BIOTECHWATCH

CANADIAN BIOTECHNOLOGY ADVISORY COMMITTEE NEWSLETTER

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WHAT'S NEW @ CBAC

LORD ROBERT MAY AND CBAC SPEAK ON GM (GENETICALLY MODIFIED) FOODS AND THE NEED FOR PUBLIC ENGAGEMENT

Indra Harry, Sembiosys Genetics, Calgary

On April 27, 2004, in an address to CBAC and invited guests, Lord Robert May, President of the Royal Society of the United Kingdom, spoke about "*The Public Policy Implications of Genetically Modified Plants in the United Kingdom*".

Lord May noted that stiff public resistance to the introduction of GM foods followed in the wake of fears about food safety, which had been fuelled by events such as the BSE (mad cow disease) crisis. He said the British government could have saved itself a great deal of grief by following the Royal Society's advice to engage the public, early on, in decisions impacting public policy. Further, he said:

"GM agenda in the 1980s benefited agri-business and the farmer, but not necessarily the consumer. Cheaper is not automatically the benefit the developed world is asking for, as the public weighs the risks and benefits. We were trying to embed in government a sense that advice on scientific issues with policy implications could not be kept confidential, but had to go public so it could be examined and better understood by citizens. We felt strongly that the public needed to know about both the good things science increasingly opens to us, from helping people live longer, healthier lives to producing cheaper more abundant foods, as well as their adverse consequences, such as climate change and population growth. We argued it was crucial to engage the public in discussions about the technology so citizens could make informed choices."

As the second generation of GM food crops deliver clear consumer benefits and address environmental concerns, the public will likely adopt an attitude similar to that applied to health products derived through biotechnology, where individuals judge the technology on a case by case basis, looking at the risk/benefit ratio for themselves and their families.

"The real worry for the future", said Lord May, "is the impact of further intensification of agriculture, including concerns over severe declines in birds and insects. We have to discuss these issues much more thoroughly and publicly."

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ABOUT US

The Canadian Biotechnology Advisory Committee (CBAC) was established in September 1999 by the Government of Canada to provide comprehensive advice on current policy issues associated with the health, ethical, social, regulatory, economic, scientific and environmental aspects of biotechnology.

To ensure objectivity and impartiality, CBAC is composed of external experts as well as representatives of the general public. Committee members bring expertise in such diverse fields as science, business, nutrition, law, environment, philosophy, ethics and public advocacy.

At any one time, there are between 12 and 20 members.

CURRENT MEMBERS:

Dr. Arnold Naimark (Chair)
Mary Alton Mackey (PhD)
Gloria Bishop
Timothy Caulfield
Pierre Coulombe (PhD)
Prabhat D. (Pete) Desai (PhD)
Barry W. Glickman (PhD)
Dr. Pavel Hamet (MD, PhD)
Lyne Létourneau (PhD)
Linda A. Lusby
Anne Mitchell
Peter W.B. Phillips (PhD)
David Punter (PhD)
Denny Warner

For more information, see CBAC's web site at: www.cbac-cccb.ca
Email: info@cbac-cccb.ca
Or contact:
Eileen Inrig, CBAC Communications, 613 954-7059

Following Lord May's remarks, CBAC member Peter Phillips offered the Canadian perspective on the challenges facing both countries in regulating GM foods, noting that the technology is "at the cutting edge of the debate about ownership and control of intellectual property—both in terms of what is morally and socially acceptable, and what is economically and politically desirable."

"Increasingly, people are demanding more from the marketplace. They want environmentally sound and socially responsive production systems and a carefully-defined and proscribed set of attributes from their food. Most of these pressures will require more, not less, governance. The challenge is that much of the governance will need to come from new actors and new institutions."

"Our options and choices are fundamentally shaped by our respective contexts. What pulls Canada and the U.K. together is our common heritage, our extensive and long-standing commercial links and our common interests through membership in a wide array of international institutions. What especially divides us is our market context. Our ability to engage in an effective national dialogue is, clearly, one area where our two governments and societies could benefit from greater exchange to help us jointly identify areas where we can work together to improve the regulation and safety of our global food system."

A MADE-IN-CANADA APPROACH TO TALKING ABOUT GM FOODS AND OTHER ASPECTS OF BIOTECHNOLOGY

A key element of CBAC's mandate is to: "…facilitate an open, transparent national conversation on key issues around the development and application of biotechnology in Canada". To this end, CBAC sponsored a project to devise a methodology that would facilitate dialogue on all issues related to the introduction of GM foods and feed into the marketplace.

CBAC convened an Exploratory Committee, with representatives from diverse stakeholder groups, to guide the project. By mid-March this year, the Exploratory Committee had succeeded in developing what they called the "GM Foods and Feed Dialogue Tool" and put it to the test with a variety of stakeholders. This fall, CBAC will post the Dialogue Tool and accompanying documents, including a user guide to a its website. The tool can be used by any organization or group wishing to facilitate dialogue on issues where there are diverging viewpoints.

