed Health Products Directorate.
- Now that the consultation phase is completed, Health Canada will conduct an analysis of the results, with a view to develop a Bill on health protection that could be tabled toward the end of 2005.
- The consultation with PAC was part of a much broader process including regional meetings. Results will be seen in the longer term.

#### **4. b) May 2004**

The PAC met in Montreal, Quebec on May 28<sup>th</sup>-29<sup>th</sup>, 2004. The theme for this meeting was “Enabling Innovation for Better Health Outcomes”. The Committee had an opportunity to tour the laboratories at Health Canada’s headquarters in Longueuil, Quebec. Lucie Myre, Health Canada’s Regional Director General in Quebec, delivered a presentation on the role of Health Canada in the Quebec region. Jean Lambert, Director General of the Health Products and Food Branch Inspectorate, addressed the roles of the Inspectorate. Participants said they appreciated the first-hand look at the product investigation process.

At this meeting, Wayne Busch, PAC Chair, and Dominic Bergeron, PAC Vice Chair, accepted nominations by PAC members to retain their current respective positions for the remainder of their three-year terms, ending November 2005.

#### **4. b. i) Animal Livestock Cloning for Food Use**

The Committee provided advice on key considerations for Health Canada for regulating Somatic Cell Nuclear Transfer (SCNT) technology and its use in food-producing livestock animals. (SCNT is the form of cloning that was used to produce “Dolly” the sheep.) The members stressed the importance of Health Canada’s role in regulating foods derived from this technology to ensure the health and safety of Canadians.

- Based on PAC’s advice, there are plans underway to create a short public-oriented document to highlight Health Canada’s role and key challenges on the topic of animal livestock cloning for food use.
- The Food Directorate also plans to explore the possibility of using a “Canadian Biotechnology Advisory Committee (CBAC) Genetically Modified Food and Feed Dialogue Tool” to allow for ethical issues to be examined more thoroughly. This is because the PAC emphasized the importance of further review of the ethical issues surrounding this technology.

#### **4. b. ii) Plant Molecular Farming**

At their May meeting, the PAC also examined the topic of plant molecular farming (PMF). This technique involves using genetically modified plants to produce substances that the plants typically do not produce naturally, such as industrial compounds or therapeutics. Members said they preferred that PMF not be allowed in food crops. However, if it were allowed, then strict containment according to international standards should apply. The PAC suggested further consideration be given to potential impacts on the farming industry and to the

importance of the federal government working collaboratively to minimize any potential environmental health risks.

- The Committee's advice was presented at Health Canada's policy-making workshop on PMF held in October 2004.
- This workshop is the next step in the Department's policy-making process regarding plant molecular farming.

#### **4. b. iii) Health Canada Framework for Biotechnology**

The Committee delivered concrete advice on how the Health Canada Framework on Biotechnology can be improved. For example, they suggested a need for further clarity on safety measures, outcomes and benefits. Members reiterated that while innovation is important, safety should not be compromised.

- Based on the PAC's advice, the final Health Canada Framework for Biotechnology was revised to have:
  - greater emphasis on health and safety throughout the document
  - clarity that this is a working document and meant for a government audience
  - clarity of ethical and social issues within the document.
- A separate document, like an executive summary, is being produced that is geared to a public audience. It will have plain language and it will be much shorter. It will also contain concrete examples of work done by Health Canada on biotechnology such as regulations, and it will be complementary to existing material.

#### **4. c) October 2004**

At their meeting on October 1<sup>st</sup> and 2<sup>nd</sup>, 2004, the PAC explored four topics: Branch Planning, Antimicrobial Resistance (AMR), Summary Basis of Decision (SBD) and External Charging.

Assistant Deputy Minister Diane Gorman welcomed the Committee and thanked them for their achievements over the past year in providing concrete advice and suggestions that have been integral to the Branch's decision making on key issues.

In regards to membership renewal, it was announced that Diane Gorman, Assistant Deputy Minister of HPFB, has renewed Dr. Sandra Wood's tenure as a PAC member for a three year term ending in November 2007.

#### **4. c. i) Branch Planning**

The Committee supported the Branch's integrated approach to planning, reporting and performance for 2004-2005. It offered suggestions for improving the Branch strategic plan, business plan and annual performance report from the perspectives of transparency and accountability. Overall, PAC's key message was that if the draft planning documents were to be designed for a public audience, the Committee suggested that more clarity and plain

language would be needed and communication tools should be explored to make public communication easier.

