Review of the New Substances Notification Regulations (Organisms)

Backgrounder

February 22, 2006

New Substances Program,
Environment Canada
Health Canada

NOTE TO READER: This document is a work in progress. The substantive content is for discussion purposes only, and reflects the initial perspectives of officials with the New Substances Program in Environment Canada and Health Canada. It will evolve and improve with feedback from readers. This document does not represent the position of the Government of Canada.

FOREWORD

This document provides background information to interested parties participating in the multi-stakeholder consultation process to review the New Substances Notification Regulations (NSNR) for Organisms. The NSNR (Organisms) prescribe the process for the notification and assessment of new substances that are living organisms. The purpose of this document is to help readers understand the NSNR (Organisms) and their administration, so that they will be better able to participate fully and fairly in the consultations.

Opportunities to solicit feedback relating to the review of the NSNR (Organisms) have included or will include regional information sessions in fall 2005, Web-based consultations, and a multi-stakeholder workshop focused on subsection 2(4) and section 4 in March 2006. The provisions in subsection 2(4) address the research and development exemption for living organisms other than micro-organisms, while section 4 governs their notification and assessment. A separate document, entitled *"Review of the New Substances Notification Regulations (Organisms): Discussion Document — Workshop on the Provisions Dealing with Organisms Other than Micro-Organisms"* is available to assist interested parties in preparing for the workshop.

The process for reviewing the remaining provisions of the NSNR (Organisms) will be determined following the workshop. Environment Canada and Health Canada will then update interested parties on the path forward.

This backgrounder and its companion discussion document were prepared by Environment Canada and Health Canada following extensive discussions with other interested federal departments and agencies, including Agriculture and Agri-Food Canada, the Canadian Food Inspection Agency, the Department of Fisheries and Oceans, Natural Resources Canada, and the Pest Management Regulatory Agency. The options proposed in the discussion document do not necessarily represent the position of all

departments and agencies involved in these discussions. The content of this backgrounder and the discussion document remains the responsibility of the New Substances Program in Environment Canada and Health Canada.

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ABBREVIATIONS

CEPA 1999	*Canadian Environmental Protection Act*, 1999
CFIA	Canadian Food Inspection Agency
DNA	deoxyribonucleic acid
DSL	Domestic Substances List
EC	Environment Canada
HC	Health Canada
MOU	Memorandum of Understanding
NSNR	New Substances Notification Regulations
PMRA	Pest Management Regulatory Agency
PNT	plant with novel traits
R&D	research and development
SNAc	significant new activity

1. INTRODUCTION

1.1 CONTEXT

The *Canadian Environmental Protection Act* (CEPA), which was promulgated in 1988 and substantially amended in 1999 (CEPA 1999), takes a proactive and preventative approach to regulating new substances. All substances that are new to Canada, including chemicals, polymers, and living organisms, must be assessed before they are imported into or manufactured in Canada in order to determine whether they may be harmful to human health or the environment, including biodiversity.[1] Section 64 of CEPA 1999 defines a substance as toxic if it is entering or may enter the environment in a quantity or concentration or under conditions that

- have or may have an immediate or long-term harmful effect on the environment or its biological diversity,
- constitute or may constitute a danger to the environment on which life depends, or
- constitute or may constitute a danger in Canada to human life or health.

The New Substances Notification Regulations (NSNR) for Organisms provide the New Substances Program with the regulatory authority and tools to make this assessment. Environment Canada (EC) and Health Canada (HC) have also developed "*Guidelines for the Notification and Testing of New Substances: Organisms",* to help clarify the obligations of notifiers and assist them in the preparation of notification packages.