A QUESTION OF PRIVACY AND HUMAN RIGHTS

CBAC Advice to Government on Genetic Research and Privacy (http://cbac-cccb.ic.gc.ca/epic/internet/incbac-cccb.nsf/en/ah00436e.html) – Genetic research poses a dilemma: understanding the mechanics of the human genome may revolutionize medicine and improve Canadians' health. However, to unravel those mysteries, researchers need access to genetic information collected from large numbers of people, which is then stored in "biobanks." While welcoming the potential health benefits of genetic research, many people have reservations about possible infringements on their privacy and human rights, depending on how their personal data is stored and who has access to it.

In 2002, CBAC commissioned four papers to identify and examine social, ethical and legal issues associated with the establishment and use of population biobanks, recognizing these issues must be addressed *before* biobanks are set up in Canada.

Equipped with the findings from these studies, CBAC developed nine recommendations for Government's consideration in an Advisory Memorandum, arguing the government is best placed to develop a consistent approach to resolving privacy and confidentiality issues. The nine recommendations include:

- Public education and consultation;
- Assess current statutes to determine the need for legislation specific to biobanking, including data collection and storage;
- Recruitment founded on scientific, legal and ethical grounds and informed consent;
- Consent requiring recognition of the potential for future commercialization;
- Policies and practices that encourage the sharing of benefits of research involving genetic material;
- Guidance from professional bodies to their members related to biobanking; and,
- Governance mechanisms to ensure privacy and human rights are adequately addressed, including new regulatory regimes if needed.

Privacy Papers – Who gets to use your genetic information and how do you ensure that information is safeguarded? This question has been the subject of extensive study at CBAC. Finding answers has been one of the Committee's priorities since 2000, when it first commissioned papers to look at the pace of genetic research and its implications, and to consider the potential for individuals to be discriminated against on the basis of their genetic profile. Following these initial studies, CBAC asked a team of legal experts, ethicists and researchers to probe deeper and examine the legal, ethical and social implications of large-scale population genetic research and information storage.

The results of that research are contained in a collection of papers to be released this fall, *"Protecting Privacy in the Age of Genetic Information."* One of the strongest messages to come from the studies is that the future of genetic research itself rests squarely on the shoulders of public confidence. The authors caution that a failure to apply the highest scientific, legal and ethical standards will inevitably undermine public trust and confidence in scientific development and the products resulting from such research. The promise of new health treatments and cures may be jeopardized unless privacy and discrimination issues are adequately addressed.

CBAC'S 2003 ANNUAL REPORT

CBAC Annual Report (http://cbac-cccb.ic.gc.ca/epic/internet/incbac-cccb.nsf/en/ah00412e.htm) – The pace of biotechnological advances in 2003 continued to outpace Government's policy-making and regulatory capacity to respond. This point is made in CBAC's annual report, released April 26th.

The report describes progress on two major projects (*the Dialogue Tool on Genetically-Modified Foods and Feeds; and, Biotechnology and Health Innovation*) and details CBAC's continued monitoring and reporting activities concerning genetic patents, GM foods, privacy and genetic information, and the incorporation of social and ethical considerations into policy making. The report also outlines CBAC's communications and outreach efforts throughout the year and provides an assessment of key biotechnology trends, developments and advances that will shape CBAC's future deliberations.

NEW SCIENCE DEMANDS NEW WAYS OF REGULATING FOR THE BENEFIT AND PROTECTION OF CANADIANS

CBAC Advice to Government on Completing the Framework for Regulating Biotechnology (http://cbac-cccb.ic.gc.ca/epic/internet/incbac-cccb.nsf/en/ah00437e.html) – By their very nature, biotechnology innovations do not fit neatly into existing categories covered by federal regulations. The world has simply never witnessed most of what the technology makes possible.

This is proving to be a challenge for regulators, as gaps in Canada's regulatory system are threatening the research, development and commercialization in Canada of biotechnology breakthroughs. Although a recognized world leader in many areas of biotechnology, if Canada does not act quickly, Canadian business will lose opportunities, which will flow to other countries. Further, Canadians will not gain the social and economic benefits of new technologies and products.

The problem isn't a lack of information. There has been extensive research into the regulation of biotechnology, including reviews of the GM food and feed regulatory systems in the past two years by the Royal Society of Canada Expert Panel as well as CBAC. These and other studies have confirmed the appropriateness of the science-based risk assessment approach currently guiding Canada's regulatory framework.

