Health Canada Santé Canada

REPORT OF THE SECOND MEETING OF 2000

RAPPORT DE LA DEUXIÈME RÉUNION de 2000

SCIENCE ADVISORY BOARD

LE CONSEIL CONSULTATIF DES SCIENCES

June 6-7, 2000

les 6 et 7 juin 2000

Health Canada
June 2000

Santé Canada
juin 2000

---------- **Note:** Contents of the Meeting Report are a reflection of the discussions of the June 6-7, 2000 Science Advisory Board Meeting. The points contained in this document are those of the Science Advisory Board and do not necessarily reflect the views of Health Canada and its employees./ Le contenu du présent rapport est le reflet des discussions de la réunion du Conseil consultatif des sciences tenue les 6 et 7 juin 2000. Les points de vue qui y sont exprimés sont ceux du Conseil consultatif des sciences et ne reflètent pas nécessairement les points de vue de Santé Canada et de ses employés.

Canada

Day 1 - Tuesday, June 6, 2000

Attending: Doug Elliott, Carol Herbert, Karen Grant, Gabriel Plaa, Rodney Ouellette, Lynn McIntyre, Russ Graham, Michel Bergeron, Allan Ronald, Neena Chappell, Stuart MacLeod, Diane Gorman, Leslie Millin, Helen Murphy, Robert McMurtry

Others: Ian Shugart, Mario Simard, Lita Cyr, Sheila Chapman, Michael Shannon, Paul Sockett, Michelle Giddings, David Dodge, Wendy Watson-Wright, Marie-Michèle Robichaud, Wendy Warren, Darlene O'Grady, Roy Hickman

Secretariat: Kata Kitaljevich, Suzanne Bassett

1. <u>Opening Remarks</u> - *(Acting Chair - Doug Elliott)*

Mr. Elliott welcomed the members to the second meeting of the Science Advisory Board (SAB). Due to its currency and the interest expressed by SAB members, a brief presentation will be made this afternoon on the Walkerton E. coli outbreak and Health Canada's role in clean water in Canada. It is agreed that the interaction issue between the federal and provincial governments and risk management between chlorinated and well water be discussed following the presentation. There is general agreement that the meeting should adjourn at 2 p.m. on Day 2 The Secretariat has noted that the agenda should be sent to Board Members before final travel arrangements are made.

2. <u>Approval of April 2000 SAB Meeting Report</u> - *(Acting Chair - Doug Elliott)*

The Meeting Record is approved with the following amendments:

- *The Minister's visit and comments should be included.*
- *The Board's mandate might need to be revisited. The wording from the TORs could be used.*
- *Re-word the discussion item on page 11 to say "science is not the most important".*
- *The essence of "service research" was not captured in its entirety. Service research is a reasonable component, but it is not new. Wording should be revised.*

Conclusion:

- *It was agreed that an amended Meeting Record be distributed for approval at tomorrow's session.*

3. <u>Overview of Issues and Events Involving HPB</u> - *(Diane Gorman/Robert McMurtry)*

Before this session was initiated, Robert McMurtry arrived and introduced himself as the first visiting Cameron Chair of Health Canada working in the DMO as an ex-officio member. The realignment issue will be discussed in more detail this afternoon. The Branch will be the recipient of $50M a year for three years as allocated in the latest federal Budget. Funds will be invested in regulatory capacity, TPP drug assessment and Food. Funding is expected for a biotech MC on GMOs. The job description for the Chief Scientist, who will report to the DM and serve the whole department, is being circulated. Drs. Morin and McMurtry sit on the Search Committee.

Discussion:

- The appointment of a Chief Scientist is considered an important step for Health Canada as it will not only increase the department's scientific capacity but it is anticipated that the nominee will advise at the senior level and strengthen the peer review process. Comments on the job description or suggestions for potential candidates are appreciated.
- The Chief Scientist would be expected to be a spokesperson on various science issues, but would not have a role similar to the Surgeon General in the U.S.
- The Chief Scientist's relationship with SAB will be important and it might be appropriate that the candidate be an ex-officio member of the Board. The expectation is that the SAB Secretariat will report to the Chief Scientist.
- The Chief Scientist's role should not only be to champion science within the department but should also have an external role in re-establishing public confidence. The appointee must be a credible spokesperson to Canadians on behalf of the department. Comments on strengthening the proposed role are welcome.
- A candidate from outside the department might be appropriate in creating links between the government and academia.
- The launch of the CIHR is scheduled for tomorrow, June 7. The new president and the Governing Council will be announced at that time. Many high quality proposals are being received. The Interim Governing Council has made recommendations on the proposed institutes, but it will be up to the Governing Council to make a final decision. SAB's best wishes are to be extended to CIHR.
- There are no recommendations for Health Canada relating to Auditor General activities/CESD Reports. A conference is scheduled for this morning.
- A meeting is scheduled for today on the department's role in biotechnology, which is on the agenda for tomorrow's session.
- The ONHP Report to the Minister was released on May 24. The Minister announced the EAC with the first meeting held two weeks ago. The Office is moving away more from the silo approach to regulating products.
- The Winnipeg Lab is being regarded as a model for a Centre of Excellence and is currently courting a potential Director.
- Recent risk management issues include the West Nile Encephalitis with no apparent evidence of the virus and a stop sale issued for cisapride or prepulsid.
- HPB Hammer Award - There should be some effort made to promote this award.

4. **<u>Health Protection Legislative Renewal</u> -** *(Ian Shugart, Mario Simard, Lita Cyr, Sheila Chapman)*

Ian Shugart arrives and is thanked by the Chair for his many contributions to SAB in the past. Ian is present along with Mario Simard, Lita Cyr and Sheila Chapman to discuss Health Protection Legislative Renewal. There is an opportunity here to enshrine principles and to focus on enabling personal information and the treatment of commercial information. Input from SAB is being sought concerning the legal requirements which should apply to the collection, use and disclosure of health information. The government collection and maintenance of information is highly relevant and if not timely, given recent HRDC developments. The first part of a new *Canada Health Protection Act* would be a statement indicating that it replaces all previous Acts. A number of issues are being addressed including: particular products, such as drugs, and drug advertising. The door will be left open to regulate future issues, such as information transfer and a Quarantine Act. There is a need for a clear legislative mandate, for funding and for an allowance of the collection of personal health and commercial information. Administrative matters dealing with regulatory issues, research and surveillance are to be covered. The Act would recognize the federal government's need to conduct health surveillance and research activities in cooperation with public authorities and would recognize that health information is inherently sensitive and must be protected. It would attempt to balance the department's need to collect, use and disclose health information to protect the health of Canadians with the need to safeguard the privacy of personal information and commercial confidentiality. This initiative is part of a broader undertaking and it will be necessary for proposed legislation to be consistent. The HIV Council has indicated that individuals must be able to control who gets access to their personal information. If the government is asking for personal information, it must be through a legislative framework that is balanced between needs. The collection of personal health information can only be collected with the consent of the individual or it can be authorized in law that it is being collected with the public's best interests in mind. An established body would need to resolve the matter by weighing the public interests against the right to privacy. A separate component would be required for commercial information.

Discussion:

- There is a requirement to determine the powers that come from a need to act, for example an outbreak. There are already many interpretations of "informed consent". Statistics Canada, which might be considered a good model, has never had a breach of trust because it has instituted the necessary legislative safeguards. There is a clear need for the major protection of all public interest in the proposed legislation.
- The Krever Inquiry Number 1 can be referenced on the confidentiality of health information. There are informal networks that share information and abuses that take place when individuals sign standard forms for insurance companies, for

example. There was the AIDS Society versus the Ontario Government where people's names went into a registry without their consent although public interest dictated that the public be informed.

- The legislation will need to be clear, otherwise it becomes a question of interpretation.
- The internet is considered public domain. If the information is there, it is considered public.
- There will be an attempt to harmonize a common federal and provincial approach. There is general agreement that information must be collected for public health purposes, but there needs to be a consistent and clear set of rules on what information is to be collected and for what reasons.
- There will be a need to ensure the public of confidentiality. The protection of the person in the *Constitution* should also include the person's personal information.

