

Review of

The New Substances Notification Regulations (Organisms)
Phase II Discussion Document

New Substances Program

Environment Canada
Health Canada

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EXECUTIVE SUMMARY

On June 15–16, 2006, in the National Capital Region, Environment Canada and Health Canada’s New Substances Program held a workshop on amending the provisions dealing with organisms other than micro-organisms as set down in subsection 2(4) and section 4 of the *New Substances Notification Regulations (Organisms)*, hereafter referred to as the NSNR (Organisms). The 2006 workshop provided background information and a discussion document, with a proposed framework for amendments, to assist interested parties in developing and sharing their views on the issues that need to be addressed to improve subsection 2(4) and section 4 of the NSNR (Organisms).

The current discussion document proposes a revised notification framework and potential notification schedules for organisms other than micro-organisms that could replace subsection 2(4), section 4, and Schedule 5 of the NSNR(Organisms). The current document draws upon the experience and feedback received from the June 2006 consultation workshop and builds further on the suggestions received. Interested parties may comment on the proposal as well as the models and scenarios that have been elaborated in this document and bring forth other ideas that they consider important. Please note that the proposals presented in this document are for discussion purposes only. While these consultations will serve as a basis to develop regulatory amendments, these proposals do not commit Environment Canada or Health Canada to adopt any of them or limit the Departments ability to adopt others.

The proposed amendments for organisms other than micro-organisms were developed in consideration of the need to

- a) address the knowledge gap for government and the lack of flexibility for proponents in the current “blanket research and development” (R&D) exemption for organisms other than micro-organisms;
- b) develop a tiered notification model with information requirements and assessment periods that are commensurate with proposed activities and their associated releases;
- c) develop or adopt containment and confinement guidelines;
- d) respond to feedback received from stakeholders since the previous consultation workshop held on June 15–16, 2006;

- e) provide better foresight regarding potential upcoming organisms that may be proposed for release; and
- f) reduce potential for unauthorized release.

The proposed amendments will enhance oversight and improve the effectiveness and efficiency of the NSNR (Organisms) to better protect the environment and human health.

In this discussion document, Environment Canada and Health Canada propose a notification model with several notification schedules. These include a comprehensive schedule for full release (anywhere in Canada) and other schedules that have varying levels of information requirements depending on the proposed activity and level of containment or confinement. Activities that are conducted in certified contained facilities with organisms that meet ‘Reduced Notification Information Requirement’ criteria would have minimal information requirements to fulfill in order to be eligible for an exemption from notification. Activities in uncertified contained facilities or under confined conditions could benefit from reduced notification schedules. Containment and confinement standards would be based on the adoption of appropriate existing guidelines and on standards or guidelines and standards to be established at a later date.

We believe that the proposals considered here are consistent with the *Cabinet Directive on Streamlining Regulation*¹. As required under this Cabinet Directive, the proposals presented here have considered the need to protect and advance the public interest in health and the environment and the need to encourage innovation and make decisions based on evidence and the best available knowledge and science. The proposals have also considered the need for the amended regulations to be accessible, understandable and accountable while striving to avoid duplication. Finally, by addressing issues that might impede research and innovation and bringing the regulations abreast with the pace of biotechnology growth in Canada, the proposals are consistent with the New Science and Technology Strategy².

¹ Government of Canada (2007). *Cabinet Directive on Streamlining Regulation*. Her Majesty the Queen in Right of Canada, 2007. ISBN 978-0-662-49149-1 (www.regulation.gc.ca).

² Government of Canada. (2007). *Mobilizing Science and Technology to Canada’s Advantage*. ISBN 978-0-662-44918-8 (URLs: www.publications.gc.ca or www.ic.gc.ca/epublications)

This document is meant to be a companion document to three other documents that were prepared earlier: (1) a background document³; (2) a discussion document⁴ distributed for the June 2006 workshop; and (3) the proceedings⁵ from the June 2006 workshop referred to in this document. All three documents are available through the New Substances website at www.ec.gc.ca/substances. If you would like to obtain copies of these documents, please contact the New Substances Program by fax at (819) 953-7155, by phone at 819-953-7156 or 1-800-567-1999 (toll free in Canada), or by e-mail at nsn-infoline@ec.gc.ca. Appendix 1 contains a bibliographical list of other useful sources of NSNR (Organisms)-related information.

³ New Substances Program, Environment Canada and Health Canada. (2006). *Review of the New Substances Notification Regulations (Organisms) – Backgrounder*. New Substances Program, Environment Canada and Health Canada. (www.ec.gc.ca/substances/nsb/pdf/backgrounder_e.pdf).