CEPA 1999 exempts new substances from the notification and assessment requirements of the NSNR (Organisms) if their use is regulated under another federal act that meets the CEPA 1999 environmental and health-protection benchmarks. The *Fertilizers Act*, *Seeds Act*, *Health of Animals Act*, *Feeds Act*, *Pest Control Products Act*, and their respective regulations

[1] The Domestic Substances List (DSL) is the sole basis for determining whether a substance is "new" for the purposes of CEPA 1999. For more information on the DSL, visit www.ec.gc.ca/substances.

have all been declared to meet these benchmarks, and are listed accordingly in Schedule 4 of CEPA 1999. All other new substances are subject to CEPA 1999, and must be notified to EC unless they are manufactured, used, or imported under the conditions and circumstances prescribed as exempt in section 106(6) of CEPA 1999 or subsections 2(3) and 2(4) of the NSNR (Organisms).

1.2 THE NSNR (ORGANISMS) AND THE SCOPE OF THIS REVIEW

The NSNR, when first published in 1994, were restricted to prescribing the process for notifying and assessing new chemical and polymer substances. In 1997, these regulations were amended by the addition of Part II.1, which detailed the process for notifying and assessing new substances that are living organisms (i.e., animate products of biotechnology).

In 1999-2000, the chemicals and polymers portion of the NSNR underwent an extensive multi-stakeholder review. Significant administrative changes that have been implemented as a result of the recommendations arising from this review have improved program delivery for all substances administered by the New Substances Program. As a result of these consultations, the NSNR have been divided into two separate regulations: the NSNR (Chemicals and Polymers) and the NSNR (Organisms), which were published in the *Canada Gazette, Part II,* in September 2005 (http://gazetteducanada.gc.ca/partII/2005/20050921/html/sor248-e.html). EC and HC are now beginning a multi-stakeholder process to review the NSNR (Organisms).

The NSNR (Organisms) apply to new substances that meet the definition of a living organism. “Living organism” is defined in section 104 of CEPA 1999 as an animate product of biotechnology. “Biotechnology” is defined in section 3 of CEPA 1999 as "the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms". Living organisms include micro-organisms and organisms other than micro-organisms (plants, invertebrates and vertebrates) that i) have been developed through the application of science and engineering, or ii) are naturally occurring and science and engineering are being applied in their use.

More specifically, the scope of the NSNR (Organisms) and, therefore the scope of this review, focuses on new substances that are living organisms and that are

- micro-organisms used, for example, in bioremediation, industrial enzyme production, food and drug production, wastewater treatment, or non-livestock feed (e.g., pet food). “Micro-organism”, as defined in the NSNR, means a microscopic living organism that is
    a) classified as bacteria, archaea, protista (which includes protozoa and algae), or fungi (which includes yeasts);
    b) a virus, virus-like particle, or sub-viral particle;
    c) a cultured cell of an organism not referred to in (a) or (b), other than a cell used to propagate the organism; or
    d) any culture other than a pure culture.

or,

- organisms, other than micro-organisms, including
    a) certain new animals (e.g., cattle modified to produce pharmaceutical proteins or to increase milk or meat production; companion animals derived from somatic-cell nuclear transfer; fish modified for growth enhancement; rats modified to create research models for the investigation of diseases); and
    b) certain new plants and seeds (e.g., grain imported strictly for processing into a food or into a pharmaceutical or industrial compound in containment; genetically modified exotic-plant species).

The NSNR (Organisms) also prescribe conditions or circumstances under which the manufacture, use, or import of a substance is exempt from its notification and assessment requirements. Subsection 2(3) of the Regulations prescribes exemptions for micro-organisms and subsection 2(4) prescribes exemptions for organisms other than micro-organisms. Substances that meet the exemption criteria outlined in subsections 2(3) and 2(4) of the NSNR (Organisms) are included in the scope of this review.

Some categories of new substances that are living organisms that do not require notification under the NSNR (Organisms) are detailed in Appendix 1. These categories are exempt from the requirements of the NSNR (Organisms), as their use is regulated under another federal act or regulation listed in Schedule 4 of CEPA 1999. As such, they do not fall under the scope of this review. For more information on these categories, contact the relevant federal authorities listed in Appendix 2.