5. **<u>Walkerton E. Coli Outbreak</u>** - *(Michael Shannon, Paul Sockett, Michelle Giddings)*

The outbreak started on May 15 and is considered local. As Health Canada was invited by the Ontario Government to become involved, LCDC epidemiologists are currently on site and the Winnipeg Lab is providing diagnostic support. More than 890 individuals are reported to have come down with symptoms, with 56 admitted to hospital. Seven deaths and possibly four others might be linked to the virus. Walkerton had experienced heavy rainfall and when it was noted that many people were becoming ill, the town issued a "boil water" notice. LCDC was informed on May 22. The investigation has taken two thrusts: a descriptive analysis is being undertaken including the history of GI illness in the town; and a cross-sectional survey is being conducted that will provide more detailed information on exposure, health and treatment outcomes and the effectiveness of the boil water notification. Three wells apparently are being investigated. This is an area of high livestock concentration with previous studies indicating some connection between livestock farming and the potential for contracting E. coli. The provinces are responsible for drinking water with the federal government providing advice, research and risk assessment. The federal/provincial sub-committee on drinking water includes representatives from both Environment Canada and Health Canada. Joint guidelines have been developed and published. The Ontario Government is planning to look at the safety of rural wells as well as pathogens in standing herds in the province have been found. The Province has suggested that a national strategy for safe drinking water be developed. Walkerton is not unique in Canada with manure management being a major problem in this country and in the U.S.

Discussion:

- Agriculture Canada, which has the lead in investigating agricultural sources, has been very supportive.
- Biological findings have not yet been confirmed the reasons for the outbreak.
- A survey was conducted to test the integrity of the system. With the testing of

water, the standard accepted method has been coliform. A quantitative testing was not done. There are new technologies allowing for more detailed testing but would not normally be used in a routine situation.

- The federal government does not examine ecologies until there is a crisis. Work done in the 90s was passed onto the Ontario Government. There has been lots of literature produced in the last few years in this area.

Afternoon Session - Dr. Yves Morin as Acting Chair welcomed David Dodge, DM, and Wendy Watson-Wright, DG. PMPD, HPPB

6. <u>Health Canada Realignment</u> - *(David Dodge, Wendy Watson-Wright)*

The realigned department will consist of six business lines relating to health promotion or protection, First Nations' health or health care policy. Eighteen months ago, IACB was created to provide a framework to ensure that knowledge got organized, shared and disseminated. Six months ago, there was the revamping of the Policy Group with a Health Policy Directorate being established for the first time in the department. As the original members of SAB are aware, the first step was HPB Transition. Realignment is another step in the process and it will become an outward and visible sign of a change in culture and on how we do business. Moving into a new century, Health Canada must be ready to respond to advances in knowledge and technology. There are general expectations for an open and transparent government that is accountable and open to the public to become more involved in decision-making. We need good linkages and with the advent of CIHR, it seemingly became time to move forward. There will be a need to find new facilities for environmental health and a university partner to move on with this initiative. We will also need a partner on geonomics as we cannot do the work internally. We will be announcing the scientific director for the Winnipeg Lab and a partnership with Manitoba Health and the University of Manitoba with various other partnerships on the horizon. We are attempting to harmonize and to bring together similar cultures, for example, all cancer, tobacco or staff dealing with drug problems would be concentrated in their respective Branch. In the new Health Products and Food Directorate, nutritionists will be joined with products people in the Food Directorate. The ONHP is up and running. TPP, due to its size and growth in biologics, will not be implemented immediately. We are moving ahead with OCAPI and we are looking at other countries for direction in this area. Biotech strategies, strategic planning and regulatory affairs, regional labs require lots of planning and discussion. The Healthy Environments and Consumer Safety Branch is to reflect both the outside environment, the workplace and interior environments. Consumer Safety will need to focus on control and prevention in areas, such as chemical and product safety, occupational health and tobacco. This group has very clear partners including, Environment Canada, Solicitor General and the provinces. The Population and Public Health Branch will seemingly face the biggest cultural challenge. There is great potential here. PIAP was cultural challenge. The Centre for Surveillance Coordination and

