Review of the New Substances Notification Regulations (Organisms)

Discussion Document

Workshop on the Provisions Dealing with Organisms Other than Micro-Organisms

May 18, 2006

New Substances Program,
Environment Canada
Health Canada

NOTE TO READER: The substantive content of this document is for discussion purposes only, and reflects the initial perspectives of officials with the New Substances Program in Environment Canada and Health Canada. This document and its companion backgrounder were prepared by EC and HC 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; however, the options proposed herein do not necessarily represent the position of all those involved. It is expected that options will evolve and improve with feedback from readers.

EXECUTIVE SUMMARY

The *New Substances Notification Regulations* [NSNR (Organisms)] under the *Canadian Environmental Protection Act, 1999* (CEPA 1999) prescribe the requirements for the notification and assessment of new substances that are living organisms. These regulations are jointly administered by Environment Canada (EC) and Health Canada (HC).

Eight years of experience with the NSNR (Organisms) and a number of significant changes in biotechnology in recent years have prompted EC and HC to re-examine their approach to regulating these substances. In February 2004, EC and HC launched the review of the NSNR (Organisms) starting with the provisions for organisms other than micro-organisms, particularly the exemption for R & D activities. Consultations on these provisions will take place at a multi-stakeholder workshop to be held in the National Capital Region in June 2006.

This document presents the key issues and proposed options for a new regulatory scheme for organisms other than micro-organisms subsection 2(4) regarding research and development exemption and section 4 regarding the information provided in a notification for manufacture or importation. This document also provides the basis upon which interested parties may comment on the issues and options identified and bring forth others they feel are important.

The proposed options were developed in consideration of the need for:

a) the amendment of the 'blanket' R&D exemption for organisms other than micro-organisms if complete containment conditions were met

b) an exposure-based notification scheme, with information requirements and assessment periods commensurate with the level of potential exposure; and,

c) the development, by EC and HC, of containment and confinement guidelines.

The amendment of the provisions dealing with organisms other than micro-organisms would make those provisions more risk-based and would improve their effectiveness to

protect the environment and human health, as the Departments would receive better information and conduct appropriate assessments of all new organisms other than micro-organisms imported into or manufactured in Canada, including those intended for R&D.

With regards to an exposure-based notification scheme, EC and HC are proposing three options :

Option 1: Replacement of the R&D exemption with a single notification category for organisms kept in containment (for organisms intended for R&D or other purposes);

Option 2: New notification categories, commensurate with the level of potential exposure;

Option 3: Project-based notification (i.e. for a group of organisms used in the course of an R&D project or study) for organisms kept in full containment and solely intended for R&D.

The development of guidelines would clarify the containment or confinement requirements of each proposed notification category.

The process for completing the review of the remaining provisions of the NSNR (Organisms) i.e. micro-organisms, will be determined once the review of subsection 2(4) and section 4 has been completed.

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1. BACKGROUND

The *Canadian Environmental Protection Act, 1999* (CEPA 1999) takes a proactive and preventative approach to regulating new substances. All substances that are new[1] to Canada must be assessed before they are imported into or manufactured in Canada in order to determine whether they may be harmful to human health and the environment, including biodiversity in accordance with section 64 of the Act[2]. Wherever this document refers to CEPA section 64 criteria it refers to the text in footnote 2.

In other words, the purpose of a risk assessment under CEPA 1999 is to identify whether a substance meets any of these criteria. The information requirements that make this assessment possible are set out in the *New Substances Notification Regulations (Organisms)* [NSNR (Organisms)].

While the NSNR (Organisms) have served their purpose well since their entry into force eight years ago, experience and a number of significant changes in biotechnology in recent years have prompted Environment Canada (EC) and Health Canada (HC) [hereafter referred to as the departments] to re-examine their approach to regulating new substances that are living organisms.

In February 2004, EC and HC launched a review of the research and development exemption and the notification and assessment requirements for organisms other than micro-organisms, respectively subsection 2(4) and section 4 of the NSNR (Organisms). These provisions were collectively known as subsection 29.16 in the former regulations[3].

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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 http://www.ec.gc.ca/substances/nsb/HTML/atcc_e.HTM.

2 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.

3 In 1999-2001, the chemicals and polymers portion of the former New Substances Notification Regulations underwent an extensive multi-stakeholder review that resulted in the division of the regulations into two separate regulations: one for chemicals and polymers [New Substances Notification Regulations (Chemicals and Polymers)] and one for living organisms [New Substances Notification Regulations (Organisms)].

Given that multi-stakeholder consultations have been and will continue to be critical to the successful implementation of the NSNR, formal consultations on these provisions will take place at a multi-stakeholder workshop to be held in the National Capital Region in June 2006. The remaining provisions of the NSNR (Organisms) dealing with micro-organisms will be reviewed at a later date.

When the regulations were developed in 1997, a decision was made to exempt research and development (R&D) involving organisms other than micro-organisms from the notification and risk assessment requirements of the NSNR (Organisms) 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, as it was assumed that organisms kept in containment were not expected to pose significant risks to human health or the environment. However, recent accidental releases of carcasses from genetically-modified animals from R&D facilities have made apparent the need to review this assumption.

A background document, entitled *Review of the New Substances Notification Regulations (Organisms)—Backgrounder* has been prepared to help readers better understand the NSNR (Organisms) and the reasons for the review. To obtain a copy of this document, please contact the New Substances Program by fax at (819) 953-7155 or by e-mail at nsn-infoline@ec.gc.ca. Appendix 1 has a bibliographical list of other useful sources of NSNR-related information.

Opportunities to provide feedback relating to the NSNR (Organisms) started with the regional information sessions held in November and December 2005. Additional upcoming opportunities will include web-based consultations and the multi-stakeholder workshop in June 2006.

The process for completing the review of the remaining provisions of the NSNR (Organisms) will be determined after the June workshop, and then communicated to interested parties.

2. OVERVIEW

This discussion document forms the core of this consultation exercise. Its purpose is twofold: first, to describe the provisions in the NSNR (Organisms) governing organisms other than micro-organisms i.e. the exemption for R & D activities (subsection 2(4)) and information provided prior to manufacture or importation (section 4) and related key issues; second, to seek the views of interested parties on these key issues and on proposed options for resolving them. Readers are welcome to comment on all aspects of subsection 2(4) and section 4 and are asked to provide those comments by July 14, 2006 to the New Substances Program by fax at (819) 953-7155 or by e-mail at nsn-infoline@ec.gc.ca.

2.1 OBJECTIVES OF THE REVIEW

The overall objective of this review is to ensure Part 6 of CEPA is implemented effectively. This will require identifying changes in the regulatory scheme for organisms other than micro-organisms under the NSNR (Organisms) that will:

- maintain or improve the Government's ability to safeguard the environment and human health (the primary objective),
- 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 existing process and proposed regulatory provisions, so that they are understood by all parties, and
- tailor a new process to potential human and environmental exposure, such that it is cost-effective, flexible, fair, and informed by science.

2.2 SCOPE OF THE NSNR (ORGANISMS) AND THIS REVIEW

The NSNR (Organisms) contains provisions for new substances that are living organisms manufactured in or imported into Canada 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), 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).

For information on categories of new substances that are living organisms and that do not require notification under the NSNR (Appendix 2), please contact the relevant federal authorities.