1.3 THE NOTIFICATION AND RISK-ASSESSMENT PROCESS

The NSNR (Organisms) require importers and manufacturers to submit a notification to the Minister of the Environment, within a prescribed timeframe, prior to importing or manufacturing a new substance that falls under the Regulations.

The *Guidelines for the Notification and Testing of New Substances: Organisms* (the Guidelines) provide guidance on the preparation of notifications. EC and HC also issue advisory notes on the New Substances Program's Web site (http://www.ec.gc.ca/substances) to further assist notifiers in understanding the Guidelines and Regulations. Notifiers are encouraged to consult with EC and/or HC by telephone during the planning or preparation of a notification, or to set up a pre-notification consultation meeting to discuss any questions they may have. Contact information for the departments is provided in Section 4 of this document.

The NSNR (Organisms) classify new substances that are living organisms into five notification categories: four for micro-organisms, and one for organisms other than micro-organisms. The specific technical and administrative information requirements and time frames for assessing notifications in each of these categories are prescribed in the Regulations and their corresponding schedules. All notifications must address the appropriate requirements.

The information requirements for micro-organisms are prescribed in subsection 2(3) and section 3 of the Regulations and in schedules 1 to 4. The information requirements for organisms other than micro-organisms are prescribed in subsection 2(4) and section 4 of the Regulations and in Schedule 5. This system enables the Government to tailor information requirements to anticipated concerns about the characteristics of specific notification categories, thereby ensuring the appropriate assessment of potential environmental and human-health risks.

The technical information prescribed in the regulations includes identification information; descriptions of any modifications made to the organism; the organism's biological and

ecological characteristics; manufacturing and quality-control methods; experimental data on toxicity, pathogenicity, and invasiveness; a description of test procedures; and exposure information, such as information on intended use, quantities manufactured and imported, disposal, and site of introduction. Potential risks to human health are assessed by HC, and potential risks to the environment (including biodiversity) by EC.

When EC receives a complete notification package, the two departments conduct risk assessments to determine whether the new substance is suspected of meeting the criteria set out in section 64 of CEPA 1999. Import or manufacture may occur only after all of the information has been received, the period for assessing the information has expired, and any risk-management measures are in place. There are five possible outcomes of the risk assessment:

1. The organism is not suspected of being toxic or capable of becoming toxic. Import or manufacture may proceed after the assessment period has expired. If the organism is eligible, provided that the listing criteria are met, it is added to the Domestic Substances List.
2. The organism is not suspected of being toxic for the use specified in the notification; however, it is suspected that a significant new activity (SNAc) may result in the organism becoming toxic. Import or manufacture for the use specified in the notification may proceed after the assessment period has expired. A SNAc notice is published in the Canada Gazette. A re-notification must be received prior to the substance being used for a SNAc[2]. If the organism is eligible, provided that the listing criteria are met, it is added to the Domestic Substances List.
3. The organism is suspected of being toxic or capable of becoming toxic. The organism can be imported or manufactured subject to specified conditions.
4. The organism is suspected of being toxic or capable of becoming toxic. The manufacture or import of the organism is prohibited pending the receipt and assessment of additional information or test results.
5. The organism is suspected of being toxic or capable of becoming toxic. The manufacture or import of the organism is prohibited for a period not exceeding two years.

[2] For instance, a micro-organism used for bioremediation in a particular ecozone may not be considered toxic in the planned location of use, but may be considered invasive in other parts of Canada. Use in a different ecozone or location in Canada could be considered a SNAc, and would require re-notification.

