

**CANADIAN BIOTECHNOLOGY  
ADVISORY COMMITTEE (CBAC)**

**Report**

**Fifth Meeting, June 22, 2000, Minto Place Suite Hotel, Ottawa, Ontario.**

**In attendance:**

**Members:** Arnold Naimark (Chair); Mary Alton Mackay; Lorne Babiuk; Gloria Bishop; Timothy Caulfield; Arthur Hanson; Michael Hayden; Suzanne Hendricks; Anne Mitchell; Peter WB Phillips; Douglas Powell; Jonathan Bjorn Syms (Regrets: Françoise Baylis; Richard Black; Robert Church; Pierre Coulombe; Thomas J. Hudson; Bartha Maria Knoppers; Murray McLaughlin; René Simard; Denny Warner).

**Staff:** Canadian Biotechnology Secretariat (CBSec) - Roy Atkinson; Norma Burlington; Linda Williams; Diane Fournier; Kelly-Anne Smith; Annie Comtois; Isabelle Groulx; Line Pepin; Camille Seetaram.

**Guests:** Michel Amar; Lynn Curry; Tim Flaherty; Michael Silverman; Peter Pauker; Chris Leclair; Francine Manseau; Rhonda Ferderber.

**1. Chair's Report**

- 1.1 The Chair provided a brief summary of selected activities he undertook on behalf of CBAC since its last meeting (see attached).
- 1.2 He elaborated on his meeting with Sir Robert May, Chief Scientific Adviser to the UK government and, in particular, on a proposal to establish an International Panel of Scientists to assess the safety of foods and crops. Copies of the proposal along with the report of Sir John Krebs, chair of the OECD-sponsored Edinburgh Conference on GM Foods (in which the concept of an international panel was broached) were provided to CBAC members (see attached). Dr. Naimark drew the attention of members to his memorandum in which he proposed that CBAC should consider submitting a commentary ("advisory memorandum") to BMCC on the UK proposal in advance of the forthcoming G-8 meetings in Okinawa in July.

**Action/Decision:**

***After a general discussion about the merits of the UK proposal, it was agreed that a draft advisory would be prepared under the guidance of the co-chairs of the GM Food Steering Committee. The draft would be reviewed by the Chair of CBAC and then distributed to Members for comment. After taking any***

*comments into account a final version would be prepared under the direction of the Chair and submitted to BMCC.*

- 1.3 The current version of the table of contents of the Annual Report had been posted on the website along with templates for use by chairs of steering committees and standing committees to solicit recommendations for items to be cited as noteworthy developments in biotechnology and to indicate what elements might be included in progress reports on the various special projects. The committee chairs were asked to solicit Members' suggested inclusions for the templates during the course of the various committee meetings.

In discussing the general orientation of the Annual Report, it was emphasized that it be couched in language suitable for a non-expert readership.

- 1.4 The Director of Operations noted that she expected to have 3 firms on a Standing Offer for CBAC to choose from for its consultations with Canadians.

## **2. Reports by the Standing Committee Chairs**

### ***2.1 Stewardship - Lorne Babiuk***

The committee examined the outline provided by Sue Sherwin for a paper to deal with the themes of public interest, justice, consumer vs. citizen, governance, scope/role of government and global stewardship, arising from a discussion at the March meeting. Members agreed that the paper should be a thoughtful, in-depth, original critique, as opposed to a skimming of the surface of these issues, and that it must be reasonably balanced. It should point the way to the issues that CBAC should consider in its own work. The committee felt that Sue Sherwin needed more guidance in formulating the outline of the paper, i.e., - what are the exact questions CBAC wants answered? It was agreed that Sue Sherwin should focus on the first three themes, with the public interest as an overarching theme. The last three themes would either be dealt with by another contractor, or they may be taken up by other CBAC committees.

