Shifting Connections

A Report on Emerging Federal Policy Relating to Women's Health, the New Genetics and Biotechnology

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This document, *Shifting Connections: A Report on Emerging Federal Policy Relating to Women's Health, the New Genetics, and Biotechnology*, was commissioned by the Working Group on Women, Health and the New Genetics, with funding obtained from the National Network on Environments and Women's Health (NNEWH). NNEWH is one of Canada's five centres of Excellence for Women's Health, all of which operate through funding provided by the Women's Health Bureau of Health Canada. This report is intended to provide a broad overview of the current federal policy environment as it relates to the interconnections between women's health, the new genetics, and biotechnology. The views herein do not necessarily represent the official policy of the sponsors.

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PART I. INTRODUCTION AND SYNTHESIS OF FINDINGS

Introduction

This document, *Shifting Connections: A Report on Emerging Federal Policy Relating to Women's Health, the New Genetics and Biotechnology*, was commissioned by the Working Group on Women, Health and the New Genetics, with funding obtained from the National Network on Environments and Women's Health (NNEWH). NNEWH is one of Canada's five Centres of Excellence for Women's Health, which operate through funding provided by the Women's Health Bureau of Health Canada.

This report is intended to provide a broad overview of the current federal policy environment related to women's health, the new genetics, and biotechnology. Its mandate was therefore one of gathering and synthesizing current information on:

i) which federal departments or agencies are centrally involved in these areas;
ii) what relevant legislation, regulations, practices and policies are in existence through or under these departments or agencies; and
iii) what relevant developments are planned, proposed or expected.

Information on the first and second areas is available through government publications and the public relations officers of federal Ministries. Information on proposed or planned developments, however, is much more difficult to obtain. It can usually only be gathered through extensive conversations and correspondence with senior civil servants and Ministerial aids. These individuals are necessarily limited in what they can reveal to the public, especially where legislation exists only in an untabled draft form, and so does not yet have Ministerial approval as official draft legislation. The sensitive nature of this information thus creates unavoidable gaps - this report is careful to note where information provided by government sources on proposed developments was only considered tentative or alternately was seen as definitive, as well as where internal government sources felt unable to provide important details.

Synthesis and Overview of Findings

It is readily apparent from the findings of this report that the federal government's activities relating to genetics and biotechnology are deeply entangled with the promises and interests of expanding private industry and in developing a stronger position on the international industrial trade market. Much current federal activity is aimed at acknowledging,

facilitating, regulating or enhancing these relationships. The relationships are constantly shifting, and there is some internal tension within the federal government in determining what form the connections ought to take. This is strongly exampled in the report sections describing the Canadian Biotechnology Strategy, the Health Protection Branch Transition Program, intellectual property activities, and the federal government's approach to labeling genetically altered foods. With regard to such developments within the Health Protection Branch Transition Program, it is not clear whether this coupling is virtually inevitable, given industry's resources compared to those of Health Canada, or if it is taken on due to a more explicit policy decision to move away from a more socialized and centralized health system to one which greater reflects free market principles. The current trend is probably a combination of these factors.

Simultaneous with this shift, and with the tension that flows from private commercial interests and cost-reduction programs as part of the federal health landscape, is a move to re-orient the health system. This re-orientation is directed at making it reflect and connect better with contemporary conceptualizations of health. This is evidenced by federal activity aimed at making policy more gender sensitive, acknowledging the role of health determinants for planning and evaluating health status, and bringing ethical considerations more directly into the decision-making arena.

This re-orientation is seen most strongly in the activities of the Women's Health Bureau, in Genome Canada's continued support for research into ethical, legal, and social issues raised by genomic research, and in the Therapeutic Products Programme developing pre-emptive guidelines on xenotransplantation. It is also quite apparent in some aspects of the Health Protection Branch Transition Program and of Canada's position *vis-a-vis* intellectual property.

The pursuit of these two trajectories creates an ideological strain. One trajectory will necessarily dominate. Given undeniable historic trends regarding power, the dominant trajectory will probably be that of industrial expansion. Nonetheless, the relationship between these two trajectories is quite complicated, and not simply diametrically opposed. For example, simultaneous with the federal government's considerations of whether to allow the patenting of higher life-forms [which industry generally desires] are extensive internal policy discussions as to whether ethical considerations could be adequately incorporated into determining patentability [which industry does not desire but the informed public would generally support].

The federal government has put sufficient resources into the second trajectory of re-orienting health policy that it can and will shape the first trajectory of private bio-pharmaceutical and biotechnological development. However, it is unclear what sorts of connections will ultimately emerge, and how long those connections will last.

At this time of transition, and the creation of extensive new legislation relating to genetics, there is a need for continuous and careful monitoring and responding to federal initiatives. This need exists for several purposes, the most obvious being to ensure that the public is the primary 'client' of the federal government to whom it is ultimately responsible and accountable. The potential for the shift towards enhanced government-industrial connections to overwhelm the concurrent shift towards understandings of health informed by social science is clearly present.

This report aims to highlight some elements of crucial issues relating to women's health, the new genetics and biotechnology, and provide a useful context in which to understand those issues – both on their own and in relation to one another. This report presents discussions of the following:

1) Health System Reform (Part II of this report)
i) The Health Protection Branch Transition Program; and
ii) The Women's Health Bureau.

The Health Protection Branch Transition Program
The Health Protection Branch (HPB) Transition Program involves a major over-haul of the practices, guidelines and legislation which Health Canada administers through the HPB as a part of its health protection mandate. This mandate consists primarily of ensuring Canadians are protected against health risks associated with products, disease and the environment. Although there is ample evidence that the health protection system has failed women (e.g. those who were prescribed DES) and others (e.g. users of the Red Cross blood supply system) in the past, some of the proposals which have thus far been put forward by the HPB Transition Program leave room for concerns that the new system may create new problems and fail in new ways to protect public health.

In particular, some proposals reflect the possibility of the HPB developing a necessarily problematic enhanced relationship with industry, and the possibility of granting private

citizens the right to prosecute companies for violations of health protection legislation (which suggests the HPB taking on a lessened role). These more ominous proposals are offered concurrently with extremely progressive ones, such as the inclusion of health determinants (e.g. socioeconomic factors) in risk management practices, ensuring new legislation adequately addresses gender, and raising the fines for violation of health protection legislation considerably.

The Women's Health Bureau

The Women's Health Bureau (WHB) was established in 1993 by the Federal Ministry of Health, to assist it in re-shaping the Department of Health's programs and policies to more properly address women's health issues. As well as consulting on a day-to-day basis within the Department, the WHB is actively engaged in supporting pro-active women's health projects and programs across Canada, such as the Centres for Excellence in Women's Health and the Women's Health Network. The WHB intends to use the on-going findings of such external bodies to revise and provide input into its broader mandate of making Health Canada's policies and practices responsive to gender.

Commentary

Although the WHB has been asked to consult on HPB Transition Program activities, the WHB suffers from being understaffed with a prodigious work load, and so has not been able to contribute fully to this major reform activity. It is extremely unfortunate that although the HPB has earmarked gender inclusiveness as one of its principles for reform, Health Canada does not appear to have matched this commitment with appropriate personnel resources.

2) Biotechnology Initiatives (Part III of this report)

i) The Canadian Biotechnology Strategy;
ii) The proposed federal legislation on new reproductive and genetic technologies; and
iii) The proposed federal regulatory framework for tissue and organ transplantation and xenotransplantation (from various animal species to humans).

The Canadian Biotechnology Strategy

The Canadian Biotechnology Strategy (CBS) is a project aimed at shaping federal policy and practice to make Canada extremely competitive on the global market for biotechnology. Given that 90% of the advanced biotechnology products on the world market are related to health, and that 59% of the firms in Canada which are worth three billion dollars or more are in the health industry, the CBS's support for this industry can be expected to have major consequences for women's health. It is therefore potentially ominous that the CBS is headed by Industry Canada, and not jointly with Health Canada. Health Canada, rather, is one of the seven Ministries which are the major partners, along with Fisheries Canada, Agriculture and Agri-Food Canada, etc.. Although the rhetoric of the CBS is clear that it intends to promote Canada as a socially and ethically responsible world leader, the tensions

which are created whenever a project sets forth to facilitate great economic gain by servicing perceived or realized health needs are certainly present.

Legislation on new reproductive and genetic technologies

'Reproductive technologies' is the label applied to practices, procedures or treatments which aim to overcome infertility or manipulate the 'conventional' conception process to produce a pregnancy. In this context, 'genetic technologies' are those techniques which examine or manipulate human genetic material used in conjunction with reproduction. The connection between reproductive and genetic technologies and women's health concerns is quite obvious, since only women can carry pregnancies their bodies are assumed to be the appropriate primary subject or object for which these technologies ought to be – and are being – developed. As discussed in this section of the report, activity directed at legislating in the area has been on-going since 1989. One bill on this topic was tabled but not passed, and a new bill is in the process of being drafted. The information which was obtained on the new bill is quite partial. Although it was ascertained that the new legislation will have a section which establishes a regulatory body and a section which prohibits certain practices, no verification could be obtained as to whether the prohibitions will be in the form of regulations or criminal sanctions. The draft legislation also appears to not address the creation of a national framework for reproductive health as was proposed in 1996.

Tissue and Organ Transplantation and Xenotransplantation

Xenotransplantation involves the transplantation of tissues and organs from one species to another for therapeutic purposes. The Therapeutic Products Programme (TPP) of Health Canada is currently developing a regulatory framework to address transplantations from the bodies of animals to those of humans, as part of a larger project to create national standards for organ and tissue transplantation. The xenotransplantation guidelines are largely prospective, as there have been extremely few examples of xenotransplantation in North America – the most common involve the transplantation of neural cells from fetal pigs into humans suffering from Parkinson's disease**.** The national standards program is of relevance for the Canadian population as a whole *vis-a-vis* genetics, biotechnology, and health, as one of the findings of internal reviewers was that transplantation practices are inconsistent from one province to another, and that the provinces are poorly organized for communicating to one another about the availability of suitable transplantation materials and recipients. The TPP will release drafts of the proposed standards for a public review process after they have been approved as 'official drafts' by the Canadian Standards Association. This is now expected to take place in Spring of 1999.

Commentary

The federal government has been mobilizing a great deal of policy-making resources around controlling the realized or potential ends towards which biotechnology can be or has been directed. It is extremely disturbing that the federal government has prioritized activity directed towards facilitating its commercial potential while stalling on legislation which would presumably protect those whose bodies are one of the primary subjects of biotechnological reproductive and genetic interventions, women and fetuses. In this light, the pre-emptive action of regulating xenotransplantation prior to its being practiced in Canada is laudable, although one must contextualize these guidelines as being developed as a specialized subset of guidelines for all transplantations, and also note that transplantations affect all citizens (i.e. both men and women), instead of primarily women. This is not to suggest criticism of the TPP for their pro-activity, but rather to place this action in contrast with that of Health Canada regarding legislating on new reproductive and genetic technologies, and gently query whether their delay could in any way reflect the gendered nature of those upon whose bodies these technologies are utilized.

3) Ownership and the New Genetics – National and International Legislation and Obligations (Part IV of this report)

i) Intellectual property activities, from patenting higher lifeforms (plants and animals) to Canada's international obligations *vis-a-vis* intellectual property (NAFTA and the WTO-TRIPS Agreement); and

ii) International legal instruments regarding genetic 'resources' of which Canada is a signatory (the United Nations Convention on Biological Diversity which is a legally binding instrument and the Universal Declaration on the Human Genome and Human Rights which is only an agreement in principle).

Intellectual Property Activities

Intellectual property activities discussed in this section centre around patenting issues, and the activities of the Intellectual Property Policy Directorate (IPPD) (a branch of Industry Canada). A patent gives the patent holder exclusive rights of commercial exploitation of an invention for a period of time. As Canadian laws now stand, there is no obligation to allow patents for transgenic plants or animals (plants or animals which have been genetically altered by the insertion of a foreign or "unrelated" gene, usually at the embryonic stage). The relevant legislation has not been interpreted to allow for their patenting, although patents have been granted for unicellular organisms. There is, however, currently an appeal

being brought to the Federal Court of Canada regarding an application to patent a transgenic mammal. Although the IPPD is consulting on how to deal with such applications, and is considering revising the patenting criteria to include ethical considerations, it is not clear whether the federal government intends to act before or after the above mentioned appeal reaches the Canadian Supreme Court. This situation is further complicated by Canada's international obligations under WTO-TRIPs Agreement. The WTO-TRIPs Agreement clearly entertains defining higher life forms as inventions, and forbids refusing a patent simply because the commercial exploitation of human, plant or animal life is prohibited by a state's laws *unless* the patent relates to diagnostic, therapeutic or surgical methods for the treatment of humans or animals or would disturb, e.g., public order. It also gives a *temporary* blanket exclusion for the patenting of plants or animals other than micro-organisms, and "essentially biological processes for the production of plants or animals," although this exclusion is to be reviewed in 1999.

International Instruments on Genetic Resources

Canada has signed two major international instruments relating to genetic resources. The United Nations Convention on Biological Diversity is a legally binding instrument, while the Universal Declaration on the Human Genome and Human Rights is not legally binding but rather operates as an agreement in principle. The UN Convention provides that signatory states are to *share* the research, development and commercialization benefits derived from genetic resources with the state from which the benefits were taken, and to recognize states as having sovereign authority over the genetic resources within their jurisdiction. It also charges signatories with fashioning their patent legislation in a manner which supports the Convention's objectives. These terms appear to have the power to shape Canada's domestic legislation. The UN Declaration proposes an ethical framework for human genetics research. Although it is not legally binding, Canada has indicated that it intends to incorporate the Declaration into domestic legislation. If adopted in whole, it would considerably shape Canadian legislation on such issues as new reproductive and genetic technologies, and other instances where genetic knowledge is at play.

Commentary

Canada is far more active in negotiating and taking on international intellectual property policy positions and obligations than national ones. This acknowledgment of intellectual property issues as globalized and entangled in North-South relations is astute, and means that Canada is involved in setting the terms for the international market instead of adopting already established ones. The genetic resources instruments provide extremely promising

templates, as they are grounded in ethical principles. The trade agreements, on the other hand, predominantly reflect economic interests, although ethical interests are acknowledged. These trade agreements are in the position to strongly influence/partially dictate the intended new Canadian intellectual property legislation. Thus although the IPPD has indicated that there will be consultations on the new national intellectual property legislation, it is unclear how much scope there will be for substantial input on certain issues. It is fortunate that the trade agreements list acceptable moral objections against permitting the patenting of certain subject materials, as these do open a door for ethics to enter the field of Canadian patent law for the first time.

4) The New Genetics – From Basic Research to Society (Part V of this report)

i) Genome Canada, the genomic research project which is being designed to replace CGAT and MELSI; and

ii) Genetically altered foods, from current regulatory practices in Canada to the proposed federal guidelines on their labeling.

Genome Research

Genome research involves the study of the genes in the DNA of an organism. Canada has recently chosen not to renew its major genomic research project, the Canadian Genome Analysis and Technology Program (CGAT), at the end of its planned five year life-span. A new Canadian genome research project is in the process of being developed, called Genome Canada. Unlike its predecessor which had allocated a specific percentage of its budget for researching the medical, ethical, legal and social issues (MELSI) raised by genomic research, Genome Canada does not expect to specifically earmark any funds for these types of research. Rather, it will judge applications 'on their merits'. That said, the organizers have expressed a strong commitment to funding such projects. There is also an interim project in place to bridge the gap, which has clearly requested parties to make applications for funding for MELSI-type projects.

Foods derived through genetic engineering

Genetic engineering involves transferring selected pieces of genetic information from one organism to another, and is most often used in Canada to create strains of crops – such as wheat – with traits such as resistance to herbicides, pests, or cold weather. Health Canada *establishes policies* relating to the safety of foods in Canada including those derived from genetic manipulation, while the Canadian Food Inspection Agency *administers* and in some cases *enforces* the statutes under which agricultural products of biotechnology are regulated.

They have together recently released a set of proposed guidelines for the labeling of genetically altered foods. The labeling of foods is of particular concern to women, as women still tend to be the primary purchasers of food and preparers of meals in heterosexual Canadian households. The proposed guidelines would not require the mandatory labeling of genetically altered foods *unless* Health Canada determines the food carries a health or safety risk. This position is supported by the United States, but rejected by the EU as well as by many Canadian consumer activist groups.

Commentary

Canada is still committed to funding basic genomic research. This is hardly surprising, given such initiatives as the Canadian Biotechnology Strategy (which is one of the funders of the interim genome research project). Genome Canada will have far greater funding than that of CGAT, mainly through donations from/partnerships with biotechnological and pharmaceutical companies. Given this enhanced budget, it is unfortunate that Genome Canada does not intend to allocate a certain percentage of its resources for MELSI-type research, as this sort of research has historically had to fight for funding. However, the organizers do seem committed to this research area, and CGAT-MELSI did spend 4% more of their budget on funding MELSI projects than the minimum they had allocated. The discussion on the proposed guidelines for labeling genetically altered foods is included in this section because it is a MELSI-type issue where the desires of industry have been presented by the federal government as the only viable practice, despite the opposite conclusions having been reached in the EU.

Acknowledgments

The information presented in *Shifting Connections* was primarily derived through long telephone conversations and multiple email exchanges with persons working within various Federal departments. Although it is not appropriate to mention these individuals by name, I do wish to thank them for their frankness and generosity. Their patience in responding to my repeated telephone calls for up-dates and verifications regarding second-hand information improved the quality of this report significantly and has left me feeling confident as to its integrity.

I would also like to acknowledge Professor Roxanne Mykitiuk of Osgoode Hall Law School for having put my name forward as a candidate to write this report, and Dr. Lorna Weir of York University for overseeing the larger project of which this is a component. Both Professor Mykitiuk and Dr. Weir have supported me in the execution of this report.

PART II. HEALTH SYSTEM REFORM

The Health Protection Branch Transition Programme

1) Background – The Health Protection Branch

The Health Protection Branch (HPB) is a division of Health Canada.[1] Its mandate is to protect Canadians against health risks associated with products and disease. Its protective activities include scientific research, monitoring public health, applying and enforcing standards legislation, and policy development. The sorts of products whose safety the HPB monitors include food, drugs, the blood supply, cosmetics, medical devices, radiation-emitting devices, pesticides and other products which may create environmental hazards, and certain other consumer and industrial products.

With respect to disease, the HPB is mainly concerned with infectious and chronic diseases, as well as environmental risks to health. The HPB researches these diseases, and surveys and tracks their occurrence as part of its strategy to manage them. The breadth of this mandate requires the HPB to operate in conjunction with other governmental departments and agencies, including Agriculture and Agri-Food Canada, the Canadian Food Inspection Agency, Fisheries and Oceans Canada, and Environment Canada.

The HPB had its budget reduced over the last few years from $237 million in 1993/94 to $212 million (a drop of $25 million) by 1997/98. Persons within the HPB confirmed that although Health Canada has shut some laboratories, no HPB laboratories have been closed. The HPB's funding was also brought back to $230 million in 1998/99, and is expected to continue to increase. This 1998/99 increase in funding was not applied evenly. Rather, some departments continue to operate on a reduced budget while the new money is directed at specific 'priority areas', including AIDS research, cancer research, blood safety, lab facilities and surveillance. The 1998/99 budget includes $38 million in funds from its cost-recovery program (the cost-recovery program is discussed below, under the heading of 'Science Core'). The federal government has also promised the HPB an additional $125 million over the next five years for blood regulation and surveillance.