Emergency Response shows real promise. The Guelph and Winnipeg Labs will be located in this Branch, but will continue to serve the entire department. The Inuit and First Nations Branch will have an Aboriginal health policy unit. It is anticipated that Treasury Board will approve the Office of the Chief Scientist on June 15. A search committee has been struck to fill the Chief Scientist position with all suggestions welcome. The department has been centrally controlled. There is no standardization in regional operations which is confusing to provincial partners. It will be a six-region structure with the exception of FNIT which will have seven. More responsibilities will be devolved to the RDG. Health Human Development will be the bridge between Health Canada and HRD. Deputies have met with staff across the country allowing for their input. A website and e-mail database have been set up to report on developments as they occur. We are now moving into the transformation phase and will be addressing cultural and linkage issues. We will need to ensure that risk management and our science capacity have not been compromised. We are looking at various mechanisms, training, skills development to assess and communicate risk. Staff have identified three themes - labs, science capacity and how to deal with policy and analytic capacity across the department.

Discussion:

- MOUs will be developed to clarify relationships between departments on various issues. For example, Healthy Human Development will be working with DVA on aging issues.
- Each new Branch will have a regulatory element and a promotion component. In addition to regulating the safety of products, Canadians will have the necessary information to make safe choices.
- Regulating drugs has been a way of providing information to prescribers about a particular substance, for example, a monograph. There is a need to ensure that the information is provided in an appropriate manner to the targeted audience.
- There will be challenge to determine our expectations from our labs. There will be some impact in the Regions relating to FNIT and classic health promotion.
- The role of SAB will be important in the realigned department. There are three basic challenges: cultural change, areas of emerging science where we have a weakness and strategic partnerships.
- It will be important that staff, for example, research scientists, feel part of a team that are working on issues of common interest. Good communication will be a key.
- SAB has, in the past, commented that good science happens when it is managed in certain ways. There doesn't appear to be a statement of principle that where possible scientists should be managed by scientists. This is an area that needs to be addressed.
- Health Canada has a constitutional role in health, but not in health care, with the exception of the First Nations.
- SAB's mandate would have become broader even without realignment. Cultural change is essential rather than singularly focussing on medical and life sciences.

With the Chief Scientist in place, the Board will have an interlocutor and a responsible person in the department for peer review and actioning processes.

- SAB will continue to maintain its direct relationship with the Minister but will be required, for example, to work with the CIHR in a different capacity than it worked with the MRC.
- Cultural change will be necessary to reconcile what might be seen as duplication of effort in the regulatory and promotion components and the dilution of the protection function in the new Branches.
- There will be a mechanism in place to look at overlapping of activities, but a consensus has not yet been reached.
- A priority for this year and next is to get the basic functioning of the regulatory part of the department on a sustainable keel. Otherwise, we could be viewed as not fulfilling our mandate as a regulator.
- There is a need to focus on the strengths of the department. The realignment document was to start the process. By July 1, it should appear on the departmental web site. Comments from SAB are welcome.
- The DM is holding ADMs accountable. Some changes are systemic and a key investment will be the selection of the right people for a specific role.
- The transition secretariat is winding down. A senior person will be designated as liaison officer in IACB, the Chief Scientist office is where the structure liaison will lie. We will continue to ensure that a Health Canada representative sits on each Institute's Advisory Board (CIHR), as appropriate. Links will be built institutionally from the beginning.

7. **<u>Human Resources (HR) Planning</u> -** *(Marie-Michèle Robichaud, Wendy Warren, Darlene O'Grady, Roy Hickman)*

The department is facing many challenges in human resources. There is a need to solicit advice and guidance on recruitment and retention. Competition for HR is heating up for two basic reasons: the baby boomer generation is preparing to retire and a mobile workforce. Health Canada has a high scientific and professional workforce (more than one third of the workforce) with fewer admin and foreign service groups when compared with other departments. In the context for HR planning, AG Reports, federal budgets, public service legislation, Canadian Human Rights Tribunal Order, changing science requirements have all impacted on the way the department handles HR. Realignment will be an opportunity to enhance our activities. A Working Group has been established to coordinate a Branch-wide strategic HR plan. There are several tools available to managers, such as the Management Development Program and various other recruitment options. Many potential employees are interested in working for Health Canada, but we need to improve our recruitment capabilities by investing in equity programs and graduate opportunities strategies. One such initiative, if approved by Treasury Board, will fund one year's salary and administrative costs to hire recent graduates. We need to take advantage of student and bridging programs etc. Retention of employees is basic. As employees

want meaningful work, there is a need to offer challenging and mentoring opportunities. Salary is not the sole issue in maintaining a stable workforce. The age profile of Health Canada employees is an average of 43.5 years with 25% of employees 50 or over. There is a need to rejuvenate the organization. By 2005, 35% of SEs will be eligible to retire and 25% of biologists, MDs, vets. In the EG Group, over 25% will reach retirement age by 2005. We are looking for input from SAB on possible recruitment tools, suggestions for marketing schemes, outreach activities etc. There is a particular challenge to recruit scientists for regulatory functions.

