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A Section by Section Legal Analysis of the Proposed Micro-Organism Provisions of the New Substances Notification Regulations

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INTRODUCTION

The New Substances Notification Regulations are regulations enacted under the Canadian Environmental Protection Act (CEPA). The Regulations consist of two parts; Part I deals with New Substances other than polymers or certain biotechnology products, and Part II deals with polymers including certain biotechnology products. Amendments are proposed for the Regulations which will include a new Part II.1 to deal with new substances that are organisms. This part will apply to micro-organisms, and will set out the information that regulatees must submit for an assessment of toxicity. The amendments will ensure that no new micro-organism will be manufactured or imported into Canada on a commercial scale before an assessment has been carried out to determine the risk posed to the environment and human health.

This report presents a legal analysis of the proposed amendments to the New Substances Notification Regulations which apply to micro-organisms. Background information on how CEPA applies to micro-organisms and the application of the regulations are included to orientate the reader to the legal framework for enforcement and compliance. The offense provisions of CEPA that relate to the Regulations are also discussed. Finally, a section by section analysis of the micro-organism provisions is presented, detailing legal requirements for regulatees.

THE APPLICATION OF CEPA TO MICRO-ORGANISMS

CEPA requires the identification and assessment of substances that are toxic. A substance is toxic under Section II if it is entering, or may enter the environment in a quantity or concentration or under conditions:

(a) having or that may have an immediate effect on the environment;

(b) constituting or that may constitute a danger to the environment on which human life depends;

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

The definition of substance in Subsection 3(1) of CEPA refers to both animate and inanimate matter including that which is capable of being dispersed in the environment. As a result of this broad definition, substances produced by biotechnology will be subject to CEPA. Biotechnology is defined in Subsection 3(1) of CEPA as the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms. Micro-organisms that are products of biotechnology are therefore subject to CEPA as well.

The Substances New to Canada provisions of CEPA require that new micro-organisms must be assessed for toxicity prior to their manufacture or importation into Canada. The Domestic Substances List is the sole basis for determining if a micro-organism is new for the purposes of CEPA. The Domestic Substances List specifies all substances that were between January 1, 1984 and December 31, 1986:

(a) manufactured in or imported into Canada by any person in a quantity of not less than 100 kg in any one calendar year; or

(b) in Canadian commerce or used for commercial manufacturing purposes.

Any person is prohibited from manufacturing or importing a new micro-organism not on the Domestic Substances List unless:

(a) the person has provided the Minister with the prescribed information on or before the prescribed date; and

(b) the period for assessing the information has expired. (Subsection 26 (1))

The Assessment of a micro-organism not on the Domestic Substances List is conducted by the New Substances Division (NSD) of Environment Canada. The assessment has the following possible outcomes:

(a) a determination the micro-organism is not suspected of being toxic and its inclusion on the Domestic Substances List;

(b) a suspicion that the micro-organism is toxic; or

(c) a determination that the micro-organism is toxic and its inclusion on the Non-Domestic Substances List.

CEPA also contains special transitional provisions that also apply to micro-organisms. These apply to persons who have manufactured or imported a micro-organism that is not on the Domestic Substances List where the manufacture or importation has occurred between January 1, 1987 and the date in with the notification provisions in Section 26 come into force. Section 26 came into force on July 1, 1994. In these circumstances, the person is prohibited from importing or manufacturing the micro-organism after July 1, 1994, unless within 180 days after that date or on or before the prescribed date, the person provides the prescribed information to NSD. The New Substances Notification Regulations will provide a date for notification under this provision.

THE APPLICATION OF THE NEW SUBSTANCES NOTIFICATION REGULATIONS

The amendments to the New Substances Notification Regulations will set out in detail the regulatee's responsibilities under Section 26 of CEPA. The amendments incorporate definitions into the Regulations that are relevant to micro-organisms. They provide important exemptions for certain micro-organisms manufactured or imported under defined conditions and under certain quantities. The amendments also establish classes or groups of micro-organisms for notification and Schedules of Information detailing the information that must be submitted for each class or group, dates by which regulatees must submit the information, the assessment period for each class or group established in the Regulations and special provisions for micro-organisms that fall within the transitional provisions of CEPA.

There are several factors that should be considered in any compliance or enforcement activity taken in regard to CEPA and the amended Regulations. Under the circumstances listed below, the regulatee will not have to provide all or some of the information set out in the Regulations.

1. The micro-organism falls under the exceptions to the definition of substance provided in Subsection 3(1) of CEPA. No notification need be given prior to import or manufacture and the New Substances Notification Regulations do not apply. The exceptions to the CEPA definition of substance and their application to micro-organisms are presented below.