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[1] Much of the data in this section is either from personal conversations or e-mail exchanges with 'Team Leaders' and team members of the five core areas (science, surveillance, risk management, legislation and program development) or from Health Canada, Information: Health Protection Branch - Facts (Ottawa: Publications, Health Canada, October 1998). General background data was pulled from the HPB Transition Consultation Documents found at http://www.hc-sc.gc.ca/hpb/transitn/index.html, which were last up-dated between November 18, 1998 and December 6, 1998.

2) The Health Protection Branch Transition Programme

Health Canada initiated an in-depth review of its health protection activities in 1997. It is examining the current practices of the Health Protection Branch (HPB) with an eye to change. The decision to examine and re-shape the health protection activities of Health Canada is grounded in several considerations. These considerations include:

- current legislation being piecemeal and inconsistent, due to its having been created over-time in response to specific concerns;
- the emergence of new health risks and health therapies which are not adequately addressed by the old system or which 'straddle' the domains of multiple statutes (for example, as drugs and medical devices are regulated by different regulations, the emergence of drug-device combinations have created uncertainties as to procedure, requirements and standards. Similarly, human organs for transplantation are treated as medical 'devices' so as to 'squeeze' them within the scope of existing legislation);
- economic pressure to develop stronger relationships with non-governmental organizations, university research communities, and industry so as to shift or minimize costs; and
- extensive internal organizational changes within Health Canada, such as the creation of the Canadian Food Inspection Agency.[2]

Health Canada expects the process of review and transition to take approximately three years. It is organizing the review under five core areas, each with a team and a team leader. The areas are science, surveillance, risk management, legislation and program development. Each of these core areas have an associated objective. Together, the five official objectives serve as the mandate for the HPB Transition. They are to:[3]

1. strengthen the science that underlies decision-making, ensure its capacity to meet current and emerging public health risks (Science Core);
2. improve and modernize the Canada-wide health surveillance network (Surveillance Core);

[2] Health Canada, Health Protection for the 21st Century: Renewing the Federal Health Protection Program (Ottawa: Minister of Public Works and Government Services Canada, July 1998) at 2.

[3] Health Canada, Shared Responsibilities, Shared Vision: Renewing the Federal Health Protection Legislation (Ottawa: Publications, Health Canada, July 1998) at 3.

3. improve the management of health risks, while explicitly recognizing the roles and responsibilities of all partners and participants in the process (Risk Management);
4. review and improve the delivery of health protection programs (Program Development); and
5 update and integrate the existing federal health protection legislation, which is currently spread through many different acts (Legislative Renewal).

3) The Five Core Transition Areas

As noted above, the five core transition areas are the science core, the surveillance core, risk management, program development and legislative renewal. These areas are discussed below.

a) The Science Core

i) Main Activities

The science core's main activity within the HPB is the review of new drugs and devices. This central activity is complimented by the related ones of gathering, generating, analyzing and providing health-related information to be used by the HPB for such purposes as making risk assessments for new drugs or devices, and developing general policy and regulations. The science core also conducts extensive in-house research on the effects of toxic substances on humans and the effects of certain microbes on animals, as well as directs resources into developing research methodologies and compiling and publishing extensive literature reviews of medical products and devices.

ii) Product Assessment

When companies want to market a new drug or device, they must provide the Science Core with a submission/notification for assessment. The content of the submission is specified by schedules developed under regulations, where different regulations have been created to address different categories of products.[4] Although some products are approved on the basis of the submission, the Science Core may decide to do a full paper review of the summarized test results referenced in the submission, or alternately may decide to conduct

[4] Different types of products are covered by different pieces of legislation. Each legislative act empowers a body to create regulations and schedules regarding the products which it covers. For example, under the Food and Drug Act, there are schedules relating to what information must be provided with regard to food additives, the potential for packaging contaminants, etc. Under the Food and Drugs Act's mandate to approve medical devices there would be different schedules for, e.g. information which must be provided to assess heart value products of animal origins, as well as a schedule of mandatory information on heart value products of non-animal origins.

their own laboratory tests. These tests may be done internally in one of Health Canada's laboratories, or be contracted out – for example, to a university researcher. Such decisions may be quite discretionary, and be made on the basis of an individual scientist's instinct that the submission does not tell the whole story or that certain other tests ought to be performed. Alternately, these procedures may be initiated in response to a product having raised health concerns in another country, due to other published test results reporting different outcomes, or due to the nature of the specific product and/or its expected market.

iii) Cost-Recovery, University/Industry Relationships, and Transition Activities

The administrative costs of these regulatory reviews is currently born by the applicant company, as part of a cost-recovery plan. Industry must pay for the service of having their product reviewed for potential market approval *regardless* of whether the submission is approved or rejected. A proposed Transition activity is to formalize this existing practice or relationship by integrating it into the proposed new legislation. This places industry – not the Canadian public – in the position of being Health Canada's client for the purposes of product review.

This raises concerns over to whom Health Canada is accountable in performing reviews – industry or the Canadian public – and what a shift in accountability could mean in terms of creating pressure to do assessments quickly. However, numerous task group leaders were confident that this was not a compromised position, rather, as one official stated:

> The client [industry] has a right to receive service which is efficient, effective, and timely but that in no way allows the client to alter the regulatory requirements nor the implementation of these regulations. The assignment of fees for the administrative cost of regulatory reviews is completely independent of the decision to approve or reject a submission.

Similar cost-recovery programs are in effect in Australia and the United Kingdom, and there have not been any difficulties. As part of the Transition Program, the HPB expects to formalize the roles, responsibilities and liabilities of industry in such situations. That is, these *de facto* cost-recovery practices will be legitimated by merging them into the health protection system as one of its integrated components.

Cost-reduction activities have had an effect on the HPB's staff. It is currently considered to be lacking in human resources, as its staff has not been increased in proportion with the

growing number of submissions for product approval. In 1997/98, there were approximately 650-700 people working the Health Canada's 40 laboratories. Of these people, about 110 were scientific researchers, while the remaining 540-590 people were technicians and support staff. As part of the HPB Transition Program, there is expected to be a "considerable" increase in the number of scientific researchers on staff in the next fiscal year. Despite this increase, or in complement with it, the HPB expects that a central component of its Science Core transition will entail fostering stronger links between its activities and those of university researchers and industry scientists so as to further reduce costs.

Although the HPB maintains that having industry as a client does not necessarily place it in a compromising situation, this seems less likely in the face of a more active plan to rely on self-reporting and research-partnerships with industry, as has been proposed by the HPB Transition Program. This tension has been recognized within the HPB, which has struck two working groups to develop practice guidelines to identify and avoid relationships and situations prone to undue influence by industry (there are currently no guidelines for these relationships). These groups are a Working Group on Conflict of Interest, and a Working Group on Partnerships and Alliances. The Working Group on Conflict of Interest is addressing issues such as:

- whether or on what terms should the HPB accept funding for testing from non-governmental organizations;
- what to do with any commercially viable product which is developed internally;
- whether or on what terms they should fund collaborative university-based research projects where one or more of the researchers also has industry funding;
- whether or on what terms should they contract research to scientists who work in private industry;
- when could cost-recovery distort the HPB's mandate;
- etc.

The Working Group on Partnerships and Alliances is primarily concerned with setting guidelines for establishing partnerships – in particular, when and under what terms a partnership is desirable and acceptable, and what should the HPB be giving or receiving in any given partnership. Most of the current partnerships are with other government departments, and were formed on a 'common sense' basis, without any standardized guidelines. The major new and formalized partner source under the HPB Transition

Program is expected to be university research departments, as the Science Core is finding that the sorts of specialized knowledge which product assessment requires is becoming more distinctive and unique than ever before, making it impossible to have sufficient expertise on staff. The Working Group is thus developing formal standardized guidelines for Memorandums of Understanding with university-based researchers.

Both of these Working Groups are in the process of writing draft guidelines. Officials within the Science Core expect that first drafts will be finished by late January, 1999. These drafts will be circulated within Health Canada and revised once more before being released for public feedback.

The Science Core is still grappling with how to manage the possible tensions created by an enhanced relationship with/reliance on industry for providing test results, although both the Working Groups are addressing this issue. One of the central safeguards which they propose under the HPB Transition Program is to pass legislation making it illegal for a manufacturer to place a dangerous product on the marketplace. Such legislation is expected to force *manufacturers* to be more explicitly responsible for ensuring product safety due to enhanced and more rigorous liability. As the law now stands, the government is responsible for ensuring product safety before releasing a product onto the market. That is, the government is primarily accountable to the public.

This proposed legislation may create a situation where instead of Health Canada being primarily responsible for ensuring that products are cleared for safety *prior* to public exposure, that industry carries this responsibility and Health Canada's interventions are more active *after* a danger has been detected through market use (i.e. protection through the threat of a harsh punishment, instead of protection by preventing product entry onto the market in the first place). This interpretation is by no means the only one, as such legislation could also create a situation where Health Canada maintains its current protective pre-market screening standards while forcing industry to *raise* its own standards due to the threat of increased liability. This legislation is discussed in more detail under the discussion of Legislative Renewal, below.

The efficacy of product assessment for safety, and the fear that since industry operates on a profit-maximizing basis it may not always act in the best interests of consumer health, are of particular concern from a women's health perspective. This is not because women's health is *more* important than the health of men, but rather because Health Canada has

approved many products in the past which are marketed *solely* to women and have had particularly deleterious health consequences.

Some argue that the serious harm caused to women by such products as diethylstilbestrol (DES), the Dalkon Shield, the Copper 7 I.U.D. and the Meme Breast Implants would not have occurred had Health Canada practiced higher safety standards, demanded higher levels of accountability, and paid more heed to adverse test results of which industry was aware while they marketed these products.[5]

[5] See Harriet Simand, "Health Protection Branch Transition" (Fall 1998) 1(4) The Canadian Women's Health Network 1 at 1 and 3.

b) The Surveillance Core

i) Main Activities

The Surveillance Core's primary activities within the HPB involve monitoring, forecasting and responding to public health trends. Central to these functions is the collecting of information as to the health status of groups of people – isolating when, where and how they became ill or injured, and how this information in turn creates patterns when combined with such information as age, gender, geographic location, socioeconomic status, occupation, etc.[6] This information is then used to identify outbreaks of communicable diseases, detect new diseases or new causes of disease or injury, set priorities for public health officials, and identify dangerous products or emerging safety issues. The Surveillance Core shares information with, and gathers information from, provincial governments, health care professionals, epidemiologists, public health and hospital laboratories, public health officials, etc.[7]

ii) Transition Objectives

Health Canada expects to fully redesign its existing surveillance network, transforming it into a single information system which is comprehensive, integrated, and standardized. This re-formation was determined to be necessary following an internal study which found the HPB is currently using over 300 different database/information management systems, very few of which are compatible with any of the other databases.[8] The principles which have been formally proposed to guide the shaping of the new system are as follows:

- flexibility with a capacity to deal with the full spectrum of health risks;
- policy relevance – support health policy development for targeted and timely public health interventions;
- integration of health surveillance findings with program development;
- explicitly agreed-upon roles and responsibilities for the federal, provincial and territorial governments, in a partnership approach;
- interconnected health information networks and databases;
- cost effectiveness with no duplication of efforts;
- respect for privacy and confidentiality of data;

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[6] *Supra* note 3.at 5-6.

[7] *Ibid*. at 6.

[8] Health Canada, "HPB Transition: Surveillance Transition" (Health Canada at http://www.hc-sc.gc.ca/hpb/transitn/surveile.html, updated November 18, 1998).

- pro-activity in issue management: early identification of significant trends and health risks; and
- effective evaluation of health programs and policies.[9]

The envisioned new system is hoped to be more cost-effective and less prone to duplications as a result of its integration of the laboratory network, and general information sharing capabilities. This national monitoring system is also expected to allow Canada to better access international health information.

iii) Transition Consultations

The Surveillance Transition Team has produced a draft proposal for the new surveillance system, entitled Integrated National Health Surveillance Network for Canada.[10] They have scheduled consultations on the proposals for January-March, 1999, and expect to gather input from such participants as representatives of provincial and territorial governments, health stakeholder groups, and other interested individuals. In particular, they want feedback on issues such as how to set standards for maintaining confidentiality and privacy, and how to ensure that data collection includes gathering information on relevant health determinants. This provides an excellent opportunity from the perspective of women's health to bring to the attention of the Surveillance Transition Team the particular ways in which gender and gender-associated socio-economic determinants figure in health conditions and outcomes.

The Surveillance Transition Team also wants input on what sorts of information industry should be mandated to report to the HPB on products on the marketplace on a continuing basis. This is an important opportunity for those concerned with women's health to impact on health protection standards by supplementing "what counts" as relevant information which must be reported and monitored.

The Surveillance Transition Team expects to have finalized draft legislation completed by the summer of 1999.

c) Risk Management

i) Main Activities

[9] *Ibid.*

[10] This document can be downloaded electronically, from the web site address: http://www.hc-sc.gc.ca/hpb/transitn/surveile.html or can be requested by e-mailing: health_surveillance@hc-sc.gc.ca.

Risk Management is the process of identifying, evaluating and managing public health and safety risks. Health Canada and the provincial health departments currently have a specific analytic framework which lists the steps the HPB must apply for the risk management process. These steps mandate procedures for identifying and assessing public health and safety risks, developing options for managing any given risk, implementing options, and monitoring and evaluating the results.[11] Health Canada examines a wide variety of health risks, including, for example, those from prescription drugs, medical devices, poor diets, consumer products, radiation, chemical hazards, water contaminants, etc.[12]

ii) Transition Objectives – Revising the Risk Management Framework

The central transition objective is to revise the risk management framework. Health Canada's internal assessment indicated that it suffers from four central weaknesses, mostly sourced in changes to public expectations/standards and to the broader context in which they operate. The first major revision would respond to the fact that the HPB is no longer the primary participant in risk assessment; rather it "is now often one of many partners."[13] The HPB wants to change the framework to explicitly recognize the roles and responsibilities of these other 'partners.'

Queries as to the nature of these partners revealed that they include academic and industry researchers, interest groups, private consultants (e.g. hired by industry or government), and researchers from other federal, provincial and territorial government agencies. The use of these partners' research for risk assessment, instead of primary reliance on internal and 'disinterested' Health Canada produced research, is based on several factors. The central reason which I was offered by a team leader was that "the Health Protection Branch has not, nor did it ever have, a monopoly in science." That is to say, the HPB does not have the resources, facilities and specialized scientific expertise which exist in academia, private research laboratories, hospitals, etc. and which are necessary to evaluate and develop all risk management practices.

The HPB believes this 'networked' system allows it to access and develop the best available scientific information, which it still strives to complement with assessments from in-house laboratories and staff scientists. The team leader emphasized that safeguards and review

[11] *Supra* note 2 at 6.

[12] *Ibid.*

[13] Health Canada, "HPB Transition: Risk Management" (Health Canada at http://www.hc-sc.gc.ca/hpb/transitn/riskman.html, updated November 18, 1998).

processes are included in every contract/agreement with any outside experts, although no information was offered as to specific examples. The transition would formalize and standardize guidelines, liabilities, roles and responsibilities for these relationships.

The second major shift which the HPB wants to address is to make risk assessment more 'holistic'. By holistic, the HPB means creating a framework which contextualizes risks relative to other risks. The current framework addresses risks associated with specific diseases, products, etc., in isolation from other risks, with no consideration of how to set priorities for resource allocation.[14]

The third major shift to the framework is to alter it to reflect a more dynamic definition of health. This is in response to changing public/scientific/academic perceptions of health. Queries as to how the HPB defines health determined that their working definition for approaching the transition is the definition proposed by the World Health Organization (WHO). WHO defines health as "a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." This change is expected to primarily be brought about by incorporating health determinants into risk management strategies.

Health determinants include a broad spectrum of factors which impact on health, such as individual coping ability and skills, the availability of health services, the physical, social and economic environment, and lifestyle and personal health practices. Part of the transition process will involve determining the relative importance of such factors for a given health hazard.

The fourth major alteration to the framework will also involve a re-orientation of its approach, from a primary focus on industry compliance to health outcomes. It is not clear whether such a shift merely involves pursuing health outcomes as one of the HPB's primary foci, or if it would involve a reduction in energies directed at insuring industry compliance. A similar re-orientation of the framework will involve correcting for the fact that the current framework is best suited to the analysis and management of chemical, radiation and microbiological risks in the environment, and not as well suited to the analysis and management of disease and products.[15] The revised framework is expected to better address these areas.

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[14] *Ibid.*
[15] *Ibid.*

The objectives for the transition, broadly described, are therefore to re-write the risk management framework to reflect current approaches to health and to develop standardized guidelines for practices – especially those involving outside 'partners.'

d) Program Development

i) Main Activities

Program development is concerned with targeting health protection issues which are in need of a special program. This process includes isolating program areas, and developing an appropriate model which both addresses the program issue and delivers the program to the targeted audience. For example, the HPB has programs to provide emergency responses to public health threats, to provide information on hazardous products, and to develop policies to prevent or reduce injuries and the spread of diseases.[16]

ii) Transition Objectives

The transition within program development is expected to focus on developing more flexible models which better monitor health outcomes and program impact. They also hope to develop better programs aimed at mental health and injury prevention, and to identify other areas where programs are needed. The transition will involve an extensive review of the current delivery system and the manner in which program development receives information. It is expected that the transition will involve creating more efficient links between program development and surveillance, and other participants in the professional health care field.

e) Legislative Renewal

i) Statutes Targeted for Revision

The HPB transition will involve a through examination of legislation which relates to health protection.[17] The HPB expects to revise legislation where necessary to meet three proposed main objectives. These objectives are:

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[16] *Ibid*. at 7; also Health Canada "HPB Transition: Program Development" (Health Canada at http://www.hc-sc.gc.ca/hpb/transitn/progdeve.html.

[17] Health Canada administers the following statutes, in whole or in part, relating to health protection: Department of Health Act, Food and Drugs Act, Quarantine Act, Radiation Emitting Devices Act, Hazardous Products Act, Tobacco Act, Controlled Drugs and Substances Act, Pest Control Products Act, Canadian Food Inspection Agency Act, Canadian Environmental Protection Act, and the Patent Act.

- to update and integrate the federal health protection legislation into a coherent, comprehensive and flexible system that is more responsive to present-day global, technological, social and cultural realities, and that provides the necessary tools to address the challenges of the future;
- to better articulate the role of the federal government in health protection in order to facilitate cooperation with other governments and stakeholders; and
- to create a clearer, more relevant and more coherent legal base for federal policy in the area of health protection.[18]

The HPB expects that the transition will involve replacing four particular statutes. These statutes are the Food and Drugs Act, the Hazardous Products Act, the Radiation Emitting Devices Act, and the Quarantine Act.

The Food and Drugs Act sets terms for the federal government to regulate "the manufacture, importation and sale of food, drugs, cosmetics and medical devices to ensure their quality, safety and effectiveness."[19] The Hazardous Products Act regulates "the sale, advertising and import of products and materials that, because of their content, design or function, could pose a health risk."[20] These items include such consumer products as children's clothes for sleeping, lighters, baby pacifiers, toys, safety glass, mattresses and hockey helmets, as well as any products which are corrosive, poisonous, flammable, or explosive.

The Radiation Emitting Devices Act "sets standards for the sale, lease and importation of radiation-emitting devices."[21] These include televisions, industrial and medical ultrasound machines, industrial and medical x-ray machines. The Quarantine Act regulates the entry into Canada of people, cargo or vehicles which may carry infectious or communicable diseases.