The PAC's advice will be incorporated for future draft planning documents and communications tools will be explored.

#### **4. c. ii) Antimicrobial Resistance**

The advice that PAC provided on AMR resulted in a deeper understanding of how the public perceives AMR risks. Committee members emphasized the importance of using targeted messages that raise public awareness. Members also suggested using regional media to reach out to various segments of the population. Messages should focus on hygiene and on appropriate use of products.

The PAC's messages and ideas will be built into future education and public awareness strategies.

#### **4. c. iii) Summary Basis of Decision**

The Committee supported the Summary Basis of Decision (SBD) initiative. *(SBDs are a new initiative of the Branch that outline the scientific and benefit/risk-based reasons for Health Canada decisions to grant market authorization for a drug or medical device).* There was general agreement on the guiding principles behind the project and PAC members were comfortable with SBD documents written in technical language to ensure transparency.

Questions and answers on the SBD will be developed to respond to public inquiries.

#### **4. c. iv) External Charging Initiative**

The PAC provided suggestions on aspects of the renewal of the branch external charging program. The main message was that safety and access are key and that fees will not compromise health and safety. It was noted that fees will not resolve resource issues, in that only a portion of the costs are actually recovered. The percentage of costs that should be recovered is an important public policy consideration. Although some members challenged the charging of user-fees they agreed that fees are a part of doing business and that only after payment should the review of a product or issuance of licenses take place. There was support for relief to small business to ensure wide access/availability of products on the market. However, no consensus was reached on the issue of fee mitigation on the grounds that the objectives might be achieved through other more effective mechanisms like the support already offered to small businesses through other government initiatives.



PAC's comments and concerns about user fees will be incorporated into discussion papers on fee appropriateness and fee mitigation. These documents will be posted on the Health Products and Foods Branch Web site for general public consultation.

**5. PAC Members' Contributions to other Branch Public Involvement Activities**

**5. a )** PAC members participated in several HPFB public involvement activities organized by Directorates in the Branch. Some of these activities included workshops and/or teleconferences on the following topics:

West Nile Regulatory Consultation Workshop, February 18-19, 2004

Health Protection Legislative Renewal, March 11, 2004

Summary Basis of Decision Consultative Workshop, June 10-11, 2004

Public Involvement Framework Regional Consultations, October – November, 2004

PAC members also provided feedback and comments on a new HPFB publication:  
*Profiles in Progress: The Health Products and Food Branch at Work*

**5. b)** Subsequent to their participation in other Branch public involvement activities, the PAC Secretariat coordinates the sharing of information and participants' feedback to ensure that other PAC members have an opportunity to hear, share or discuss feedback from their consultations.

During the consultation on Summary Basis of Decision, a scientific reviewer commented that the participating PAC member's comments were very insightful and informed.

When relating this story at the last PAC meeting, the PAC member noted that because of his experience on the PAC, he:

- has gained the knowledge about what the Branch is looking for and
- can feel assertive and effective in bringing a different perspective at Branch consultations.

**6. Evaluation: Conditions for Mutually Profitable Meetings**

Committee members appreciate receiving background information in their language of choice accompanied by the specific questions that will be asked of them at least two weeks prior to each meeting. These background materials provide an opportunity for members to be well-prepared prior to the meeting.

Members are also eager to ensure that there is a maximum of three topics per meeting for in-depth discussions – a goal facilitated by background materials that is clear, concise and in plain language.

## **2004 HPFB PAC Annual Report**

In 2004, the PAC Secretariat adopted a new evaluation approach for each consultation session. The Committee welcomed the new evaluations forms and approach. The PAC members and HPFB officials who participate in future consultations will now provide their feedback and evaluation subsequent to each consultation session.

Now that PAC members have experienced a wide variety of consultations, they easily recognize a high quality, meaningful consultation. If a consultation is not of that quality, they feel comfortable enough to say so. Overall, PAC members have found the consultation sessions to be very well organized, allowing for very productive, interesting and informative sessions.

### **7. The Road Ahead: Plans and Priorities for 2005**

The Public Advisory Committee appreciates the opportunity to continue to address agenda items that align themselves with the strategic priorities of the Health Products and Food Branch.