Discussion:

- There will be a need to afford new scientists the opportunity to interact with the external scientific community, for example, CIHR and academia.
- The subject of doctors and nurses is a professional issue and is not the same as the retention of scientists.
- Support and collaboration with universities is important to young researchers and research assistants.
- Members should tour the labs and talk to the scientists in their own milieu.

Conclusion:

- *This issue should be brought back to SAB for further discussion.*

8. **<u>Science Capacity</u>** - *(Robin Hill)*

The realignment of the science capacity is a continuation of the HPB Transition and science platform. It takes into account the work undertaken by PIAP and establishes stronger links between science and policy. A number of unresolved issues concerning the placement of labs under realignment must be considered. This is an opportunity for a change for the better. A focus group, as selected by the champions, has been formed between HPPB and HPB. It has been tasked with defining the main scientific capacity issues in creating the new Branches and for when science becomes the responsibility of the entire department. Issues identified are those of direction: quality of peer review and accreditation; and management of science. This Group has held brainstorming meetings to prepare for consultations scheduled for the end of June. Following the consultations, it is anticipated that a report will be prepared for presentation to the Deputy and the Champions. Science is the creation of new knowledge. For the purposes of consultation, we would need to include biological and social scientists. The Group will also need to address resource allocation and funding continuity. Some programs will need funding over several years. We will need to focus on priority setting over the next few years and establish links with other science capacities, such as the CIHR, academia, Centres of Excellence. Some fear has been expressed concerning the science capacity across three Branches. There will be an obligation on participants in the consultations to identify material useful for the science program and to suggest structures and processes. It is anticipated that we will be able to report on the results of the consultations by the end of

September.

Discussion:

- PMRA, regional participants and employees working in policy in the other Branches will be invited to participate in the consultations.
- It is important to acknowledge physical scientists, particularly chemists, otherwise this could be a serious impediment to the drug review process.
- Priority setting has to be a major element. The greatest vulnerability is that the science program is not performing due to the lack of people and strategic alliances.
- Good strategic planning is required from the beginning. With the huge explosion in biotech, there are fears that Health Canada lacks the tools to address scientific changes.
- There is not enough vision in priority setting. We could possibly use some public input in this area.
- Research must address future problems. The basis of dealing with a problem, such as the E. coli outbreak, are multi-disciplinary teams with in-house expertise.
- Planning will be crucial as executive committees cannot be expected to provide this function solely on their own. Researchers must be involved with the process completed in stages. Any themes generated by the executive committee should be circulated and consultations with facilitators should be undertaken.
- Priority setting needs to be done at various levels and scientists need to be encouraged to come forward with their ideas.
- Another unique feature of Health Canada is its response capacity that depends on generalists well-rounded in a variety of skills. Other experts could be consulted, as required.
- Health Canada has certain legislative obligations and there is the liability issue. Funding in the budget for controlled drugs and substances needs to to reviewed in light of the overall priority setting exercise.

Meeting adjourned at 5:15 p.m.

Day 2 - June 7, 2000

Attending: Diane Gorman, Karen Grant, Gabriel Plaa, Rodney Ouellette, Michel Bergeron, Russ Graham, Yves Morin, Neena Chappell, Lynn McIntyre, Stuart McLeod, Leslie Millin

Others: Joel Weiner, Brenda Pilon, Hsing Lee, Tilak Gunawardhane, Daniel Galarneau, Richard Viau, Peter Hill, Renee Harden, Sithian Pandian, Tim Flaherty, Alvin Cater, Ian Shugart

