Health Products and Food Branch (HPFB) Public Advisory Committee (PAC)
May 28-29, 2004
"Enabling Innovation for Better Health Outcomes"
Hilton Bonaventure Hotel, Montreal, Quebec

Attendance

PAC Members: Adam Andruschak, Dominic Bergeron (Vice Chair), Nadine Blum, Wayne Busch (Chair), Thomas Connor, Jocelyn Côté, Neil Faulkner, Robert Girard, Robert Grose, Don Holloway, Lena Hozaima, Daniel Lazaric, Tina Martin, Nancy McColl, Sandra Wood.

Office of Consumer and Public Involvement (OCAPI): Roger Farley (Director General), Sylvie Cantin (Director, Public Involvement and Outreach), Sameena Khan (Program Officer), Shari Silber (Senior Public Involvement Officer), Julie Bernier (Quebec Regional Public Involvement Officer).

Facilitator: One World Inc. - Jacquie Dale.

Guests:

HPFB Food Directorate: Luc Bourbonnière (Scientific Evaluator, Novel Foods Section), Mireille Prud'homme (Acting Director, Bureau of Food Policy Integration), Nora Lee (Acting Section Head, Novel Foods Section), Theresa Paolasini (Regulatory Policy Officer, Bureau of Food Policy Integration), Johanna Jennings (Scientific Evaluator, Novel Foods Section), Marie-Josée Bolduc (Regional Liaison Officer, Quebec Region).

HPFB Office of Biotechnology and Science: Dr. Pierre Charest (Director General), Ryan Hum (Science Policy Analyst), Dr. Irene Hay (Biotechnology Policy Analyst).

Quebec Region: Lucie Myre (Quebec Regional Director General, Health Canada), Jean Lambert (Director General, Inspectorate, HPFB).

Minutes of the Proceedings

The Public Advisory Committee provided advice on Somatic Cell Nuclear Transfer (SCNT) cloning and its use in food producing livestock animals. SCNT is the form of cloning used to produce "Dolly" the sheep.

The members provided advice on what should be Health Canada's key considerations in regulating this technology. In addition, the PAC provided concrete examples on how the Food Directorate should move forward with public awareness activities for this issue.

1. Issues regarding SCNT Cloning of Food Production Livestock

As part of this consultation, the Public Advisory Committee was asked to identify concerns that PAC and other Canadians may have regarding SCNT cloning of food production livestock.

The PAC indicated that health and safety of both animals and humans are paramount. PAC highlighted the importance of Health Canada to regulate in this area and to monitor developments on this issue. The members noted that there are many different interpretations of the meaning of "safe" in the public domain.

Ethical considerations were frequently voiced by the members. In addition, PAC indicated that there needs to be consideration and analysis of consequences that may occur (e.g. potential increased costs to consumers if added costs assumed by industries are passed onto consumers).

PAC members wanted assurance that diversity in the food supply would be protected and that consumers would be able to make informed product choices.

2. Considerations in Regulating Food Derived from SCNT Cloned Animals and their Offspring.

The PAC members re-iterated the importance of Health Canada maintaining its key role in regulating and monitoring food derived from SCNT cloned animals and their offspring, in the event these products are allowed on Canadian market shelves.

The PAC also advised that ethical aspects be considered in the regulatory process.

Other considerations include the impact on diversity of the food supply and the need to monitor the impact of unintended consequences.

It was suggested that Canada take a lead role in the international regulatory community and consider international research activities in this area when further developing the Canadian position on this issue.

To enable consumers to make informed choices, the PAC members recommended the Branch take into account the education and scientific literacy of the public when communicating on regulations and safety.

3. Public Awareness and Communication Messages to the Public at this Stage

The PAC felt that the principles of openness and transparency should be inherent in communications messages to the public.

Members suggested that balanced information should be provided to the public as early as possible. The concept that "knowledge is not dangerous" was mentioned.

Communications messages from Health Canada should not indicate a promotion of cloning or its technologies, but rather include information about: what is known about the technologies and their impacts, what is unknown and that Health Canada is working on the issues. The public should also be informed about the differences between types of technologies, such as between genetic modification and cloning.

The PAC advised that since health and safety are paramount, communications messages should focus on Health Canada's role to protect the health of Canadians.

It was suggested that television be used as the medium to communicate messages to the public.