The mandates of these statutes and their scope would be revised and incorporated into a single act, tentatively entitled "the Health Protection Act." Provisions relating to risk management and surveillance (discussed above) would also be incorporated into this proposed act. Due to the extensive and tentative nature of the proposed possible revisions,

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[18] *Supra* note 3 at 11.
[19] *Ibid.* at 5.
[20] *Ibid.*
[21] *Ibid.*

they are not discussed in detail here except with regards to enforcement and compliance, although many have been discussed under the appropriate core areas, above. Reference should also be made to Health Canada's discussion paper which lists 73 'focus' questions.[22] Health Canada has proposed a tentative list of principles to shape the new legislative framework, and thus any legislative revisions to the core areas, above. These principles are that the legislation should:

a) recognize the role of the federal government in health protection and public health surveillance;
b) respect the responsibilities of the federal, provincial and territorial governments in matters of public health and risk management, and promote collaboration among them;
c) adhere to sound principles of risk management and risk communication;
d) favour co-operation among all stakeholders;
e) promote the use of sound science-based information in decision-making;
f) be fair, equitable and transparent;
g) address the issues of accountability and liability;
h) take into account ethical considerations;
i) acknowledge socioeconomic and cultural factors;
j) recognize that gender must receive appropriate attention in assessing health concerns;
k) meet Canada's international obligations including free trade agreements;
l) be sensitive to the importance of economic development;
m) address issues within Health Canada's mandate;
n) reflect Health Canada's commitment to the principles of population health;
o) reflect Health Canada's commitment to the principles of sustainable development; and
p) encourage creativity and advances in design and technology.[23]

It is not clear how the HPB envisions the relationship between these principles, especially those which may be in tension with one another. For example, juggling the principle of acknowledging socioeconomic factors with that of being sensitive to the importance of economic development. There is a similar possible tension between the principle of taking into account ethical considerations with that of meeting obligations set out in free trade agreements (as some may find some aspects of current free trade agreements to be

[22] *Ibid*. at 23-34.
[23] *Ibid*. at 22.

inherently unethical). Queries as to how such tensions would be resolved led to assurances that the HPB's central mandate of health protection remains primary.

ii) Compliance and Regulation

The HPB is not entirely clear on how it envisions possible changes to enforcement practices, although it is certain that there will be changes. Compliance is currently enforced primarily under the Criminal Code, or by requesting manufacturers to voluntarily remove a product from the market place or cease an activity. Voluntary withdrawals are often requested for hazardous products, as under the current Hazardous Products Act, regulations on health and safety are enacted on a case-by-case basis and do not exist on a blanket basis (e.g. the regulations do not forbid 'hazardous' products *per se*).

The result of this approach is that a large number of consumer products are not subject to any federal legislation or standard. Where Health Canada believes such a product is hazardous, it can only issue a public warning and then pass a new regulation regarding that product, or else ask the manufacturer to pull it off the market. Where a product, device, or practice is captured by any of the health protection legislation, Health Canada can either lay criminal charges or ask the company to cease the offending activity. Where charges are laid, Health Canada officials maintain that the process is unduly lengthy, and that the fines are inadequate to create a proper deterrence. For example, the maximum fine that can be imposed on a drug manufacturer for violations of the Food and Drugs Act is only $5,000.

The HPB is considering the introduction of a wide range of legal actions and remedies, both civil and criminal. Proposed civil actions would include provisions empowering consumers to bring civil suits against manufacturers for the violation of health protection legislation.[24] The HPB is similarly considering shaping the legislation to allow private individuals to bring enforcement actions, such as injunctions, against companies.[25] This raises the obvious issue of whether the HPB is envisioning replacing federal enforcement with civil enforcement by private parties.

In response to queries regarding whether the HPB intends to de-criminalize health protection enforcement, a senior official indicated that "[t]he allegations to the effect that we are trying to de-regulate are completely false!" This official also indicated that a

[24] *Ibid*. at 33.
[25] *Ibid*. at 33.

provision which the HPB felt certain would be added to the new legislation is one which would make it illegal for a party to manufacture, import, distribute or sell any product which might be an unreasonable health hazard, regardless of whether there were specific regulations adopted regarding that product (definitions for terms such as 'unreasonable health hazard' have not yet been determined).

The official added that "the manufacturer would be held responsible as a matter of principle, and health [sic] Canada could take enforcement action in all cases." The HPB wants to raise the maximum fines considerably, and has proposed strengthening its inspection powers. It has also proposed confiscating profits from illegal activities and recovering the cost of seizing and destroying illegal products on top of fining for the production/sale/etc. of such products.

iii) Transition Consultations

Health Canada has hosted consultations on its discussion paper.[26] Major consultations took place in September and October, 1998, in Halifax, Winnipeg, Vancouver, Ottawa, Montréal and Toronto. Participants included industry representatives, health care professionals, academics, non-governmental organizations, consumer groups, etc. These consultations were generally criticized by participants as having been organized by a rigidly pre-determined agenda, resulting in discussions not addressing some issues which participants had identified as pivotal. Although Health Canada attempted to modify its approach in response to these criticisms at the later consultations, some participants continued to find the dialogues inadequate.

The results of the consultations are currently under analysis, and are supposed to be used to help draft a formal legislative proposal of recommendations and options. This proposal is supposed to be drafted by the summer of 1999, and will be distributed for comment at that time. These comments are expected to help shape the final draft legislation, which will then be presented to Cabinet for consideration.

4) The Science Advisory Board

The federal Health Ministry established a Science Advisory Board to give independent advice on the HPB Transition Program in 1997.[27] The Board is to operate at arm's length

[26] *Ibid.*

[27] Health Canada, "Health Minister Announces Members of Science Advisory Board" (Press Release, December 9, 1997). As of January, 1999, the Chair of the Board is Roberta Lynn Bondar (OC., OOnt., MD, PhD, FRCP(C)).

from the Ministry, and to report directly to the federal Minister of Health. Its terms of reference[28] specify that it is to provide guidance overall and on specific issues regarding how to position the scientific, technical and policy aspects of the HPB during the transition and in the future. Its responsibilities are to:

a) advise on ongoing measures required to ensure HPB science retains the confidence of the public;
b) examine previous decisions to ensure the adequacy of the in-house scientific base to meet current and future scientific challenges;
c) review and advise on the scientific and technical adequacy of HPB programs, procedures, methodologies, protocols, and tests; and
d) review and advise on the adequacy and scientific basis of frameworks for proposed guidelines, standards or regulations under legislation administered by HPB:
    - recommend, as appropriate, new or revised criteria or standards for setting priorities for public health issues or programs;
    - review and advise on new information needs and on future human resource needs for scientific and technical programs;
    - provide advice on partnerships and strategic linkages with local, regional and international agencies, recognizing the particular importance of collaboration with provinces and territories; and
    - review and advise on scientific and technological trends in a global context and the issues and opportunities that are driving this change.

The Board is envisioned as surviving the HPB Transition, with an indefinite life span. Board members are appointed by the Minister of Health, and serve terms of no more than three years. The Board has no decision-making authority, nor does it have responsibility for implementing its advice. Board members are forbidden from requesting or receiving instructions from persons or organizations which are external to the Board. They also must

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Members are: R. Douglas Elliott (BA, LB), R.A. Graham (BA, CChem, MCIC), Jean McEachran Jones (CM, LLD, MSW), Mohamed A. Karmali (MB, ChB, MRCP(UK), FRCP(Glasg.), FRCP(C)), Nuala Patricia Kenny (SC, BA, MD, FRCPC, LLD(Hon)), Wilbert Joseph Keon (MD, FRCSC), Fernand Labrie (OC., OQ., MD, PhD, FRCPC, FRSC), Lynn McIntyre (MD, MHSc, FRCPC (Community Medicine)),John S. Millar (BSc, MHSc, MD, FRCP(C)), Leslie Millin (BA, CMS(Oxon.)), Yves Morin (OC, OQ, ONM, MD, FRCP(C)), Gabriel L. Plaa (PhD), Ellis Rubinstein (BA), Bernard Schwetz (DMV, PhD), and Karen M. Semchuk (PhD). Ex Officio Members are Henry G. Friesen (MD, FRCP(C), FRSC, OC); Michèle S. Jean (BA, MEd, MA); and Joseph Z. Losos (MD, DECH, FRCP(C), FACPM).

[28] Health Canada, "Terms of Reference: Science Advisory Board" (Health Canada at http://www.hc-sc.gc.ca/hpb/transitn/science/index.html).

disclose any real or perceived conflicts of interest which could arise or do arise as a part of the Board's deliberations.

It is interesting to note that although the five core transition areas all propose shifts which would have the HPB actively incorporate approaches and concepts of health which are more holistic and use understandings derived from e.g., social science research, such as health determinants, this focus does not surface in the responsibilities of the Science Advisory Board. However, the Board is mandated to include "a body of independent scientists, health professionals, consumer advocates, business people and social scientists,"[29] and the membership list does include individuals with backgrounds in such areas as social work. As discussed below, it is evident from their meeting reports that the Board members are indeed approaching health from a multi-factorial perspective.

The Board has had four meetings, all in 1998, and has scheduled six bi-monthly meetings for 1999, starting in late January. Summary reports of recommendations and observations from past meetings have been published and are available on-line.[30] A cursory examination of these reports indicates that they are providing highly qualitative feedback to the HPB, and are quite aware of the danger of economic tensions distorting decisions about health protection.

These reports also indicate that the Board has recently responded to the first draft of a new HPB transition document, tentatively titled: "Health Protection Program: Visions for the 21st Century."[31] This document describes a new vision and mission statement for the HPB. At each meeting, the Board hears reports from one or more core area team leaders on their current activities, and responds with recommendations and critiques. Although the Science Board meeting reports consist primarily of summarized responses, they may still prove a valuable resource for outsiders who are interested in knowing about the internal activities of the HPB, and/or want a sense of what sort of feedback the Minister is getting from his official 'arm's-length' advisory body.

5) Public Involvement/Consultations

The HPB Transition Program established the Working Group for Public Involvement in May, 1997. Its members are all Health Canada staff members, mostly from within the

[29] *Ibid.*

[30] See the web cite at http://www.hc-sc.gc.ca/hpb/transitn/science/index.html.

[31] This document is not yet publicly available, as it is at a very preliminary stage.

HPB.[32] The Working Group's mandate extends beyond the Transition Program, as it will continue to operate as a government-public conduit for HPB activities in the future. This working group organized the public consultations described above regarding the Surveillance Core and the Legislative Renewal.

The Working Group's goal is to develop a framework for public involvement and input into HPB programs and initiatives. The Working Group had a draft framework which it brought to the Legislative Renewal consultations, and so at that time also gathered feedback for how to create a more effective system for dialogue. The Working Group has revised its framework, but is not yet able to release it to the public.

The Working Group has established a Public Resource Network, composed of representatives from stakeholder groups and members of the public. The Working Group uses this Network for quick consultations and feedback on issues as they arise.

6) Commentary

The proposals which have been made regarding the HPB Transition Program involve major legislative and policy shifts. They are wide-ranging, but loosely follow proposed sets of guiding principles or objectives which sometimes appear to be in conflict with one another. Some proposals are presented or described as essentially 'done deals', such as the creation of a 'Health Protection Act' and the formal partnering of the HPB with university and private researchers. Others are presented as mere queries put forward for public input and responses, such as introducing powers for private citizens to press suits against companies for the violation of health protection legislation. The lack of clarity as to envisioned results of the transition, and the rather common invocation of economic restraints and cost-effectiveness makes it extremely difficult to evaluate the seriousness of the proposals. This forces one to respond to each proposal as though the HPB intends to enact it as legislation.

Health Canada participants in the HPB Transition Program are extremely aware of the potential for compromise due to the heightened reliance on industry which appears to have already occurred on in the HPB on a *de facto* basis. Their awareness and concern is reflected in such activities as striking Working Groups on Conflict of Interest, and on Partnerships and Alliances. These groups will propose standardized guidelines and

[32] See Appendix One for a list of Working Group members.

safeguards, but issues of enforcement, economic pressure and industry pressure for fast results will presumably continue to stress the activities of the HPB.

<u>Appendix One</u> – Working Group for Public Involvement. Membership List as of January 1, 1999.

Mary Hegan Project Manager
HPB Transition

Anna Gravell
Public Involvement

Francine Archambault
Information & Education Program

Leslie Buchanan Jones
HPB Communications

Mary Bush
Foods Directorate

Stephanie Charron
HPB Ontario Regional Office
Educational Services

Ria Demos
Environmental Health Directorate

Karen Dodds
Foods Directorate

Marion Law
Therapeutic Products Programme

Mary Jane Lipkin
Health Promotion and Programs Branch

Tony Myres
Environmental Health Directorate

Anji Nahas
Risk Management Framework

Wendy Shatner
Bureau of Strategic Planning

Bruce Smith
Policy Planning and Coordination
Branch Directorate

Greg Smith
HPB, Western Region

Wendy Warren
Human Resources

Stephen Waxman
Legislative Renewal

<u>Ex-officio Members</u>

Francine Archambault
Information & Education Program

Rod Raphael
Director General
Environmental Health Directorate

Patricia Younger
Financial Services

The Women's Health Bureau

1) Introduction

The Women's Health Bureau was established in 1993 by the Federal government as a division of Health Canada.[33] The Bureau has a four-pronged mandate. It is to:

- promote an understanding of gender as a critical variable in health;
- analyze and assess the impact of policies, programs and practices in the health system – broadly defined – on women and women's health;
- ensure that women's health concerns receive appropriate attention and emphasis within Health Canada; and
- maintain an ongoing relationship with major health and women's organizations.

The Bureau is not intended to be a separate 'program' of Health Canada. Rather, it is primarily to act in co-ordination with other divisions within the Department of Health, to ensure that the programs and policies they develop properly address women's health issues. Health Canada writes that:

> Ultimately, the activities of the Women's Health Bureau are intended to enhance the responsiveness of the Canadian health system generally to the health needs and concerns of women, in keeping with the Beijing Platform for Action and the Federal Plan for Women's Equality.[34]

It thus has a very strong long-term policy-development orientation. This agenda is difficult for the Bureau to achieve, due to structural issues such as being under-staffed (they currently have only two policy analysts), and often experiencing difficulty in locating adequately trained individuals to hire as contract-researchers (they often need people with strong feminist analytic skills who are capable of qualitative and quantitative social science research as well as skills in, e.g. epidemiology). The Bureau also finds that it is unable to pursue all of the areas which it has identified as in need of their input. For example, by late fall, the WHB had not yet been able to spare one of their two analysts long enough for them to give much input into the Canadian Biotechnology Strategy. Although one analyst is

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[33] Information for this section was obtained through Health Canada press releases, publications and web sites, as well as from literature distributed by the various Centres of Excellence in Women's Health. It also draws heavily from conversations and email exchanges with individuals from the Women's Health Bureau and the Canadian Women's Health Network.

[34] Health Canada, "Women's Health Bureau: Roles and Responsibilities" (statement released April 8, 1998, at www.hc-sc.gc.ca/pcb/whb).

working hard at providing input into the Health Protection Branch Transition program, this work is juggled with numerous other pressing projects, such as pushing for the explicit inclusion of the needs of girls in "children's" health initiatives. Nonetheless, the Bureau is centrally involved in Health Canada's development of its Women's Health Strategy.

2) Health Canada's "Women's Health Strategy"

The Women's Health Bureau both heads the development of the 'Women's Health Strategy' and co-ordinates its implementation. The Strategy has four central 'umbrella' objectives. They are to:

- ensure that Health Canada policies and programs are responsive to sex and gender differences and to women's health needs;
- increase knowledge and understanding of women's health and women's health needs;
- support the provision of effective health services to women; and
- promote good health through preventative measures and the reduction of risk factors that most imperil the health of women.[35]

Health Canada, through the WHB, is currently formally engaged in several initiatives which respond to these objectives. Current initiatives include:

a) *Applying a department-wide gender-based analysis process to new activities and policies in the areas of health system modernization, population health, risk management, direct services, and research;*

b) *The development of tools and methodologies to implement gender-based analysis;*

c) *Producing a 'Status Report on the Health of Canadian Women' which uses a health determinants approach;*

d) *Monitoring and assessing the impact of the health reform process on women's health;*

e) *Implementing joint Canada-USA initiatives in women's health; and*

f) *Developing a women's health research agenda to help co-ordinate policy-setting among federally-funded research programs.*

3) Information on the "Women's Health Strategy" Initiatives

a) Applying a department-wide gender-based analysis process to new activities and policies

The Women's Health Bureau has retained Margrit Eichler to assist them in applying a department-wide gender-based analysis process to new activities and policies in the areas of

[35] *Ibid.*

health system modernization, population health, risk management, direct services, and research. The WHB has conducted one trial workshop of 25 members of Health Canada, intended to teach the participants the meaning and relevance of performing gender-based analysis. This workshop has received extremely high evaluations by the participants, many of whom expressed surprise at how relevant they now found gender to be! The WHB is still determining how to move from this trial workshop to a systematic plan whereby the entire department will undergo such workshops, and what shape follow-up activities should take.

b) Developing tools and methodologies to implement gender-based analysis

This project is being undertaken in conjunction with the Gender-Equity Lens project of the Maritime Centre of Excellence for Women's Health (MCEWH). This project is aimed at developing tools for policy makers and politicians to use when formulating and evaluating health policy. The tools are being designed to show how health policies affect women and men differently, so that policy can be developed which does not disadvantage women. The project also entails the development of an educational framework and training material to teach effective gender analysis techniques to policy makers and politicians. The WHB intends to use their findings to help re-orient Health Canada's practices.

c) Producing a 'Status Report on the Health of Canadian Women' which uses a health determinants approach

This strategy has not yet begun by Christmas, 1998, mostly due to difficulty in finding a qualified consultant who could bring together medical expertise with quantitative methodology skills, excellent communication skills and strong feminist analysis. It appears that a qualified individual has been located, but the contract details are still not finalized. Once the project begins, the WHB expects that the report should take slightly more than one year to be completed.

d) Monitoring and assessing the impact of the health reform process on women's health

The most significant activity reported for this initiative was associated with Pat Armstrong's[36] private research on the context for health care reform as well as with a committee chaired by Pat Armstrong. This committee is the Cross Centre[37] Committee on Women and Health Care Reform. This committee co-ordinates health reform-related research performed at the various Centres. In particular, it has organized regional scans on

[36] Dr. Pat Armstrong is the Director of Canadian Studies at Carleton University.

[37] "Centre" refers to the five Centres for Excellence in Women's Health, described below.

health reform and privatization. These scans are to gather information on such topics as cost-shifting, location of services, responsibility for and monitoring of services, etc. These scans will be used during a workshop on March 26-7, 1999, to develop templates for identifying policy issues, service gaps, etc. These templates are expected to be flexible and so be able to easily incorporate new information as the health care reform situation in Canada continues to change. Representatives from the WHB also stressed that they are called on for day-to-day consultations across the entire department *vis-a-vis* reform.

e) Implementing joint Canada-USA initiatives in women's health

Health Canada, and the United States Department of Health and Human Services, signed a U.S.- Canada Program of Cooperation Agreement on August 10, 1996, at the end of the first "Canada-U.S.A. Women's Health Forum". The Agreement was undertaken as "an expression of good will" and so is not a legally binding instrument.

The Agreement is supposed to affirm the commitments of Canada and the United States to giving active support for women's health, particularly as expressed in the Fourth World Conference on Women in Beijing (1995) and the International Conference on Population and Development held in Cairo (1994).[38] The agreement is aimed at facilitating collaborative work through joint initiatives and ongoing information exchange between the two countries.