Secretariat: Kata Kitaljevich, Suzanne Bassett

9. **<u>Office of Consumer Affairs and Public Involvement</u> -** *(Joel Weiner - OCAPI Team - Richard Viau, Daniel Galarneau, Tilak Gunawardhane, Peter Hill, Renee Harden and Alvin Cater (consultant))*

The core of the OCAPI team will be based in Ottawa with a representative in all Regions. OCAPI is about opening doors and is being created in response to both internal and external criticisms from groups, such as Parliamentary Committees and the Sierra Club. One of the fundamental objectives of the Office is to ensure that it will not become just another PR forum, rather it will be a new way of doing business. One idea was to talk directly to stakeholders during the planning process to determine their requirements and expectations from Health Canada. OCAPI has been instrumental in building horizontally and collegiality and will build relationships with OGDs and international regulatory agencies. Working department-wide, its initial focus will be on health protections issues within the new HPF Branch. We want OCAPI to evolve to meet Canadians' expectations. There are plans to go public by activating the website. An e-mail box is being discussed but there will need to be the capability to respond in a timely manner. A mailing list is being built for a brochure. The post-launch activities will go out at the beginning of the planning cycle. Initially when the formation of OCAPI was announced, there were expectations that it would have an ombudsman role. This will not be the case, however, due to its limited capacity.

Discussion:

- OCAPI has a clear idea of its role but realizes that it would be impossible to be all encompassing from the outset.
- OCAPI must work closely with the programs areas that have done the policy work on a specific issue to ensure that they respond in a timely manner.
- Advocacy groups are the ones that would likely criticize the Office if it does not meet expectations as they are focussed and well informed.
- Concerning the public involvement issue, OCAPI would need to provide a response indicating that a policy initiative is underway or that consultations are planned.
- The objective is to build public confidence and be accountable. The general view at this time is to start small and grow. Consumer groups were contacted during the planning process.
- The proposed brochure is too broad and the consumer should be able to expect an immediate reply in the form of an appreciation response for contacting the Office. There needs to be a policy on how to deal with international requests. The website could probably use various information including the number of hits and possibly a discussion group forum so that all input and comments can be viewed by anyone contacting the site. Coop Science students might be an option to respond to e-mails.
- Advocacy groups want risks assessments and related information provided by the sponsors.

- OCAPI is supported across the Branch and is regarded as a mechanism in support of its mandate.
- OCAPI is meant to provide information to the public and must be seen as promoting involvement and accountability.
- There is a need to move from the culture of secrecy to that of transparency. For example, in the U.S., advisory boards are open to the public.
- OCAPI has been considering establishing a consumers' council that would provide ongoing advice and monitor performance.
- The Deputy has challenged OCAPI to work with the Food Program on the GM foods issue.

10. **<u>The Precautionary Approach in Health Canada</u>** - *(Ian Shugart)*

The federal government's ability to implement the precautionary principle, as part of its efforts to assess and manage risk, has been put through significant tests over the past decade. The increasing role of science-based risk assessment, coupled with a public demand for governments to implement the precautionary principle, will require the federal government to come to a better understanding of this concept and how it relates to risk assessment and management and the science capacity associated with its effective implementation. During previous discussions of the SAB, particularly those surrounding blood safety, questions were raised as to the manner in which the precautionary principle was part of the decision-making process in Health Canada. In public health, the precautionary principle is a well-established tenet and a core value. It is legislated under the CEPA and is part of the current legal framework. Obligations to the precautionary principle are founded in the Rio Declaration of 1992, the Krever Commission, and in CEPA and include a number of definitions based on key wording such as: "serious or irreversible damage"and "lack of full scientific certainty. There is a problem of definition and a need to focus on clear language. There is a tendency to defer difficult decisions based on a lack of full evidence. Erring on the side of caution before any compelling evidence is produced only comes into play when not all the evidence is produced. The precautionary principle depends on science to trigger its invocation. The "duty of care" is not the same concept as the precautionary principle. The use of precaution is fundamental to risk management. There is not a significant difference between the precautionary principle and the precautionary approach. Some considerations in the application of precautionary principles are scientific knowledge, risk severity and tolerance, perceived immediacy and cost effectiveness of action. To gain public confidence, evidence needs to be presented. A peer review is a good method to authenticate. The international context needs to be considered as there is a variation between domestic and international law. Canada should be insisting on the proper application of the precautionary principle as there are implications for government, but we need the capacity to respond. There should be a constant obligation to assess our capacity for action.