⁴ ——— (2006). *Review of the New Substances Notification Regulations (Organisms) – Discussion Document: Workshop on the Provisions Dealing with Organisms Other than Micro-Organisms*. New Substances Program, Environment Canada and Health Canada. (www.ec.gc.ca/substances/nsb/pdf/BIOdisc_e.pdf).

⁵ ——— (2006). *Proceedings of the Workshop on the Provisions Dealing with the Research and Development Exemption Criteria (ss. 2(4)) and the Notification Requirements (s. 4) for Organisms Other than Micro-organisms*. June 15-16, 2006, Gatineau, Quebec. Environment Canada and Health Canada. (www.ec.gc.ca/substances/nsb/pdf/proceedings_e.pdf).

1. Background

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) takes a proactive and preventive approach to assessing new substances before they are introduced into the marketplace. Subject to certain prescribed exceptions, substances that are new⁶ to Canada must be assessed before they are manufactured in or imported into Canada in order to determine whether they may be toxic (i.e. harmful) to human health or the environment, including biodiversity as defined in section 64 of CEPA 1999.

The *New Substances Notification Regulations (Organisms)*, hereafter referred to as NSNR (Organisms), implement Part 6 (Animate Products of Biotechnology) of CEPA 1999 and outlines notification and information requirements for any person manufacturing or importing into Canada new substances that are living organisms. The information currently submitted under the NSNR (Organisms) is used to perform a risk assessment under CEPA 1999 to make a determination as to whether a substance meets any of the criteria set out in section 64 of CEPA 1999.

The NSNR (Organisms) contain a framework for notification and assessment for micro-organisms (section 3), including research and development exemptions (subsection 2.3) and correspondingly subsection 2.4 and section 4 for organisms other than micro-organisms. The current discussion document deals only with organisms other than micro-organisms that fall within the scope of the NSNR (Organisms).

While the NSNR (Organisms) have served their purpose well since their entry into force ten years ago, experience and a number of significant developments in biotechnology in recent years have prompted Environment Canada and Health Canada to review these regulations.

The June, 2006 consultation addressed the framework for the part of the NSNR (Organisms) dealing with the notification and assessment requirements (section 4) for organisms other than micro-organisms, including the research and development exemptions (subsection 2(4)). (A

⁶ 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/nsb/HTML/atcc_e.HTM.

discussion document and proceedings are available on the New Substances website (www.ec.gc.ca/substances), as well as a backgrounder document, which elaborates on the NSNR (Organisms) and the need for their review). The outcome of this June 2006 workshop indicated that stakeholders agreed with the need to review the NSNR (Organisms) for organisms other than micro-organisms. Stakeholders appreciated the government's effort at consulting early in the regulatory review process but indicated that further consultation on these provisions would be required once the government had more details on the proposed notification schedules. Environment Canada and Health Canada therefore incorporated, as much as possible, the comments from stakeholders and elaborated further on the proposed amendment. This is captured in the current discussion document, which will be used as the supporting document for the December 2007 multi-stakeholder consultation.

2. Scope of the *New Substances Notification Regulations (Organisms)*

The scope of the NSNR (Organisms) is explained in the companion documents used for the consultation workshop of June 15-16, 2006. Briefly, the NSNR (Organisms) deal with animate products of biotechnology that are new and do not make any specific distinction between genetically modified organisms and those produced through assisted reproductive techniques such as animal cloning (e.g. through somatic cell nuclear transfer). In this document, only sections dealing with organisms other than micro-organisms are discussed.

According to section 4 of the NSNR (Organisms), a person who manufactures or imports an organism other than a micro-organism must provide the information specified in Schedule 5. The NSNR (Organisms) also prescribe conditions⁷ or circumstances under which the manufacture or import of new organisms other than micro-organisms intended for research and development purposes are exempt from their notification and assessment requirements.

⁷ Section 4 These Regulations do not apply in respect of an organism, other than a micro-organism, that is a research and development organism and is imported to or manufactured in a facility from which there is no release into the environment of

- (a) the organism;
- (b) the genetic material of the organism; or
- (c) material from the organism involved in toxicity.

Examples of organisms other than micro-organisms for which there are notification provisions and exemptions (subsection 2.4, section 4, and Schedule 5) in the NSNR (Organisms) may include:

- 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 non-food or non-feed uses).