Despite the plethora of reports and recommendations – five other regulatory review and development processes are currently underway – none of these efforts has yet resulted in draft regulations. Stressing that the time for action is overdue, CBAC's Advisory Memorandum on Completing the Biotechnology Regulatory Framework recommends that the federal government:

- Reaffirm its confidence in, and commitment to, the current scientifically-based regulatory framework for GM and other novel foods and feeds;
- Implement by December 2004 the recommendations of both the Royal Society Expert Panel and CBAC on measures to strengthen and support the regulation of GM foods and feeds;
- Extend the biotechnology regulatory framework to other products of biotechnology by December 2004; and,
- Address any deficiencies if the expertise and capacity are not currently in place to meet these deadlines.

ASSESSING AND ADOPTING BIOTECHNOLOGICALLY BASED HEALTH INNOVATIONS

Leading experts and representatives from the federal and provincial governments, industry, health agencies and academia took part in a CBAC-sponsored Expert Roundtable Discussion in Ottawa in late April this year to explore the assessment and adoption of biotechnology health innovations. The full-day session addressed two central questions:

- Do our health systems, as they are now organized and operated, equip Canada to make the choices that will achieve optimum health benefit for Canadians?
- If not, what needs to be done?

Participants identified and prioritized current and emerging issues involved in the assessment and uptake of biotechnological health innovations. Participants also flagged key policy initiatives that governments should undertake to meet these challenges. CBAC will incorporate recommendations generated by the discussions into its advice to Government in its report, *Biotechnology and Health Innovation* to be released in the near future.

Best practices

Consultation and citizen engagement

While citizen engagement is a priority of CBAC, no single organization has the market cornered when it comes to good ideas about involving citizens in decisions that impact public policy. Here is a sampling of citizen engagement activities undertaken by other national and international organizations focused on a variety of issues.

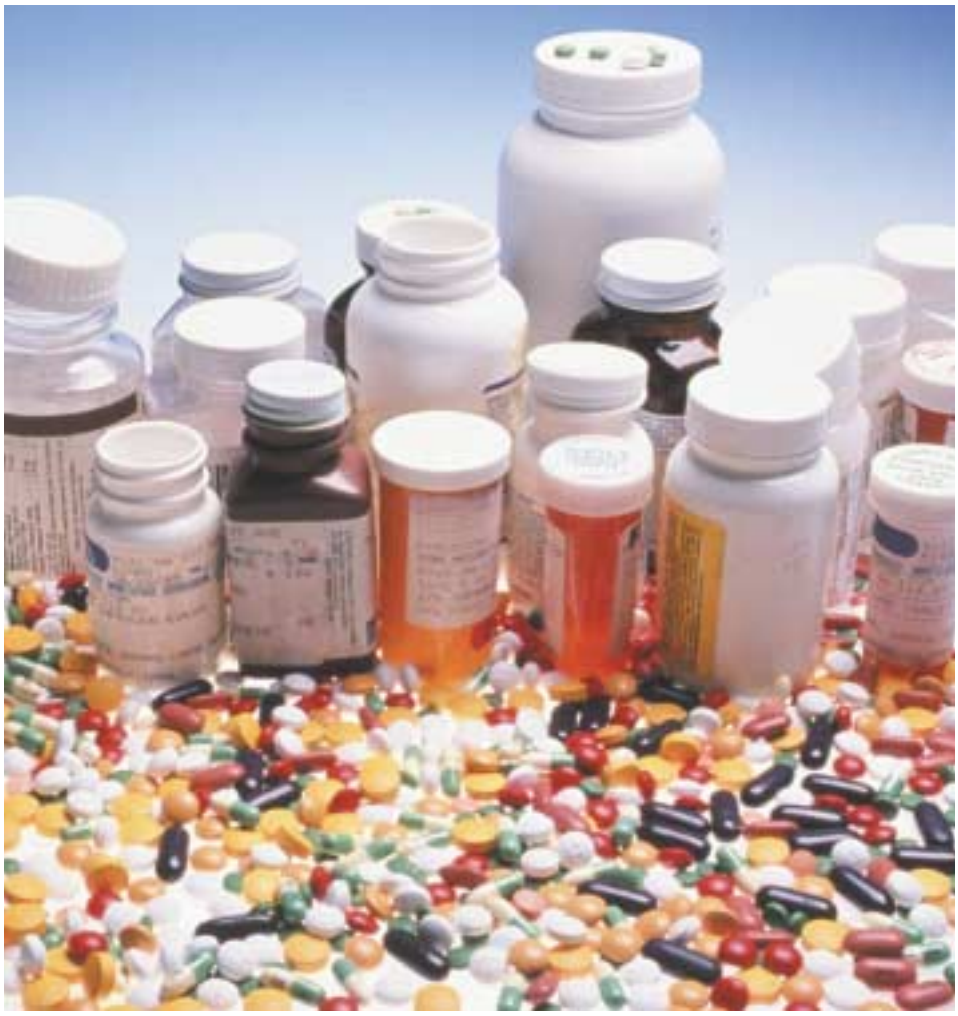
ENSURING SAFETY OF THERAPEUTIC PRODUCTS

Public Policy Forum Stakeholder Consultation to Strengthen Canada's Regulatory Process for Therapeutic Products – Canada's overarching priority in regulating biotechnology products is ensuring the health and safety of Canadians. Successive Speeches from the Throne and federal budgets have outlined the Government's determination to make sure that Canadians not only benefit from technological breakthroughs, but they are also protected from any adverse risks.