1.4 WHY REVIEW THE NSNR (ORGANISMS)?

The NSNR (Organisms) have been in force for eight years. Experience gained by all parties over this time has persuaded EC and HC that a review of the Regulations is now timely given the following:

- new developments and approaches in the rapidly evolving science that underpins the assessment and management of new biotechnology substances require the ongoing improvement of the Regulations;
- the public has expressed concerns over the rapid pace of developments in the field of biotechnology in Canada and abroad, and needs government assurance with regard to the protection of human health and the environment, including biodiversity;
- recent accidental releases involving transgenic animal carcasses from research and development (R&D) facilities;
- not all of the notification categories for micro-organisms (i.e., schedules 1 to 4) have proven useful, and a single notification category (i.e., Schedule 5) to accommodate all organisms other than micro-organisms may not be sufficient; and,
- the need to ensure coherence with newer government policies and initiatives, such as Smart Regulation (www.regulation.gc.ca), and, where possible and appropriate, alignment of the Regulations and the Program with those of other federal departments and agencies.

The overall purpose of the review of the NSNR (Organisms) is to give interested parties an opportunity to discuss and propose changes to the Regulations and the Program. The objectives of the review are to

- maintain or improve its mandate under CEPA to safeguard the environment and human health (the primary objective)[3];
- enhance EC's and HC's awareness of all living organisms within the scope of the NSNR (Organisms), including those manufactured or imported for the purposes of R&D;
- clarify the notification process and regulatory provisions, so that they are understood by all parties and are enforceable; and
- tailor the process to the issue, such that it is more cost-effective, flexible, fair, and science-informed.

[3] Environmental and human-health protection takes precedence over economic or other considerations in this review. Where objectives are at odds, decisions will favour the primary objective.

1.5 THE PROCESS FOR REVIEWING THE NSNR (ORGANISMS)

Based on an independent contractor's report, EC and HC are proceeding with the review of the NSNR (Organisms) through regional information sessions (held in November and December 2005), Web-based consultations, and a multi-stakeholder workshop focused on subsection 2(4) and section 4 (to be held in June 2006). These provisions are a priority for review because EC and HC believe that they must be addressed as soon as possible in order to ensure the continued protection of human health and the environment, including biodiversity. The issues and proposed options pertaining to subsection 2(4) and section 4 organisms are detailed in the discussion document, which is available at http://www.ec.gc.ca/substances/nsb/eng/consul_e.htm.

Following the workshop, EC and HC will consider a multi-stakeholder consensus-building process and other mechanisms to review the remaining sections of the NSNR (Organisms). Each of these mechanisms is detailed in the contractor's report at http://www.ec.gc.ca/substances/nsb/eng/consul_e.htm.

2. OVERVIEW OF BIOTECHNOLOGY REGULATION

The 1993 Federal Regulatory Framework for Biotechnology, as updated by the 1998 Canadian Biotechnology Strategy, is intended to ensure that the benefits of biotechnology are realized in a way that protects health, safety, and the environment. The 1993 Framework resulted from an agreement among federal regulatory departments and agencies on principles for an efficient and effective approach to regulating biotechnology substances and products, with a priority on health, safety, and the environment. It recognizes that federal departments and agencies with expertise and experience related to specific classes of substances and products will take primary responsibility for the regulation of new living organisms that fall within their areas of expertise.

CEPA 1999 was designed to strengthen this horizontal approach to regulating biotechnology substances by establishing it as the federal benchmark for assessing and managing health and environmental risks. Specifically, all new substances that are living organisms must be notified and assessed through CEPA 1999, unless the Governor in Council has determined that another act meets the CEPA 1999 environmental- and health-protection benchmarks. Five acts and related regulations have been deemed as meeting these benchmarks and are currently listed in Schedule 4 of CEPA 1999: the *Fertilizers Act*, *Seeds Act*, *Health of Animals Act*, *Feeds Act*, and their associated regulations (which are administered by the Canadian Food Inspection Agency); and the *Pest Control Products Act* and its regulations (which are administered by the Pest Management Regulatory Agency).