In Canada, several other federal authorities regulate biotechnology products. Statutes and Regulations that have provisions for environmental risk assessment equivalent to those under CEPA 1999 are listed in Schedule 4 of CEPA 1999. Therefore, categories of new substances that are living organisms and that fall within the scope of the Statutes and Regulations listed in this Schedule are exempted from NSNR(Organisms) and do not require notification (see Appendix 2). However, all other living organisms require notification under the NSNR (Organisms) irrespective of whether they may also be falling under the oversight of other federal authorities.

3. Justification for the Review

The intent of Part 6 of CEPA 1999 is to protect human health and the environment from the potential harmful effects of new substances that are living organisms. Environment Canada and Health Canada are committed to protecting the environment and human health while minimizing the impact of regulations on innovation. Environment Canada and Health Canada are striving to achieve a regulation that is more efficient and effective, more flexible and timely, understandable and with minimal duplication throughout the regulatory process.

When the *New Substances Notification Regulations* were developed in 1997, a decision was made to exempt research and development involving organisms other than micro-organisms from the notification and risk assessment requirements if they were manufactured in or imported to a contained facility and if they were kept in containment such that there was “no release” into the environment. It was assumed that organisms kept in such containment were not expected to pose significant risks to human health or the environment because there would be no exposure. It was

also assumed that if there were to be an unauthorized release, the environmental, human health, international trade and public reaction consequences would be small, because the quantities involved would be small. However, recent experiences have made apparent the need to review this assumption. As well, Environment Canada and Health Canada recognize that the current regulatory model is not flexible and does not take into account the dynamic range of activities within the field.

Furthermore, the current NSNR (Organisms) have only one notification category for all activities associated with all organisms other than micro-organisms. It is a “one-size-fits-all” approach that covers all activities and their resulting exposure (degree of release) to the environment, regardless of any containment or confinement.. The amended regulations will need to integrate notification requirements that are commensurate with the activity, type of organism, and the potential for environmental and human exposure. In addition, the proposed regulatory regime needs to recognize the reality of current research and development activities.

At the June 2006 consultation, there was general agreement with the above and the need to provide for intermediate notification schedules or requirements between the contained and full-release scenarios. There were also calls to consider research and development activities involving a large number of model organisms in a project setting. The following proposed model attempts to address these stakeholder concerns.

4. Proposed Model

4.1 Notification Model and Major Themes

The proposed model by Environment Canada and Health Canada is summarized in the flow chart presented in Figure 1. The proposed model attempts to better align the notification process with the way in which activities involving organisms other than micro-organisms are conducted and currently overseen by existing institutions such as funding agencies, accreditation bodies at universities and research institutions.

As mentioned at the June 2006 consultation, there was strong support from stakeholders for a graduated approach to information requirements that would differ according to level of risk (exposure or hazard), as there is with the micro-organisms portion of the NSNR (Organisms). It

was felt that the approach to be followed by the New Substances Program should include minimum information for contained research and development or other activities with organisms in containment but greater information sets for activities such as field studies and full release.

Risk assessments take into account both hazard and exposure. The proposed approach makes a distinction between organisms that may pose a hazard because of their nature of pathogenicity, toxicity or invasiveness **and** potential exposure to those hazards. Because risk is based on the assumption that a hazard will be realised due to exposure, the degree of risk will depend on the level of containment intended for the organism. The list of administrative and technical information requirements (including any experimental data and accompanying documents) and duration of the assessment period would vary, depending on the proposed activity, which in turn is linked to containment, confinement or release categories. In general terms, the more significant the potential exposure from the proposed activity, the more information the notifier would need to provide.

The proposed amendments are intended to provide a more flexible exemption and notification model and schedules with information requirements that are tailored to a wide range of activity scenarios. Proposed information requirements for all the schedules are presented in Appendix 3. Broadly, the schematic presented in Figure 1 is divided into three overarching themes or categories: containment, confinement and full release.

4.1.1 Containment

Containment, by acting as a barrier to exposure, addresses the overall risk to the environment and human health associated with an organism and the proposed activity. Environment Canada and Health Canada will consider the development or the adoption of containment and confinement guidelines that would set a minimum standard for meeting containment requirements for different groups or species of organisms based on a set of physical, operational, transport and disposal considerations. The level of containment proposed will be examined in the risk assessment to determine whether it is adequate to minimize environmental and human health risks associated with the organism subject to notification requirements.