The NSNR (Organisms) also prescribe conditions or circumstances under which the manufacture or import of new organisms intended for R&D purposes are exempt from its notification and assessment requirements. Subsection 2(4) prescribes exemptions for R&D organisms other than micro-organisms. Substances that meet the exemption criteria outlined in subsection 2(4) of the NSNR (Organisms) are an integral part of the scope of this review.

Subsection 2(4) of the NSNR (Organisms) states that a person who manufactures or imports an organism other than a micro-organism shall provide the information specified in Schedule 5, unless the organism is an R&D substance 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.

In order to meet the exemption criteria in this subsection, neither the organism, its nucleic acids (i.e. DNA, RNA), nor any materials involved in toxicity are released from the R&D facility. Otherwise a Schedule 5 notification is required.

The review of subsection 2(4) and section 4 provides an opportunity to integrate current scientific knowledge on the possible exposure and risks associated with the release of genetic material and its uptake by organisms in the environment into the Regulations, as well as to implement a more exposure-based approach to regulating organisms other than micro-organisms under the NSNR (Organisms).

3. KEY ISSUES AND PROPOSED OPTIONS

3.1 KEY ISSUES

The key issues identified by EC and HC pertaining to subsection 2(4) and section 4 of the Regulations are:

- the need for more information on R&D activities taking place across Canada,
- the need for an approach to notification that is commensurate with the potential for environmental and human exposure, and
- the need for more clarity in the regulatory provisions.

Retaining the current R&D exemption and notification scheme (i.e. Schedule 5), will continue to:

- impede the ability of EC and HC to carry out their mandates,
- create inconsistencies in and uncertainties over the application of the provisions dealing with organisms other than micro-organisms, and
- hamper attempts to make the regulatory process more flexible, science-informed, fair, and cost-effective for all interested parties.

3.1.1 Need for more information

New organisms other than micro-organisms that are manufactured in or imported to a facility for R&D purposes from which there is no release are not subject to the notification and risk-assessment requirements of the NSNR (Organisms). This lack of information has created challenges for EC and HC since subsection 2(4) of the NSNR (Organisms) was implemented. These have included concerns about EC's ability to fully and effectively promote and verify compliance within the R&D area, conduct timely preventative actions, pursue regulatory foresight activities, and improve scientific knowledge related to the environmental and human-health impacts of new organisms other than micro-organisms that are subject to these provisions. Recent incidents in which carcasses of R&D organisms have been released from research facilities have shown that maintaining a categorical exemption such as subsection 2(4) has limited the government's ability to assess potential risks to human health and the environment.

3.1.2 Need for a graduated approach

Under the current NSNR (Organisms) regime, there is only one notification category (i.e. "all-or-none" approach) for new organisms other than micro-organisms. This category covers a wide range of groups (e.g. certain livestock, fish, pets, reptiles, rodents, insects, and plants), as well as a wide range of use patterns and exposure scenarios. Unless the organism is meant for R&D only[4] and all the conditions set out in subsection 2(4) are met, a Schedule 5 notification must be submitted at least 120 days prior to import or manufacture. Because of this broad application, the information requirements for completing a Schedule 5 notification are necessarily extensive in order to allow for a risk assessment that considers the release of the organism anywhere in Canada. This "one size fits all" approach does not recognize that the requirements for notification should be commensurate with the potential for environmental and human exposure.

3.1.3 Need for more clarity

In the past, notifiers have had difficulty understanding precisely what they need to do to meet the regulatory requirements. Although further guidance concerning the application of the subsection 2(4) exemption criteria was provided in *New Substances Notification Advisory Note 2002-01*, experience to date indicates that more work must be done in this regard. More clarity and transparency in the regulatory system will help notification proponents ensure that their regulatory submissions are complete, and that the organisms notified will be assessed in a timely manner.

3.2 PROPOSED APPROACH

Recent releases of new organisms other than micro-organisms from R&D facilities have made it apparent that EC and HC require appropriate information on all activities pertaining to organisms subject to subsection 2(4) and section 4, including those conducted for R&D purposes. In order to accomplish this, the departments are proposing the following changes to the existing notification approach:

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[4] An organism is meant for R&D only if it will undergo systematic investigation or research, by means of experimentation or analysis other than test marketing, the primary objective of which is a) to create or improve a product or process or b) to determine the technical viability or performance characteristics of a product or process; and only if it is intended to be imported to or manufactured in a contained facility from which there is no release of the living organism, its genetic material, or material from the organism involved in toxicity.

a) the removal of the R&D exemption for organisms other than micro-organisms.

b) an exposure-based notification scheme, in which the information requirements and assessment periods would be commensurate with the level of potential exposure, and

c) the development, by EC and HC, of containment and confinement guidelines.

3.2.1 Removal of the R&D exemption for organisms other than micro-organisms

By requiring notification prior to import or manufacture of all new organisms intended for R&D, EC and HC would have access to basic information, such as the name and address of the notifier, the identity of the organism, the organism's proposed use, the anticipated quantity of manufacture or import, and the intended transport and storage measures. This would allow for an assessment of risk under CEPA 1999, and would provide the departments with the opportunity to implement a variety of control measures if a risk to the environment or human health was identified. Such information would also enable EC's enforcement officers to make timely inspections. In the event of a release, the Ministers of the Environment and of Health would be able to respond in a more efficient manner as basic information would be readily available.

This proposed change would also enable the two departments to better anticipate technology advances and acquire the appropriate expertise and capacity to conduct risk assessments for substances derived from new and emerging technologies. It would also allow them to provide additional guidance to notifiers to increase awareness of and compliance with the Regulations through compliance promotion and other activities, and allowing them to plan better for new and emerging technologies and for emergency response.

In summary, removing the R&D exemption criteria in conjunction with the continuation of compliance promotion activities would address the issues of lack of information available to EC and HC and lack of awareness of the Regulations by the regulated community. It would better enable compliance promotion and compliance verification, and would maintain or improve the safeguard of human health and the environment, including biodiversity.

3.2.2 Exposure-based notification – Options

The removal of the R&D exemption for new organisms other than micro-organisms will create a need to notify these substances. Environment Canada and Health Canada considered several options and settled on three viable options for an exposure-based notification scheme that is founded on the requirement to notify prior to import or manufacture:

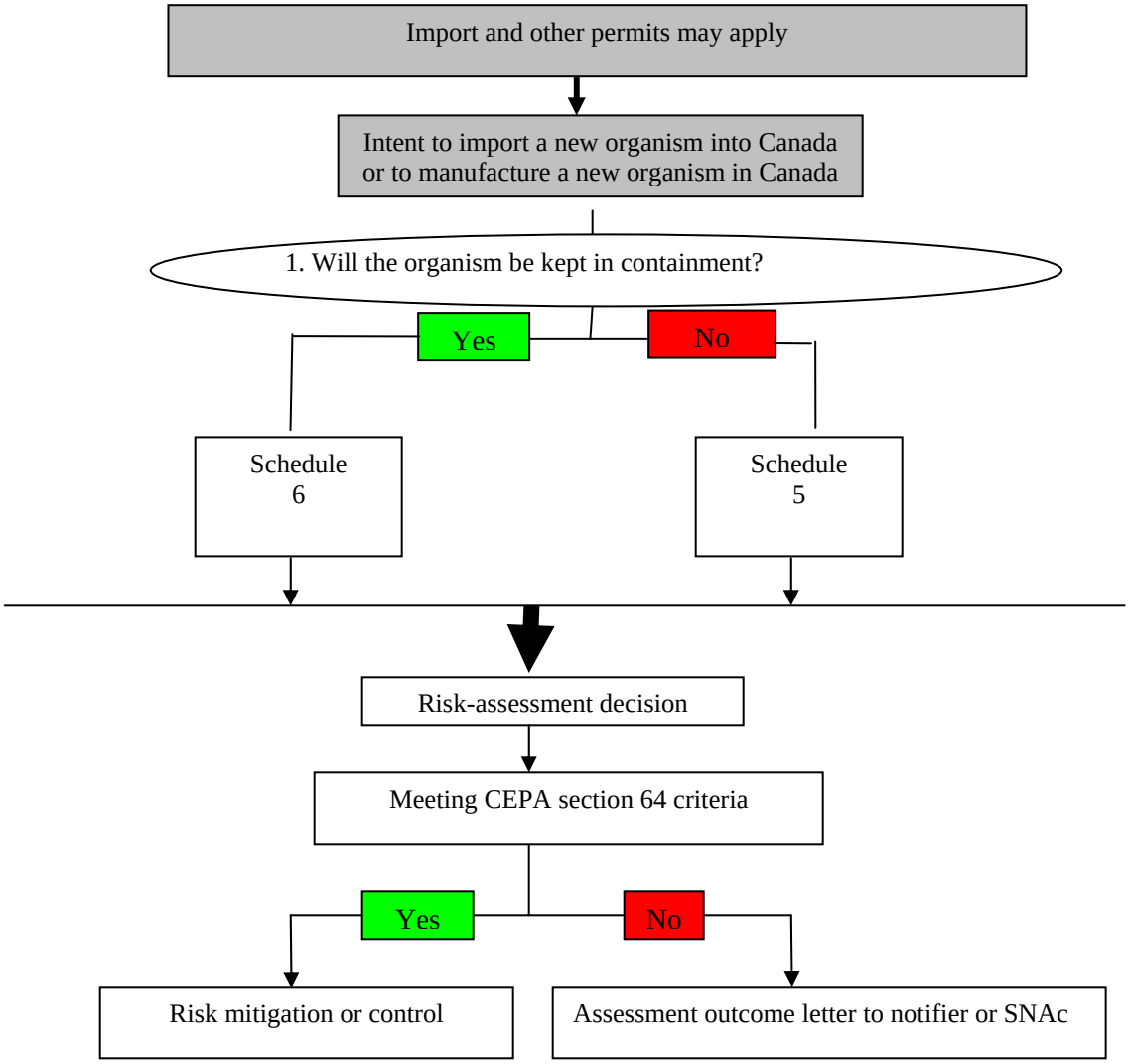
Option 1: Adding a single notification category for organisms kept in containment (for organisms intended for R&D or other purposes);
Option 2: Adding two notification schedules for organisms kept in containment (for organisms intended for R&D or other purposes) and two notification schedules for confinement;
Option 3: Adding a project-based notification (i.e. for a group of organisms to be used as part of an R&D project/study) for organisms kept in full containment and solely intended for R&D.

Following are brief descriptions of the three options and a preliminary analysis of each option's effectiveness in addressing the key issues identified in Section 3 of this document, its implementation costs, and its impact on other objectives (such as the introduction of new issues). These and other options will need to be evaluated during the workshop in terms of the needs, issues, and concerns of other potentially affected parties. For a full list of the criteria/factors considered by EC and HC in this preliminary analysis, see Appendix 3.

3.2.2.1 Option 1: Single Notification Category for Organisms Kept in Containment

This option involves a single schedule that would apply to all organisms intended for import or manufacture under containment, whether for R&D or other purposes (e.g. commercialization). Figure 1 illustrates the proposed notification scheme under Option 1. A notification would be required prior to import or manufacture. Proponents intending to import or manufacture organisms under full containment would need to provide only a subset of the information requirements listed in Schedule 5.

Figure 1: Proposed Notification Scheme for Option 1



Advantages:

- authority already exists for making such schedules; therefore, no legislative changes will be required;
- will enhance EC's and HC's awareness of all regulated activities taking place in Canada, which will place the departments in a better position to conduct risk assessments, take appropriate management actions prior to import or manufacture, and promote and verify compliance;
- is consistent with the current regime for new substances under CEPA 1999;
- will likely help to sustain and build public confidence in the federal biotechnology regulatory system, as EC and HC will conduct risk assessments on all new organisms covered under the NSNR (Organisms).

Disadvantages:

- compared to the status quo, will result in cost implications for R&D sector associated with the preparation of the notification package, including potential delays in activities. Tailoring the process to lower the regulatory burdens for organizations or individuals involved in R&D activities outside of full containment could, however, minimize negative impacts on innovation;
- compared to the status quo, it will require additional resources in EC and HC to process and assess notifications for contained organisms;
- may create confusion for some notifiers (in cases where exemptions under other regulations would apply to the new organism).

3.2.2.2 Option 2: Separate Notification Categories and Schedules for Organisms Kept in Containment or Confinement

Figure 2 illustrates the proposed notification scheme under Option 2. This option would entail the establishment of two separate schedules for organisms intended to be imported or manufactured for R&D or other purposes (e.g. commercialization) under containment and two notification schedules for confinement. These would include

a. a simplified schedule to cover organisms intended to be maintained under full containment (Schedule 9);

b. a more elaborate schedule comprising more comprehensive information requirements to cover organisms intended to be kept under basic containment (Schedule 8); and,

c. two schedules to cover confined releases for field trials (Schedule 7) or for other purposes such as grazing for animals in a confined space (Schedule 6).

Both categories of containment (i.e. Schedules 8 and 9) would require notification prior to import or manufacture, but the assessment period for the full-containment schedule could be very short. In addition, all