The key regulatory departments and agencies have been working closely with one another to fulfill the goals and principles of the 1993 Framework within the constraints of their respective legislation and mandates. The following are some examples of their efforts:

- The Canadian Food Inspection Agency, EC, and HC have drafted notification guidelines for the environmental assessment of biotechnology-derived livestock animals[4] based on Schedule 5 of the NSNR.
- In 2004, Fisheries and Oceans Canada, EC, and HC concluded a memorandum of understanding (MOU) detailing how the three departments will work together to assess the environmental and indirect human-health effects of aquatic organisms with novel traits under CEPA 1999. Efforts to implement the MOU include the development of regulations to meet the CEPA 1999 benchmark. This initiative is expected to clarify the regulatory processes for such organisms.
- In 2001, EC and HC signed an MOU in which HC agreed to process and conduct the environmental risk-assessment of products covered under the *Food and Drugs Act* until the Environmental Assessment Regulations are in place and listed in Schedule 4 of CEPA 1999.
- Regulatory departments and agencies are considering how to address other rapidly emerging technologies, such as plant molecular farming.

[4] http://www.inspection.gc.ca/english/anima/vetbio/abu/biotech/guidedirecte.shtml

3. CANADA'S BIOTECHNOLOGY COMMUNITIES[5]

Biotechnology is not an industry or sector in the traditional sense. Rather, it is understood as an enabling technology platform that contributes to a variety of sectors (including agriculture, health, environment, food processing, aquaculture, bioinformatics and natural resources). These sectors research, develop, and provide new methods of production and breeding, make new products, provide new services, and find new ways to improve quality of life.

Generally speaking, Canada's biotechnology initiatives comprise a wide variety of public- and private- sector players, including companies, governments, research institutes, hospitals, universities, and technical colleges. The establishment of significant biotechnology service-industry, research-community, and industrial product-development sectors in Canada has made it one of the largest biotechnology centres in the world. Since 2001, these sectors have employed some 12 000 people, and their rapid rate of growth is expected to continue into the foreseeable future.

Canada is a strong player in biotechnology. With approximately 500 companies in operation, Canada ranks second in the world to the United States, and ranks third after the United States and the United Kingdom in generating revenues. However, many of the Canadian companies are very small. In fact, 10 of them account for 70 per cent of the market capitalization of all Canadian biotechnology companies. The greatest concentration of the Canadian biotechnology companies is in the therapeutics sector (approximately 50 per cent), followed

[5] The text in this section was gleaned from the following sources: the Canadian Conference Board of Canada Report entitled *Biotechnology in Canada – A Technology Platform for Growth*, December, 2005; the CBAC Web site, including *The Key to the Future—2004 Canadian Biotechnology HR Study*; *Scan of Canadian Strengths in Biotechnology*, prepared by Science-Metrix for the National Research Council of Canada in January 2005 (http://www.biotech.ca/PDFs/BTC_StateReport2004_en.pdf); and *Assessing Biotechnology as a 21st Century Technology Platform for Canada*, prepared by the Conference Board of Canada for the Canadian Biotechnology Secretariat in May 2005. Given the rapidly evolving nature of biotechnology, all figures in this backgrounder are approximations, and are intended only to provide a broad snapshot of activities relating to the biotechnology communities in Canada.

by agriculture (18 per cent), food processing (10 percent), environment (7 per cent) ; bioinformatics, aquaculture, natural resources (10 per cent combined).

Canada's biotechnology sector is distributed across the country. The dominant players are Quebec, with 146 companies, followed by Ontario (129), and British Columbia (91). Within the biotechnology sector, Quebec, Ontario, Alberta, and British Columbia are strong players in health-care, Saskatchewan in agriculture, and Atlantic Canada in aquaculture, forestry, and biodiversity.

In 2004, the Canadian biotechnology market was worth approximately CDN $18 billion, which is comparable to that of other major players, including the United Kingdom and Australia. The number of start-up biotechnology companies in Canada continued to grow through 2002 and beyond, due to several key factors: government funding of various research facilities, refundable research-and-development tax credits from federal and provincial governments, and fairly easy access to para-government and private seed capital.