It is recognized that many organisms have low inherent hazard (similar to risk group 1 micro-organisms). These organisms could meet the criteria for Reduced Notification Information Requirements (RNIR) as long as they are contained. To qualify for Reduced Notification Information Requirements, an organism should meet **all** of the following proposed criteria:

- The organism must be identified and characterized to appropriate taxonomic level;
- Not be subject to other federal health- or safety-related regulations (e.g., *Health of Animals Regulations*);
- Not be toxigenic, pathogenic, parasitic or harmful to humans, the environment or biodiversity.
- Not have any modification or manipulation that may increase the ability to transfer any modified or manipulated genetic material; and
- Not have any modification or manipulation that may result in a greater ability to thrive outside containment or to breach containment.

A typical example of a RNIR organism could be a knockout mouse (that is, a mouse whose genetic modification involves deletion or inactivation of a specific gene), used in a contained facility, and that has not gained any advantage in terms of ecological fitness, pathogenicity or toxicity as a result of the genetic change when compared to the wild-type.

It is assumed that the risk posed by activities qualifying under the RNIR criteria will be reduced considerably because the hazards associated with the host organisms to be modified or the nature

of the genetic modifications are well characterized and documented by a significant body of research and because containment will provide a secondary level of protection.

Proponents using RNIR organisms would be eligible for the exemption if their activities are conducted in a certified facility. We envision two mechanisms by which a proponent could obtain an exemption from notification: a) an application to EC/HC for exemption with minimal information provided at a level appropriate to determine whether the criteria are met or b) certification of the research facility by an external body with periodic reporting to EC/HC. Activities conducted in an uncertified facility would be notified under Schedule 8; this schedule is aimed at streamlining the information requirements for notifiers when working with low risk organisms in a contained facility. Organisms under confinement and full release would not be considered to meet the RNIR criteria. A similar approach is adopted by other countries (e.g., New Zealand, Australia) where confinement is considered a controlled 'release' from containment. All other contained organisms that do not meet criteria set out for Schedule 8 or are not eligible for the exemption, would require notification under Schedule 7.

Notifiers may demonstrate activities in appropriate containment by one of two means: (a) certification or (b) providing a description of the facility and activity as part of a notification using Schedule 8. The regulations will be structured to facilitate notification or eligibility for exemption as the case may be. Therefore, a notifier who intends to conduct activities in a certified contained facility would provide proof of certification as evidence of appropriate containment in the relevant notification package or use the exemption process.

The exemption process would address activities including those involving a large number of similar, RNIR organisms (at least same species) that are part of the same project. Documentation for the exemption could, for example, include minimal information such as name, address, description of the research project and facility, and an attestation that the facility is certified to be in compliance with an appropriate and accepted biosafety containment standard.

Although the categories of notifications meeting containment requirements (Schedules 7 and 8) would still require notification prior to manufacture or import, the assessment period for these schedules could be correspondingly shorter as compared to confined and full release schedules.

Information requirements for these notifications would be less extensive than the current Schedule 5. The proposed Schedule 7 would require additional information (relative to Schedule 8) since organisms notified under this schedule will not meet the proposed Reduced Notification Information Requirements criteria.

4.1.2 Confinement

In addition to containment, the proposed model contains one notification schedule for confinement which would include experimental field study release and non-experimental confined release (Schedule 6). This schedule could apply to living organisms kept occasionally or permanently outside of containment, and imported or manufactured for research and development or for commercial purposes. This schedule would be appropriate for organisms that would, for health and welfare reasons, for example, be permitted outside of containment and for which appropriate confinement measures would be implemented. This could include, for example, confinement in secure fenced fields or any other applicable confinement controls. Such controls would be outlined in proposed containment and confinement guidelines.

This schedule would enable notifiers to conduct field studies to collect data (e.g., on the potential environmental effects of the organism or for breeding trials). An experimental field study would involve the release in confinement of a research and development organism other than a micro-organism, using the minimum area, time frame, and quantity of organisms required to meet the objectives of the trial or test.

4.1.3 Full Release (Introduction anywhere in Canada)

Full release is intended to cover release of organisms other than micro-organisms into the environment as currently required under Section 4 of the NSNR (Organisms). The Full release schedule (Schedule 5) would be appropriate for living organisms imported or manufactured for unrestricted release. This notification schedule applies to the manufacture or import of an organism for introduction anywhere in Canada that does not meet the criteria for notification under any other schedule specified by the NSNR (Organisms). The information requirements for notification under this schedule are the most elaborate. The proposed information requirements in this new Schedule 5 would be nearly identical to those in the current Schedule 5 of the NSNR(Organisms).

