QUEEN
TP
248.195
.C2
C35
1998
v.1
c.2

IC

Renewal of the Canadian Biotechnology Strategy

Resource Document

Other Related Activities

Government of Canada Gouvernement du Canada

Canada

Queen
TP
248.195
.C2
C35
1998
v. 1
c. 2

Renewal of the Canadian Biotechnology Strategy

Resource Document

Industry Canada
Library - Queen

MAR 17 1998

Industrie Canada
Bibliothèque - Queen

Other Related Activities

Renewal of the Canadian Biotechnology Strategy Resource Document 1 is available electronically on the Industry Canada *Strategis* web site at: **http://strategis.ic.gc.ca/cbs**

Additional print copies of this roundtable consultation paper are available from:

Distribution Services
Industry Canada
Room 208D, East Tower
235 Queen Street
Ottawa ON K1A 0H5
Tel.: (613) 947-7466
Fax: (613) 954-6436
E-mail: publications@ic.gc.ca

For information about the contents of this discussion paper and the consultation process, or to submit your responses to the paper, please contact:

Canadian Biotechnology Strategy Task Force
Room 799B, East Tower
235 Queen Street, 7th Floor
Ottawa ON K1A 0H5
Tel.: (613) 946-2848
Fax: (613) 946-2847
E-mail: cbstf@ic.gc.ca
Web site: **http://strategis.ic.gc.ca/cbs**

This document can be made available in alternative formats for persons with disabilities upon request.

© Her Majesty the Queen in Right of Canada (Industry Canada) 1998

Cat. No. C21-22/2-1998
ISBN 0-662-63399-7
51795B

CONTENTS

1.1	RENEWAL OF THE *CANADIAN ENVIRONMENTAL PROTECTION ACT*	1
1.2	BIOSAFETY PROTOCOL	2
1.3	REPRODUCTIVE AND GENETIC TECHNOLOGIES	3
1.4	WORLD TRADE ORGANIZATION PATENT REVIEW	4
1.5	PRIVACY LEGISLATION	5
1.6	HUMAN GENOME DECLARATION	6
1.7	CODEX COMMITTEE ON FOOD LABELLING	7
1.8	SAFETY OF XENOTRANSPLANTATION	8

Biotechnology is an enabling technology that has a wide variety of manifestations that cannot be dealt with in detail in the roundtable consultations. The activities listed in this resource document are part of the government's ongoing program. Individuals or organizations wishing more information are invited to follow up with the listed contact point.

1.1 Renewal of the *Canadian Environmental Protection Act*

The *Canadian Environmental Protection Act* (CEPA) contains provisions that require all new substances, including biotechnology substances (organisms and products of organisms such as enzymes), to be assessed for potentially adverse effects before they are manufactured or imported. Regulations covering these substances took effect September 1, 1997. CEPA does not cover new substances regulated under other federal legislation.

A Bill to renew CEPA, drafted in 1996, contains a new part for living biotechnology substances. The draft Bill to renew CEPA retains existing provisions regarding biotechnology substances, while clarifying certain issues related to scope.

The federal government and the Minister of the Environment have stated their commitment to passing the Bill early in this mandate. The CEPA Bill is currently being prepared for reintroduction into the House of Commons.

For further information, contact:

CEPA Office
Environment Canada
Tel.: (819) 953-0142
Fax: (819) 997-0449
E-mail: cepa@ec.gc.ca

1.2 Biosafety Protocol

Negotiations are under way to develop a Biosafety Protocol under the United Nations Convention on Biological Diversity. The protocol will be designed to protect biological diversity from any adverse effects resulting from the transboundary movement of living modified organisms, including those made through biotechnology.

At the heart of the protocol will be a requirement for advance informed agreement before parties can import living modified organisms. Canada already requires such an agreement.

The next negotiating session is set for July 1998. Negotiations are expected to conclude in 1998.

For further information, contact:

Biodiversity Convention Office
Environment Canada
Tel.: (819) 953-4374
Fax: (819) 953-1765
E-mail: BCO@ec.gc.ca

1.3 Reproductive and Genetic Technologies

The Royal Commission on New Reproductive Technologies was established in 1989 to examine the social, medical, legal, ethical, economic and research implications of new reproductive technologies, and to recommend policies and safeguards.