As Table 1 shows, the majority of firms employ fewer than 50 individuals, but spend large sums of money on R&D—a sign that they are still in their growth phase. On the other hand, large firms employing more than 150 employees reap significant revenues with minimal R&D expenditures. Table 2 lists some of Canada's key R&D biotechnology communities.

Table 1. Biotechnology Indicators in Canada, 2003

Size	Number of Innovative Companies[1]	Number of Biotechnology Employees	Biotechnology Revenues ($ millions)	Biotechnology R&D Expenditures ($ millions)
Small (0 – 49 employees)	352	3557	469	495
Medium (50 – 149 employees)	77	3746	909	699
Large (>150 employees)	61	4628	2443	293
Total	496	11 931	3821	1487

[1] Refers to firms that use biotechnology to develop products or processes. In this survey, a firm was considered innovative if it has one or more biotechnology products or processes on the market, it is currently developing products or processes that require the use of biotechnology, or it considers biotechnology central to its activities or strategies.
Source: Statistics Canada (2004). *Biotechnology Use and Development Survey—2003* (preliminary). *The Daily*, catalogue number 11-001-XIE, December 14, 2004. (http://www.statcan.ca/Daily/English/041214/d041214d.htm)

Table 2. Research and Development Biotechnology Communities in Canada Affected by the Review of the NSNR (Organisms)*

Type of Organism	Type of Biotechnology[6]	Application[6]	Major Institutions[7]
Lab animals: rabbits, rodents (e.g., rats, mice, gerbils, hamsters), primates (e.g., baboons, monkeys)	- gene expression, gene mapping, genomics, proteomics, gene transfer, nuclear transfer, *in vitro* fertilization, cloning, cryopreservation, embryo transfer, etc.	- model for animal and human diseases, human and animal therapeutics, xenotransplantation, gene therapy, immunology, improved reproduction, knockouts, stem cells, neurology, etc.	Universities: 21 Private firms: 197 Government centres: 28
Major livestock : cattle, pigs, sheep, goats, chickens, turkeys	- gene expression, gene mapping, nuclear transfer, cloning, transgenesis, embryo transfer, *in vitro* fertilization, gene detection, genomics, proteomics, etc.	- improved reproductive performance and yield of animal products - biopharming, recombinant proteins, therapeutics, and xenotransplantation - detection of genetically modified products	Universities: 11 Private firms: 36 Government centres: 10
Fish: fin fish (e.g., Atlantic salmon, coho salmon, rainbow trout, zebra fish, Pacific salmon, Arctic char, tilapia, etc.)	- gene expression, gene mapping, cryopreservation, transgenesis, gene detection, genomics, proteomics, cloning etc.	- improved growth, reproduction, disease resistance and environmental tolerance - detection of genetically modified products - pollution detection - biopharming and therapeutics	Universities: 14 Private firms: 15 Government centres: 3
Other species: aquatic species (e.g., zebra fish, frogs, algae, and invertebrates), arthropods (e.g., insects, spiders, worms)	- gene mapping, gene detection, genomics, DNA extraction, culturing techniques, etc.	- pollution detection, conservation, synthesis of recombinant proteins - biological control of agricultural pests - waste disposal and recycling	Universities: 17 Private firms: 20 Government centres: 7

*Note: numbers are approximate.

6 These are not comprehensive lists. Other examples may also apply.

7 Figures for private firms were extrapolated from the Industry Canada Web site (http://strategis.ic.gc.ca/epic/internet/inlsg-pdsv.nsf/en/h_hn00079e.html) and from an unpublished EC report, *Overview Industry Profile of Notifiers of New Substances (Organisms other than Micro-organisms)*, September 2005. They represent the firms engaged in therapeutics (rabbits, rodents, and primates), agriculture (livestock), aquaculture (fish), and environment (other species).