4.2 Summary of the Notification Schedules

Table 1 summarizes the regulatory schedules and categories in the proposed notification model.

Table 1. Summary of categories and schedules

	<i>Category</i>	<i>Description</i>
Schedule 5	Full release	Most comprehensive set of information requirements. Appropriate for release of organisms anywhere in Canada. Longest assessment period.
Schedule 6	Confinement: Confined release and Experimental field study release	Appropriate for activities conducted with established confinement measures** (including field studies). Intermediate assessment period.
Schedule 7	Containment: Not RNIR*	Appropriate for any activity in containment** not covered by Schedule 8. Most comprehensive containment schedule. Short assessment period.
Schedule 8	Containment: RNIR* uncertified facility	Appropriate for any activity in containment** with RNIR* organisms. Modest information requirements. Shortest assessment period.
Exemption	Containment: RNIR*, certified facility	Name, address, description of research project, proof of certification

* RNIR: Reduced Notification Information Requirements.

** Containment and Confinement Guidelines (existing or to be later developed).

This proposed notification model is consistent with the activity-based notification models currently in place under the NSNR (Organisms) for micro-organisms, as well as with other regulations in Canada and legislation in some other countries (New Zealand and Australia). It recognizes that there are some organisms with low hazard potential, and that some organisms can be adequately maintained under conditions of containment or confinement. It also recognizes the need for an increasingly comprehensive risk assessment as the level of potential environmental exposure increases.

The proposed activity-based notification model would enable some manufacturers and importers to submit notifications with a shorter assessment periods and fewer information requirements than currently needed. Additionally this would allow for more flexibility for activities with varying levels of containment or to conduct experimental field studies in confinement. It would also encourage innovation and help reduce costs associated with meeting the current research and

development exemption criteria by providing more scenarios to those who intend to conduct work outside of full containment while still managing releases.

5. Containment and Confinement Guidelines

The notification model proposed in this document defines notification categories based on the level of containment and/or confinement of the organism. It is therefore important that notifiers fully understand what constitutes containment or confinement and that the proposed manufacture or importation meets specific requirements as identified in the appropriate notification schedules. Environment Canada and Health Canada have begun work on developing supporting documents that will form guidelines or tools for use by notifiers. Environment Canada and Health Canada will consider the development of new guidelines on containment and confinement (where possible with other federal departments and agencies) or the adoption of existing ones from other jurisdictions (ex. Appendix Q of the US NIH Guidelines) where appropriate.

There is a need for a clear and common understanding of what is and is not acceptable relative to the containment or confinement of organisms other than micro-organisms. This would ensure that the notification and assessment regime set out in Part 6 of CEPA 1999 remains effective in protecting the environment and human health from the potential risks posed by new living organisms. These proposed guidelines would set the minimum requirements for various levels of containment or confinement for different groups of organisms based on a set of physical, operational, transport and disposal requirements. The containment and confinement levels will consider hazards intrinsic to the organisms and those associated with subsequent activities.

The following are the anticipated advantages and challenges associated with the development or adoption of containment and confinement guidelines.

Advantages

- will clarify the containment or confinement requirements for both the regulated community and enforcement officers, thereby improving compliance and facilitating verification of compliance;
- will require less detail to be provided in a notification package when containment measures and controls are in place;

- will provide a level playing field and notifiers will know what to expect;
- may reduce time and cost for notifiers to submit a notification package to the New Substances Program;
- is consistent with the current regime for new substances under CEPA 1999; and
- will reduce the likelihood of unauthorized release.

Challenges

- may not be comprehensive enough to adequately cover all possible groups of organisms and/or uses or biosafety considerations (i.e. there may be gaps); and
- may delay the review process if such guidelines have to be newly developed and incorporated by reference in the NSNR (Organisms)

6. Certification, Accreditation and Existing Oversight

The concept of certifying containment facilities that meet appropriate biocontainment standards has been previously mentioned in this document. The advantage of obtaining certification of a facility is that it makes one eligible for the exemption when working with RNIR organisms. The only proposed information that would need to be provided in this case would be name, address, description of the research project and an attestation or proof of certification of the facility. The purpose of certification and accreditation is to ensure that the containment facility meets certain standards: it must protect persons outside the facility from exposure to the organism(s), prevent the release of the organism into the environment, and ensure the safety of people working with the organism.