The agreement stipulated that four 'core groups' would be established as the first joint initiatives.[39] These core groups are in the areas of:

- breast cancer;
- smoking cessation and tobacco use prevention (focused on girls, adolescents and young women);
- research (including clinical trials); and
- information networking (formalize the connections between Health Canada and the United States Department of Health and Human Services, as well as national and local organizations such as the Canadian Women's Health Network and the National Women's Health Information Centre in the U.S.).

[38] Health Canada and The United States Department of Health and Human Services, "Program of Co-operation on Women's Health" (signed August 10, 1996, Ottawa).

[39] As of November 13, 1998, no other core groups had been established.

These four core groups have not yet been established, although their timelines had assumed major activity would be underway by 1997. Their establishment awaits the finalization of the proceedings from the Canada-U.S.A. Forum. Although the proceedings themselves are complete, the Women's Health Bureau is still in the process of working through logistical details with the Office of Women's Health in Washington, D.C. They expect to be back on track in early 1999.

f) Developing a women's health research agenda to help co-ordinate policy-setting among federally-funded research programs.

These programs include the Centres of Excellence for Women's Health and the Canadian Women's Health Network.

i) Centres of Excellence for Women's Health (CEWH)

In June of 1996, the Health Minister announced the five successful candidates for federal funding as centres under the CEWH Program. The centres are not to conduct biomedical or clinical research. Rather, they are to approach health from a multi-determinants approach, which situates health as including social, cultural, political and economic factors. To qualify, each centre had to propose a broad multi-disciplinary mandate which included:

- collecting and analyzing health information and data;
- conducting research on key women's health issues;
- providing policy advice to governments and health organizations;
- generating and communicating information to a wide range of audiences; and
- building networks of individuals and groups involved in women's health locally, nationally and internationally.[40]

The centres are to operate as partnerships among academics, community-based organizations and policy-makers. The centres all have a six year life-span (1996-2002), and, on average, will each receive two million dollars in funding over that life-span.

The five centres are:

1) The B.C. Centre of Excellence for Women's Health.

This centre has three main research themes. Each of these themes are pursued in conjunction with a theme committee. The themes are: health status and health determinants (redefining and documenting women's physical and mental well-being and the range of factors affecting women's health); healthy women in healthy communities (examining and

[40] Health Canada, Press Release, June 25, 1996 "Successful Candidates for Centres of Excellence for Women's Health Announced."

developing the interaction between women and their communities and the resulting impact on health); and developing women-centered care (examining and developing the interaction between women and the health care system). This centre has chosen to focus its policy agenda on developments which will improve the health status of women who are marginalized and face multiple disadvantages in health due to socioeconomic status, race, culture, sexual orientation, geography, disability and/or addiction.[41]

2) Prairie Women's Health Centre of Excellence.

This centre has organized its research around five themes. The work in each theme area is over-seen by a Theme Advisory Group, which acts to co-ordinate activity both within the centre and with the wider community. The themes are: gender analysis and determinants of health within a population health model (mapping gender differences in health services utilization); consumer input and control relative to health policy (case study); the impact of social support on health; the effects of health reform on women (comparative research between provinces); and evaluating gender-specific health services programming.[42]

3) National Network on Environments and Women's Health.

Research at this centre focuses on the impact of three key environments on women's health. These environments are: workplaces (including women's paid and unpaid work, unemployment, labour adjustment and the impact of restructuring); health systems (including traditional and non-traditional forms of health care, formal and informal practices, and women's understanding of health and risks to their health); and policy (including social, economic and health policies that affect women's well-being and access to services)[43].

4) Le Centre d'excellence pour la santé des femmes.

This centre's research agenda targets two themes. They are: the development of strategies to improve the health of immigrant and Native women (identifying problem areas, cultural perceptions and expectations, special needs, access barriers, post-immigration trauma, etc.); and to develop strategies to assist women in their role as informal caregivers by

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41 Health Canada, "Centres of Excellence for Women's Health - Update, Summer 1997" at 3.

42 Health Canada, "Centres of Excellence for Women's Health - Update, Summer 1997" at 4-5.

43 *Ibid*. at at 5-6; NNEWH Brochure "National Network on Environments and Women's Health: A Centre of Excellence for Research in Women's Health" (Toronto: York University, 1997).

identifying key areas of need and change (e.g. knowledge transfer from formal to informal caregivers).[44]

5) Maritime Centre of Excellence for Women's Health.

This centre has developed its research agenda as having three themes which cut across all their research projects. These themes are: the meaning of health from women's perspectives; the determinants of health; and the dimensions of women's health status. The centre's research will focus on investigating the determinants of women's health for their entire life span, and the determinants in the context of marginalized women living in poverty.[45] Their main mandate is "to provide analysis, advice and information on key women's health issues to government and health organizations on a solicited or unsolicited basis *and* to contribute to the refinement of a Women's Health Framework and a women's health research agenda for Canada."

ii) Canadian Women's Health Network

The Women's Health Bureau is also providing some funding to the Canadian Women's Health Network (CWHN) as a part of the Centres for Excellence in Women's Health (CEWH) Program (two million dollars over six years). However, these funds do not cover all of the CWHN's costs, so CWHN must also seek outside resources and depends heavily on volunteers.

The CWHN was launched in 1993 by women representing over 70 Canadian organizations which shared the central concern of improving women's health. It is now a broad network of individuals, groups, organizations and institutions, and includes health care workers, educators, advocates, consumers, and others committed to sharing information, resources and strategies for bettering women's health.

The CWHN's objectives include:[46]

- providing easier access to health information, resources and research;
- producing user-friendly materials and resources;
- promoting and developing linkages to information and action networks;
- providing forums for critical debates;

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[44] *Supra* note 42 at 7-8.
[45] *Ibid.* at 8-9.
[46] Canadian Women's Health Network Home page, www.hc-sc.gc.ca/pcb/whb.

- acting as a ‘watchdog’ on emerging issues and trends which may affect women’s health;
- working to change inequitable health policies and practices;
- advocating for community-based participatory research models; and
- promoting women’s involvement in health research.

The CWHN complements the CEWH Program by providing a location for its research dissemination, and assisting in information-sharing and networking with interested parties across Canada.

4) Commentary

The Women’s Health Bureau is a central player in the re-shaping of Canada’s health care program into a program which can begin to better serve the interests and needs of Canadian women. Given the tenacious ideologies which have shaped the existing structure and practices, this is a formidable task. The WHB has chosen to draw heavily upon and support the development of external resources, such as the Canadian Women’s Health Network. Despite this strategic approach, the WHB is clearly having difficulties keeping up with its mandate due to structural issues such as having been allocated insufficient staff resources. This shortage is particularly apparent in the tension members of the WHB express at having to let proactive projects slide due to the need to respond immediately to daily ‘crisis’ issues and the activities of other groups within Health Canada.

PART III. BIOTECHNOLOGY INITIATIVES

The Canadian Biotechnology Strategy

1) Introduction to Biotechnology

Industry Canada uses the term 'biotechnology' as an umbrella label to describe an extensive spectrum of scientific applications. It defines biotechnology as an 'enabling technology' which makes use of living organisms, or parts of living organisms, to provide new methods of production or make new products.[47] Older forms of biotechnology, by this definition, would include using living bacteria and fungi to make cheese, or live yeast to make bread. Newer forms of biotechnology are discussed in other parts of this report, such as implanting genes from one plant or animal into another sort of organism.

2) The Predecessor to the 1998 Canadian Biotechnology Strategy

The federal government approved the framework for a National Biotechnology Strategy in 1983.[48] The four central objectives of the strategy were to:

1) strategically focus biotechnology research and development;
2) ensure an adequate supply of individuals qualified to work in biotechnology;
3) encourage communication and collaboration between researchers in different sectors; and
4) create a climate which would encourage industry to invest in biotechnology.

Central to this framework was the creation of a National Biotechnology Advisory Committee (NBAC), which advised the Minister of Industry, as well as an Interdepartmental Committee on Biotechnology (ICB) which was to coordinate the activities of various governmental departments.[49] The NBAC membership was entirely from Industry, and it's mandate was to focus on science and scientific developments. Their mandate did not formally include a focus on the commercialization of biotechnology, nor did it include a consideration of public issues raised by biotechnological research.

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[47] Industry Canada, The 1998 Canadian Biotechnology Strategy: An Ongoing Renewal Process (Ottawa: Distribution Services, 1998) (released November 17, 1998) at 2.

[48] See summary report on the 1983 National Biotechnology Strategy at: http://strategis.ic.gc.ca/SSG/bh00194e.html. See also National Biotechnology Advisory Committee, Sixth Report "Leading into the Next Millennium" (Ottawa: Industry Canada, 1998) [hereinafter "Sixth Report"].

[49] See "Sixth Report" at 70.

The NBAC was asked in 1997 to prepare a report which placed Canada in terms of international biotechnology competition, and which also reflected on the structure of the committee itself. Their report, the "Sixth Report", identified a number of recommendations. It prioritized three:

- the Canadian government must actively 'champion' biotechnology;
- the Canadian government must attract qualified individuals; and
- the Canadian government must develop competitive policies on intellectual property and regulatory approvals.

The "Sixth Report" cautioned that these developments required input from a different sort of advisory committee. They advised that a new committee ought to be formed which could effectively speak to public interest issues and which could accommodate socio-ethical debate.

3) The 1998 Canadian Biotechnology Strategy

The renewed Canadian Biotechnology Strategy (CBS) was announced on August 6, 1998.[50] The new strategy took approximately 15 months to be developed. It started with the establishment of a CBS Task Force to co-ordinate the renewal efforts of the departments of Industry, Health, Environment, Agriculture and Agri-Food (and the Canadian Food Inspection Agency), Natural Resources, Fisheries and Oceans, and Foreign Affairs and International Trade.[51] The CBS Task force used the "Sixth Report" (described above), a number of other commissioned research reports, and input from federal, provincial and industry representatives to write a series of consultation documents. These consultation documents were used to gather responses and input from a series of "broad-based stakeholder consultations" across Canada from March to May of 1998.[52] The "vision statement" for the CBS remained unchanged from the initial consultation document to the update report released on November 17, 1998. It is:

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[50] Industry Canada has developed an extensive web site on the Canadian Biotechnology Strategy. Most of the data in this section is either from the web site or from conversations and email exchanges with individuals at Industry Canada who are involved in the CBS. The home web site is located at: http://strategis.ic.gc.ca/SSG/bh00127e.html.

[51] Industry Canada, The 1998 Canadian Biotechnology Strategy: An Ongoing Renewal Process (Ottawa: Distribution Services, 1998) (released November 17, 1998) at 3. Fifteen other federal departments and agencies also participated, but have not been isolated as central to the CBS's activities.

[52] *Ibid.* at 3.

> To enhance the quality of life of Canadians in terms of health, safety, the environment, and social and economic development by positioning Canada as a responsible world leader in biotechnology.[53]

The strategy's "guiding principles" also remained unchanged from those proposed in the consultations documents. The guiding principles centre on:

> ...reflecting Canadian values; engaging Canadians in open, ongoing, transparent dialogue; promoting sustainable development, competitiveness, public health, scientific excellence and an innovative economy; and ensuring responsible action and cooperation domestically and internationally.[54]

The strategy also has ten "themes for concerted action", compiled out of proposals gathered during the consultation process. These themes include: regulation to protect public health; biotechnology for public health advantage; and technology commercialization. Rather than write an extensive list of the themes and the manner in which the CBS has tentatively proposed to act on them, a copy of their summary on these issues is attached to this report (see Appendix One). The Department of Industry, as the head of CBS, will decide which of these themes should be immediate priorities, and shortly begin actions to implement those themes. The CBS intends to create a concrete implementation plan for each of the theme areas.[55]

The strategy's objectives also include positioning Canada "as an ethically and socially responsible world leader in the development, commercialization, sale and use of biotechnology products and services". These objectives clearly reflect the fact that more than 90% of the advanced biotechnology products on the world market are related to health, and that 59% of the firms in Canada which are worth three billion dollars or more are in the health industry.[56]

4) Biotechnology Ministerial Coordinating Committee (BMCC)

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[53] *Ibid.* at 8.
[54] *Ibid* at 8.
[55] *Ibid*. at 11, 14-17.
[56] CBS Renewal Factsheet: Research and Development in Biotechnology, at http://strategis.ic.gc.ca/SSG/bh00231e.html.

The strategy will be implemented through the newly created Biotechnology Ministerial Coordinating Committee (BMCC)[57]. The BMCC is to oversee all CBS activities and address issues which touch the mandates of different federal departments. The BMCC will be composed of the federal ministers of Industry, Agriculture and Agri-Food, Health, Environment, Fisheries and Oceans, Natural Resources, and International Trade, though it will be chaired by Industry.

5) The Canadian Biotechnology Advisory Committee (CBAC)

Following the advice of the NBAC, part of the renewed strategy includes the creation of the Canadian Biotechnology Advisory Committee (CBAC). The CBAC will advise to the BMCC. This 12 to 20 member committee is supposed to operate as "an expert, arm's length panel to advise ministers on biotechnological issues, raise public awareness and engage Canadians in discussions on biotechnological matters."[58] Although it will advise on ethical, social, regulatory, economic, scientific, environmental and health aspects of biotechnological practices and policies, the CBAC will not have the authority to arbitrate or control regulatory decisions.[59]

The CBAC is in the process of being formed.[60] The CBS Task force has compiled a list of potential members of the Nomination Panel from staff within the seven key departments. The Panel will have a Chair and two members, and the Chair will serve both as the Chair for the Nomination Panel as well as the Chair for the Advisory Committee. The Ministers of the various departments involved are to make a joint decision on the selection of these three individuals. A short list of potential Chairs was given to the Minister of Industry in mid-December, 1998. As of the end of January, the selection had not yet been made, although it is hoped that the Chair will be named in mid to late February. Once these individuals have been selected, the Panel will determine how to accept nominations, and develop selection criteria. The nomination period is expected to last for approximately six to eight weeks. The Panel is expected to submit approximately 30 names to the 7 Ministers who are members of the BMCC. The Ministers will then decide who will be on the CBAC. It is hoped that the first CBAC meeting will take place in late spring or early summer.

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[57] CBS Renewal Factsheet: Canadian Biotechnology Advisory Committee, at http://strategis.ic.gc.ca/SSG/bh00230e.html.

[58] *Supra* note 51 at 7.

[59] *Ibid.* at 8.

[60] Personal Communication, January 29, 1999.

The CBS does not want committee members to be selected based solely on being 'representatives' of interest groups. Instead, they are to be appointed primarily "on the basis of individual merit."[61] Nonetheless, there are three general categories of committee members which the CBS expects the Nomination panel to use as a general basis for guiding their recommendations. The CBS hopes that the panel will find a balanced distribution between:

> 1) individuals with an *academic background* - they hope to locate persons with experience/ appointments in both science and ethics.
> 2) representatives from *industry* - they want individuals who have a "statesman-like" approach to biotechnology, and do not feel a "rabid devotion" to their cause.
> 3) individuals from *"civil society"* - they hope to attract individuals who can bring "an ethical voice", and may also have affiliations with organizations concerned with consumers, health, the environment, labour, etc.

There is also discussion of trying to locate two individuals who will be "lay persons".

The Advisory Committee is also empowered to create ad hoc working groups as necessary. These working groups may include representatives from specific interest groups, private individuals with relevant concerns, as well as individuals with relevant expert knowledge.

6) Current Federal Regulatory System for Biotechnology

In the Federal government, legislative responsibility for health and environmental assessment of biotechnology products is divided between Environment Canada, Health Canada, the Canadian Food Inspection Agency, and the Department of Fisheries and Oceans. Table 1 shows which regulations apply to various sorts of biotechnological products.

Table 1: Legislative Responsibility for Biotechnology[62]

Products regulated	**Federal Body**	**Act**	**Regulations**
Products for uses not covered under other federal legislation	Environment Canada, Health Canada	Canadian Environmental Protection Act[63]	New Substances Notification Regulations

[61] *Supra* note 51 at 8.

[62] This table is a modified version of the table found published within: "CBS Renewal Factsheet: The Federal Regulatory System," at http://strategis.ic.gc.ca/SSG/bh00232e.html.

[63] R.S.C. 1985, c.16 (4th Session) (Unofficial Chapter No. C-15.3).

Drugs, cosmetics, medical devices, and foods	Health Canada	Food and Drugs Act[64]	Food and Drug Regulations, Medical Devices Regulations, Cosmetic Regulations
Fertilizer supplements, including novel microbial supplements	Canadian Food Inspection Agency	Fertilizers Act[65]	Fertilizers Regulations
Plants, including plants with novel traits and forest trees	Canadian Food Inspection Agency	Seeds Act[66]	Seeds Regulations
Veterinary biologics	Canadian Food Inspection Agency	Health of Animals Act[67]	Health of Animals Regulations
Pest control products	Health Canada	Pest Control Products Act[68]	Pest Control Products Regulations
Aquatic organisms (under development)	Fisheries and Oceans	Fisheries Act[69]	Fisheries Regulations

The Canadian Environmental Protection Act is intended to serve as a legislative gap-filler. It indicates that if a biotechnological product is not assessed for health and environmental impact under any other act, that Environment Canada and Health Canada have the authority to undertake these assessments. Health Canada also has authority, under the Food and Drugs Act, for the assessment and control of the nutrition, quality and safety of food, and the safety and effectiveness of human drugs and medical devices. This authority applies to any biotechnological products and processes associated with these areas of jurisdiction. The Canadian Food Inspection Agency, and its current responsibilities for regulating the agricultural products of biotechnology, are discussed in a separate section of this report.

7) Sector Consultation Documents

The Canadian Biotechnology Strategy released proposed approaches for each of the seven key federal departments as 'Sector Consultation Documents' in March of 1998. These documents are quite extensive. The CBS has not yet released similarly comprehensive revised sector strategies following the consultation process, but rather only six 'Sector

64 R.S.C. 1985, F-27.
65 R.S.C. 1985, F-10.
66 R.S.C. 1985, S-8.
67 S.C. 1990, c.21 (Unofficial Chapter No. H-3.3).
68 R.S.C. 1985, P-9.
69 R.S.C. 1985, F-14.

Overview' statements.[70] The new sector approaches are still under development. The CBS does not expect to be able to release any more specific or detailed information until other preliminary work has been completed (e.g. activating the Canadian Biotechnology Advisory Committee, determining which 'themes' for action will be prioritized, etc.).

Below are summaries of the CBS Sector Overviews of health and health industries, agriculture and agri-food, and environment and the environmental industries.[71]

a) Sector Overview of Health and Health Industries

Much of the CBS's discussion of this sector describes the benefits of biotechnology to Canadian health and health care, as well as the already realized expertise of Canadian companies in the biotechnologically assisted health industry. For example:

> Biotechnology ... is used for disease surveillance, diagnosis, treatment and prevention. It permits the identification of disease agents where conventional means do not succeed, allows better tracking of pathogens, facilitates earlier detection, and provides therapeutic products and processes... In bio-pharmaceuticals, Canada has significant strengths in molecular biology, cancer treatments, neuro-degenerative diseases, bone disease and viral infections...[72]

It also refers to the potential for increasing the revenues of such companies and the accompanying growth in the economy and in opening employment possibilities.

The Sector Overview identifies key challenges which the Sector Strategy must be able to address for the optimal commercialization of this industry. They include:

- developing a regulatory system which is sufficiently flexible as to keep pace with product growth and development;
- maintaining strong 'basic science' funding;
- improving technology transfer (e.g. from public non-profit researchers into the private sphere) and the commercialization of research;

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[70] Although there was a Sector Consultation Document for Industry, the CBS has not released a 'Sector Overview' of its revised approach to Industry.