Micro-organisms:	-genetically modified to produce - cellulose, xylanases, etc. - lipases, proteases, amylases, etc. - fabrics (polyester) - vitamins and antibiotics	- degradation of cellulose and breaking down of wood cells during pulping - fading and softening of fabrics (e.g., jeans) -conversion of agricultural wastes into fermentable sugars for the production of fuels (e.g., ethanol, alcohol) -removal of proteins, grease, and starch stains from clothes -removal of proteins from contact lenses -fermentation of corn sugars to produce plastics and polyester -production of the key intermediates of certain antibiotics -production of vitamin B12	To be determined

4. FURTHER INFORMATION

The accompanying discussion document is available at http://www.ec.gc.ca/substances/nsb/eng/consul_e.htm. Readers requiring more detail on the New Substances process are strongly encouraged to review the NSNR (Organisms), the Guidelines, and specific advisory notes. All of this information is available on the New Substances Program's Web site at http://www.ec.gc.ca/substances. Appendix 3 provides a detailed annotated bibliography on all aspects of the NSNR (Organisms), the New Substances Program, and related matters. Information on the review of the NSNR (Organisms) will be posted at http://www.ec.gc.ca/substances/nsb/eng/consul_e.htm as details become available. Questions or comments may be directed to

- Danielle Rodrigue, New Substances Division, Environment Canada, at (819) 953-9477 or danielle.rodrigue@ec.gc.ca, or
- George Arvanitakis, New Substances Assessment and Control Bureau, Health Canada, at (613) 941-6080 or george_arvanitakis@hc-sc.gc.ca.

APPENDIX 1: CATEGORIES OF SUBSTANCES THAT ARE LIVING ORGANISMS THAT DO NOT REQUIRE NOTIFICATION UNDER THE NSNR (ORGANISMS)

APPLICABLE LEGISLATION AND REGULATIONS	RESPONSIBLE DEPARTMENT OR AGENCY	NEW SUBSTANCE (whether imported, made, or sold in Canada)
Seeds Act and Seeds Regulations www.inspection.gc.ca/english/reg/rege.shtml	Canadian Food Inspection Agency www.inspection.gc.ca	All plants with novel (new) traits (PNTs)[8]—including food crops, trees, and horticultural and marine plants—intended for planting in the environment (novel plant species with novel traits are not covered; PNTs in greenhouses are exempted)
Feeds Act and Feeds Regulations www.inspection.gc.ca/english/reg/rege.shtml	Canadian Food Inspection Agency www.inspection.gc.ca	All living organisms in livestock feeds, including novel feeds (pet food is not covered)
Health of Animals Act and Health of Animals Regulations (Veterinary Biologics) www.inspection.gc.ca/english/reg/rege.shtml	Canadian Food Inspection Agency www.inspection.gc.ca	All living organisms in novel veterinary biologics (i.e., live veterinary products such as certain animals vaccines and test kits) (does not cover transgenic animals)
Fertilizers Act and Fertilizers Regulations www.inspection.gc.ca/english/reg/rege.shtml	Canadian Food Inspection Agency www.inspection.gc.ca	All living organisms in new fertilizers (i.e., chemicals) and new novel supplements (i.e., organisms)
Pest Control Products Act and Pest Control Products Regulations http://laws.justice.gc.ca/en/P-9/index.html	Health Canada, Pest Management Regulatory Agency www.hc-sc.gc.ca/pmra-arla	All living organisms in pest-control products

[8] A PNT is defined as a plant containing a trait not present in plants of the same species already existing as stable, cultivated populations in Canada, or is present at a level significantly outside the range of that trait in stable, cultivated populations of that plant species in Canada.