The Commission issued its final report in November 1993. Its 293 recommendations dealt with the prevention of infertility, the management of assisted reproduction, sex selection for non-medical reasons, prenatal diagnosis techniques and gene therapy, judicial intervention in pregnancy and birth, and the use of fetal tissue.

The Commission made three major recommendations:

- the creation of legislation to prohibit a range of practices, including sex selection for non-medical purposes, the buying and selling of human eggs, sperm and embryos, germ-line genetic alteration, and commercial pre-conception or "surrogacy" contracts
- the creation of a National Reproductive Technologies Commission to license, regulate and monitor these technologies
- the prevention of infertility.

Bill C-47, the *Human Reproductive and Genetic Technologies Act*, was introduced in June 1996 but did not become law before the federal election was called on June 2, 1997. It dealt with the prohibitions recommended by the Royal Commission. Health Minister Rock has stated that he hopes to introduce a new bill that will take a comprehensive approach to reproductive and genetic technologies as soon as possible.

For a copy of Health Canada's "*New Reproductive and Genetic Technologies: Setting Boundaries, Enhancing Health,*" contact:

Publications and Distribution
Health Canada
Tunney's Pasture
Postal Locator: 0900C2
Ottawa ON K1A 0K9
Tel.: (613) 954-5995
Fax: (613) 941-5366

1.4 World Trade Organization Patent Review

Canadian patents have been issued for unicellular organisms, but no patent claims covering a plant or an animal have been granted. However, the Harvard Onco-mouse patent application remains before the Federal Court awaiting a decision.

With a view to the upcoming 1999 World Trade Organization (WTO) reviews, Industry Canada, through consultations, will develop a position on the patenting of higher life forms. The central issue is whether and to what extent patent claims covering plants and animals should be granted, and what exemptions and safeguards are needed to protect the public interest. Another key issue is whether ethical and moral aspects should be considered in granting patents.

While the United States grants patents for all biotechnological products and processes that meet its established patentability criteria, the European Patent Office, while employing similar criteria, has excluded from patentability plant and animal varieties and inventions that offend public order on morality grounds.

For further information, contact:

Intellectual Property Policy Directorate
Industry Canada
Tel.: (819) 952-2527
Fax: (819) 952-1980

1.5 Privacy Legislation

To participate in the information society fully and with confidence, both consumers and businesses need to be able to share information and conduct transactions knowing that their data are protected. As consumers, we need assurances that our personal information will enjoy a basic level of protection, no matter who we deal with. Business needs a predictable and fair environment, with clear rules for all.

In order to foster the growth of such an environment, enabling Canada to become a leader in electronic commerce, the government has committed to developing a legislative framework that will protect personal information, while allowing for the flow of information that is essential to our ability to compete in a global economy.

As a first step in that process, the departments of Industry and Justice have released a public consultation paper titled *The Protection of Personal Information: Building Canada's Information Economy and Society*. The paper proposes using the Canadian Standards Association (CSA) Model Code for the Protection of Personal Information, which represents a consensus among businesses, consumer groups and government as a starting point, and seeks input on the various issues that must be addressed by the proposed legislation.

The paper is available electronically at: **http://strategis.ic.gc.ca/privacy**. All Canadians are encouraged to read and respond to the paper by March 27, 1998.

For further information, contact:

Electronic Commerce Task Force
Industry Canada
Tel.: (613) 991-4029
Fax: (613) 957-8837
E-mail: demers.suzanne@ic.gc.ca

1.6 Human Genome Declaration

On November 11, 1997, the Universal Declaration on the Human Genome and Human Rights was adopted in Paris by the United Nations' Educational, Social and Cultural Organization (UNESCO) General Conference.

The Declaration is the first international text on the ethics of research, seeking to underscore the dignity and rights of persons, while recognizing the need to protect freedom of research. The text of the Declaration pursues the following three major directions: protection of the person, promotion of knowledge and development of "solidarity" and cooperation.

The Declaration is intended as an instrument of exhortation and therefore is not legally binding.