A membership renewal/recruitment strategy will be adopted in 2005, as the membership tenure of 15 out of the 17 members will expire in November of 2005. Because the majority of these 15 members have indicated their interest in renewing their tenure for another three years, one of the challenges ahead will be to ensure that appointments of members are scheduled to allow for continuity and systematic rotation.

The Committee appreciates the presence of management staff and executive officials of the Branch at meetings. The PAC also appreciates and would like to continue to see the ongoing efforts made by the Branch Offices and Directorates to provide the PAC with an update on how their advice has been used from previous meetings.

#### **2005 Upcoming Meetings**

**February 18-19<sup>th</sup> - Ottawa, Ontario**

**May 27-28<sup>th</sup> - Halifax, Nova Scotia**

**October 14-15<sup>th</sup> - Ottawa, Ontario**

**8. 2004 FINANCIAL REPORT**

**APPROXIMATE COSTS INCURRED FOR EACH PAC MEETING**

	<b>Approximate Costs per Meeting</b>
<b>Hotel costs</b> <i>(Catering &amp; Boardrooms bookings)</i>	\$ 8 000.00
<b>Travel costs for participants /speakers</b> <i>(flight, ground transportation, meals, accommodations and incidentals)</i>	\$ 15 000.00
<b>Facilitation</b>	\$12 000.00
<b>Document Translations</b>	\$2 000.00
<b>Audiovisual services and equipment</b> <i>(Duocom)</i>	\$6 000.00
<b>Printing services</b>	\$3 000.00
<b>TOTAL APPROXIMATE COST</b>	\$ 46 000.00 per meeting
<b>Staffing</b>	
<i>1 full time Program Manager</i>	
<i>50% of a Senior Public Involvement Officer</i>	
<i>50% of an Administrative Officer</i>	

**Total estimated cost per year including staffing is approximately \$200, 000.00**

**Annex A: Record of PAC Meetings held, 2002-2004**

<p><b>2004</b></p>	<p><b>February 20-21<sup>st</sup> Ottawa, Ontario</b></p> <p><b>May 28-29<sup>th</sup> Montreal, Quebec</b></p> <p><b>October 1-2<sup>nd</sup> Ottawa, Ontario</b></p>	<ul style="list-style-type: none"> <li>• Public Involvement Strategy</li> <li>• Legislative Renewal: Advertising of Health Products</li> <li>• Dispute Resolution</li>   <li>• Animal Livestock Cloning for Food Use</li> <li>• Health Canada Framework for Biotechnology</li> <li>• Plant Molecular Farming</li>   <li>• HPFB Strategic Planning</li> <li>• Antimicrobial Resistance</li> <li>• Summary Basis of Decision</li> <li>• External Charging</li> </ul>
<p><b>2003</b></p>	<p><b>Jan. 31-February 1<sup>st</sup> Ottawa, Ontario</b></p> <p><b>May 22-23<sup>rd</sup> Vancouver, B.C.</b></p> <p><b>October 17-18<sup>th</sup> Ottawa, Ontario</b></p>	<ul style="list-style-type: none"> <li>• Regulatory Process (information)</li> <li>• Decision- Making Framework (information)</li> <li>• Drug Approval Process (information)</li> <li>• Nutritional Labelling (information)</li> <li>• Review of Canada’s Food Guide</li> <li>• Regional Network of Citizens</li>   <li>• Western Regional Office (information)</li> <li>• Legislative Renewal</li> <li>• Risk Communication</li> <li>• Biotechnology and Health Communication Plan</li>   <li>• Patented Medicines (information)</li> <li>• Openness and Transparency (part one)</li> <li>• Communicating Drug Safety Information</li> <li>• Health Products and Food Branch Integrated Planning</li> </ul>
<p><b>2002</b></p>	<p><b>November 22-23<sup>rd</sup> - Ottawa, Ontario</b></p>	<ul style="list-style-type: none"> <li>• Overview of HPFB (information session)</li> <li>• Overview of the Office of Consumer and Public Involvement (information)</li> <li>• Citizen Engagement (information)</li> <li>• Speech From the Throne and HPFB Initiatives (information)</li> <li>• Food Irradiation</li> </ul>

## **Annex B: Profiles of the Public Advisory Committee Members**

### ***Atlantic Sector***

Don Holloway has broad experience in committee and community work including active membership in Health Canada's National Advisory Council on Aging (just completed a five-year term as president), the National Pensioners and Senior Citizens Federation, Premier's Council on Social Development for Newfoundland and Labrador, and President of Newfoundland and Labrador Pensioners and Senior Citizens 50+ Federation.