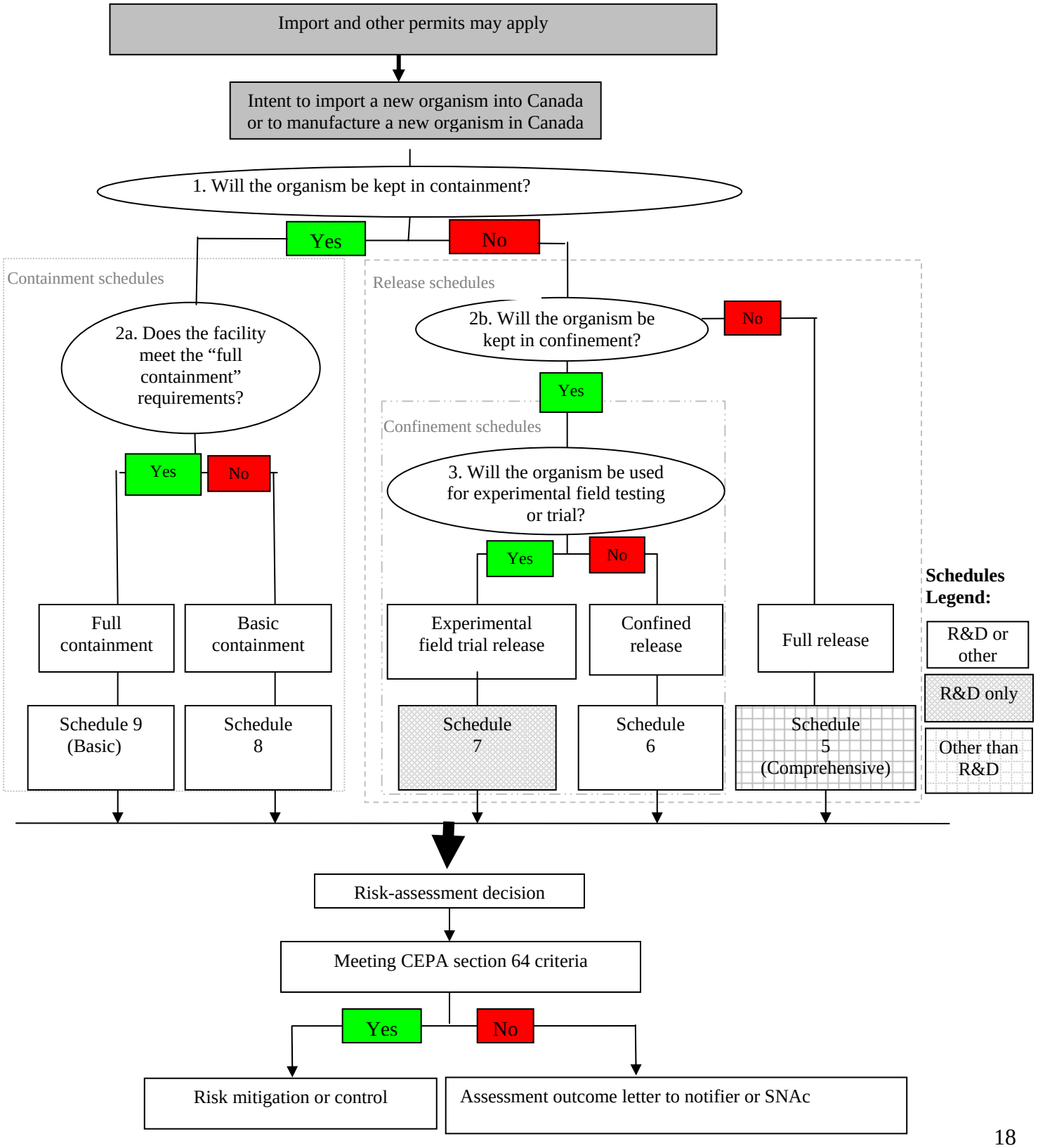
procedures would involve a risk-assessment process but, in the case of full containment applications, this could be limited to considerations such as those listed in Appendix 4. Similarly, notifications for confinement could have reduced information requirements than the current Schedule 5. The process that would be used under this Option for making the determination of the most appropriate schedule for a given organism is outlined in Appendix 5.

This proposed notification scheme is consistent with the exposure-based notification schemes currently in place under CEPA 1999, as well as with other regulations in Canada (Appendix 6) and legislation in some other countries. It recognizes that, in some cases, some organisms can be adequately maintained under conditions of basic containment or confinement, and that data required to address potential environmental impacts may best be generated through field trials/testing. It also recognizes the need for an increasingly comprehensive risk assessment as the level of potential environmental exposure increases.

The proposed exposure-based notification scheme would enable some manufacturers and importers to submit a notification with a shorter assessment period and fewer information requirements than the current Schedule 5 for work with varying levels of containment, or to conduct field trials. It would also encourage innovation and help to reduce the costs associated with meeting the current R&D exemption criteria by providing more options to those who intend to conduct work outside of full containment while still managing releases.

It cannot be expected that all individuals or organizations currently manufacturing or importing organisms other than micro-organisms for R&D purposes, and who intend to continue doing so after the new provisions enter into force, would have their notification packages ready when the new Regulations come into effect. As such, transitional provisions with different time periods for notification would need to be considered for currently exempted organisms. Since it is unlikely that all notification packages for organisms other than micro-organisms that were submitted under the existing regulations will have been taken through to a final decision before the new provisions come into force, transitional arrangements would also be considered for such notifications.

Figure 2 Proposed Notification Scheme under Option 2



Advantages:

- same as those listed in Option 1;
- will reduce information requirements, costs and assessment periods for organisms intended to be kept outside of full containment (and which currently require a Schedule 5 notification).

Disadvantages:

- same as those listed in Option 1;
- has the potential to reduce costs for organisms intended to be kept outside of full containment applications as a Schedule 5 (full release) notification is currently required.

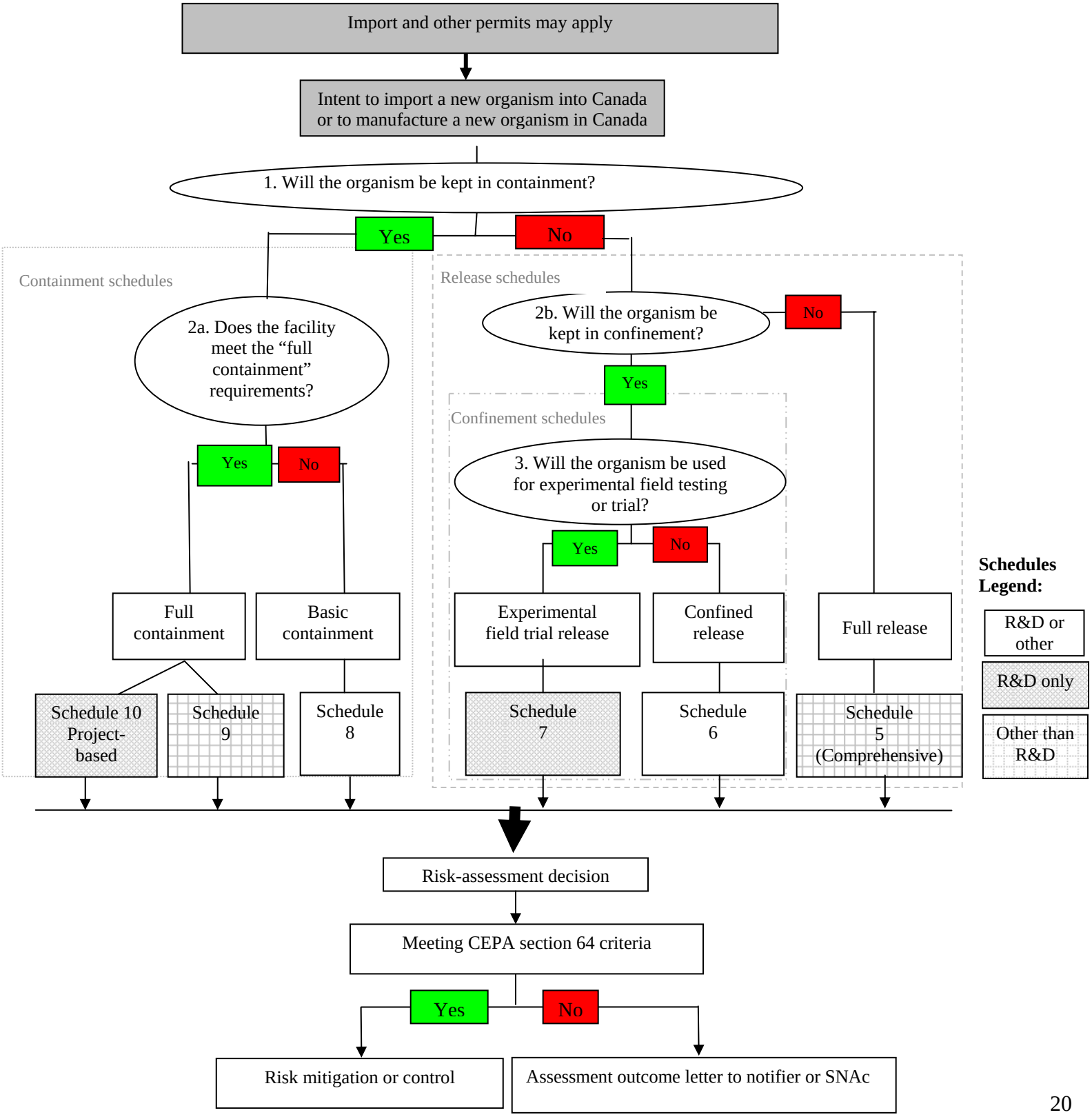
3.2.2.3 Option 3: Project-Based Notification (i.e. for a Group of Organisms to be used as part of an R&D project/study) for Organisms Kept in Full Containment and Solely Intended for R&D