APPENDIX 2: CONTACTS IN OTHER REGULATORY AGENCIES AND DEPARTMENTS

Canadian Food Inspection Agency:

***Seeds Act* and Regulations**
Plant Biosafety Office
Plant Products Directorate
59 Camelot Drive
Ottawa ON K1A 0Y9
Canada
Phone: (613) 225-2342
Fax: (613) 228-6140
E-mail: pbo@inspection.gc.ca

***Feeds Act* and Regulations**
Feeds Section
59 Camelot Drive
Ottawa ON K1A 0Y9
Canada
Phone: (613) 225-2342
Fax: (613) 228-6614
URL:
http://www.inspection.gc.ca/english/tools/feedback/commene.shtml

***Fertilizers Act* and Regulations**
Fertilizers Section
59 Camelot Drive
Ottawa ON K1A 0Y9
Canada
Phone: (613) 225-2342
Fax: (613) 228-6629
E-mail: fertilizer@inspection.gc.ca
engrais@inspection.gc.ca

***Health of Animals Act* and Regulations:**
Animal Health Division
59 Camelot Drive
Ottawa ON K1A 0Y9
Canada
Phone: (613) 225-2342
Fax: (613) 228-6612
URL: http://www.inspection.gc.ca/english/tools/feedback/commene.shtml

Pest Management Regulatory Agency:

Pest Management Information Service
2720 Riverside Drive, A.L. 6606D2
Ottawa ON K1A 0K9
Canada
Phone: 1-800-267-6315 (toll-free in Canada) or (613) 736-3799 (outside Canada)
Fax: (613) 736-3798
E-mail: prma_infoserv@hc-sc.gc.ca

Fisheries and Oceans:

Office of Aquatic Biotechnology
Department of Fisheries and Oceans
200 Kent St., 12W107
Ottawa ON K1A 0E6
Canada
Phone: 1-866-633-6676 (toll-free in Canada) or (613) 993-9343 (outside Canada)
Fax: (613) 993-7665
E-mail: aquabiotech@dfo-mpo.gc.ca

APPENDIX 3: ANNOTATED BIBLIOGRAPHY OF USEFUL SOURCES OF INFORMATION RELATED TO THE FEDERAL REGULATION OF BIOTECHNOLOGY*

The Environment Canada's New Substances Program Web site at http://www.ec.gc.ca/substances/nsb/eng/index_e.htm is essential reading on various aspects of the New Substances Program, the NSNR (Organisms), and the Guidelines for notifiers. These topics are the focal points of the multi-stakeholder consultation exercise to review the NSNR (Organisms). The site (through the multi-stakeholder consultations link at http://www.ec.gc.ca/substances/nsb/eng/consul_e.htm) also includes valuable information on the 1999-2000 review of the program, and the NSNR relating to chemicals and polymers.

The Canadian Biotechnology Advisory Committee provides expert advice to the federal government on ethical, social, regulatory, economic, scientific, environmental, and health aspects of biotechnology. The Committee's Web site contains useful information on various aspects of biotechnology regulation and policy at http://cbac-cccb.ca.

A detailed overview of the **Canadian Biotechnology Strategy** and the roles and responsibilities of major players in biotechnology within and around the federal family can be found at http://biotech.gc.ca/epic/internet/incbs-scb.nsf/vwapj/11865_CAN_BIO_REP_Ev9.pdf/$FILE/11865_CAN_BIO_REP_Ev9.pdf

Action plan of the federal family on **the regulation of food biotechnology**: http://www.hc-sc.gc.ca/english/protection/royalsociety/intro.htm

Web links to federal biotechnology regulations, guidelines and contacts: http://www.bioportal.gc.ca/splash.asp.

Previous/current consultations on **biotechnology regulations** by federal departments:

- Canadian Food Inspection Agency - animal biotech http://www.inspection.gc.ca/english/sci/biotech/tech/aniconsulte.shtml
- Canadian Food Inspection Agency, HC - novel foods, HC guidelines: http://www.hc-sc.gc.ca/food-aliment/mh-dm/ofb-bba/nfi-ani/e_consultation_main.html
- HC – environmental-assessment regulations: http://www.hc-sc.gc.ca/ear-ree/ear_infosheet_e.html
- March 2003 summary of Canadian public opinion survey/research on biotech issues: http://biotech.gc.ca/epic/internet/incbs-scb.nsf/vwGeneratedInterE/by00148e.html#5

*Note: It is anticipated that this bibliography will evolve as stakeholders identify additional relevant documents and information.