4. TOUR OF THE FOOD AND DRUG LABORATORIES IN LONGUEUIL, QUEBEC

The Public Advisory Committee visited Health Canada's headquarters in Longueuil, Quebec. Lucie Myre, Health Canada's Regional Director General for Quebec, delivered a presentation to the PAC on the role of Health Canada in Quebec. Jean Lambert, Director General of the HPFB Inspectorate of Health Canada, also presented an overview of the roles and responsibilities of the Inspectorate.

The Inspectorate manages the licensing processes for regulated establishments and the industry inspection, product investigation and enforcement activities related to the manufacturing, importation and sale of marketed health products in Canada. To support these activities, the Inspectorate operates the Pharmaceutical Microbiology and Chemistry Labs that the PAC members toured. The PAC members also toured the Food Microbiology and Chemistry Labs (Food Directorate) and the Drug Analysis Service Lab (HECS). The PAC appreciated their first hand opportunity to view the work taking place in all of these laboratories.

5. PLANT MOLECULAR FARMING

The PAC identified their concerns regarding plant molecular farming (PMF). PMF involves using genetically modified plants to produce substances that the plants typically do not produce naturally, such as industrial compounds or therapeutics. Members also provided advice on whether they thought Health Canada's proposed regulatory approach is sufficient.

5.1 Benefits and Risks of Plant Molecular Farming

The Public Advisory Committee commented that plant molecular farming is an innovative technology with medical and economic potential because it can serve as a possible remedy to current production limitations in bioreactor vats by yeast or mammalian cells. Other benefits cited by PAC members include the introduction of new compounds for new cures, a revival and diversification of the agricultural economy, broader availability and advancement of therapeutic/pharmaceutical products that may possibly reduce costs. However, the PAC stated that any savings in production costs for pharmaceutical companies must be passed on to Canadian consumers.

The members raised concerns about the unknown effects and risks that PMF may pose such as implications of cross-contamination of existing food crops, impurities in drugs, risks of mutations, bioterrorism and potential contamination of the food supply.

It was also highlighted that there may be a significant impact to the farming industry in Canada as a shift away from food production to pharmaceutical production by farmers may take place, with an added risk of increased control over farming by patent-holders.

5.2 Plant Molecular Farming in Food Crops

The PAC was presented with the following argument: "There is a wealth of biological and genetic information on food crops, which some people argue makes food crops the best choice for molecular farming because so much is known about how they interact with the environment". Based on this statement, PAC members discussed whether PMF should be allowed in food crops or not.

The PAC concluded that the preference is not to allow PMF in food crops, but if PMF in food crops was allowed, there should be strict containment according to international standards to prevent cross-contamination and to demonstrate that the government is in control.

5.3 The Proposed Regulatory Approach

Members identified that the regulatory approach taken by Health Canada must benefit all Canadians.

There is a need to identify who will be controlling production as well as a need to review the patent process. The PAC suggested that Health Canada should also hold some patents to ensure public benefit. They also advised that Health Canada scientists and regulators try to steer corporate developers toward other non-food crops whose genetics and growing habits are also well-known, such as horticultural and row crops such as cotton and flax.

PAC members voiced the importance of federal government departments to work collaboratively to maximize the benefits while minimizing any risks to Canadians.

6. HEALTH CANADA FRAMEWORK FOR BIOTECHNOLOGY

The PAC was provided with an overview and examples of challenges facing Health Canada and the federal government related to biotechnology. They were presented with the draft Health Canada Framework for Biotechnology. This document provides an operating framework for Health Canada in biotechnology as it defines the Department's regulatory roles and responsibilities, opportunities, challenges and priorities. Based on this information, the PAC members gave advice on the Framework and its applicability at the federal government level. The PAC also shared their views on the usefulness of this document to a general public audience.

6.1 Balance between Ensuring Safety while making Promising Technologies available to Canadians.

The members stated that in the Framework, overall, the balance is not clear. The PAC provided advice on how Health Canada can move forward in enhancing the balance in the current Framework. For example, they suggested additional text to include: greater emphasis devoted to health and safety; further details on ethical and social issues; and a clarification of the purpose of the document stating clearly that it is a working document designed for the federal government's internal use.

The PAC's key message was that health and safety are paramount and should be prominent throughout the Framework. They felt that the basic pillars are present, but noted that balance would need to change depending on each issue. The members also asked that the Branch consider how resources devoted to biotechnology would impact on the health system.

6.2 The Framework's Handling of Ethical, Social and Cultural Issues

The PAC members had varied opinions on how well the Framework handles product safety issues that are not strictly science related. A key message from the PAC was that the Framework requires more explicit details about the mechanisms to be used that would involve ethical, social and cultural considerations in decisions. They suggested, for example, the Branch could consider an ethical and cultural advisory committee in addition to scientific advisory committees.