Unlike the organism-by-organism approach that is currently in place and that applies in Options 1 and 2, this option would allow organisms belonging to the same species and used as part of a single R&D project to be notified and assessed on a project-by-project basis. Its aim would be to better align the notification process with the way in which research is generally being done. Indeed, the researcher may wish to perform a series of genetic modifications (and, thereby, possibly create new organisms) in the intermediate stages of the project. Under the current approach, each of these new organisms would be notifiable if the R&D exemption criteria were not met. Figure 3 illustrates the proposed notification scheme under this option.

If this option was chosen, it would not apply to organisms intended for activities other than R&D (e.g. commercialization). Therefore, its implementation would require that an additional category be put in place to cover such organisms. This would mean that a group notification category (Schedule 9) would apply to fully contained R&D organisms, while fully contained organism intended for other applications would be notifiable under a different schedule (Schedule 10).

As in Options 1 and 2, this option would require a transitional period during which the current exemption would continue, and possibly a phased-in approach.

Figure 3: Proposed Notification Scheme for Option 3



Advantages:

- same as those listed in Option 1;
- will be less onerous in time and cost to the affected R&D sector (will reduce time for researchers to prepare a notification) compared to Option 1;
- will be less costly for EC and HC to process and assess notifications for R&D organisms intended for full containment compared to Option 2.

Disadvantages:

- same as those listed in Option 1;
- differs from the current organism-by-organism approach; therefore, may cause confusion. As a result,
  - current procedures and tools in place to process notifications will initially need major adjustments to allow group notifications, resulting in longer delay in implementation within the New Substances Program, and
  - risk-management actions may be organism-specific, which will likely complicate the process;
- regulators will be required to conduct a risk assessment on more than one organism within the same time frame normally afforded for a single organism.

3.2.3 Development of Containment and Confinement Guidelines

As an additional measure to help achieve the objectives of the regulatory scheme, EC and HC have initiated the first steps towards the development of containment and confinement guidelines. The current provisions in the NSNR (Organisms) and *Guidelines for the Notification and Testing of New Substances: Organisms* (EC and HC, 2001) do not provide standards to help notifiers determine what containment measures are considered sufficient, or which measures contribute to minimizing a "release into the environment". This has resulted in regulatees and government officials having various interpretations of what constitutes "no release". There is a need for a clear and common understanding of what is and is not acceptable relative to the containment of organisms other than micro-organisms to ensure that the regulatory scheme remains effective in protecting the environment and human health from the potential risks posed by new living organisms.

The notification schemes proposed under Options 1, 2 and 3 delineate notification categories based on the level of containment and/or confinement of the organism. In order for notifiers to easily identify which schedule applies to the organism they are working with, EC and HC propose that the requirements for each level of containment and/or confinement be clearly outlined in a guidelines document.

These guidelines would set the minimum standard for various levels of containment and/or confinement for different groups of organisms based on a set of physical, operational, transport, and disposal requirements for any of Options 1, 2 or 3. The development of such guidelines would require approximately six months to complete.

The following advantages and disadvantages are projected for the development 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, when notifying, on containment measures and controls in place;
- will likely improve compliance and public confidence;
- may reduce time and cost for notifiers to submit a completed notification package to EC and HC;
- is consistent with current regime for new substances under CEPA 1999.

Disadvantages:

- may not be comprehensive enough to cover all possible groups of organisms and uses adequately;
- if such guidelines are developed and incorporated by reference in the Regulations, will likely delay the review process by six to nine months;
- since guidelines for the containment of organisms currently exist under other government departments or agencies, adding another set of guidelines may create confusion and some duplication.

4. NEXT STEPS

Feedback obtained from both the multi-stakeholder workshop and comments received via the web-based consultations will be carefully considered when developing a framework for the new regulatory scheme of subsection 2(4) and section 4 of the NSNR (Organisms). Environment Canada and Health Canada expect to report back to all participants their responses and action items emanating from the multi-stakeholder

workshop and the web-based consultations. It is anticipated that a final report will be produced detailing all of the proposals and decisions.

5. FURTHER INFORMATION

Appendix 1 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.

Readers can respond electronically to the questions posed in this discussion document through the New Substances Program Web site at http://www.ec.gc.ca/substances. Readers can also e-mail, mail, or fax their responses to:

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Anyone with questions or comments, or in need of further information, may contact Ms Rodrigue at the coordinates above, or George Arvanitakis of Health Canada's New Substances Assessment and Control Bureau at (613) 941-6080 or george_arvanitakis@hc-sc.gc.ca.

ABBREVIATIONS

CIBio	Biosafety Internal Commission (Brazil)
CCAC	Canadian Council on Animal Care
CEPA 1999	*Canadian Environmental Protection Act, 1999*
CFIA	Canadian Food Inspection Agency
DNA	deoxyribonucleic acid
DSL	Domestic Substances List
ERMA	Environmental Risk Management Authority (New Zealand)
FDA	Food and Drug Administration (United States)
GM	Genetic modification
GMOs	genetically modified organisms
GTA	Gene Technology Act (Australia)
LMO	Living modified organisms
MAFF	Ministry of Agriculture, Forestry and Fisheries (Japan)
MECSST	Ministry of Education, culture, science, Sports and Technology (Japan)
MPCA	microbial pest control agent
NSNR	New Substances Notification Regulations
PMRA	Pest Management Regulatory Agency
PNT	plant with novel traits
R&D	research and development
SNAc	significant new activity

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 the ministers of the Environment and Health have to assess the information submitted by a notifier under the NSNR.

Basic containment. **Containment** under conditions meant to restrict the **release** into the **environment** of an organism other than a **micro-organism,** and any material that may be used to propagate it (e.g., sperm, eggs, pollen, spores, tubers, cuttings, rhizomes).

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 CEPA 1999.