The containment facility must be inspected by a person or organization qualified to assess compliance with the biosafety requirements for the certification or accreditation of a contained facility. The New Substances Program proposes to use accreditation bodies that have authority in certifying containment facilities under existing guidelines or guidelines yet to be established. The New Substances Program proposes to cooperate with organizations that are positioned to contribute to setting guidelines, and certifying and inspecting facilities—for example institutional biosafety committees, an external standards-setting organization, or other federal departments or agencies.

GLOSSARY

The following definitions are given in the context of this document, and may not be appropriate in another context.

Assessment period: The prescribed number of calendar days within which the Ministers of the Environment and Health must assess the information submitted by a notifier under the NSNR (Organisms).

Biotechnology: 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, as defined in section 3 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999).

Confined release: **Release** under conditions of **confinement**.

Confinement: The use of physical, chemical, operational or biological controls (or a combination thereof) to limit or restrict the **release** or dispersal from a specific area of an organism other than a micro-organism and any material that may be used to propagate the organism (e.g., sperm, eggs, pollen, spores, tubers, cuttings, rhizomes).

Containment: The use of physical, chemical, operational or biological controls (or a combination thereof) within an enclosed building with walls, a floor and a ceiling or in an area within such a building (e.g., a laboratory) to restrict contact of an organism other than a micro-organism with humans and the environment.

Domestic Substances List: The list compiled by the Minister of the Environment under section 66 of CEPA 1999, as amended from time to time by the **Minister** under subsection 105(1) or subsection 112(1) of the Act.

Environment: As defined in subsection 3(1) of CEPA 1999, the components of the Earth, including (a) air, land, and water; (b) all layers of the atmosphere; (c) all organic and inorganic matter and living organisms; and (d) the interacting natural systems that include components referred to in (a) to (c).

Experimental field study release: The **release** under conditions of **confinement** of a **research and development organism** other than a **micro-organism**, using the minimum area, time frame, and quantity of organisms required to meet the objectives of the trial or test.

Full release: **Release** of an organism other than a **micro-organism** outside of **containment** and/or **confinement**.

Living organism: A **substance** that is an animate product of **biotechnology**.

Micro-organism: A microscopic **living organism** that is

- (a) classified in the Bacteria, the Archaea, the Protista, which includes protozoa and algae, or the Fungi, which include 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 such an organism; or
- (d) any culture other than a pure culture.

Minister: The Minister of the Environment.

Ministers: The Minister of the Environment and the Minister of Health.

Organism: “organism” means a living organism as defined in section 104 of CEPA 1999, except in the following provisions:

- (a) paragraph (c) of the above definition of “micro-organism”;
- (b) paragraphs 2(4)(b) and (c);
- (c) paragraph 1(d) and subparagraphs 1(e)(vi) and (viii) of current Schedule 5;
- (d) paragraph 2(d) of current Schedule 5;
- (e) subparagraph 3(d)(iii) and paragraph 3(f) of current Schedule 5; and
- (f) items 5 to 7 in current Schedule 5.

Release: To discharge, spray, inject, inoculate, abandon, deposit, spill, leak, seep, pour, emit, empty, throw, dump, place or exhaust (as defined in section 3 of CEPA 1999).

Research and development organism: As defined in the NSNR (Organisms), a **living** organism that is undergoing systematic investigation or research by means of experimentation or analysis other than test marketing, the primary objective of which is to

- (a) create or improve a product or process;
- (b) determine the technical viability or performance characteristics of a product or process; or
- (c) evaluate the organism, prior to its commercialization, through pilot plant trials, production trials (including scale-up), or customer plant trials, so that technical specifications can be modified in response to the performance requirements of potential customers.

Risk assessment: The scientific evaluation of information to estimate the likelihood that a **living organism** is a risk to the environment and human life and health according to the criteria set out in section 64 of CEPA 1999.

Substance: As defined in section 3 of CEPA 1999, any distinguishable kind of organic or inorganic matter, whether animate or inanimate, including

- (a) any matter that is capable of being dispersed in the environment or of being transformed in the environment into matter that is capable of being so dispersed or that is capable of causing such transformations in the environment;
- (b) any element or free radical;
- (c) any combination of elements of a particular molecular identity that occur in nature or as a result of a chemical reaction; and
- (d) complex combinations of different molecules that originate in nature or are the result of chemical reactions, but that could not practicably be formed by simply combining individual constituents.

Toxicity: The capacity of any substance to cause injury to humans, animals, plants or micro-organisms.