#### **Action/Decision:**

*It was agreed that CBSec will draft a revised Terms of Reference and send them to the committee for approval before a contract is let. Anne Mitchell will also be asked to comment on them since she deals with consumer issues in her own work. A draft will be produced for the CBAC meeting in September, with the final version to be completed by January 2001.*

It was noted that the chair, Lorne Babiuk, will be out of the country until July 15, and in his absence interim chair responsibilities will go to Tim Caulfield.

## **2.2 Citizen Engagement - Gloria Bishop**

The committee received a presentation on a Public Engagement Strategy. After discussion of the points raised in the presentation the committee reaffirmed the importance of ensuring that its communications reflected its neutrality and that both the public at large and special stakeholder groups should be addressed in the Public Engagement Strategy.

### **Action/Decision:**

***The following actions/decisions were agreed upon:***

- The research focus of the committee would be on public awareness***
- The Citizen Engagement Standing Committee would be more proactive, especially in regard to developing an action plan for positioning CBAC as a trusted, credible and accessible body and for enhancing its visibility.***
- The Committee will support the work of Special Projects Steering Committees in connection with the design of public consultations (including the establishment of reference groups) and will recommend a mechanism for deciding on which public consultation processes are to be implemented.***
- Attention will be paid to the elements of the website having to do with general accessibility for the public; with special attention being paid to the interactive, “open forum” elements.***

## **2.3 Economic & Social Development - Mary Alton Mackey**

The committee discussed the Global Trade Solutions (GTS) proposal on Competitive Intelligence Studies.

### **Action/Decision:**

***It was agreed that the CBSec was to ask GTS to provide a clear methodology and to focus mainly on benchmarking and emerging issues set out under 1 and 5 in their proposal. A revised proposal is to be requested by CBSec based on these comments.***

The committee plans on producing a report that will pull together and provide an overview of biotechnology information and activities. It will include basic tombstone data on biotechnology activities covering the period 1995 to 2000, an international comparison of biotechnology companies (number and areas of activities), an assessment of the biotechnology patents issued in Canada in the past three years. identification of the main research areas, in universities and research institutes, identification of the provincial activities and initiatives. Employment patterns.

**Action/Decision:**

*It was agreed that the CBSec will seek proposals from outside contractors and then the committee will decide which proposal and contractors it prefers.*

**3. Reports from Project Steering Committee**

**3.1 Genetically-Modified (GM) Foods - Peter Phillips & Suzanne Hendricks**

**International Developments**

Peter Pauker (DFAIT) presented an oral status report on international activities and issues around genetically modified food, specifically CODEX and, OECD work initiated by the G-8 leaders which would be discussed at their meeting in Japan in mid-July 2000. The ensuing discussion focussed on Sir Robert May's Proposal. Special emphasis was placed on the need to have an international policy dialogue on issues of food safety that embraces both science and non-science issues and for the dialogue to be conducted under the aegis of a body such as the UN that includes both developed and developing countries.

**Action/Decision:**

*It was agreed that the CBSec would provide a first draft of an "Advisory Memorandum" for the committee to review at its conference call on July 4, 2000.*

**Public Consultation on GM Foods**

A GM Food consultation plan was presented by Michel Amar for discussion. It included the establishment of a Reference Group (18-20 people) of stakeholders to provide input on CBAC's research coverage and its consultation document. It was suggested that CBAC form one as soon as possible. In the Instruments of Consultation Plan it was suggested that the face-to-face component should have more public input.

**Action/Decision:**

*It was agreed that:*

- the committee would have a conference call every Tuesday at 11:00am (Ottawa time) beginning on July 4, 2000.*
- CBSec go ahead with the proposal of Michael Hart on Food Labelling/Trade Obligations*

- *Morven McLean should be contacted by CBSec to determine interest/availability to do international regulatory approval system comparison. Countries would be USA, UK, Japan, Australia/New Zealand and maybe one or two others in discussion with her for approval of co-chairs. CBSec to draw up terms of reference for international comparison study and engage Dr. McLean if interested and available).*

## **Other Matters**

The committee noted that the Regulators Workshop/Technical Briefing on June 23, 2000 is to be a baseline for governance review and a template for international comparison. Feedback is expected on Edna Einseidel's paper by Friday June 30, 2000 and Paul Thompson's paper by July 10, 2000.