Confined release. **Release** in **confinement.**

Confinement. The use of physical, chemical, operational, or biological controls (or a combination thereof) to limit or restrict the exit or dispersal from a specific area of an organism other than a micro-organism and any material that may be used to propagate it (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. 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), as defined in subsection 3(1) of CEPA 1999.

Experimental field trial release. 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.

Full containment. **Containment** under conditions meant to restrict the **release** into the environment of an organism other than a micro-organism, its genetic material, and all associated waste.

Full release. Intended **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 as a 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 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: A **living organism.**

Precautionary principle. The principle that if threats of serious or irreversible damage exist, a lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation (CEPA 1999, preamble).

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, 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** meets CEPA section 64 criteria as a result of inherent hazard of and exposure to the living organism.

Section 64 criteria.

(a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity,

(b) constitute or may constitute a danger to the environment on which life depends, or

(c) constitute or may constitute a danger in Canada to human life or health.

Significant new activity (SNAc). As adapted from section104 of CEPA 1999, in respect of a **living organism**, any activity that results or may result in (a) the entry or **release** of the **living organism** into the environment in a quantity or concentration that, in the **Minister's** opinion, is significantly greater than the quantity or concentration of the **living organism** that previously entered or was released into the environment or (b) the entry or **release** of the **living organism** into the environment or the exposure or potential exposure of the environment to the **living organism** in a manner and circumstances that, in the **Minister's** opinion, are significantly different from the manner and circumstances in which the living organism previously entered or

was released into the environment or of any previous exposure or potential exposure of the environment to the **living organism**.

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.

Appendix 1: Annotated Bibliography of Useful Sources of information Related to new substances*

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.

Appendix 2: 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 (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 (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	CFIA www.inspection.gc.ca	All 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	CFIA www.inspection.gc.ca	All 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	CFIA www.inspection.gc.ca	All 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 new substances in pest-control products

Appendix 3: Criteria Used to Assess the Options Identified by Environment Canada and Health Canada

In assessing the merits of each of the options presented in Section of the *Review of the New Substances Notification Regulations (Organisms)—Discussion Document,* Environment Canada (EC) and Health Canada (HC) considered the following non-prioritized criteria/factors:

- Legal implication: whether the proposed option is currently within the general authority of the Government, or whether specific legal authority would be needed that is currently not available under the *Canadian Environmental Protection Act, 1999* (CEPA 1999) (i.e., CEPA 1999 would need to be amended).

- Support for the environmental and human-health protection mandate of CEPA 1999: whether the option provides EC and HC with the information needed to assess potential risks to human health and the environment, including biodiversity.

- Consistency with the current regime under Part 6 of CEPA 1999: whether the option requires notice and risk assessment prior to import into or manufacture in Canada.

- Potential impact on research and development organizations.

- Potential impact on the industry (i.e., commercial applications).

- Potential impact on public confidence: the extent to which the public feels confident that human health and the environment are protected.

- Potential impact on EC and HC: the short- and long-term operational requirements, both organizational and financial, including the personnel needed to administer them and to conduct inspections.

- Potential impact on compliance and enforcement: whether EC and HC would be aware of all regulated activities taking place in Canada and, thereby, able to effectively promote and verify compliance.

- Alignment with current policies/practices of other federal regulatory departments or agencies (for an overview of current policies/practices under other federal biotechnology regulations, see Appendix 6).

Appendix 4: Core Information Requirements for Proposed Schedules

- Notifier's details (e.g., name, address)
- General proposed use (e.g., R&D, export only, import for production of pharmaceuticals in containment)
- New substance pre-notification consultation number assigned, if applicable
- Identification of the organism (to species level)
- Identification of the manufacturer, importer, vendor, country or point of origin, date of arrival, and site of landing, and a description of any domestic movement, with location(s)
- Description of the facility where import or manufacture will take place
- Anticipated annual quantity of organisms to be imported, if applicable
- Anticipated annual quantity to be manufactured, if applicable
- Intended and potential uses within Canada
- Description of expected modes for the organism's transport (if applicable) and storage
- Contingency plan in case of release

Appendix 5 – Proposed Notification Scheme and Schedules under Option 2

Under the proposed notification scheme IN Option 2, determination of the most appropriate schedule for a given organism would be based on the level of potential environmental and human exposure resulting from the intended use. The process for making this determination would pass through a series of four decision points, as illustrated in Figure 2 of this document:

1) Will the organism be kept in a contained facility?

If the answer is "YES", the notifier would be directed to decision point 2a, leading to one of two containment schedules.

If the answer is "NO", the notifier would be directed to decision point 2b, leading to one of three release schedules.

2a) Does the facility meet the "full containment" requirements?

If the answer is "YES", the notifier would be required to submit a Schedule 9 notification prior to the import or manufacture of the organism. Schedule 9 is intended for organisms used under full containment (i.e., conditions meant to restrict the release into the environment of the living organism, its genetic material, and all associated waste). Full containment would have to be done in accordance with the physical, operational, transport, and disposal requirements outlined in the containment and confinement guidelines.

If the answer is "NO", the notifier would be required to submit a Schedule 8 notification prior to the import or manufacture of the organism, and the assessment period would be longer than that of a Schedule 9 notification. Schedule 8 is intended for organisms used under basic containment, which is meant to restrict the release into the environment of the living organism and any material that may be used to propagate it without extensive manipulation (i.e., sperm, eggs, pollen, cuttings, spores, tubers, rhizomes). Basic containment would have to be done in accordance with the physical, operational, transport, and disposal requirements outlined in the containment and confinement guidelines.

2b) Will the organism be kept in confinement?

If the answer is "YES", the notifier would be directed to decision point 3, leading to one of two confinement schedules.

If the answer is "NO", the notifier would be required to submit a Schedule 5 notification prior to the import or manufacture of the organism, and the assessment would be the longest of all five proposed schedules. Schedule 5 is intended for

organisms proposed to be fully released into the environment (i.e., without any measure in place to confine it or restrict its dispersal).

3) Will the organism be used for experimental field-trial release?

If the answer is "YES", the notifier would be required to submit a Schedule 6 notification prior to the import or manufacture of the organism. Schedule 6 is intended for R&D organisms proposed to be released into the environment for the purpose of conducting a field trial that would use the minimum number of organisms, area, and time frame required to achieve the objectives of the study. Confinement of the organism and any material used to propagate it during the experimental field trial would have to be done in accordance with the physical, operational, transport, and disposal requirements outlined in the containment and confinement guidelines.

If the answer is "NO", the notifier would be required to submit a Schedule 7 notification prior to the import or manufacture of the organism. Confinement of the organism and any material used to propagate it would have to be done in accordance with the physical, operational, transport, and disposal requirements outlined in the containment and confinement guidelines.

Precise timelines for submitting the information/data would need to be established for each of the proposed notification categories. In general, the proposed scheme follows the existing approach for the notification of micro-organisms under the New Substances Program, which takes into account differences in potential environmental and human exposure. As such, the extent of information and data requirements would vary from one notification category to another. For instance, these requirements would be less comprehensive for organisms kept under full containment; hence, the time required by EC and HC to assess the information would be relatively short. It is estimated that Schedule 9 (full containment) would have the shortest notification period, and Schedule 5 the longest.