Discussion:

- There first needs to be a risk assessment followed by the precautionary principle.
- The precautionary principle concept needs to be revisited. Its application should be based on a case by case situation and could prove difficult to implement.
- The issue of qualitative evidence being empirical and biological plausibility might also be included in the presentation.
- In the context of removing a drug from the market in Canada, the normal response would be to avoid invoking the precautionary principle, but instead it would be more appropriate to maximize the scientific certainty, where possible, in dealing with a non-problematic product.
- If new evidence came to light that remedial action was not necessary or appropriate, for example with donor deferral, the application of the precautionary principle would be changed.
- A retrospective case study is a good way to test the model and to learn from it. There is a need for another framework and a political principle which is different from the precautionary approach.

11. **<u>Investing in Biotechnology MC: Proposed Activities under the Regulatory Portion</u>** - *(Joel Weiner)*

The 1998 renewal of the Canadian Biotechnology Strategy puts greater emphasis on stewardship, citizen engagement, ethical, legal and social issues. Of the 10 policy themes, the following two were identified as priorities: R&D (Genomics) and maintaining and improving the regulatory system. The 1999 Budget provided $55M for genomics research in government labs and the 2000 Budget allocated $160M towards the creation of Genome Canada. Budget 2000 also provided $89.5 M to be shared by the regulatory departments, including Health Canada which gets approximately $49.5M. The CFIA, which gets about $30M, has the lead on the Treasury Board submission that is targeted for completion by early June. The funding in Health Canada is to be spent in four thematic areas. This issue concerns regulatory components and transparency, engagement and public confidence. There has been some criticism directed at Health Canada concerning its biotech strategy. While there is acceptance that good work is being accomplished in this area by the department, there are concerns about linkages, coherency and comprehensiveness. Although Health Canada has been an active participant in the Canadian Biotech Strategy, a consultant has been hired and a departmental process is underway concerning how we should organize and fund including issues that need to be focussed on. There is a need for long-term testing and surveillance, especially concerning biotech, in the allocation of resources. LCDC has proposed developing a methodology for long-term testing but the absence of mandatory labelling and the segregation of crops would need to be addressed.

Discussion:

- As this area appears to be a future trend, funding for genomics will be ongoing.
- The process would come under an internal peer review. The federal government has provided support to the CIHR and Genome Canada has provided funding for

external core scientific expertise. The public wants government to have the capacity to review and to not always rely on consultants.

- As we are one of six biotech departments, we don't have control over timing, for example it an omnibus submission. Criteria under which we could submit projects was narrow with projects being reviewed interdepartmentally.
- It is strongly recommended that external input and advice for feasibility and review of projects be sought. The apparent lack of lab equipment is noteworthy.
- There is a need to build a base of multi-disciplinary people that can be applied in a variety of issues and to be able to respond to the public. More collaboration might be needed with the CIHR and Genome Canada.
- There is also a need to ensure that scientists are not reinventing the wheel as far as this issue is concerned. Health Canada might want to establish a committee, with both internal and external membership, to ensure that each researcher contacts experts and forms strategic alliances, as appropriate.
- Nothing in presentation precludes peer review or linkages.

12. **<u>Biotechnology Derived Foods Update</u>** - *(Marc Le Maguer)*

Over the past year, increasing attention has been paid in Canada to the use of biotechnology derived foods. This attention is based largely on the concerns of advocacy groups that these foods and ingredients have not been adequately evaluated in terms of their potential long-term impact on human health and that they have not been sufficiently identified or labelled to allow consumers the choice to buy them or not. In the U.S., as of May 3, there is a requirement for notification. A safety assessment involves looking at the genetic modification and is based on the consequences of that part of the DNA being modified. It is important that information relating to patents be kept confidential as there are limits as to what can be made public because of intellectual property rights. There is a need to look at possible effects on the population, for example, allergenicity and a team approach involving external consultation is also required. The regulatory system, as part of the approval process, might require that industry conduct long-term experiments for long-term effects and that the department establish a protocol and methodology. The labelling issue when there is a change in the composition of foods needs to be addressed. If there are allergenic compounds, labelling becomes mandatory. On the labelling issue, it is Health Canada's role to address safety side allergens and nutritional information while the CFIA is responsible to review this issue from a misrepresentation and fraud context. Two options are being considered for general labelling: characteristics different from traditional requirement for labelling; and stipulating mandatory method of production - no longer equivalent to traditional food, or DNA. Voluntary labelling for production methods is under study. An Expert Scientific Panel is reviewing the future of scientific development in food biotech and is preparing a report to be sent to Health Canada, the Canadian Food Inspection Agency and Environment Canada on the science capacity that government will require to ensure the safety of foods under this growing industry. The Report is expected in the fall.