### **3.2 Intellectual Property/Patenting of Higher Life Forms - Lorne Babiuk**

#### **Workshop Proposal**

Dr. Bartha Knoppers, chair of the committee, had instructed the Secretariat on behalf of the committee to develop a workshop proposal which would consist of a panel approach including BioteCanada, member companies, Industry Canada, CBAC members and others as appropriate. The proposal was to be developed by a consultant in coordination with the committee and BioteCanada. Chris Leclair, of Strategic Policy Choices presented a workshop proposal. Objectives, key elements of the consultation process as well as next steps were presented and discussed.

The objective for the workshop is to undertake an examination of how Canada's system of IP protection can be improved to enhance its ability to exploit technological innovation and to ensure that consumers are protected. In particular, the workshop is seen as an opportunity to discuss the present practical circumstances that industry executives find themselves in (i.e. what is working and what could be improved upon to advance IP and biotechnology). In addition the workshop should provide a contemporary view of the role of the patenting function in stimulating economic growth and the effects of the burgeoning numbers of patents on the ability to conduct research.

#### **Workshop Design**

The participants in the workshop should represent the full spectrum of stakeholders (including pharmaceutical firms), recognizing that firms of different sizes and at different stages of development have different concerns and patenting needs. All members of CBAC would be invited to attend this workshop if they have an interest but that the IP/PHL Committee members would be the primary CBAC representatives. Within the limit of about 20 primary participants consideration should be given to having the university sector represented as well as the research councils insofar as they support activities at the interface between publicly-funded research and

the private sector.

The workshop was seen as consisting of discussions of issues and questions prepared in advance by CBAC with a view to eliciting whatever consensus there may be on the recommendations CBAC might make to government in connection with IP/PHL. Further consideration needs to be given to the specifics of the workshop program. (e.g., Will there be presentations by designated participants? If so, on what topics and for what purpose?). Other issues to be determined include the process for defining and producing the background material to be made available to participants, the identification of workshop participants and the process for inviting them.

**Action/Decision:**

*Chris Leclair will draft the proposal and forward it to Kelly-Anne Smith before the end of next week. Kelly-Anne will then forward the proposal to the committee, who will then finalize it as well as select the 2 main contact people.*

*Others who should be consulted in the ongoing planning of the workshop include Tom Tom Brzustowski (NSERC), Graham Macoloni, and Dr. René Simard in his capacity as Chair of the Advisory Council on Science and Technology.*

**Memorandum of Understanding (MOU) - CBAC and Industry Canada**

An MOU is being developed in relation to the technical assistance being provided to the IP/PHL Steering Committee by the Corporate Governance Branch of Industry Canada. Committee members discussed the MOU and made several revisions to the document. Of particular importance is that a more formal separation between the work of CBAC and CBSec is to be provided for, as well as fitting the MOU into a broader context. The revised MOU is attached.

**Action/Decision:**

- *CBSec is to forward a copy of the original MOU to the members.*
- *Members agreed to a conference call during the week of July 16<sup>th</sup>, 2000.*
- *Research study terms of reference and proposed contractors are to be forwarded by CBSec to committee members*

**3.3 Incorporating Social and Ethical Considerations into Biotechnology - Arthur Hanson**

The members of the P3 and P5 committees met jointly with Tim Flaherty and Michael Silverman (Interdepartmental Working Group on Ethics and Public Confidence of the Canadian Biotechnology Strategy). A workshop is being planned by the Interdepartmental Working Group to discuss Derek J. Jones paper *Government and Biotechnology: Ethics Frameworks to Manage Moral Uncertainty & Policy Development*.