There were varied opinions on whether or not scientific considerations should precede ethical considerations, but overall, members felt that ideally, scientific considerations should be considered at the same time as ethical, social and cultural considerations as this could generate better health outcomes.

6.3 The Required Guidance towards Regulating Biotechnology

Overall, the PAC commented that every technology has its own set of applicable values and that there is a need for some general guidelines. In regards to whether the Framework provides the right guidance, PAC members felt that there are voids in the Framework about Health Canada's role in steering the issues. They suggested the inclusion of a checklist or guidance criteria. They also agreed that safety measures, outcomes and benefits should be stated clearly. Members reiterated that while innovation is important, safety should not be compromised.

The PAC suggested that guidance information related to implementation of the Framework, such as regulations on biotechnology-derived products, would be useful to include in the document.

Members also highlighted that there should be a means to identify the necessity for a particular technology since there are many technologies already available for use. The guidance should help identify a particular technology that will prove to be most beneficial and most cost-effective.

6.4 Usefulness of the Health Canada Framework on Biotechnology to the General Public in Understanding how Health Canada Manages Biotechnology

The PAC felt that the Framework is very broad and attempts to cover a complexity of issues that relate to both the realms of biotechnological applications in addition to research and development related to biotechnological innovations.

The PAC had a wide range of views towards the usefulness of this document to the public audience. In general, members agreed that this material would not address the specific information that would be helpful. PAC suggested that a summary of the document and greater information focusing on concrete examples of what Health Canada (in particular Health Products and Food Branch) does with respect to biotechnology (e.g. development of regulations, evaluation of biotechnology-derived products) would be beneficial.

7. PAC MEMBERSHIP RENEWAL

Members agreed on a proposed renewal process that was outlined at the meeting.

Initial ideas for a recruitment process were also identified. Members agreed that OCAPI should keep an ongoing list of potential members. Members also agreed that there be a recruitment committee. Further details about a recruitment process will be discussed at a future PAC meeting.

8. TENURE ANNOUNCEMENT FOR PAC CHAIR AND VICE CHAIR

Robert Grose placed a motion forward during an in-camera session for PAC members.

It was proposed that Wayne Busch, PAC Chair, and that Dominic Bergeron, PAC Vice Chair, retain their current positions for the remainder of their first three year term, ending November 2005.

The proposed motion was seconded by Sandra Wood and accepted unanimously by all PAC members present.

9. REGIONAL UPDATE

- In Western Canada, the Avian flu and BSE are still having considerable economic and environmental impacts.

- In Eastern Canada, nurse practitioners, midwives and pharmacists are now being allowed to prescribe certain medications. This has raised concerns for other professional groups.

- Water quality and concerns about the de-listing of health services were cited as key health issues in Ontario and in the Outaouais region.

- Members also identified the rapid expansion of biotechnology innovation in Canada. Biotechnology firms in Canada seem to now be moving their focus from research and development to the creation of products.

- There is a growing trend in the U.S.A. towards metabolic syndrome (obesity associated with heart disease, stroke, diabetes, etc.). Prevalence of obesity in Canada is high and if left uncontrolled, the impact of metabolic syndrome could potentially have devastating health effects in the future among Canadians.

- The health status of Aboriginal Peoples in Canada, measured by life expectancy and several other health indicators such as infant mortality, birth weight, suicide and injury and tuberculosis, is significantly worse than the health status of the general Canadian population.

ACTION ITEMS

1. OCAPI and the involved Directorates will brief the Assistant Deputy Minister and the Branch Executive Committee on the advice from PAC.

2. The Chair will canvas members for items for the next agenda and will share the suggestions with the OCAPI Secretariat.

3. Feedback received by OCAPI from consultations attended by PAC members will be distributed to the rest of the PAC prior to the next meeting.

4. OCAPI will prepare a rationale for hosting some future PAC meetings in a smaller community setting. OCAPI will review practices by other committees.

5. The Chair will continue to forward items of information to PAC members, as he has been regularly, related to areas where the PAC has had an impact.

6. The Food Directorate will develop a short communication document for the general public on the issue of animal livestock cloning for food use. On behalf of the Food Directorate, OCAPI will submit the document to the PAC for comments prior to the next PAC meeting (to be held October 1-2, 2004)

7. The PAC members indicated they would appreciate some background information on the roles and responsibilities of Health Canada as compared to the Canadian Food Inspection Agency. OCAPI will prepare some background information and distribute this at the next meeting.