How the Proposed Notification Scheme Would Work

The following are examples of how the proposed notification scheme would work:

i) Schedule 5: Full Release
For organisms intended for release outside of a contained facility, and where schedules 6 (confined release) and 7 (experimental field-trial release) would not apply, the organism would have to be notified under Schedule 5. This schedule would not apply to organisms intended for R&D purposes, but would be appropriate for living organisms imported or manufactured for unrestricted commercial release, for uses such as

- food,
- the commercial marketing of reproductive materials,
- companion animals (e.g., cats, dogs), and

- invertebrates for composting or bioremediation.

ii) Schedule 6: Confined Release
Confined release would be appropriate for organisms that would, for health and welfare reasons, be permitted outside of containment, and for which appropriate confinement measures would be implemented, as outlined in the containment and confinement guidelines. This schedule could apply to living organisms imported or manufactured for R&D or commercial purposes, such as

- animals used to produce pharmaceuticals and kept in a confined area for grazing, and
- fish held in outdoor tanks and used for the production of food, feed, or other products.

iii) Schedule 7: Experimental Field-Trial Release
Schedule 7, although not a pre-requisite for submitting Schedule 5, would be available to notifiers wishing to conduct field trials to collect data (e.g., on the potential environmental effects of the organism). This schedule would only apply to organisms kept under confinement for experimental field-trial purposes, such as

- to determine efficacy, and
- to conduct breeding trials.

iv) Schedule 8: Basic Containment
Basic containment would be appropriate for organisms contained in greenhouses, aviaries, laboratories, and wet-holding facilities that meet the physical, operational, transport, and disposal requirements outlined in the containment and confinement guidelines. This schedule could apply to living organisms imported or manufactured for R&D or commercial purposes and kept in a contained facility that doesn't meet the full containment requirements. These could include such organisms as

- animals used for producing pharmaceuticals, and
- invertebrates or rodents used for research.

v) Schedule 9: Full Containment
Full containment would be appropriate for organisms maintained in laboratories that meet the physical, operational, transport, and disposal requirements outlined in the contaminant and confinement guidelines. This schedule could apply to living organisms imported or manufactured for R&D or commercial purposes and kept in a contained facility from which there would be no release of the organism, its genetic material, or its associated wastes (e.g., bedding material, biological fluids), for uses such as those listed for Schedule 8. To meet these requirements, the proponent would be expected to ensure that operational procedures and practices are in place such that the organism, its nucleic acids and proteins, and any tissues, carcasses, and wastes derived from it undergo appropriate treatment before being released from the facility. Appropriate treatment could consist of incineration, alkaline hydrolysis, or other treatment or disposal methods proven to be effective.

Appendix 6: Federal Acts and Regulations Applicable to the Environmental and Human-Health Assessment of New Substances that are Animate Products of Biotechnology

This table summarizes various Canadian acts that regulate animate products of biotechnology, and most of which are listed in Schedule 4 of the *Canadian Environmental Protection Act, 1999* (CEPA 1999) (except the *Fisheries Act*). These acts may also regulate inanimate products of biotechnology; however, this scope is not covered. For all purposes of interpreting and applying the law, consult the official versions of the relevant acts and regulations.

Act and Regulations	Scope of Legislative Authority	Notification/Authorization Categories/Groups
CEPA 1999 New Substances Notification Regulations for Organisms [NSNR (Organisms)]	- Part 6 of CEPA 1999 regulates living organisms that are products of biotechnology and not currently on the Domestic Substances List, or for a use regulated under another act listed in Schedule IV. - Subsection 106(7) gives the Governor in Council the power to list acts and regulations in Schedule IV of CEPA 1999. Listing in Schedule IV exempts from notification and assessment under CEPA 1999 and the NSNR those living organisms that are for a use regulated under the listed acts and regulations, which are 1. *Pest Control Products Act* and Regulations 2. *Seeds Act* and Regulations 3. *Fertilizers Act* and Regulations 4. *Feeds Act* and Regulations 5. *Health of Animals Act* and Regulations	Four notification categories for micro-organisms:* Schedule XV (120 days) applies to the manufacture or import of micro-organisms that will be introduced into the environment a) anywhere in Canada, b) into an ecozone where not indigenous, or c) in accordance with confinement procedures. Schedule XVI (30 days) applies to the manufacture or import of micro-organisms not for introduction outside a contained facility. Schedule XVII (90 days) applies to the manufacture or import of micro-organisms for introduction in an experimental field. Schedule XVIII (30 days) applies to a micro-organism manufactured at the same site from which it was isolated and where it will be introduced. One notification category for organisms other than micro-organisms: Schedule XIX (120 days) applies to the manufacture or import of animals and plants (other than micro-organisms), except those intended for research and development (R&D)

		and manufactured in or imported to a facility from which there is no release into the environment [refer to subsection 29.16 of the NSNR (Organisms)]. *Based on factors such as volume of import/manufacture and proposed level of containment. This system of notification categories/groups allows the government to match information requirements with anticipated concerns about potential level of environmental and human exposure to the new substance.
Pest Control Products Act (PCPA)[5] and Regulations	- Section. 6 of the Pest Control Products Regulations states that subject to section 5, every control product[i] imported into, sold or used in Canada or used or contained in another control product in Canada shall be registered in accordance with these Regulations. This provision excludes transgenic plants that confer pesticidal properties, as such plants are regulated under the *Seeds Act* and Regulations. - Invertebrate biological control agents, such as beneficial arthropods and nematodes, fall under the jurisdiction of the *PCPA* and Regulations.	Current Pest Management Regulatory Agency policy exempts from the requirements of a research authorization research that is conducted in a laboratory. The requirements for research with microbial pest control agents (MPCAs) are outlined in Regulatory Proposal PRO93-05, *Research Permit Guidelines for Microbial Pest Control Agents*. MPCAs are not eligible for exemption from the requirements of either a research permit or research notification for outdoor and greenhouse trials. Research notifications for MPCAs do not require data or scientific evaluation if all the following conditions are satisfied: the MPCA is indigenous to the ecozone of intended application, the trial area is on up to 10 hectares of land or one surface

[5] Section 2 of the PCPA defines control product as any product, device, organism, substance, or thing that is manufactured, represented, sold, or used as a means of directly or indirectly controlling, preventing, destroying, mitigating, attracting, or repelling any pest, and includes (a) any compound or substance that enhances or modifies or is intended to enhance or modify the physical or chemical characteristics of a control product to which it is added, and (b) any active ingredient used for the manufacture of a control product.