Discussion:

- The Standards Board uses a principles approach and looks at what should go on the label, specifically for processed food.
- In Europe, labelling is required, but besides being unenforceable there are no methods to detect general modifications.
- Industry should provide biomarker tool kits.
- There is a need to look at a legislative framework for Health Canada and to develop a baseline, a perception of risk and risk tolerance.
- 90% of food on the market has not gone through any approval process.
- The CFIA must get environmental impact data when there has been a general modification to seed in accordance with the *Seed Act*.
- The management of organic food must be handled in a three-step process: good manufacturing practices with protocols, inspection, labelling and information to the consumer.

13. <u>Food Directorate Proposal: Research in support of the evaluation of safety and nutritional quality of foods developed through the application of genomics</u> - *(Marc Le Maguer)*

In August 1998, the Government announced the renewal of the National Biotechnology Strategy renaming it the Canadian Biotechnology Strategy, Genome Science was one of the two key priorities. In 1999-2000, genomics funding in Health Canada was $2M with 14 projects undertaken. The Food Directorate has developed a strategy that addresses research needs to support the responsibility for the evaluation of foods through the application of genomics. The objectives of the Genomics Research Initiative at Health Canada are the development of molecular detection technologies and molecular disease markers; and the evaluation of the safety of new technology and new products for improved food safety and nutrition. The Food Directorate Study Group, formed in January 2000, has been tasked with reviewing what is currently being done in genomics in the Directorate in terms of the objectives of the Genomics Research Initiative; with determining ways in which the science base can be strengthened to address public concerns of the impact of GMF's on human health; and with ensuring that effective methods and approaches are available to assess the safety and nutritional quality of the increasingly complex modified foods that are expected to make up the next generation of GMFs. A critical mass of research is being conducted on this issue across the country. There is a need for a knowledge base in regulatory process to allow for decision-making. The knowledge base would require a risk assessment and focus on the science: allergenicity, food processing enzymes; and natural toxicants. Under CEPA regulations relating to food additives and biotech foods, Health Canada must conduct an environmental assessment for toxicity, long-term and acute effects and undertake the development of a method for GMF detection and biomarkers. If the department sets standards that require labels, there will be a requirement to develop a methodology to allow enforcement and capacity consequences. A key component will be collaboration as

the costs associated with research in this area are high.

Discussion:

- Canada could be in a difficult position internationally by not having conducted long-term studies on the human health implications for GM foods already in existence.
- It is probably safe to say that health and safety were not considered in the initial stages but we are working on connecting early with the CFIA in product trials.
- With novel foods, long-term studies are required from a nutritional point of view to demonstrate first level effects.
- There is a requirement for health markers and on how to measure the effect from a public health perspective.
- From a legislative point of view, agriculture and seeds are the responsibility of Agriculture Canada, but when a product becomes available for human consumption, Health Canada gets involved.
- The Royal Society Panel has asked DFO for information on GM fish.
- The DNA chip technology is being patented so quickly that there might be a requirement for a regulation to allow the government access for public health purposes.
- The CIHR will probably have an Institute on nutrition which Health Canada should seek representation.

14. Miscellaneous

- The next meeting is scheduled for September 12-13, 2000. The Agenda will include the following issues: TPP Cost Recovery, a Response to the DRP, Peer Review, Risk Decision-Making Framework, a Report on Realignment and the broader mandate for SAB.
- The voluntary Lab visit will be scheduled for October.
- The revised Report on the April meeting is approved with amendments.
- Gratitude is expressed to members in attendance.

Meeting Adjourned.