**Action/Decision:**

- *The Steering Committee agreed to collaborate with the Interdepartmental Working Group.*
- *CBSec to obtain the work plan and mandate of the Interdepartmental Working Group (WG) on Ethics and Public Confidence of the Canadian Biotechnology Strategy and circulate it to members.*
- *CBSec is to provide a copy of the completed McDonald synthesis paper to the Working Group, to coordinate information sharing between CBAC and WG and to identify additional ways in which the two groups might appropriately work together.*
- *The committee agreed to provide questions for the workshop on ethical aspects of biotechnology.*

**McDonald Synthesis Paper**

It was noted that the revised paper incorporating CBAC comments was much improved. The need to address challenges associated with trying to “do” ethics in a pluralistic society was emphasized. The following additional comments arising from discussion of the paper were made.

- Re: Section V., Gaps and potential areas for future research. It was noted that the precautionary principle (Part A) is becoming increasingly important to governments when making biotech policy, but that P3 does not want to duplicate work that is being done by the GM food PSC, or by the Expert Science Panel on the Future of Food Biotechnology. In Part B, a sentence should be inserted that defines what is meant by the “fourth hurdle” in biotechnology. This should not be described as a “restriction”. In Part C, *Promoting while regulating*, more discussion is needed on international dimensions of conflict of interest. This is a big issue for all countries and is to be dealt with in CBAC’s GM food project. In addition equity issues need to be discussed regarding south versus north.
- A few factual errors were noted and in general the paper, while not perfect, fulfilled the contractual requirements.

**Action/Decision:**

- *It was agreed that any additional factual errors should be emailed to Linda Williams by the end of July.*
- *The paper should be ready for distribution to the whole CBAC committee by mid-August, and at the latest at the CBAC September 28, 2000 meeting.*
- *The paper to be posted on the CBAC private and public web sites when it is approved by the committee.*

**New Members**

The question of a new member for the Committee was discussed.

**Action/Decision:**

- It was agreed that the new member for the committee should possess a background in ethics *and* religion.
- The top two candidates identified are Eric B. Beresford and Peter H. Denton.
- Art Hanson will talk to Peter in Winnipeg, and if he is still “in the race”, he will try and talk to Eric when he is in Toronto in August.
- Art Hanson will write the terms of reference for the new member and circulate them for comments. A final decision regarding the new member is pending until there can be a discussion by all members of the ethics committee.

***3.4 The use of Novel Genetically Based Interventions - Timothy Caulfield***

The committee had a briefing from representatives of Health Canada (Francine Manseau and Rhonda Ferderber) who are working on legislation on reproductive and genetic technologies. The following points were made:

- The legislation is necessary to develop national standards, to protect Canadians, to prohibit some research that is unacceptable, to control activities that are desirable but that require regulation and to manage ethical and social concerns.
- Scope of legislation: “the application of technology to human genetic material (genes, cells, embryos and fetuses) for reproductive purposes; and the use of human gametes, embryos or fetuses for any purpose including research and medical uses.”
- The legislation will not cover xenotransplantation and the creation of organisms that cannot live by themselves.
- The regulatory body, as part of the comprehensive policy framework, would carry out



some typical functions: policy activities, licensing and enforcement, health information - registries and surveillance, and communications- public education and consultations.

- \_ The major points of the legislation that the PSC have to look at are gene therapy and stem cells.
- \_ The legislation will have substantial impact on CBAC's mandate (licence for stem cell and germ-line alteration...) and on research.

**Action/Decision:**

- \_ *The steering committee will not undertake any specific work at this time, but will focus on finding out what is happening in Canada in its areas of interest for the annual report.*
- \_ *The committee will follow developments under the Hastings Centre research project "Reprogenetics: A Blueprint for Meaningful Moral Debate and Responsible Public Policy" that is intended to cover many of the issues of interest to the committee. Both Tim Caulfield and Maria Bartha Knoppers are part of this project. This project is an opportunity to inform them about CBAC.*

### **3.5 Genetic Privacy – Michael Hayden**

As noted above, the committee had a briefing by Tim Flaherty and Michael Silverman of the Interdepartmental Working Group on Ethics and Public Confidence in Biotechnology of the Canadian Biotechnology Strategy.