Thomas Connor is a former Deputy Minister, Department of Development, Government of Prince Edward Island. He has considerable leadership experience, has a broad interest in health issues, is active in volunteer work, and has held positions in various provincial organizations.

Daniel Lazaric is an anesthesiologist practising in Nova Scotia. He is a young health sector professional and provides representation from the rural and regional areas.

### ***Québec Sector***

Claudine Larocque has training in acupuncture, shiatsu and homeopathy. She has been a homeopathic clinician for the past 12 years. She is second vice-president of the Fédération des professionnelles and has participated in the various consultations initiated by Quebec's Minister of Health and Social Services. The federation represents more than 5,000 health and social services professionals in Quebec.

Jocelyn Côté has a combined science and education background. In addition to his role as a primary school teacher, Mr. Côté was a member of the Conseil supérieur de l'Éducation in Québec. He is committed to promoting healthy living in youth and young adults and represents the young Francophone community.

Neil Faulkner has an extensive background in public policy and public health issues. He has been actively involved in public health policy and risk assessment as a former Assistant Deputy Minister with Health and Welfare and with Indian Affairs and Northern Development. Mr. Faulkner is also experienced in community and committee work and is representative of the Anglophone community in Québec.

### ***Ontario Sector***

Nadine Blum is a graduate of McMaster University's Biology and Pharmacology Co-op Program and is now studying at Osgoode Hall Law School with a view to developing a career in health law and policy. Ms. Blum has received many awards and scholarships and has been actively involved in community and volunteer work.

Nancy McColl has both national and international work experience and has a solid understanding of the rural and agricultural communities in Canada. Ms. McColl has participated in volunteer and community work through various organizations including Leadership Ottawa. She is currently working in the field of teaching and education.

Dominic Bergeron is a professor and coordinator of the Biotechnology Program at Ottawa's French-language college, La Cité collégiale. He has completed his post doctoral studies at the National Research Council and has recently received an award for his teaching abilities in the Capital.

## 2004 HPFB PAC Annual Report

Tina Martin is a policy analyst with the Health Secretariat of the Assembly of First Nations in Ottawa. An Ojibway from the Wikwemikong First Nation, she is a graduate of the University of Alberta. She has been involved in a series of committees including the National Steering Committee for the Canada Prenatal Nutrition Program and Fetal Alcohol Disorder and the first Nations and Inuit Health Committee of the Canadian Paediatric Society.

### *Prairies Sector*

Reverend Robert Girard has a keen interest in health care matters. He retired from his senior management position as executive director, Mission, at Saint Boniface General Hospital. Reverend Gerard has a combination of various committee and community experience.

Lena Hozaima's extensive academic and clinical background, including a Master's degree in Cardiovascular Sciences, has allowed her to work closely with medical doctors and patients. Through her continuous commitment as a volunteer, such as public speaking, with Heart and Stroke Foundation and other venues, she has gained broad experience with various patient groups.

Wayne Busch has been involved in health care issues at the local, provincial, and national level. He has a keen interest in all aspects of health promotion, health education, preventative health care and natural health and therapeutic products. Mr. Busch has broad experience in both community and committee work and represents the rural sector of the prairies.

Robert Grose has a keen interest in health care matters, particularly regarding nutrition and therapeutic products. He was a founding member of the Canadian Association of Healthcare Human Resources Management and has served on numerous other boards and committees. Mr. Grose is well respected in his community and noted for his interpersonal and communications skills.

### *Western Sector*

Sandra Wood has broad experience in health sciences, academics, administration and management. As a dental specialist in periodontics, she commonly deals with health issues that are affected by nutrition, systematic problems, drugs, biologics and medical devices.

Yoe Sook Youn is a director of the Canadian Ethnocultural Council, vice-chairman of the Federation of Korean Canadian Associations and a visiting professor at the Graduate School of Kyonggi University, South Korea. She has experience in both community and committee work, including the position of president of the Korean Canadian Cultural Association of British Columbia.

Adam Andruschak has recently retired after 35 years of senior fiscal and business management service in public education. He believes strongly in government programs that promote healthy eating and informed use of food, natural health products and therapeutic products. During the past five years. Mr. Andruschak has worked on a variety of projects involving public/private partnerships and public consultation.