APPENDICES

APPENDIX 1: Annotated bibliography*

- New Substances Program** **Environment Canada's New Substances Program** website, at www.ec.gc.ca/substances/nsb/eng/home_e.shtml, provides essential information on various aspects of the New Substances Program, the *New Substances Notification Regulations (Organisms)*—also referred to as 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 New Substances Program site (through the multi-stakeholder consultations link at www.ec.gc.ca/substances/nsb/eng/consultations_e.shtml) also includes valuable information on the 1999–2000 review of the Program, and the NSNR on chemicals and polymers.
- Canadian Biotechnology Advisory Committee** Website: <http://cbac-cccb.ca>. The **Canadian Biotechnology Advisory Committee** provides expert advice to the federal government on the ethical, social, regulatory, economic, scientific, environmental and health aspects of biotechnology. The Committee's website contains useful information on various aspects of biotechnology regulation and policy. No longer active.
- Canadian Biotechnology Strategy** A detailed overview of the **Canadian Biotechnology Strategy** and the roles and responsibilities of major players in biotechnology, both within the federal family and those closely connected to it, 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](http://biotech.gc.ca/epic/internet/incbs-scb.nsf/vwapj/11865_CAN_BIO_REP_Ev9.pdf/$FILE/11865_CAN_BIO_REP_Ev9.pdf). No longer active.
- Action Plan of the Government of Canada** Website: http://www.hc-sc.gc.ca/sr-sr/pubs/gmf-agm/RSC_response-reponse_SRC_e.html. In response to the Royal Society of Canada's Expert Panel Report titled: "Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada".
- Bioportal** Web links to federal **biotechnology regulations, guidelines and contacts**: www.bioportal.gc.ca/splash.asp. Your window to biotechnology at the Government of Canada:
- Biotechnology consultations** Previous and current consultations on **biotechnology regulations** by federal departments:
- Canadian Food Inspection Agency – animal biotechnology -** <http://www.inspection.gc.ca/english/anima/biotech/2004/cabcbae.shtml>
- Canadian Food Inspection Agency, Health Canada – novel foods,** Health Canada guidelines: http://www.hc-sc.gc.ca/fn-an/index_e.html
- Health Canada** environmental-assessment regulations: http://www.hc-sc.gc.ca/ewh-semt/eval/index_e.html
- Industry Canada** March 2003 summary of Canadian public opinion survey/research on biotechnology issues: <http://biostrategy.gc.ca/english/View.asp?pmiid=524&x=546>
- Biosafety – Federal Government**
- Public Health Agency of Canada** Office of Laboratory Biosafety: <http://www.phac-aspc.gc.ca/ols-bsl/about-propos/index.html>

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- Canadian Food Inspection Agency* – Plant biosafety: <http://www.inspection.gc.ca/english/plaveg/bio/pbobbve.shtml>
- Canadian Food Inspection Agency* – Animal biotechnology: <http://www.inspection.gc.ca/english/sci/biotech/bioteche.shtml>
- Biosafety – Canadian Universities*** Information on biosafety policies, procedures and roles played by institutional biosafety committees in some Canadian universities reviewed during the preparation of this discussion document can be found on the following websites:
- Dalhousie University* – Biohazards assessment: <http://www.dal.ca/~research/Biohazardsform.pdf>
- Memorial University of Newfoundland* Genetically Modified Animal Sheet – <http://www.mun.ca/acs/pdf/gma.pdf>
- Queens University* Import and export of biological material: <http://www.safety.queensu.ca/safety/policy/eh&s/bioimport.pdf>
- University of British Columbia* Health, Safety and Environment: <http://www.hse.ubc.ca/>
- University of Manitoba* Chemical and biological safety: http://www.umanitoba.ca/admin/human_resources/ehso/chembio_safety/index.html
- University of Ottawa* Biosafety manual: <http://www.uottawa.ca/services/ehss/biosafety%20manual.pdf>
- University of Saskatchewan* Biosafety program: http://www.usask.ca/research/ethics_review/biosafety.php
- University of Toronto* Biosafety policies and procedure manual: <http://www.ehs.utoronto.ca/Assets/ehs3/biomannual/bm.pdf>
Biosafety certificate: <http://www.ehs.utoronto.ca/Assets/ehs3/Biosafety/m9.pdf>
- University of Waterloo* Biosafety committees – Terms of Reference: <http://www.safetyoffice.uwaterloo.ca/hse/committees/bsc.htm>
- University of Western Ontario* Biosafety committees – Terms of Reference: http://www.uwo.ca/humanresources/facultystaff/h_and_s/terms_of_ref/biosafety_comm_terms.pdf
- Other jurisdictions*** Information on biotechnology regulations in other jurisdictions that were reviewed during the preparation of this discussion document can be found in the following websites:
- Australia:* Office of the Gene Technology Regulator: <http://www.ogtr.gov.au/>
- New Zealand:* Environmental Risk Management Authority: <http://www.ermanz.govt.nz/>
- United Kingdom:* Health and Safety Executive: <http://www.hse.gov.uk/>
- United States:* National Institute of Health Guidelines For Research Involving Recombinant DNA Molecules: <http://www4.od.nih.gov/oba/>