		hectare of water (confined to property), there is no cooperator involvement, the treated crop is destroyed, and the application is by ground equipment only.
Seeds Act and Regulations	- Section 2 of the *Seeds Act* defines "seed" as any plant part of any species belonging to the plant kingdom, represented, sold, or used to grow a plant. - The Canadian Food Inspection Agency (CFIA) is responsible for the regulation of the release of all plants with novel traits (PNTs). The trigger for assessment is the presence of a novel trait in a plant, rather than the specific means by which it was produced. - Section 107 of the Seeds Regulations defines "novel trait", in respect of seed, as a characteristic of the seed that (a) has been intentionally selected, created, or introduced into a distinct, stable population of cultivated seed of the same species through a specific genetic change, and (b) based on valid scientific rationale, is not substantially equivalent, in terms of its specific use and safety both for the environment and for human health, to any characteristic of a distinct, stable population of cultivated seed of the same species in Canada, having regard to weediness potential, gene flow, plant pest potential, impact on non-target organisms, and impact on biodiversity. - Examples of PNTs assessed under the *Seeds Act* include canola, corn, flax, potato, soybean, and wheat.	Authorization is required before a person may undertake either the confined release or unconfined release of seed (Part V, Release of Seed). According to section 108, seed grown in containment in such a manner that there is no release into the environment of any genetic material from the plants derived from the seed is exempt from Part V. Documentation for importation is required under the *Plant Protection Act* and Regulations.
Feeds Act and Regulations	- The CFIA, under the authority of the *Feeds Act*, regulates livestock feeds manufactured and sold in Canada or imported into Canada, unless exempted by section 4 of the Act (section 3) - Under the *Feeds Act* (section 2), "feed" means any substance or mixture of substances containing amino acids, anti-oxidants, carbohydrates, condiments, enzymes, fats, minerals, non-protein nitrogen products, proteins or vitamins, or pelletizing, colouring, foaming or flavour agents and any other substance manufactured, sold or represented for use a) for consumption by livestock, b) for providing nutritional requirements for livestock, or c) for the purpose of preventing or correcting nutritional disorders of livestock, or any substance for use in any such substance or mixture of substances.	Authorization is required before a person may release a novel feed (subsections 4.1 to 4.4, inclusive).

	-According to the Feeds Regulations, "feed" includes a feed derived through biotechnology. - "Livestock", as defined by the *Feeds Act*, means horses, cattle, sheep, goats, swine, foxes, fish, mink, rabbits, and poultry, and includes such other creatures as may be designated by regulation as livestock for the purposes of the Act. No other creatures are currently designated by regulation. - A "novel feed", as defined by the Feeds Regulations, is a feed comprising an organism or organisms, or parts or products thereof, that (a) is not set out in Schedule IV or V, or (b) has a novel trait. - "Novel trait", as defined by the Feeds Regulations, means a characteristic of the feed that (a) has been intentionally selected, created, or introduced into the feed through a specific genetic change, and (b) based on valid scientific rationale, is not substantially equivalent in terms of its specific use and safety both for the environment and for human and animal health, to any characteristic of a similar feed that is set out in Schedule IV or V. - Examples include PNTs (i.e., herbicide-tolerant corn), modified micro-organisms, micro-organisms not previously approved for use in Canada for livestock feed, and products and by-products (e.g., meat meal, whey) from transgenic animals.	
Fertilizers Act and Regulations	- The CFIA, under the authority of the *Fertilizers Act*, regulates fertilizers and supplements sold in Canada or imported into Canada - All substances that are manufactured, sold, or represented for use in the improvement of the physical condition of soils or to aid plant growth or crop yields are considered supplements, as per the definition. - Substances that are supplements require registration under the *Fertilizers Act*; examples include legume inoculants (*Rhizobia*) and *mycorrhizae*	Authorization is required before a person may release a novel supplement (subsections 23.1 to 23.4, inclusive).

	- A "novel supplement", as defined by the Fertilizer Regulations, means (a) a supplement that is not registered and not exempt from registration or (b) a supplement that is derived through biotechnology and has a novel trait. - A "novel trait", in respect of a supplement derived through biotechnology, as defined by the Fertilizers Regulations, means a characteristic of the supplement that (a) has been intentionally selected, created, or introduced into a distinct, stable population (of supplements) of the same species through a specific genetic change and (b) based on valid scientific rationale, is not substantially equivalent, in terms of its specific use and safety both for the environment and for human health, to any characteristic of a similar supplement that is in use as a supplement in Canada and is considered safe for use as a supplement in Canada.	
Fisheries Act and Regulations	- Under sections 54 to 56 of the Fishery (General) Regulations, no person may release live fish into fish habitat or transfer live fish to a fish-rearing facility without a license. The Minister of Fisheries and Oceans may issue a license if: (a) the release or transfer of the fish would be in keeping with the proper management and control of fisheries, (b) the fish do not have any disease or disease agent that may be harmful to the protection and conservation of fish, and (c) the release or transfer of the fish will not have an adverse effect on the stock size of fish or the genetic characteristics of fish or fish stocks. - the Fishery (General) Regulations apply to the oceans and freshwater of Nova Scotia, New Brunswick, British Columbia, Prince Edward Island, Newfoundland and Labrador, the Yukon Territory, Nunavut, and the Northwest Territories. - The definition of fish is found in section 2 of the Fisheries Act, which states that "fish" includes (a) parts of fish, (b) shellfish, crustaceans, marine animals and any parts of shellfish, crustaceans or marine animals, and (c) the eggs, sperm, spawn, larvae, spat, and juvenile stages of fish, shellfish, crustaceans, and marine animals. - Similar regulations exist for the other provinces. In some cases, provincial regulations apply. - Section 4 of the Fisheries Act states: “Nothing in this Act precludes the granting by the Minister of written permission to obtain fish for purposes of stocking or	

	artificial breeding or for scientific purposes." - This section is also used by the Minister to grant licenses for the release of live fish to fish habitat and the transfer of live fish to fish rearing facilities in some regions. - Under sections 3, 4, and 5 of the Fish Health Protection Regulations, import permits are required for import or transfer within Canada of cultured fish or the eggs of wild fish. - Cultured fish are defined as fish propagated by man in a fish culture facility. - These regulations apply only to those species listed in Schedule I (currently, only Salmonids).	
Health of Animals Act and Regulations	- Under the *Health of Animals Act*, the CFIA is responsible for regulating the manufacturing, importation, preparation, preservation, packaging, labeling, testing, storage, sale, distribution, and use of veterinary biologics in Canada. According to the definition in section 2, "veterinary biologic" means (*a*) a helminth, protozoa, or micro-organism, (*b*) a substance or mixture of substances derived from animals, helminths, protozoa or micro-organisms, or (*c*) a substance of synthetic origin that is manufactured, sold, or represented for use in restoring, correcting, or modifying organic functions in animals or for use in the diagnosis, treatment, mitigation, or prevention of a disease, disorder, or abnormal physical state, or the symptoms thereof, in animals. - These veterinary biologics regulations cover a diverse range of products, such as vaccines, antibody products, and diagnostic kits, used for the diagnosis, prevention, control, or treatment of a wide range of infectious diseases of animals. These products are derived from materials of animal or microbial origin, and may be produced by conventional microbiological methods or by modern techniques of biotechnology.	Pursuant to 121 (1), no person shall import a veterinary biologic into Canada unless it is done under and in accordance with a permit issued by the Minister. In addition, according to 123, no person shall prepare, manufacture, preserve, pack, label, or test a veterinary biologic unless it is done under and in accordance with an establishment licence issued by the Minister. Under section 124, no person shall manufacture a veterinary biologic unless it is done under and in accordance with a product licence issued by the Minister. A permit to release is further required before a person may release a veterinary biologic (subsections 120.3 to 120.6, inclusive). According to subsection 120.2(2)(b), these provisions do not apply in respect of the release of a veterinary biologic that contains organisms under containment or in accordance with the containment procedures in a manner that prevents the dissemination of any genetic material from the veterinary biologic into the environment.