[71] I have not included summaries of the overviews for aqua-culture, forestry, and mining and energy.

[72] *Supra* note 51 at 18.

- making start-up capital available for new biotechnology companies;
- improving access to international markets; and
- improving access to provincial markets by addressing provincial differences in drug-listing strategies, pricing formulas, and general requirements.

The CBS included in its 'Health and Health Industries Sector Overview' a comment that industry and the science community are aware of the socio-ethical considerations raised by biotechnology, and that these "are already addressed in their day-to-day work."[73] Such a comment may suggest that although the CBS will itself have an ethical Advisory Committee, that the desired flexible regulatory system may be somewhat self-regulating by industry.

b) Sector Overview of Agriculture and Agri-Food

The CBS describes agriculture and agri-food as accounting for 8% of Canada's GNP, with global sales of biotechnologically-engineered agricultural products of over $5 billion. Much of the overview describes the benefits of planting crops with novel traits, and gives examples of recent biotechnological advances.[74] For instance, using enzymes to remove lactose from milk products for lactose-intolerant consumers, and using genetic engineering to introduce insect-resistant traits to crops so farmers need use fewer chemical pesticides (see the section on "Labeling of Novel Foods Derived Through Genetic Engineering" for a more detailed discussion of this area).

The overview isolates several challenges to success in this area.[75] The three primary issues are:

- building public confidence in biotechnological agricultural and agri-food products;
- meeting private sector commercialization needs; and
- ensuring access to foreign markets.

<u>i) building public confidence in biotechnological agricultural and agri-food products</u>

The overview proposes that public confidence requires meeting the public's information needs. Although the overview states that these needs have not yet been determined, it does assume that clear and timely information must be made available on enforcement activities, regulations, etc.

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[73] *Ibid.* at 18.
[74] *Ibid.* at 19.
[75] *Ibid.*

ii) meeting private sector commercialization needs

Regarding private commercialization needs, the overview indicates that Canada must foster relationships between the research community (i.e. publicly funded university-based researchers) and the private sector, and identify priority areas for commercialization. This challenge is contextualized by the global race to sequence the genomes of commercially valuable crop species, and then patent inventions based on using the genomic information[76] (see the section on "Intellectual Property Activities" for a more detailed discussion). The clear fear is that another state's nationals will patent the genetic information first, requiring all subsequent users of that information to pay a user-fee for the lifetime of the patent. Canada is not taking the position that such genetic information should not be owned, but rather that it wants the profits to belong to Canadian industry and/or for Canadian industry to not be forced to pay other state's companies for the right to use the patented genetic information.

iii) ensuring access to foreign markets

The recognized challenge in accessing foreign markets is the absence of internationally harmonized standards.[77] However, the overview notes that Canada is involved in several international fora which work to facilitate global market activity, including the harmonization of biotechnology standards.

c) Environment and the Environment Industries Overview

The CBS sees the 'environment industry' as a major growth area, due to increasing demands for biotechnological products which allow for efficient waste detoxification processes, the biological monitoring of pollutants, the ecological restoration of poisoned areas, cleaner burning fuels, etc. The CBS notes that:

> Major Canadian strengths include our technical expertise in specific and broad-based bio-remediation (the biological clean-up of effluents) involving soil and waste-water treatment applications...[78]

The primary challenges which the CBS sees to the successful commercial 'renewal' of this industry are as follows:

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[76] *Ibid.*

[77] *Ibid.*

[78] *Ibid.* at 20.

- the sector must shift from being an area where the participants work on individual un-coordinated projects, without strategic alliances and partnerships between companies and with "limited integration into the broader Canadian environmental industry;"[79]
- the sector needs better public acceptance and support; and
- the government must respond to industry's demand for a more predictable and transparent regulatory process which more clearly demarcates between the responsibilities of the federal, provincial and municipal governments.

8) Commentary

It is extremely difficult to separate the rhetoric of the CBS from its probable impact on the lives of Canadian women. On the one hand, the CBS has explicitly recognized a need for biotechnological activities to be scrutinized for their socio-ethical implications, and for them to be analyzed in terms of public policy and public interest issues. The CBS consistently speaks to the importance of developing the industry in a fashion which is socially and ethically responsible.

On the other hand, it is not clear where the CBS would draw a line in the sand. That is, it is not entirely clear how they would balance lucrative economic benefits with ethical ramifications. Although the CBS speaks to pursing development in an ethical fashion, it never actually describes any guiding set of ethical principles. It may be that such principles will be developed by the Advisory Committee as a part of its mandate. However, that committee only has the power to make non-binding recommendations, and clearly any principles they put forward will be suggested *after* the groundwork for the CBS has already been established.

This is particularly ominous given that the CBS has articulated the position that industry already incorporates 'the relevant socio-ethical considerations' into its every-day decisions about biotechnological projects, suggesting a self-regulating approach. However, the CBS has identified building public confidence in biotechnology as an important element of its agenda for sector development. Presumably, such a goal is not attainable unless the public feels that the players are being accountable and responsible in their activities, and are pursuing them in a fashion which the public finds respecting and respectable.

[79] *Ibid.* at 20.

Appendix One – A Reproduction of "Annex A: Ten Key Themes in the CBS Workplan" (from The 1998 Canadian Biotechnology Strategy: An Ongoing Renewal Process (Ottawa: Distribution Services, 1998) at 14-17).

1. Building public confidence and awareness, and communicating accurate, balanced, easy-to understand information to Canadians

Public opinion surveys and focus group tests suggest that, relative to people in other industrialized countries, Canadians have a comparatively high level of interest in and acceptance of biotechnology. However, Canadians' detailed knowledge of biotechnology is limited. Most important, the public wants assurance that biotechnology products and services are safe for humans, animals and the environment.

Consultation participants stressed:

- using credible sources such as government, health care professionals, scientists, educators and NGOs to convey information;
- recognizing the difficulties of conveying science-based information in a thoughtful, understandable manner to reduce the potential for misinformation;
- increasing the visibility of regulatory processes, providing support for the communication of regulatory matters, including risks and benefits, to the public to "de-mystify" regulatory operations, and better explaining of how they function and protect the public interest; and
- explaining more proactively the issues surrounding food labeling and Canada's current policy.

Possible actions:

- work with public and private sector partners to coordinate and enhance respective information and public education functions;
- develop a comprehensive, coordinated communications strategy to inform Canadians about the regulatory system and other biotechnology-related activity;
- articulate and promote the CBS vision in Canada and abroad;
- encourage biotechnology companies and/or industry associations to work with customers and stake-holders to develop voluntary codes of practice for use in Canada and abroad;
- promote research in and awareness of the ethical, legal and social issues associated with biotechnology; and
- celebrate Canadian achievements in biotechnology science and commercial applications.

2. Further expanding Canada's research and development and science base to support Canadian competitiveness in biotechnology as well as the regulatory system

Canada undertakes 3-4 percent of the world's R&D, based on patents and publications. However, a recent citation index review (1992-97) by the National Research Council showed that Canadians have strong citation ratings of 6

percent or more in many biotechnology-related fields. Consistent with this, biotechnology accounts for almost 10 percent of overall Canadian expenditures on R&D. These strengths have not gone unnoticed internationally. Several American and European organizations have located in Canada to take advantage of our excellent research base and infrastructure. This theme is designed to build and capitalize on these strengths.

Possible actions:

- identify key strategic choices in biotechnology platforms/domains in basic research, research to support the regulatory framework and the public good, and research related to wealth creation, innovation and commercialization;
- examine the effectiveness of the R&D tax-credit policy as the technology matures and commercializes;
- develop proposals for effective biotechnology foresight functions;
- identify key activities and partnerships to support the formation of biotechnology clusters; and
- explore ways to encourage industry to develop, diffuse and adopt biotechnology for cleaner industrial products and processes.

Possible research and development priorities identified in CBS research and development consultations

- Genomics — including bio-informatics, sequencing amplification and functional genomics
- Genetic engineering
- Peptide and protein engineering
- Antigens/vaccines/immunology
- Bio-diagnostics
- Bio-remediation

Other research areas noted in the R&D consultations included microbiology, molecular drug design, drug delivery, fermentation/bio-processing/bio-transformation and molecular signaling/molecular interactions.

A fundamental conclusion from the R&D consultations was that, to be globally competitive, Canada must make strategic choices among possible science platforms and invest in those areas.

3. Regulating to protect health and the environment

The federal government remains committed to maintaining Canada's high regulatory standards and international leadership for the protection of health and the environment. This will require the continuous improvement of the regulatory system — within the context of the existing federal regulatory framework — to accommodate the growing demands that new biotechnology applications will place on it.

Possible actions:

- greater emphasis on generating the scientific knowledge and information needed to support biotechnology regulatory decisions;
- identify options to make the regulatory system more efficient, effective, responsive and predictable, using tools such as international bench-marking, performance standards and monitoring;
- improve international and domestic regulatory cooperation, harmonization and related R&D programs (for example, through mutual recognition agreements); and
- provide the general public with clear, timely information on regulatory processes, decisions and enforcement activities.

4. Promoting the use of biotechnology for public health and safety

Building on current efforts, this theme involves applying the federal government's resources and considerable expertise in areas such as research, health and disease surveillance, prevention and treatment to improve public health. Possible areas for further work include disease diagnosis and treatment, and safer, more nutritious and healthful foods.

Biotechnology's greatest impact, both in Canada and globally, is in human health. Some 90 percent of all biotechnology products on the global market are health related. More than 40 percent of the new drugs in clinical trials are products of biotechnology. In Canada, nearly 60 percent of Canadian biotechnology companies focus directly on health care.

5. Modernizing Canada's intellectual property laws

Modernizing Canada's intellectual property laws and ensuring their effective administration would significantly improve the domestic investment climate in knowledge-based sectors such as biotechnology. This point was stressed in many of the consultation sessions.

Possible actions:

- review Canada's intellectual property laws and policies in relation to the vision, principles and goals of the renewed CBS;
- use international bench-marking, stakeholder consultations and the new CBS structures to help develop a Canadian position regarding the World Trade Organization review of the patenting of higher life forms;
- analyze the implications of amending the Plant Breeders' Rights Act consistent with the 1991 UPOV Convention (International Union for the Protection of New Varieties of Plants); and
- ensure that the Canadian Intellectual Property Office's patent review process meets or surpasses international performance standards.

6. Facilitating measures to help accelerate the application and commercialization of new technologies

Possible actions:

- identify options for removing possible financing gaps facing the biotechnology sector; and
- improve technology transfer from government lab-oratories, universities and research institutes to the private sector.

7. Demonstrating responsible world leadership to improve market access and acceptance as well as stewardship in developed and developing countries

The public opinion research showed strong support among Canadians to position the country as an inter-national leader in biotechnology in terms of the quality of research and products as well as the stringency of standards and regulations. Respondents underlined that the CBS should build on our national tradition of responsible global leadership.

Possible actions:

- develop a comprehensive strategy for improving market access including an international communications strategy, technical support to exporters and better coordination of federal and provincial market access and export promotion activities;
- promote Canada as a preferred location for investment in biotechnology; and
- review Canada's international development assistance policies and programs in relation to the CBS vision and goals, particularly with regard to the developing countries to which Canada exports or is likely to export, and work with Canadian and local industry and other stakeholders to build indigenous capacity in these countries to capture the benefits of biotechnology and assess and manage the risks. This would help lesser developed countries to enhance their quality of life, ensure environmental sustainability and improve their risk management systems. These and other actions, including Canada's contributions to international negotiations, will help to ensure that the international harmonization of regulatory systems reflects Canadian values and high standards for stewardship.

8. Developing human resources

The availability of technology and management skills is becoming a limiting factor to biotechnology development, both for the private sector and for government.

Possible actions:

- examine immigration procedures and other impediments to the international recruitment of highly qualified personnel and experienced managers;
- develop innovative strategies to meet the human resources needs of regulatory departments;
- work with the provinces and other partners, particularly the Biotechnology Human Resources Council (BHRC), to increase the availability and skill sets of technical and managerial personnel; and
- work with the BHRC, provinces and other partners to further integrate ethical, legal and social issues into educational programs and the standards of professional associations.

9. Improving policy-relevant data collection and analysis

Few data are collected domestically or internationally on biotechnology-related industry activities or biotechnology-related R&D. Database development — for example, on industry structure, expenditures, revenues and market trends, government policies, programs and spending, technology and product diffusion and use, and international benchmarks — is needed to support policy development and to monitor and assess the impacts of the CBS in the future.

Possible actions:

- assess federal data needs and work with Statistics Canada to develop best collections and monitoring tools;
- work with partners to design, implement and maintain a national biotechnology database;
- develop international bench-marking tools.

10. Building sector strategies and action plans

Because biotechnology is an enabling technology with many different applications, efforts to promote its responsible development centre on delivery at the sectoral level.

Possible actions:

- direct sector departments to work with their stake-holder community and other interested parties to develop and refine sector strategies and plans.

Legislation on New Reproductive and Genetic Technologies

1) Introduction[80]

There is a wide range of practices which are referenced by the label of 'new reproductive and genetic technologies.' Some of these practices are actually quite old. 'Reproductive technologies' is the label applied to practices, procedures or treatments which aim to overcome infertility or "manipulate the conventional conception process" to produce a pregnancy. New reproductive technologies thus include *in vitro* fertilization, assisted insemination (both with a partner's sperm as well as with a donor's sperm), surrogacy arrangements, and post-menopausal pregnancy.[81] In this context, 'genetic technologies' are those techniques which examine or manipulate human genetic material used in conjunction with reproduction. They include such practices as sex-selection, embryo research, prenatal diagnosis and human embryo cloning.[82]

2) The Royal Commission on Reproductive Technologies

The Royal Commission on Reproductive Technologies was created in 1989. Its mandate was to consider the medical, economic, legal, social, ethical, and research implications of new reproductive technologies, and from these considerations recommend appropriate legislative policies, practices, guidelines and safeguards. The scope of its considerations included such areas as prenatal diagnosis, gene therapy, the use of fetal tissue for medical treatment, judicial intervention into pregnancy, the management of assisted reproduction, germ-line genetic alteration, causes of infertility, and the commercialization of human genetic material.

The Royal Commission commissioned many in-depth subject-specific reports, producing its own final report in 1993. This report contained 293 recommendations. Central to these recommendations was:

1) the creation of a national body which would license, regulate, and monitor the use of legal reproductive technologies,
2) the creation of legislation which would prohibit specific practices such as sex selection for non-medical purposes and commercial surrogacy contracts, and

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[80] Information for this section was mostly drawn from Health Canada publications, Bill C-47, and extensive conversations and e-mail exchanges with persons within Health Canada and working under/advising to the Minister of Health.

[81] Minister of Health, New Reproductive and Genetic Technologies: Setting Boundaries, Enhancing Health (Ottawa: Minister of Supply and Services Canada, 1996) [hereinafter Setting Boundaries] at 11.

[82] *Ibid.*

3) the pursuit of strategies aimed at preventing infertility.

Despite much public criticism, these recommendations were virtually ignored for several years. In anticipation of Bill C-47 (described below), the Department of Health created a voluntary interim moratorium in July of 1995. This voluntary moratorium was with regards to several of the practices which the Royal Commission had suggested should be prohibited. They were:[83]

- sex-selection for non-medical purposes;
- buying and selling ova, sperm and embryos – but excluding reimbursement for costs incurred by the collection, storage and distribution of these tissues for persons other than a donor;
- germ-line genetic manipulation;
- maintaining and growing embryos in artificial wombs;
- cloning human embryos;
- creating animal-human hybrids;
- retrieving eggs and sperm from cadavers or fetuses for fertilization and implantation;
- research involving the maturation of sperm or eggs outside the body; and
- commercial surrogacy or preconception arrangements.

As discussed below, the Department did establish a committee to advise on the development of legislation (see Appendix One for committee members). This committee's tasks also include advising to the Deputy Minister on the voluntary interim moratorium. The committee has found that the voluntary moratorium has been largely observed within Canada, with the exceptions of commercial surrogacy/ preconception arrangements and the buying and selling of ova and embryos. Advertisements requesting these services or genetic materials are most often found in Canadian college newspapers and are usually placed by private American facilities. There are also some private Canadian facilities placing such ads. A second route for procuring ova and embryos has been through offers to reimburse the costs of IVF as a "trade" for a woman's or couple's "extra" ova or embryos following a woman's use of IVF for her own reproductive purposes [this is not technically in violation of the moratorium]. The committee has also found that there is some cross-border "shopping" from Canada into the United States for services such as sex selection for non-medical purposes.

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[83] *Ibid*. at 25-6.

2) The Human Reproductive and Genetic Technologies Act

On June 14, 1996, the Minister of Health introduced Bill C-47, the Human Reproductive and Genetic Technologies Act. Bill C-47 adopted some of the recommendations put forward by the Royal Commission in 1993. However, it was mostly concerned with listing prohibited practices (s.4 - s.7), and creating a criminal enforcement mechanism (s.8 - s.12). As well as criminalizing the practices which were subject to the voluntary moratorium, Bill C-47 also prohibited:

- implanting human embryos into animals or vice versa (s.4(1)(d));
- using human sperm, eggs or embryos for assisted reproduction without the informed consent of the donor (s.7);
- conducting research on human embryos later than 14 days after conception (s.4(1)(j));
- creating embryos outside a woman's body for the sole purpose of research (s.4(1)(k); and
- offering to provide or pay for any of the prohibited practices (s.4(2) and (3)).

This bill was not intended to 'stand alone.' Rather, a second bill was planned which would amend Bill C-47 and introduce a regulatory management regime (the 'Second Bill').[84] However, Bill C-47 was not passed into legislation within a year of its having been tabled, and so 'fell off the table' in June of 1997 when the next federal election was called.

3) The Proposed New Human Reproductive and Genetic Technologies Act

a) Timing for Release of the New Bill

Health Canada has been working on a new bill which is described as intended to comprehensively address reproductive and genetic technologies, much as the 'Second Bill' described above was expected to operate. This bill has not yet been tabled, and so its proposed contents are not publicly available. Persons within the Department of Health have repeatedly indicated that the bill is due for release "soon" – in September of 1998, the bill was expected to be tabled by December, in November the date was moved to the new year, and in December word from within the Department of Health was that "at present, no date has been chosen for introduction of legislation in this field."

[84] *Supra* note 81 at 26-7.

Unofficial reasons offered for the delay reference a variety of issues and difficulties. They include the Hepatitis-C blood scandal having been a priority for Ministry resources this fall, a sense within the Department that there is insufficient public will to back the legislation, and the announcement by South Korean scientists in mid-December that they have successfully cloned human embryos. A more formal reason for delay has been attributed to concerns within the Department that the proposed legislation is insufficiently prospective in its approach to prohibitions and the creation of a regulatory management structure. That is, Department officials described apprehension that the proposed legislation as it stands does not adequately address possible future developments which could undermine or circumvent the legislation's purposes. Despite these delays, one advisor to the Minister of Health felt able to offer assurances that the Minister is committed to getting the bill on the table during this session of Parliament.

b) The Content of the New Bill

Although it is not possible for 'outsiders' to see the actual contents of the proposed new bill, persons within the policy division of Health Canada have been clear that the current draft is quite similar to the 'Second Bill' described above. The contents of the 'Second Bill' were outlined in a 1996 government publication, New Reproductive and Genetic Technologies: Setting Boundaries, Enhancing Health.[85] The proposed bill is expected to have two main sections. One portion will cite prohibitions, which are expected to be quite similar to those cited under Bill C-47. No one within the Department of Health would confirm whether and/or how the list would be altered. The second portion will describe regulatory procedures for the management of new reproductive and genetic technologies. Persons within the Department of Health confirmed that the proposed management body is expected to be quite similar to the one described in Setting Boundaries.