Discussion in the Committee focussed on the desirability of coordinating the deliberations of CBAC with the work being done by CBSec in its non-CBAC role. This coordination could include:

- \_ a possible CBAC/CBSec joint round table on issues surrounding genetic privacy for early 2001 with a date being set before the middle of July 2000.
- \_ information sharing on work plans and joint commissioning of background papers.

It was noted that the Canadian group of UNESCO would like to be a part of this joint working group.

## **Genetic Testing and Genetic Discrimination**

It was noted that information is needed on what has happened in Canada in respect of discrimination experienced by individuals with disorders detected by genetic testing. The idea of commissioning a survey of groups for whom genetic testing has been available for a while (i.e.; Huntington's, breast cancer), to determine prevalence of discrimination, was discussed..

### **Action/Decision:**

- *Set date for CBAC/CBSec roundtable*
- *CBSec to see that Oscapella report revised by October, 2000.*
- *CBSec to circulate copies of Gold and Rivard papers.*

## **4. Other Business**

### **4.1 *Guidelines re CBAC's Intellectual Property***

Information was requested concerning the policy and/or regulations pertaining to the ownership of intellectual property particularly as it relates to research studies for CBAC. Legal Affairs advised that Her Majesty owns the copyright in research/study papers commissioned by CBAC but may on request provide non-exclusive authorization for the author to publish the paper. The note from Legal Affairs is attached.

### **4.2 *Conference Attendance Guidelines***

- The Chair provided CBAC with the guidelines he will be using in approving reimbursement of expenses incurred by members in attending conferences; namely:
  - Travel and associated costs will normally be covered for attendance at conferences where such attendance is at the request of the Chair of CBAC.
  - Where a member of CBAC is attending a conference on his/her own initiative and wishes to incorporate activities related to CBAC that incur additional costs, a request in writing for assistance in defraying such additional costs should be submitted in writing to the Director of Operations who will consult with the Chair of CBAC.
  - Where a member of CBAC is attending a conference on his/her own initiative and wishes to incorporate activities related to CBAC that incur additional costs, a request in writing for assistance in defraying such additional costs should be submitted in writing to the

Director of Operations who will consult with the Chair of CBAC.

### ***4.3 CBAC Operations (Including Items from In Camera Discussion)***

#### **CBAC Meetings**

A general discussion was held about the frequency, format and content of CBAC meetings in which the following points were made:

- The amount of activity and the volume of work in progress requires more frequent meetings of CBAC.
- Using CBAC meetings to run concurrent sessions of steering committees and standing committees militates against CBAC as a whole participating sufficiently in discussions of projects and events in which they have an interest.
- More use should be made of teleconferencing for meetings of CBAC as a whole in order to improve attendance and avoid the dislocation and expense of travel to face to face meetings.
- Regular meetings of the Executive Committee should be activated to assist in planning effective use of CBAC meetings.

#### **Separation of Functions**

The Chair described the discussions he had been having with the Executive Director of CBSec on methods to more clearly separate the functions of staff involved in general CBSec activities and those devoted to CBAC. The Executive Director has obtained approval to increase CBAC's share of the CBSec funding appropriation. This will permit a level of staffing that should suffice to support a reasonable level of independent CBAC activity.

#### **Action/Decision:**

- *Face to face CBAC meetings will be supplemented by intervening monthly teleconference meetings.*
- *Teleconferences should be facilitated by having a single "permanent" call in number.*

- *Meetings of both kinds will focus on “committee of the whole discussions” on substantive study topics.*
- *CBSec to canvass members on preferred day/time of each month.*
- *Standing Committees should be in the background and be issue and theme oriented.*
- *The Executive Committee will meet monthly by teleconference, 10 days to 2 weeks before CBAC meetings to set agendas.*
- *Next meeting of CBAC Committee of the whole on September 28, 2000 in Ottawa followed on September 29, 2000 with CBAC IP/PHL Workshop on economic/investment/issues (open to all CBAC members).*

Approved: Original Signed by  
Dr. Arnold Naimark, Chair

Date: September 28, 2000  
September 28, 2000