Probably the area of biotechnology with the greatest potential impact on peoples' well-being is therapeutic products. Understanding this, Health Canada developed a Therapeutics Access Strategy policy framework. To guide its development, the Health Products and Food Branch of Health Canada established 15 advisory committees, most with membership from the scientific, health or academic communities. A Public Advisory Committee was also set up specifically to provide advice from the consumer/public perspective.

In June 2003, Health Canada engaged the Public Policy Forum to organize *Deliberation on Improving Canada's Regulatory Process for Therapeutic Products*, a public consultation held in Ottawa that brought together 50 stakeholders. It was a different kind of consultation than had ever been attempted in the past. The objective was not to achieve consensus but, rather, to develop a common understanding and identify concrete actions to improve the regulatory process.

At the wrap-up of the session, stakeholders acknowledged they each had a stake in creating a strengthened regulatory process and personal responsibilities associated with it. They concluded that, despite deeply vested interests and healthy tensions among participants, this should not preclude healthy dialogue, ongoing debate and contributions to the process. (*http://www.ppforum.ca/ow/ow_e_05_2003.htm*)



Further examples from the US outline options for consensus building. The following is a brief synopsis of the lessons learned and shared by these organizations:

BIG ISSUES NEED LARGE-SCALE PUBLIC ENGAGEMENT

AmericaSpeaks

The level of cynicism about governments and politicians' credibility has perhaps never been higher than it is today, as promises are regularly broken and misdeeds are frequently exposed in the media. Given this credibility gap, how do policy makers meaningful consult with citizens about major public policy issues?

The Washington D.C. based not-for-profit organization has developed a *Taking Democracy to Scale* model for citizen engagement following two years of research involving academics,

practitioners, foundations, elected officials and citizen activists. The model is based on the belief that more than simply informing citizens to increase their trust in government, it is essential to help people actually impact the governance processes that most affect their lives. Its research has concluded that public forums that have no impact breed skepticism and distrust.

AmericaSpeaks convenes "21st century Town Meetings" to engage citizens in local, regional and national governance discussions. It ensures that more than 50% of the participants are unorganized, unaffiliated citizens and residents. The beauty of the *Taking Democracy to Scale* model is that, thanks to technology, it can engage anywhere from 500 to as many as 10,000 citizens at a time, in one place or across multiple sites. Ordinary citizens, government officials and others involved in the dialogue collectively produce recommendations on public policy. AmericaSpeaks provides a neutral space so people to make up their own minds about the topic under discussion.

The new-generation town hall meetings have been used to address issues ranging from social security and land-use planning, to municipal budgeting and city-wide strategic planning, as well as the public's input on future use of "ground zero" post September 11th . A follow-up study of the post 9/ll public dialogue concluded that citizen deliberation can open peoples' minds and change their views, providing direct benefits to decision-makers, advocacy groups and citizens.
http:// www.americaspeaks.org

FORUMS FOR THE PUBLIC'S VIEW

PEW Initiative on Food and Biotechnology

The acceptance and success of any agricultural biotechnology product ultimately depends on consumer confidence in the regulatory system's ability to ensure food safety and protect the environment.

The Pew Initiative on Food and Biotechnology, in Washington D.C., provides an independent and objective source of credible information on agricultural biotechnology for the public, media and policymakers. It doesn't advocate for or against agricultural biotechnology but, instead, offers information and encourages dialogue to move the discussion about the technology beyond conflict and toward a process of constructive engagement.

In early 2001, PEW began a project called "The Stakeholder Forum", involving a small group of representatives from industry, public institutions, academia, consumer and environmental groups. They worked for two years to develop a consensus about recommendations to enhance the regulatory review process for agricultural biotechnology products.

In the end, they were unable to reach consensus. However, all participants agreed the process formed lasting relationships that would positively influence the ongoing debate about agricultural biotechnology. PEW is currently pulling together the many reports, presentations and research commissioned to aid this group, so policymakers and the public can benefit from their findings.
http://pewagbiotech.org

Ahead of the Curve: Biotech Developments

Biotechnology is evolving at a breathtaking pace. Every month there are new advances in some corner of the world. Future issues of Biotech Watch will include biotechnology developments, as reported by key scientific journals that are relevant to those issues CBAC is charged with addressing in its advice to government.