The regulatory body described in Setting Boundaries would exist as an agency of Health Canada, administering regulations passed by the Governor-in-Council under powers authorized by the legislation. The body would issue licenses for acceptable practices, and set standards for practicing new reproductive and genetic technology techniques. These standards include personnel qualifications, donor screening procedures, and directions for the storage, collection, disposal and use in research of human sperm, ova, embryos, and fetal tissue.[86] The regulatory body would also have administrative enforcement powers,

[85] *Ibid.*

[86] *Ibid.* at 28-9.

including conducting compliance inspections, seeking injunctions against anticipated or extant violations of the legislation, obtaining search warrants, and powers of seizure and forfeiture.[87] While the regulatory body could revoke or suspend licenses, the Attorney General would lead any prosecutions under the proposed act.

Persons within Health Canada could not confirm whether all prohibited acts were still proposed to be subject to criminal sanctions as indicated in Setting Boundaries. Some women's groups suggested some activities were better addressed through regulation instead of criminalization. These groups were centrally concerned that criminalization would in some instances result in particularly vulnerable women bearing the consequences of criminal sanctions or 'going underground' "when societal pressure and systemic factors have forced her into desperate acts."[88] The criminalization instead of regulation of specific practices, such as selling ova, were generally critiqued as ignoring the sexual-economic stratification of society or alternately as being patronizing and infringing on women's rights to available knowledge about their bodies.[89]

Setting Boundaries also described the creation of information registries under the regulatory body. Persons within the Ministry of Health confirmed that there would be registries, and that they would closely resemble those proposed in Setting Boundaries. These included:[90]

- a registry of donors' medical and social history and the children conceived through specific donor's genetic material;
- a registry tracking the success rates of various reproductive technologies as well as the location of fertility clinics and practitioners;
- a registry tracking the health of all women and men who have taken infertility drugs; and
- a registry tracking the health of all children conceived and born through assisted reproduction.

No information could be obtained as to whether Health Canada still intends to produce a 'Framework for Sexual and Reproductive Health', as proposed in Setting Boundaries.[91] This

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[87] *Ibid*. at 29-30.

[88] National Association of Women and the Law, The National Association of Women and the Law Response to Bill C-47 and Working Document on New Reproductive and Genetic Technologies: "Setting Boundaries, Enhancing Health" (Ottawa, National Association of Women and the Law, 1997) at 5. Also see general discussion at 5-8.

[89] *Ibid*. at 6-7.

[90] *Supra*, note 81 at 31-3.

[91] *Ibid*. at 34-8.

framework was intended to be forward-looking, and bring together the ideas and activities of provincial government actors, community groups, physician groups, etc., to create an over-all strategy for promoting reproductive and sexual health and addressing the causes of preventable infertility, such as sexually transmitted diseases. Health Canada was supposed to have conducted consultations in 1996/97 with provinces, territories and non-governmental organizations. It does not appear that these consultations actually occurred, and no one within the Department of Health could confirm whether they will occur.

In sum, verbal confirmations were offered that the new legislation will be quite close to that described in Setting Boundaries with regards to the list of prohibited practices and activities, the creation of a national regulatory body which would exist as an agency, and of the creation of the four registries. Persons working in the Health Ministry office and at the Department of Health felt unable to reveal any information as to the regulatory mechanism, whether the prohibited practices will still be linked to criminal sanctions, and whether Health Canada is still dedicated to developing a framework for sexual and reproductive health.

Appendix One – Members of the Advisory Committee on Reproductive and Genetic Technologies as of January 29, 1999.

MEMBERS:

Ms. Madeline Boscoe (Chair)
Women's Health Clinic
Winnipeg, Manitoba

Dr. Jeffrey Nisker (Co-chair)
Professor of Obstetrics and Gynaecology
Chair, Reproductive Endocrinology
University of Western Ontario
London, Ontario

Ms. Shashi Assanand
Executive Director
Vancouver and Lower Mainland
Multicultural Family Support
Services Society
Vancouver, B.C.

Ms. Phyllis Creighton
Anglican Church of Canada
Toronto, Ontario

Dr. Louis Dallaire
Chef du Service de Génétique Médicale
Hopital Ste. Justine
Montréal, Québec

Ms. Sherry Franz
Infertility Counsellor
Private Practice
Toronto, Ontario

Dr. Abby Lippman
Professor
Department of Epidemiology
McGill University
Montréal, Québec

Ms. Mary MacLennan
Canadian Human Rights Commission
Halifax, Nova Scotia

Dr. Sheilah Martin
Professor
Faculty of Law
University of Calgary
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Dr. Susan Sherwin
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PROVINCIAL OBSERVER:

Ms. Martha Forestell
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SECRETARIAT:

Ms. Francine Manseau
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Xenotransplantation

1) Background

The Therapeutic Products Programme (TPP) of Health Canada is currently developing a regulatory framework to address the transplantation of tissues and organs from one species to another.[92] Such inter-species transplantation is called xenotransplantation. For example, xenotransplantation activities in the United States have involved transplanting a heart from a chimpanzee into a human, and the clinical practice of transplanting neural cells from fetal pigs into humans suffering from Parkinson's disease. American researchers are also investigating the possibility of xenotransplanting animal pancreatic cells into humans suffering from diabetes.

Health Canada currently recognizes two major sources of risk associated with xenotransplantation. Persons who receive organs from other humans must usually be treated with immunosuppressive drugs for their entire lives to prevent their bodies from rejecting the graft. It is expected that human immune systems will react far more violently to tissues from another species than they do to tissues from other humans, and so it will be difficult to prevent their bodies from rejecting the xenotransplanted organs and tissues.

The second major issue is the risk of zoonotic diseases. Zoonotic diseases are diseases which are transmitted from animals to humans. Known zoonotic diseases include rabies, malaria, Lyme disease, anthrax, Chagas disease and hantavirus.

2) Current status

Xenotransplantation is not prohibited in Canada. Health Canada does, however, have the right to regulate it as a new therapy under the Food and Drugs Act.[93] As of May, 1998, no clinical trials involving xenotransplantation have been approved by Health Canada.

3) Federal Activity – Developing National Standards for All Transplantations

The system for organ and tissue transplantation *between humans* came under heavy criticism in 1994, following a report prepared jointly by the Canadian Association of Transplantation and the Canadian Transplantation Society on the safety of organ and tissue transplantation in

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[92] This section was drawn primarily from conversations and e-mail exchanges with members of the Blood, Tissue, Organ and Xenograft Project of the Therapeutics Products Programme of Health Canada, as well as from Therapeutic Products Programme, "Proposed Risk Management Framework to Address the Safety of Tissues and Organs for Transplantation in Canada" (Ottawa: Health Canada, 1998).

[93] R.S.C. 1985, F-27.

Canada.[94] The report found that as health delivery is a provincial concern, transplantation practices were extremely irregular from one province to another, and that there was insufficient communication between provinces to make the best use of available tissues and organs.

This report lead to a cooperative project to develop national safety standards and practices. This project has involved the establishment of an expert working group[95] to draft a Canadian General Standard for the Safety of Organs and Tissues used in Transplantation. This General Standard is to be used as a template for developing specific standards for different subsets of organs and tissues. Once completed, these standards will be referred to the Canadian Standards Association.

Although not yet finalized, the standards-based regulatory framework will consist of the following elements:

- Transplant practices described within the National Standards will be made mandatory through their reference in a regulation under the Food and Drugs Act.
- All transplant programs will be required to submit reports to demonstrate compliance with the National Standards.
- All transplant programs will be required to register with the TPP and provide regular activity and adverse event reports.
- The TPP will be empowered to conduct audits of transplant programs and to respond to non-compliance to the National Standards or serious adverse events.

4) The Xenotransplantation Expert Working Group

Although the Expert Working Group over-sees the drafting of the standards, they chose to initiate several splinter expert working groups, who would craft the general standards to work for a specific subset of transplantation activities. One of these splinter groups is the Xenotransplantation Expert Working Group, whose mandate is to draft guidelines and safety standards which specifically address xenotransplantation (see Appendix One for a list of working group members and their affiliations). Part of their consultations involved hosting

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[94] Health Canada commissioned report, "Safety of Organ and Tissue Transplantation in Canada", authored by Organ Sharing Canada (released December 1994).

[95] As of May, 1998, the core members of the expert working group are: Dr. Calvin Stiller (Chair), Dr. John Dossetor (Ethicist), Dr. Paul Dubord (Ocular), Dr. Alan Eves (Haematology), Dr. Paul Grieg (Liver/Solid Organ), Dr. Michael Gross (Tissues), Dr. John Jarrell (Reproductive), Ms. Susan McCabe (Lay Member), Dr. Wilbert Keon (Thoracic), Dr. Hans Messner (Bone Marrow/Stem Cells), and Dr. Norm Kneteman (Liver/Solid Organs).

a conference, the "National Forum on Xenotransplantation: Clinical, Ethical and Regulatory Issues" from November 6-8, 1997.

The Therapeutics Products Programme cannot release the draft of the proposed Xenograft standards until it has been approved as an "official draft" by the Canadian Standards Association. However, some indications of the 'flavour' of the draft can be drawn from its detailed Table of Contents, although it is clearly dangerous to make much of such extrapolations.[96] It appears that the use of xenotransplantation is rationalized by the working group based on the current demand for organs in Canada. Although some consideration is given to outlining ethical principles which would presumably guide any xenotransplantation activities, much of the standard focuses on the procurement, screening and selection of animals as sources for xenotransplantation. It also sets forth what appears to be explicit guidelines for the development of clinical xenotransplantation programs.

5) The Public Review Process

The Expert Working Group has completed final drafts of the National Standards, and subset National Standards for such areas as xenografts. As of May, 1998, these drafts had been forwarded to the Canadian Standards Association (CSA). The CSA will format the Standards into documents which meet the Standards Council of Canada criteria for National Standards. These documents will undergo a public review process. This review process is expected to be initiated in the winter of 1999. The target date for enacting these regulations under the Food and Drugs Act is Spring, 1999.

6) The Canadian Biotechnology Strategy[97]

The CBS is not officially or formally involved in the development of the Xenotransplantation standards. However, the CBS has indicated that it is extremely interested in the potential benefits of xenotransplantation as a form of biotechnology.[98] The CBS views xenotransplantation as an area with great promise, involving technology with which Canada has expertise, but still having unknown risks.

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[96] Unfortunately, the draft Table of Contents was released to me on the condition that I not circulate it. I only have permission to reference it in a general manner.

[97] See the section on the Canadian Biotechnology Strategy.

[98] Personal Communication, Therapeutics Products Programmes, Health Canada, October 13, 1998.

Appendix One – Members of the Xenotransplantation Working Group

Dr. Michael Gross (Chair)
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Dr. Jim Wright
Pathology Dept.
Isaak Walton Killam Children's Hospiital
Halifax, Nova Scotia

Dr. Gary Levy
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Toronto, Ontario

Dr. David Grant
Director, Liver Transplantation
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Dr. Gilly Griffin
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PART IV. OWNERSHIP AND THE NEW GENETICS – NATIONAL AND INTERNATIONAL LEGISLATION AND OBLIGATIONS

Intellectual Property Activities

1) Background

Canada's intellectual property policies are primarily formulated within a branch of Industry Canada known as the Intellectual Property Policy Directorate (IPPD).[99] As well as advising Federal ministries on national matters, the IPPD works with the Department of Foreign Affairs and International Trade in determining Canadian positions for international intellectual property matters. For example, the IPPD has formulated the Canadian position in negotiating with the World Trade Organization (WTO), the North American Free Trade Agreement (NAFTA), the World Intellectual Property Organization (WIPO), and the Asia-Pacific Economic Cooperation (APEC).

The IPPD reviews and revises many of the Federal laws which are administered by the Canadian Intellectual Property Office. This legislation includes The Patent Act,[100] and The Copyright Act. Persons with the IPPD are currently debating how to revise The Patent Act in response to pressures to allow the patenting of genetically altered higher life forms.

A patent is a form of intellectual property. It gives the patent holder exclusive rights of commercial exploitation of an invention for a period of time. In Canada, this time period is usually 20 years. These exclusive rights mean not only that the inventor receives monetary compensation for the use of the invention, but also that the inventor controls the terms of *use* of the patented product or entity.[101]

As the Patent Act now stands, the requirements for granting a patent are quite straightforward. The inventor or the inventor's legal representative files an application with the Commissioner of the Patents Office.[102] The application must correctly and fully

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[99] This section was drawn from a variety of sources. The main sources include: close readings of the discussed Canadian legislation, caselaw and international legal instruments, referenced secondary sources including research papers commissioned by the IPPD and reports issued by Industry Canada, and conversations/email exchanges with individuals within the Canadian Intellectual Property Office and the Intellectual Property Policy Directorate.

[100] Patent Act, R.S.C., c.P-4

[101] M. Leaffer (Ed.), International Treaties on Intellectual Property (2nd Ed.) (Washington, D.C.: Bureau of National Affairs, 1997) at 2-3.

[102] Patent Act, s.27(1).

describe the invention, and how the inventor contemplates it will be used or operated.[103] The application must also describe the exact manner for creating the invention in such detail that the creation process could be duplicated by an expert in the relevant field, as well as an explicit set of claims which distinctly describe the subject-matter of the invention.[104] Complications with patent applications often arise over whether the description is sufficiently detailed, or whether the subject-matter of the patent application qualifies as an 'invention'. 'Invention' is defined in the Patent Act as:

> ... any new or useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter.[105]

The Commissioner has no discretion but to grant a patent for any invention if the inventor complies with these steps and criteria, and meets some other minor requirements.[106] As it now stands, the Patent Act has been interpreted to allow for the patenting of plant and animal *cells.*[107] However, attempts to patent a soy-bean variety have been rejected[108], as has an attempt to patent a "family-line" of genetically altered mice[109] (see discussion below).

2) The Patenting of Genetically Altered Higher Life Forms and Plants

As noted above, applications to patent plants in Canada have been unsuccessful. Ownership rights to plants are currently granted under the Plant Breeders' Rights Act.[110] The Act only applies to certain plant varieties which are listed in the Plant Breeder's Rights Regulations.[111] The requirements to obtain these rights are similar to, but less rigorous than, those for obtaining a patent. The applicant must prove that the new plant variety is clearly distinguishable from all known varieties, can be reproduced in a stable and consistent fashion, is homogeneous to the point that any variations are predictable,

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[103] Patent Act, s.27(3)(a).

[104] Patent Act, s.27(3)(b) and (4).

[105] Patent Act, s.2.

[106] Patent Act, s.27(1).

[107] See *Re Application for Patent of Connaught Laboratories* (1982), 82 C.P.R. (2d) 32, where the Patent Appeal Board allowed the patenting of a bovine cell-line, and *Re Application of Abitibi Co*. (1982), 62 CPR (2d) 81 where the Patent Appeal Board found a yeast culture could be patented.

[108] See *Pioneer Hi-Bred Ltd.* v. *Canada (Commissioner of Patents)*, [1987] 3 F.C. 8 (F.C.A.).

[109] *Harvard College* v. *Canada (Commissioner of Patents)* (1998), 79 C.P.R. (3d) 98.

[110] S.C. 1990, P-14.6.

[111] The plant varieties which can be 'owned' under the Plant Breeders's Rights Act are as follows: african violet, alfalfa, apple, barley, bean, cherry, chrysanthemum, corn, dianthus, flax, grapes, oats, pea, pear, poinsettia, potato, poentilla, rape, rose, soybean, strawberry, wheat and yew.

describable and commercially acceptable, and has not yet been commercialized.[112] The applicant must also disclose certain information, such as how the plant variety was developed.[113]

The rights granted to plant breeders under this act are much more narrow than those granted to patent holders under the Patent Act. Plant breeders' rights are limited to a monopoly on the *production and selling* of the propagating material of a plant – its seeds and/or cuttings.[114] Once a farmer has bought seeds from a plant breeder, the farmer has the right to i) re-sell the original seeds, ii) plant the seeds and sell the crop, and iii) plant the seeds, sell the crop while retaining its seeds and sow those seeds. The farmer does not have the right to sell seeds sown from his or her crop.[115] As well as having the right to plant his or her own seeds, farmers are also protected by an advisory committee which monitors seed prices – the Plant Breeders' Rights Act created both this committee as well as a compulsory licensing system for any party who wishes to exercise breeder rights under the Act.[116]

The implications of granting patents for plants are quite clear. If a plant variety was patented, then a farmer would be prevented from using the seeds which he or she took from the previous year's harvest. He or she would have to buy seeds each year. The granting of such patents would have devastating implications for situations such as trying to develop self-sustaining farming practices in the South.

3) The Patenting of Genetically Altered Mammals

The IPPD has been engaged in consultations over whether to allow applications to patent biotechnological processes and 'products', such as transgenic mammals. A transgenic mammal is a mammal whose genetic make-up was intentionally altered by the insertion of a foreign or "unrelated" gene while at the embryonic stage. Such mammals may pass on their altered genetic make-up to their off-spring. The IPPD has commissioned a number of research papers to identify ethical, legal and economic issues associated with patenting higher life forms.[117] Although these reports lend some indication of the sorts of issues the

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[112] *Supra* note 110 at s.4(2) and (3).

[113] See s.19-21 of the Regulations.

[114] *Supra*, note 110 at s.5(1).

[115] See a more detailed discussion at N. Derzko, "Plant Breeders' Rights in Canada and Abroad: What are these rights and how much must society pay for them?" (1994) 39 McGill Law J. 144 at 160-163.

[116] *Supra*, note 110 at ss. 32, 73 and 74.

[117] Research papers commissioned by the IPPD on ethics and the law include: "Ethical Issues Associated with Patenting Higher Life Forms", T. Schrecker, C. Hoffmaster, M. Somerville, C. Elliot, and E Keyserlingk (released May 12, 1998); "Issues Relating to the Patentability of Biotechnology Subject Matter", J. Rudolph (released January 20,

IPPD considers worth addressing, the positions supported by these reports are only those of the individual authors.

In the United States, Harvard College received a patent for a line of transgenic mice in 1988.[118] These mice, known as "OncoMouse", were genetically altered such that a mouse born of this blood line will be predisposed to developing malignant tumors (the mice were "designed" for scientific research into carcinogens and cancer treatments). The American patent is worded broadly, applying to any "transgenic non-human mammal all of whose germ cells and somatic cells contain a recombinant activated oncogene sequence introduced into said animal, or an ancestor of said animal, at an embryonic stage". It could thus include any mammal into which the oncogene has been successfully introduced.

Harvard College filed an application to patent the "OncoMouse" mammal in Canada. Such applications require approval by the Patent Board, a regulatory body which administers the Patent Act. The original Examiner of the application rejected most of the claims made in the application. Harvard appealed to the Patent Appeal Board. The Patent Appeal Board heard and rejected most of the claims as well. It released its decision on August 4, 1995. Harvard appealed this finding to the Trial Division of the Federal Court of Canada. The Trial Division dismissed the appeal, and released its decision on April 12, 1998.[119] Harvard has informed the IPPD that it will appeal this finding to the Appeal Division of the Federal Court.