Canada intends to play an active role in ensuring domestic implementation of the Declaration and in follow-up discussions among UNESCO Member States on how best to ensure the broadest possible and most effective means of international implementation. In this regard, Canada will pursue a number of unresolved concerns, shared by many other countries. These concerns include, for example, the requirement to fully engage governments and potentially "vulnerable" groups in follow-up mechanisms and consultations.

For further information, contact:

Science and Technology Division
Department of Foreign Affairs and
International Trade
Tel.: (613) 995-9259
Fax: (613) 944-0111
Web site: **http://www.dfait-maeci.gc.ca**

1.7 CODEX COMMITTEE ON FOOD LABELLING

Health Canada is responsible for setting labelling policies on health and safety matters. The new Canadian Food Inspection Agency is responsible for developing non-health and safety food-labelling regulations and policies, including those pertaining to new foods derived through biotechnology.

General principles for labelling foods from biotechnology have emerged from a series of multi-stakeholder consultations over the past four years. Specifically, there is support for labelling in the case of a health or safety concern such as allergenicity or a significant nutritional change in the food. Voluntary negative ("does not contain") or positive ("does contain") claims are permitted, providing the claims are truthful and not misleading. As these principles are consistent with the *Food and Drugs Act*, changes to these regulations are not required.

Canada is a member of CODEX Alimentarius Commission and works with the CODEX Committee on Food Labelling to arrive at a common international position on this matter. The next meeting of the CODEX Committee is in May 1998.

For further information, contact:

Biotechnology Strategies and Coordination Office
Canadian Food Inspection Agency
59 Camelot Drive
Nepean ON K1A 0Y9
Tel.: (613) 225-2342
Fax: (613) 228-6604
Web site: **www.cfia-acia.agr.ca**

Office of Food Biotechnology
Health Protection Branch
Health Canada
Sir Frederick Banting Research Centre
Tunney's Pasture
Ottawa ON K1A 0L2
Tel.: (613) 952-7322
Fax: (613) 952-6400
Web site: **www.hc-sc.gc.ca/datahpb/datafood**

1.8 Safety of Xenotransplantation

The prospect of xenotransplantation raises the issue of xenozoonoses, that is, the transmission of animal infections to the human host. Concerns include the source and characterization of donor animal organs and tissues intended for human transplantation.

People's ethical, social, and religious perceptions and attitudes, and legal norms also need to be considered. Psychological, cultural and societal concerns require frank public debate, and the dissemination of accurate information.

A Standards-based Regulatory Framework is being developed by Health Canada to address the safety of transplantation. A key component of this approach is the development of a Canadian General Standard (CGS) on Safety of Organs and Tissues for Transplantation and of specific standard subsets for individual organ and tissue groups, including one for xenotransplantation. These standards will be recognized under the National Standards System of Canada and referenced in the Food and Drug Regulations. The proposed framework will include methods to verify compliance, adverse event reporting and patient registries and will be administered by the Therapeutic Products Programme of Health Canada with both stakeholder and provincial government participation.

The Therapeutic Products Programme sponsored a National Forum for public and professional opinion development and decision making on the future clinical use of xenotransplantation in Ottawa, November 6–8, 1997.

The National Forum on Xenotransplantation represented the first opportunity for the staff of the Therapeutic Products Programme to consult broadly with stakeholders — health professionals; patient, animal care and consumer groups; ethicists; industries; and research groups on the clinical, ethical and regulatory issues of xenotransplantation.

Information from the National Forum on Xenotransplantation will be reviewed by an external expert committee in the further drafting of a xenotransplantation standard. The Forum proceedings will be published and made available to stakeholders and other interested parties. Comments from participants attending the Forum and feedback from the Forum report will be reviewed as part of the Therapeutic Products Programme's consultative approach to risk management of new biotherapeutic therapies.

Canada is breaking new ground in the development of national standards covering the safety of tissues and organs used in transplantation. It is anticipated that this initiative will be seen as a positive step forward on the international front and may well be used by other countries in developing their own risk management frameworks.

For further information, contact:

The Therapeutic Products Programme
Health Canada
Health Protection Building
Tunney's Pasture
Ottawa ON K1A 0L2
Tel.: (613) 957-0369
Fax: (613) 952-7756
E-mail: dann_michols@hc-sc.gc.ca
Web site: **www.hc-sc.gc.ca/hpb-dgps/therapeut/**