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

APPENDIX 2: Categories of living organisms that are regulated by Acts and Regulations listed in Schedule 4 of CEPA 1999

APPLICABLE LEGISLATION AND REGULATIONS	RESPONSIBLE DEPARTMENT OR AGENCY	NEW SUBSTANCE (whether imported, made, or sold in Canada)
<i>Seeds Act and Seeds Regulations</i> www.inspection.gc.ca/english/reg/rege.shtml	Canadian Food Inspection Agency (CFIA) www.inspection.gc.ca	All plants with novel traits (PNTs)—including food crops, trees, and horticultural and marine plants—intended for planting in the environment
<i>Feeds Act and Feeds Regulations, 1983</i> www.inspection.gc.ca/english/reg/rege.shtml	CFIA www.inspection.gc.ca	All livestock feeds, including novel feeds
<i>Health of Animals Act and Health of Animals Regulations (Veterinary Biologics)</i> www.inspection.gc.ca/english/reg/rege.shtml	CFIA www.inspection.gc.ca	All novel veterinary biologics (i.e., live veterinary products such as certain animal vaccines, antibodies and test kits)
<i>Fertilizers Act and Fertilizers Regulations</i> www.inspection.gc.ca/english/reg/rege.shtml	CFIA www.inspection.gc.ca	All new fertilizers (i.e., chemicals) and new novel supplements (i.e., organisms)
<i>Pest Control Products Act and Pest Control Products Regulations</i> http://laws.justice.gc.ca/en/P-9/index.html	Health Canada, Pest Management Regulatory Agency www.hc-sc.gc.ca/pmra-arla	All new substances in pest control products

APPENDIX 3: Proposed notification information requirements for the different Schedules
see next page

Information Map for the Proposed Schedules

Organisms imported or manufactured for introduction under:

Schedule 5 Full release	Schedule 6 Confinement	Schedule 7 Containment (Non-RNIR)	Schedule 8 Containment (RNIR)
Identification and general characteristics of the organism	Identification and general characteristics of the organism	Identification and general characteristics of the organism	Identification and general characteristics of the organism and a description of how it qualifies as an RNIR organism
Procedures or modifications done to the organism	Procedures or modifications done to the organism	Procedures or modifications done to the organism	Procedures or modifications done to the organism
Information to characterize the level of exposure during importation and/or manufacture	Information to ascertain the adequacy of confinement and characterize the level of exposure during importation and/or manufacture	Information to ascertain the adequacy of containment and characterize the level of exposure during importation and/or manufacture	Information to ascertain the adequacy of containment and characterize the level of exposure during importation and/or manufacture
Information to characterize the level of exposure following the introduction of the organism in Canada	Information to characterize the level of exposure following the introduction of the organism at the site of confined- or experimental study release	Information to characterize the level of exposure following the introduction of the organism into the containment facility	Information to characterize the level of exposure following the introduction of the organism into the containment facility
Information to characterize the environmental fate of the organism following the release in Canada	Information to characterize the environmental fate of the organism following the release at the site of confined- or experimental study release		
Information to determine and describe the potential involvement of the organism in adverse environmental effects following release	Information to describe the potential involvement of the organism in adverse environmental effects following release		
Information to describe the potential involvement of the organism in adverse human health effects	Information to describe the potential involvement of the organism in adverse human health effects	Information to describe the potential involvement of the organism in adverse human health effects	
All other information	All other information	All other information	All other information
Identification of other notified government agencies	Identification of other notified government agencies	Identification of other notified government agencies	Identification of other notified government agencies

Legend:

	General hazard identification and characterization for the organism		Broader risk characterization related to potential involvement of the organism in adverse environmental or human health effects
	Hazard identification and characterization due to procedures or modifications done to the notified organism		All other information that may be useful in risk characterization
	Exposure characterization		