The primary ground under which the Federal Court rejected the application was the finding that a mammal could not be considered an "invention" due to its complexity. Although the presence of the oncogene was reproducible, the rest of a mouse's genetic make-up – "the precise mouse, the precise location and the precise quality of the gene"[120] were found to be outside the control of the researchers. The court also noted that Harvard had

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1997); "Banking of Human Materials, Intellectual Property Rights and Ownership Issues: International Policy Positions and Emerging Trends in the Literature", B. Knoppers and M Hirtle (released April 22, 1998). Research papers commissioned by the IPPD on economic aspects of patenting higher life forms include: "Background Economic Study of the Canadian Biotechnology Industry", James G Heller Consulting Inc. (released December 16, 1996); "The Potential Impacts of Patenting Biotechnology on the Animal and Agri-Food Sector", L. Martin and V. Amanor-Boadu (released January 27, 1997); "Forest Biotechnology in Canada: Analysis of Intellectual Property Rights and Protection of Higher Lifeforms", I Vertinski and S. Globerman (released November 25, 1997); and "Potential Impacts of Patenting Lifeforms on the Aquatic Products Sector in Canada", E. Blewett and D. MacDonald (released April 21, 1998).

[118] See U.S. Patent No. 4, 736, 866 (1988).

[119] *Harvard College* v. *Canada (Commissioner of Patents)* (1998), 79 C.P.R. (3d) 98.

[120] *Harvard College* at para. 32.

successfully patented the process for creating "OncoMouse", and so were already guaranteed any monies which would come from the use of the mice. This suggests that the application is aimed not so much at cornering profit from this line of special mice, but rather as a trial case for setting a precedent for the right to patent mammals.

The IPPD is closely watching this judicial process. Policy advisors are carefully analyzing the various judgments, and using them as launching pads to begin to formulate the IPPD's policy position on the patenting of higher life forms and transgenic mammals.

4) Ethics and Patenting

Members of the IPPD have stated that one of the primary questions under discussion is *whether ethical issues* ought to figure into the granting of patents. As the Patent Act now stands, all the requirements are technical and relate to meeting certain empirical standards, such as being able to reproduce results and having a useful application. The requirements do not include any criteria which speak to public interest issues, such as the morality of granting industrial ownership over certain sorts of subject-matter.

The judge in the federal court OncoMouse challenge, described above, noted that the Crown solicitor had argued that the patent application should fail due to the negative social consequences of allowing higher life forms to be patented. However, the judge found that the Patent Act did not allow him the authority to consider competing social values and interests in presiding over a patent application.[121] A judge would similarly be unable to consider the ethical implications of allowing the patenting of plant varieties.[122]

The inclusion of ethical factors would significantly alter the patenting process in Canada, as it would require the Commissioner to deliberate over broader social issues when asked to grant a patent, instead of simply checking to see if the application met a near-mechanical check list. This is an extremely contentious issue. Members of industry are strongly opposed to this possible change.

5) The Canadian Biotechnology Strategy

The Canadian Biotechnology Strategy (CBS) Taskforce is expected to play a central role in developing new intellectual property policy, as part of its official mandate is to guide

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[121] *Harvard College* at para. 34-35.

[122] Plants are currently not patentable in Canada. Rather, rights to a much more limited monopoly on the propagating material of new breeds of plants can be granted under the Plant Breeder's Rights Act, S.C. 1990, c.P-14.6.

biotechnological legislative developments to maximize their commercial potential (see the section on the CBS). Persons within the IPPD have indicated that Industry Canada – which chairs the CBS – intends to make patenting a high priority, and that federal draft legislation which addresses the patenting of higher lifeforms is expected to be tabled within three years.

This national legislation will be passed after Canada has taken an international position on the patenting of higher life forms, as the World Trade Organization (WTO) will be reviewing its position in 1999 (see discussion below). The CBS has stated that there will be consultations aimed at developing a Canadian policy, but is unclear whether these consultations will be directed to Canada's international position, domestic position, or both.[123]

6) International Instruments

Canada is bound to abide by a number of international legal treaties which contain clauses relating to intellectual property and so impact on the issue of owning and trading in transgenic entities, from plants to animals. These treaties may be interpreted as imposing certain restrictions on Canada's domestic legislation. Two central treaties, the World Trade Organization (WTO) – TRIPs Agreement[124] and the North American Free Trade Agreement (NAFTA)[125], were formulated as trade agreements, and so were written to facilitate commercial interactions on the global economic market.

a) The Trade Treaties

i) The WTO-TRIPS Agreement

The WTO-TRIPs Agreement has a section which specifically addresses what shall constitute patentable subject-matter for all member states (see Appendix 1). It clearly entertains the patenting of plants, animals and micro-organisms as inventions.[126] It indicates that, in general, patents are to be available for any inventions, whether products or processes, in all fields of technology, provided they i) are new, ii) involve an inventive or non-obvious step, and iii) are capable of industrial application or are useful.[127] This general

[123] Industry Canada, The 1998 Canadian Biotechnology Strategy: An Ongoing Renewal Process (Ottawa, Distribution Services: 1998) (released November 17, 1998) at 6.
[124] The WTO-TRIPS Agreement was concluded in 1994. Canada became a party to this treaty on January 1, 1995.
[125] NAFTA was concluded in 1992. Canada signed NAFTA on December 17, 1992 and ratified it on June 23, 1993.
[126] WTO-TRIPS, s. 5. Article 27 is the most relevant portion of this treaty for the purpose of this section.
[127] WTO-TRIPS, Art. 27, para. 1 and footnote 5.

obligation to grant patents provided the subject-matter meets these technical criteria is subject to certain exceptions. These exceptions are specified in the Agreement.

Member states are permitted to refuse to grant patents for inventions for the purpose of protecting public order or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment. However, such exclusions cannot be made "merely" because the commercial exploitation of human, plant or animal life is prohibited by a state's laws.[128] Member states thus appear to be disabled from legislating a prohibition against the patenting of transgenic plants and animals based solely on a principled objection to the commercial exploitation of these entities.

The Agreement does specifically allow for the exclusion, without qualification, of patenting diagnostic, therapeutic and surgical methods for the treatment of humans or animals.[129] It also gives a *temporary* blanket exclusion for the patenting of plants or animals other than micro-organisms, and "essentially biological processes for the production of plants or animals."[130] This temporary exclusion is to be reviewed 4 years after the Agreement came into force.[131] This means that the right to exclude granting patents for plants, animals and biological processes may be removed or modified in 1999.

ii) NAFTA

NAFTA has a section which addresses intellectual property and patenting.[132] The NAFTA clause contains virtually identical wording to the WTO-TRIPS provision (see Appendix Two). The major difference is that it does not provide for a review of its provisions which allow the member states to refuse to grant patents for plants and animals, without qualification. However, this difference is of little significance, given that all the member states of NAFTA – Canada, the United States and Mexico – have signed the WTO-TRIPS Agreement.

7) Commentary

Intellectual property is a quickly growing area, which has been identified as extremely lucrative on the international market. Canada has been a central player in the international

[128] WTO-TRIPS, Art. 27, para. 2.
[129] WTO-TRIPS, Art. 27, para. 3(a).
[130] WTO-TRIPS, Art. 27, para. 3(b).
[131] WTO-TRIPS, Art. 27, para. 3(b).
[132] Part Six, Chapter 17 addresses intellectual property. Article 1709 addresses patents.

scene, especially given that the WTO-TRIPS Agreement borrows heavily from NAFTA in its treatment of intellectual property issues. The CBS has indicated in its 'themes' (see the Appendix attached to the section on the CBS) the intention to modernize Canada's patenting laws. It is not clear what this will mean for the status of plants. Although it has not made any commitment to consider ethical issues as a part of this modernization, it is committed to reviewing the laws and policies in relation to the vision, principles, and goals of the renewed CBS.

Appendix One – Excerpts from Part V (Patents) and Part VII (Institutional Arrangements) of the WTO - TRIPs Agreement

Article 27: Patentable Subject Matter (from Part V)

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. See footnote5. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2.Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect order public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

3.Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Footnote 5: For the purposes of this Article, the terms “inventive step” and “capable of industrial application” may be deemed ... to be synonymous with the terms “non-obvious” and “useful” respectively.

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Article 65: Transitional Arrangements (from Part V)

1. Subject to the provisions of paragraphs 2, 3 and 4, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement.

2. A developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1, of the provisions of this Agreement other than Articles 3, 4 and 5.

3. Any other Member which is in the process of transformation from a centrally-planned into a market, free-enterprise economy and which is undertaking structural reform of its intellectual property system and facing special problems in the preparation and implementation of intellectual property laws and regulations, may also benefit from a period of delay as foreseen in paragraph 2.

4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.

5. A Member availing itself of a transitional period under paragraphs 1, 2, 3 or 4 shall ensure that any changes in its laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of this Agreement.

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Article 70: Protection of Existing Subject Matter (from Part VII: Institutional Arrangements)

8. Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:

(a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;

(b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and,

(c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).

Appendix Two – Excerpts from Part 6, Chapter 17 (Intellectual Property) of NAFTA

Article 1709: Patents

1. Subject to paragraphs 2 and 3, each Party shall make patents available for any inventions, whether products or processes, in all fields of technology, provided that such inventions are new, result from an inventive step and are capable of industrial application. For purposes of this Article, a Party may deem the terms "inventive step" and "capable of industrial application" to be synonymous with the terms "non-obvious" and "useful", respectively.

2. A Party may exclude from patentability inventions if preventing in its territory the commercial exploitation of the inventions is necessary to protect order public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to nature or the environment, provided that the exclusion is not based solely on the ground that the Party prohibits commercial exploitation in its territory of the subject matter of the patent.

3. A Party may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than microorganisms; and

(c) essentially biological processes for the production of plants or animals, other than non-biological and microbiological processes for such production.

Notwithstanding subparagraph (b), each Party shall provide for the protection of plant varieties through patents, an effective scheme of sui generis protection, or both.

4. If a Party has not made available product patent protection for pharmaceutical or agricultural
chemicals commensurate with paragraph 1:

(a) as of January 1, 1992, for subject matter that relates to naturally occurring substances prepared or produced by, or significantly derived from, microbiological processes and intended for food or medicine, and

(b) as of July 1, 1991, for any other subject matter,

that Party shall provide to the inventor of any such product or its assignee the means to obtain
product patent protection for such product for the unexpired term of the patent for such product granted in another Party, as long as the product has not been marketed in the Party

providing protection under this paragraph and the person seeking such protection makes a timely request.

International Instruments on 'Genetic Resources'

Canada has signed two major international documents relating to genetic resources.[133] One, the United Nations Convention on Biological Diversity,[134] is a legally binding instrument. A second, the Universal Declaration on the Human Genome and Human Rights,[135] is not legally binding but rather operates as an agreement in principle.

1) The United Nations Convention on Biological Diversity

The United Nations Convention on Biological Diversity originated as a protective instrument. It was conceived of as an international legal instrument to promote the conservation and sustainable use of biological diversity on a global scale.[136] It was also intended to prevent developing countries from being excessively exploited by developed countries and Big Industry in their search for biological ingredients, by mandating its members to manage the effects of their activities in a fashion which is conservation sensitive, regardless of the jurisdiction in which their activities occur.[137] It was thus designed to address the near-unfettered and poorly compensated exploitation of developing countries' biological resources by large industrial interests.

The Convention's Objectives state it is to be interpreted to promote:

> ...the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate *access to genetic resources* and by appropriate *transfer of relevant technologies*... [138]

"Genetic resources" are defined as "genetic material of actual or potential value", and "genetic material" is defined as "any material of plant, animal, microbial or other origin containing functional units of heredity".[139] The benefits to be shared with the "host" state

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133 Information for this section was drawn from a close reading of the two treaties, an Intellectual Property Patenting Division report [see footnote 138, below], and several conversations with individuals within the Science and Technology Division of the Department of Foreign Affairs and International Trade.

134 The Biodiversity Convention was concluded 1992. Canada acceded to it on December 4, 1992

135 UNESCO adopted this declaration on November 11, 1997

136 Convention on Biological Diversity (1992), background statement.

137 Convention on Biological Diversity, Article 4, Scope.

138 Convention on Biological Diversity, Article 1, Objectives [emphasis added].

139 These definitions are found in the Convention on Biological Diversity, Article 2, Use of Terms.

are conceptualized as those which result from research, development and commercialization.[140]

The Convention recognizes states as having sovereign rights over their natural resources and so the ultimate authority to determine access to genetic resources located within their national jurisdiction[141]. However, it also burdens states with the obligation to not impose restrictions that run counter to the objectives of the Convention[142] and to cooperate in fashioning their patent and intellectual property rights laws in a manner that supports the Convention's objectives.[143] As can be gleaned from the section on intellectual property activities, neither Canada's Plant Breeder's Act nor Canada's Patent Act speak to 'sharing the benefits' with host states. These potential obligations may be part of the reason why the United States has refused to ratify this Convention.

These provisions would appear to have the power to change national and international law. The consensus view which has emerged, however, is that the Convention does not change national laws as they relate to intellectual property or the patenting of life forms.[144]

According to the Biodiversity Convention Office (Environment Canada), members of the Convention are currently working on developing a 'Biosafety Protocol'. This protocol will set the terms for the transboundary movement of living modified organisms. Such organisms include those created by biotechnological means. The protocol will require any party wishing to import living modified organisms into another member state to have secured informed agreement in advance of the importation. The next meeting to discuss the protocol is scheduled for July, 1999. Environment Canada expects the protocol to be drafted and passed in 1999.

2) Universal Declaration on the Human Genome and Human Rights

The Universal Declaration on the Human Genome and Human Rights is the first international document to propose an ethical framework for human genetics research. It was drafted by the International Bioethics Committee of UNESCO, and was adopted unanimously by the 186 member states attending the UNESCO 1997 General Conference.

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[140] Convention on Biological Diversity, Article 15, Access to Genetic Resources.

[141] Convention on Biological Diversity, Article 15, para. 1, Access to Genetic Resources.

[142] Convention on Biological Diversity, Article 15, para. 2, Access to Genetic Resources.

[143] Convention on Biological Diversity, Article 16, para. 5, Access to and Transfer of Technology.

[144] IPPD commissioned report, "The Biodiversity Convention, Intellectual Property Rights, and Ownership of Genetic Resources", Main researcher: Barbara Lane Kagedan (released April 20, 1998) at 1.

As noted above, it is not a legally binding treaty. Rather, it is a set of guiding principles which the signatories commit to making efforts to incorporate into their national legislation.[145]

The Declaration sets out four main principles as to the relationship between human dignity and the human genome.[146] They are that:

> i) "the human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity";
> ii) human dignity requires respect for every human's rights "regardless of their genetic characteristics";
> iii) the rejection of genetic reductionism by recognizing that the "genome, which by its nature evolves, is subject to mutation. It contains potentialities that are expressed differently according to each individual's nature and social environment including the individual's state of health, living conditions, nutrition and education"; and
> iv) "the human genome *in its natural state* shall not give rise to financial gains"

These basic principles are supposed to underlie the rest of the Declaration.

The Declaration sets a framework for research, treatment or diagnosis affecting an individual's genome. The framework requires:[147]

- prior, free and informed consent for participation;
- recognition of the right of each individual to decide whether to be informed of the result of genetic examinations;
- protection against discrimination based on genetic characteristics which infringes on human rights, fundamental freedoms or human dignity;
- confidentiality of genetic information associated with an identifiable person; and
- the right "to just reparation for any damage sustained as direct and determining result of an intervention affecting [an individual's] genome".

The Declaration prohibits research which is contrary to human dignity, "such as reproductive cloning of human beings,"[148] and asserts that human genome research must not

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[145] Universal Declaration, Section G: Implementation of the Declaration.
[146] Universal Declaration, Section A: Human Dignity and the Human Genome, Art. 1-4.
[147] Universal Declaration, Section B: Rights of the Persons Concerned, Art. 5-9.
[148] Universal Declaration, Section C: Research on the Human Genome, Art. 11.

prevail over respect for human rights.[149] However, it also states that freedom of research is part of the right to freedom of thought, and is necessary for the progress of knowledge.[150] The Declaration places responsibility on both public and private science policy-makers to create state-specific genome research frameworks which allow for "the free exercise of research on the human genome" while giving regard to the principles in the Declaration.[151]

Finally, the Declaration examines issues surrounding international co-operation.[152] It encourages the international dissemination of scientific knowledge concerning the human genome and the fostering of scientific and cultural co-operation, in particular between industrialized and developing countries. It also supports enhancing the research capacities of developing nations.

Canada has signed the Declaration, and publications by the Canadian Biotechnology Strategy state that Canada will implement it domestically.[153] However, conversations with individuals within the Science and Technology Division of the Department of Foreign Affairs and International Trade indicate that Canada has only involved itself in implementation issues at an international level. Canada has not yet undertaken any activity to incorporate the Declaration into domestic legislation. Canada is participating in an inter-governmental committee which is to work through the details of international implementation, and has continued to have representation on the International Bioethics Committee of UNESCO. Persons within Foreign Affairs indicated that they had no information at all as to plans to bring the Declaration under federal legislation, and that there was nothing in the history of the file to suggest that such activity was at all imminent.

3) Commentary

By virtue of having signed these two instruments, Canada has asserted a willingness to commit itself to developing ethically and socially-conscious standards and procedures *vis-a-vis* 'genetic resources' on the international trade market. It is not clear why Canada has not yet actively incorporated these two instruments into domestic legislation. This is particularly puzzling with regards to the UN Declaration, given the current federal activity in establishing standards and creating regulations regarding new reproductive and genetic

[149] Universal Declaration, Section C: Research on the Human Genome, Art. 10.
[150] Universal Declaration, Section C: Research on the Human Genome, Art. 12.
[151] Universal Declaration, Section D: Conditions for the Exercise of Scientific Activity, Art. 13-16.
[152] Universal Declaration, Section E: Solidarity and International Co-operation, Art. 17-19..
[153] CBS On-line, "Resource Document 1: Other Related Activities" at http://strategis.ic.gc.ca/SSG/bh00185e.html.

technologies,[154] and its imminent activation of the major research project Genome Canada.[155] A possible explanation is that these treaties will only be respected in their violation (i.e. be acknowledged as limitations when activities actively infringe upon the agreements), or that they set such minimal standards that they are already respected in most practices. A more optimistic explanation could be that existing federal intentions are actually already conceptually in line with the terms and intentions of the agreements.

[154] See the section titled " Legislation on New Reproductive and Genetic Technologies."
[155] See the section titled "Genome Research."

PART V. THE NEW GENETICS – FROM BASIC RESEARCH TO SOCIETY

Genome Research

1) Introduction

Genome research involves the study of the genes in the DNA of an organism.[156] There is currently an international effort to identify and map all the 50,000 – 100,000 genes which are estimated to be present in the human genome by the year 2005. This effort is called the International Human Genome Project. The four major investors in the Project are the United States, Japan, Britain and France, who have collectively spent 3 billion dollars on genome research since the Project was commenced in 1991.[157] Canada formally initiated support for the Project in 1992, with the creation of the five-year Canadian Genome Analysis and Technology Program (CGAT). As discussed below, activities are underway to create the successor to CGAT, a program called Genome Canada.

2) The Canadian Genome Analysis and Technology Program

The Canadian Genome Analysis and Technology Program (CGAT) was formed in 1992, with a five year budget of 22 million dollars.[158] Although CGAT was managed and administered by the Medical Research Council (MRC), this management was in partnership with Industry Canada, the National Cancer Institute of Canada (NCIC), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council (SHHRC).

The objectives of CGAT were to:[159]

- build on existing strengths to create new capabilities in genomics that will enhance and maintain Canada's international position;

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[156] This section was compiled with reference to MRC press releases, newspaper articles, the MRC web-site, and conversations with individuals who were involved with CGAT-MELSI or are involved with the new Genome Canada project.

[157] P. Tam, "$25 Million Grant Revives Gene-Mapping Effort" Ottawa Citizen, July 17, 1998; "Genome Task Force is Preparing a Proposal for Genome Canada", Research Money, May 27, 1998.

[158] P. Tam, "$25 Million Grant Revives Gene-Mapping Effort" Ottawa Citizen, July 17, 1998.

[159] B. Knoppers, Ed., Socio-Ethical Issues in Human Genetics (sponsored by the MELSI Committee, Canadian Genome Analysis and Technology Program) (Cowansville, Quebec: Les Editions Yvons Blais, 1998) at ix.

- coordinate Canadian genome research to achieve a critical mass of effort, with a focus on genetic mapping and sequencing, technology development, information management, and analysis of social, ethical, and legal issues;
- direct resources to areas of research that complement the activities of the international human genome project, and avoid overlap in Canada;
- train a new generation of researchers, knowledgeable in the field of genomics and genetic analysis, and developing expertise on social, ethical and legal aspects;
- respond to Canadian health, social and industrial interests; and
- facilitate access by Canadian industry to both domestic and international genome research plans and findings.

CGAT's guidelines indicated that at least 7.5% of its funds were to be for research which would investigate the ethical, legal and social implications of extensive genomic research and knowledge. This led to the founding of the CGAT-MELSI (medical, ethical, legal and social issues) Advisory Committee in 1993 (see Appendix One for a list of the Committee Members). The Advisory Committee had the following mandate and strategy:[160]

Mandate:

- To identify priority medical, ethical, legal and social issues in Canada;
- To promote exchange on MELSI issues;
- To assist the CGAT Management Committee on MELSI issues, and
- To facilitate the study of unique Canadian MELSI opportunities.

Strategy:

- To convene MELSI forums,
- To develop strategies for dialogue on MELSI,
- To compile a compendium of research relevant to MELSI,
- To invite policy papers or research studies as needed, and
- To communicate with groups in other jurisdictions working on MELSI.

CGAT ended up spending over 11% of its general budget on MELSI projects. Appendix Two lists the major research projects which MELSI funded, and Appendix Three lists the research projects which MELSI commissioned. MELSI also sponsored a number of workshops, and was invited to submit comments on the United Nations Declaration on the

[160] *Ibid* at x.

Human Genome and Human Rights.[161] Along with CGAT, MELSI officially ended in April of 1997.

[161] See the section "International Instruments on 'Genetic Resources.'"

3) Genome Research Centres and the Genome Task Force

Following the demise of CGAT-MELSI, the Medical Research Council continued to operate its Genomics Research Program. It budgeted one million dollars a year for genome research. This money is divided between contributing to the funding for opening genome research centres across Canada,[162] and the Genome Task Force. Genome research centres are expected to begin operations commencing in 1999. The most prominent centre, the Genome Sequence Centre in Vancouver, will be headed by Nobel Prize winner Michael Smith and will focus on cancer research. A research centre is also scheduled to open in Halifax, with a focus on mapping the genomes of various bacteria. Other centres are to be established at the Centre for Applied Genomics at Toronto's Hospital for Sick Children, and at McGill University in Montréal.

The Genome Task Force, headed by Dr. Lap-Chee Tsui,[163] was assigned the project of envisioning a new Canadian genome research project. The Task Force recommended a strategy which it called "Genome Canada." This recommendation was approved by the Medical Research Council in July, 1998.[164]

4) Genome Canada

a) The Proposed Project

The MRC has announced that Genome Canada is expected to be launched in the fall of 1999, and that the MRC has committed $25 million over the next five years to human genome research. Genome Canada is planned to be a multi-partnered initiative into genome research. While CGAT was jointly-funded by government agencies, the MRC hopes to raise funds for Genome Canada both from other government agencies as well as by partnering with biotechnology and pharmaceutical companies and with the agriculture and forestry sectors.[165] Their goal is to raise $250 million for genome research over the next five years.[166]

The MRC has also established a MELSI subcommittee to its own Standing Committee on Ethics, which will advise Genome Canada. This subcommittee is already partially in place, advising to the interim project (described below). The subcommittee's members are listed in Appendix Four.

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[162] *Supra* note 158.

[163] Dr. Lap-Chee Tsui is also chief geneticist at the Hospital for Sick Children in Toronto.

[164] Press release, "Canada Returns to Cutting Edge Research", MRC, Ottawa, July 22, 1998.

[165] *Ibid.*

[166] *Supra* note 158.

Very few details have been released on the predicted shape of Genome Canada, such as its mandate and objectives. This is possibly because it is still in the early stages of development, and its form will presumably be influenced by the parties who commit funding as 'partners'. The MRC has not released any statement regarding the role it intends or hopes private industry to play within Genome Canada, aside from being 'partners' through funding.

b) The Interim Project

As Genome Canada will not be established until late in 1999, a transitional program has been put in place under the MRC's Genomic Research Program. It is funded jointly by the MRC at one million per year, and by the Canadian Biotechnology Strategy, which has committed $500,000 per year. This program is operating much as CGAT- MELSI did, with the difference that money will be awarded to projects 'by merit' without regard to funding categories. That is, there is no budget specifically allocated for MELSI-type projects. However, the MRC has put out a call for MELSI-type research applications for projects of up to one year duration. These applications were due January 7, 1999. The MRC has identified the following as a non-exhaustive list of potential research areas which it would fund under the interim project:

- genetic privacy and confidentiality
- concepts and perceptions of normalcy, disability, genetic risk
    - interpretation of genetic information by health professionals, individuals, families, communities
    - application of data obtained from epidemiological studies to individual care
    - relationship between genetics, environment and disease
    - 'enhancement' interventions
- public policy/regulation
    - philosophical, social, ethical, legal basis, etc. for specific issues such as germ-line therapy, embryo research and cloning, transgenics, genetically modified organisms
    - transgenerational justice
    - intellectual property issues
    - wrongful birth/life
- pharmacogenetics/ genetic epidemiology
- commercialization issues
    -intellectual property issues

    - impact on research community
    - public and/or private provision of genetic services
- biodiversity and human diversity
    - impacts on specific populations
- perceptions, communication and education issues
    - ‘genohype’ and ‘genophobia’
- impacts and integration of genomics/genetics into health care
    - relationships between health care providers and patients
    - resource allocation issues
    - evidence-based health care/standards of care

These proposed areas appear to indicate that the MRC is still committed to funding the sorts of projects which were supported under CGAT-MELSI.

Appendix One – Members of the MELSI Advisory Committee for CGAT

Dr. Bartha Knoppers
Chairperson
Faculté de droit
Université de Montréal

Dr. Michael Burgess
Centre for Applied Ethics
University of British Columbia

Dr. Bernard Dickens
Faculty of Law
University of Toronto

Dr. Jane Evans
Dept. of Human Genetics
University of Manitoba

Dr. Béatrice Godard
Unité de recherche en épidémiologie
Centre de researche
Hotel-Dieu de Montréal

Dr. Judith Hall
Chair of the Dept. of Pediatrics
University of British Columbia
Children's Hospital

Dr. Patricia Kaufert
Dept. of Community Health Sciences
University of Manitoba

Dr. Edward Keyserlingk
McGill Centre for Medicine, Ethics and Law
McGill University

Dr. Margaret Lock
Dept. of Social Studies of Medicine
McGill University

Ms. Judith Miller
Health Policy and Bioethics Consultant
Ottawa

Mr. Ralph Walker
Executive Director
Huntington's Society of Canada
Cambridge

SHHRC Observer
Ms. Elaine Isabelle
Director General, Program Branch

MRC Staff
Ms. Genny Cardin
Dr. Karl Tibelius

Appendix Two – Research Projects Funded by MELSI

Kathleen Glass, McGill Centre for Medicine, Ethics & Law
Genetic experimentation and clinical research: continuities and discontinuities
Awarded $55,755

Beatrice Godard, Centre hospitalier, Cote-des-Neiges
Maladies génétiques: vécu et compréhension des familles participantes
Awarded $8,780

Michael Hayden, Medical Genetics, University of British Columbia
Predictive testing for Huntington Disease
Awarded $437,687

Michael Hoy, Economics, University of Guelph
The socio-economic effects of genetic screening
Awarded $83,044

Bartha Knoppers, Faculté de droit, Université de Montréal
Research and human genetic material: persons, property, patents and policy in Canada
Awarded $127,353

David Malkin, Pediatrics, Hospital for Sick Children (Toronto)
Psychological impact of predictive genetic testing for cancer
Awarded $417,065

Paul Ritvo, Toronto Hospital, General Division
Familial genetic risk assessment: Psychological adjustment
Awarded $81,358

David Roy, Clinical Research Institute of Montréal
Genomics and multifactoral disease: towards an ethics for complexity
Awarded $233,674

Linda Surh, Pediatrics, University of Ottawa
An alternative approach to health care decision-making in molecular genetic services
Awarded $291,164

Kathryn Taylor, Princess Margaret Hospital (Toronto)
Developing practice guidelines for heritable cancer risk information providers
Awarded $190,680

<u>Appendix Three</u> – Research Contracts Commissioned by MELSI

Kenneth Bassett, Health Services & Policy Research, U.B.C.
Un-mapping genetics from culture: problematizing the conflation of 'cultural communities' with genetically defined 'populations'
Commissioned $10,000

Timothy Caulfield, Health Law Institute, University of Alberta
Commercialization and human genetics in Canada: legal issues
Commissioned $9,020

Jane Evans, Human Genetics, University of Manitoba
General guidelines for implementing population-based genetic screening
Commissioned $7,630

Sonia Le Bris, Faculté de droit, Université de Montréal
Comparative international positions and recommendations on human genetics
Commissioned $10,000

Trudo Lemmens, Faculté de droit, Université de Montréal
The use of human genetics in life, disability and additional health insurance: an analysis of the legal and ethical debate
Commissioned $10,000

Appendix Four – Members of the MRC Subcommittee to the Standing Committee on Ethics (for MELSI-type projects) as of January 29, 1999

Members

Barbara McGilvrey (Chair), B.C. Children's Hospital, Vancouver, BC.
Tim Caulfield, Director, Health Law Institute, University of Alberta, Edmonton, AB.
Bartha Knoppers, Faculty of Law, University of Montréal, Montréal, PQ.
Kathleen Morrison, Canadian Cystic Fibrosis Foundation.
(for -MELSI

Labeling of Novel Foods Derived Through Genetic Engineering

1) Introduction to Genetic Engineering and Novel Foods

Genetic Engineering is the transfer of selected pieces of genetic information from one organism to another.[167] It is used, often in conjunction with 'traditional' reproductive techniques, to produce new plants and foods which have "novel characteristics". It allows the introduction of traits which may not be able to enter a given organism's genetic make-up through 'traditional' breeding practices, such as resistance to a particular herbicide or extreme cold, the ability to survive drought, or an expedited ripening process.

The Canadian Food Inspection Agency (CFIA) defines novel foods as:[168]

i. Foods that have not previously been used as food,
ii. foods from a process not previously used for food in Canada, or
iii. foods modified such that:
    a. the food results from genetic manipulation and exhibits one or more characteristics that were not previously identified in that food, or the food results from production by a genetically manipulated organism exhibiting such new characteristics,
    b. the food contains microorganisms not previously used as a food or to process food, or
    c. the food is modified from the traditional product or produced by a process that has been modified from the traditional process.

2) Regulatory Framework for Genetically Engineered Agricultural Products and Food Labeling

Health Canada and the CFIA are jointly responsible for federal food labeling policies and practices in Canada. Under the *Food and Drugs Act*., Health Canada is responsible for establishing policies and standards relating to the safety and nutritional value of food sold in Canada, risk assessment, analytic testing research and auditing the CFIA's activities. These responsibilities extend to setting labeling policies regarding health and safety for all food, including genetically engineered food.

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[167] This section was drawn from the Canadian Food Inspection Agency's recent publications and web site, as well as from conversations and e-mail exchanges with individuals at the Canadian Food Inspection Agency and at the Manufactured Food Program of the Canadian Food Inspection Agency.

[168] CFIA, Novel Food Guidelines, September 1994.

The CFIA was created in 1997, as a corporate body which would report to the Minister of Agriculture and Agri-Food Canada.[169] The CFIA is responsible for administering the Acts under which agricultural products of biotechnology are regulated. Some relevant legislation which the CFIA administers and/or enforces, and the biotechnological products which they regulate are presented in Table 1.[170]

Table 1

Product	Act	Biotechnological Products
Agri-food products (meat, dairy, eggs, fruits, vegetables, honey, etc.)	Meat Inspection Act,[171] Canadian Agricultural Products Act[172]	No biotechnological foods to date. Chymotrypsin has been genetically engineered from micro-organisms (used to make cheese, instead of rennin from slaughtered calves' stomachs).
Livestock feeds, additives	Feeds Act[173]	Novel feeds.
Plants	Seeds Act,[174] Plant Protection Act[175]	Plants with novel traits, plants with novel traits and genetically engineered micro-organisms.
Animals, veterinary biologics	Health of Animals Act[176]	Vaccines produced by or containing genetically engineered organisms.

The CFIA is responsible for the enforcement of the Consumer Packaging and Labeling Act[177] and the Food and Drug Act[178] as they relate to food, and the administration of the *Food and Drug Act* as it relates to food. It is also responsible for the development of food labeling regulations and policies which are not associated with health and safety issues. For example, it develops policies to protect consumers from food labeling, packaging, and

169 Canadian Food Inspection Agency Act, S.C. 1997, c.6 [Unofficial Chapter No. C-16.5).

170 This table is partially based on the CFIA's web page on Biotechnology, Agriculture and Regulation. It is located at www.cfia-acia.agr.ca/english/ppc/biotech/geninfor.html.

171 R.S.C. 1985, c.25 (1st Supp.) [Unofficial Chapter No. M-3.2].

172 R.S.C. 1985, c.20 (4th Supp.) [Unofficial Chapter No. C-0.4].

173 R.S.C. 1985, F-9.

174 R.S.C. 1985, S-8.

175 S.C. 1990, c.21 [Unofficial Chapter No. P-14.6].

176 S.C. 1990, c.21 [Unofficial Chapter No. H-3.3].

177 R.S.C. 1985, C-38.

178 R.S.C. 1985, F-27.

advertising which is fraudulent, or contains misrepresentations. It also prescribes the basic food labeling requirements, such as listing ingredients.

3) Current Status of Genetically Engineered Agricultural Products

There are many genetically engineered agricultural products which are currently registered for use in Canada. They include the following:[179]

Plants with novel traits: There have been over 4,000 field trials in Canada of genetically engineered plants since 1988. Health Canada has only given food safety approval to 36 such plants, including varieties of canola, corn, tomato, potato, soybean, cottonseed and squash. General environmental releases, which allow the plant to be grown commercially, have been granted for 31 plants with novel traits. These plants include canola, corn, potato, soybean, wheat and flax. Nine of these plants have been formally registered as crop varieties.

Microbial Fertilizer Supplements: There have been 5 field trials of genetically engineered fertilizers since 1991 in Canada. No such fertilizers have been registered for commercialization in Canada.

Novel Feeds: A total of 31 plants with novel traits have been approved for use as livestock feed in Canada. They include canola, corn, potatoes, soybeans and cotton.

Veterinary Biologics: These biologics include animal vaccines produced by or containing genetically engineered components. A total of 41 genetically engineered veterinary biologics have been registered in Canada since 1988.

4) The Guidelines for Labeling Genetically Altered Food

The Canadian Food Inspection Agency, in conjunction with Health Canada, produced their recommended set of guidelines for the labeling of genetically engineered foods in May, 1998. This set of guidelines has not yet been formally approved within the Ministry of Health (although some specific guidelines have been finalized, others are still under discussion). Phrased generally, the guidelines which the CFIA and Health Canada support are:

[179] CFIA, "Information Bulletin: Labeling of Genetically Engineered Foods in Canada" (Ottawa: Office of Biotechnology, Canadian Food Inspection Agency, May 1998).

- To require mandatory labeling *if there is a health or safety concern* (e.g. allergens, or a significant compositional change). Health Canada has the discretion to determine whether a product raises such concerns.
- To ensure that labeling is understandable, truthful and not misleading.
- To permit *voluntary* positive labeling on the condition that the claim is not misleading or deceptive and the claim itself is factual [e.g. "This product contains genetically engineered tomatoes"].
- To permit *voluntary* negative labeling on the condition that the claim is not misleading or deceptive and the claim itself is factual [e.g. "This product does not contain any genetically engineered organic ingredients"]

Thus, genetically engineered foods would only need to be labeled as such if Health Canada finds that the food raises a health or safety concern. The CFIA, in supporting these guidelines, maintained that "Consumer choice can already be accommodated through Canadian legislation via voluntary labeling by companies."[180] This rather intriguing assertion appears to suggest the position that industry will voluntarily do whatever is necessary to gain or maintain market share [as long as it does not *violate* legislation], and so consumer choice is accommodated through market pressure.

Some interest groups and individuals indicated during the consultations for the guidelines that they wanted mandatory labeling for all genetically engineered products. This label could simply be a "logo" or "trademark."[181] This desire was described as sourced in the consumer "right to know" and the right to "choose safe foods."[182] The exercise of these rights was argued to entail having knowledge about whether a product was genetically engineered at the point of sale. However, the CFIA reports that it decided against this option as impractical, unenforceable, and potentially meaningless.

The CFIA found that the practical difficulty and cost of tracking foods within the food system so as to know whether the food contains any genetically engineered components or ingredients outweighed any benefit to Canadian consumers. They similarly found that the government would not be able to enforce mandatory labeling, as in many cases there is no

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[180] *Ibid.*

[181] There were three major sets of consultations since 1993 on genetic engineering and food. These resulted in a proposal which was circulated for comment. Public comments on the proposal are summarized at: http://www.cfia-acia.agr.ca/english/ppc/foodinsp/infolete.html.

[182] See http://www.cfia-acia.agr.ca/english/ppc/foodinsp/infolete.html.

way to distinguish between a genetically engineered food product and one which is not except through extensive and expensive genetic testing. They also found that "so many foods would have some ingredient or component that has been genetically engineered that the labels would be meaningless."[183] Finally, they determined that labeling genetically engineered food in response to religious dietary requirements was inappropriate, as religious requirements were simply outside the mandate of the government.

5) Broader Context

Canada is a member of the United Nations agency responsible for setting international food standards, the CODEX Alimentarius Commission, and also works with the CODEX Committee on Food Labeling. The most recent CODEX Committee meeting was in May, 1998, and ended in a stalemate.[184] The central issue was whether genetically altered foods ought to be labeled as such. Canada put forward the position outlined above, that they should not have special labeling unless there is a proven health risk or change in nutritional content. Canada was supported in this position by the United States and some Latin American countries. The European Union, supported by India and several Asian countries, took the position that all genetically altered foods ought to be subject to mandatory labeling. The fact that the EU believes mandatory labeling is not only possible but necessary suggests that Canada's arguments to the effect that mandatory labeling is impossible are not necessarily as strong as Canada has indicated. It is worth noting that Canada's position on labeling is similar to that described as Canada's position in other areas touched on within this report. Canada has chosen not to impose actual regulations – except where there is an identified health and safety concern – but instead decided that industry can be left to self-regulate on a voluntary basis.

[183] CFIA, "Information Bulletin: Labeling of Genetically Engineered Foods in Canada" (Ottawa: Office of Biotechnology, Canadian Food Inspection Agency, May 1998).

[184] "Disagreement still lingers on the issue of labeling genetically altered foods", The Globe and Mail, May 30, 1998.