   (a) a mixture that is a combination of substances and does not itself produce a substance that is different from the substances combined. (Subsection 3(1))

   This exception has relevance to micro-organisms that are combined in a formulation or a consortium. A formulation is a deliberate mixture of pure cultures of micro-organisms. The formulation itself is not a substance because it falls within this exception. However, each pure culture in the formulation is a substance and may require separate notification.

   A consortium is a complex culture that is not a pure culture and is not deliberately formulated. For example, a collection of diverse organisms may be isolated from sludge or soil. It may be very difficult to characterize all the micro-organisms. The consortium does not fall within this exception and is subject to notification under CEPA as a substance.

   (b) any manufactured item formed into a specific physical shape or design during manufacture and has, for its final use, a function or functions dependent in whole or in part on its shape or design. (Subsection 3(1))

   Immobilized micro-organisms may be contained in a column used in processing a chemical substance. Micro-organisms may also be used in biofilters. In these examples, the column and the structural framework of the biofilter fall within this exception and are not notifiable under CEPA. However, the micro-organisms in the column or the biofilter may be subject to the notification provisions of CEPA and the New Substances Notification Regulations.

   (c) any animate matter, or any complex mixtures of different molecules that are contained in effluents, emissions or wastes that result from any work, undertaking or activity. (Subsection 3(1))

   Micro-organisms contained in effluents, emissions or wastes would fall within this exception to the CEPA definition of substances and would not be subject to the New Substances Notification Regulations. However, any subsequent use of these materials could qualify them as notifiable substances.

2. The micro-organism falls within the exemption from notification provisions in Subsection 26(3) of CEPA and, hence, the New Substances Notification Regulations do not apply. The exemptions and their application to micro-organisms are set out below.

   (a) A substance that is manufactured or imported for a use that is regulated under any other Act of Parliament that provides for notice to be given prior to the manufacture, import or sale of the substance and for an assessment of whether it is toxic. (Paragraph 26(3)(a))

   Certain micro-organisms fall under the jurisdiction of other Acts of Parliament. For example, micro-organisms used in pest control require notification and assessment under the Pest Control Products Act. The exemption from notification under CEPA and the New

Substances Notification Regulations would apply to such micro-organisms. However, if a pest control micro-organism had a new application, then the notification provisions of CEPA and the Regulations would apply.

(b) A substance that is manufactured or imported in a quantity that does not exceed the maximum quantity as prescribed as exempt. (Paragraph 26(3(e))

Maximum quantities of micro-organisms that are exempt from notification under CEPA may be prescribed in regulations. The New Substances Notification Regulations contain an exemption in Section 29.11 for research and development micro-organisms imported or manufactured in quantities of set amounts under specified conditions.

3. The regulatee has applied for and been granted a waiver for any of the requirements for prescribed information under Subsection 26(4) of CEPA. The regulatee would thus not have to provide certain information requirements as set out in the New Substances Notification Regulations.

Waivers are only granted under the specific circumstances set out in Subsection 26(4) of CEPA. The Minister of Environment must publish in the Canada Gazette a notice stating the name of any person to whom a waiver is granted and the type of information to which it relates. (Subsection 26(5))

The NSD can provide guidance on whether CEPA, the Regulations or parts of the Regulations apply to micro-organisms on a case by case basis. Close coordination with NSD will be required in all circumstances where enforcement and compliance is considered.

THE OFFENSE PROVISIONS IN CEPA THAT RELATE TO THE REGULATIONS

Section 116 of CEPA provides that it is an offense to contravene any regulation under the Act. Any provision of the New Substances Regulations that is not adhered to in the notification process could lead to prosecution. However, Sections 112 to 114 set out specific offenses for contravening the notification provisions of CEPA. These are directly related to the New Substances Notification Regulations which provide the detailed requirements for notification. The sections of CEPA that establish these offenses and an explanation of their relation to the Regulations are presented below.

1. Subsection 112(a) establishes that an offense is committed by every person who fails to provide the Minister of Environment with the information as required in Section 26, the notification provisions.

The New Substances Notification Regulations set out the detailed requirements for notification under Section 26 of the CEPA. If a regulatee fails to submit the information required by the Regulations, then Section 26 of CEPA has been contravened and an offense has been committed under Subsection 112(a).

2. Subsection 112(b) establishes that an offense is committed by every person who fails to notify the Minister of Environment as required under Subsection 26(6). Subsection 26(6) of CEPA places a duty on regulatees to make notification of any corrections to the information and to submit such corrections as soon as possible after learning of them.

A regulatee may have submitted results from tests or literature reviews in compliance with the requirements established in the New Substances Notification Regulations. If the regulatee learns of corrections to such information and fails to make notification as soon as possible, then Subsection 26(6) has been contravened and an offense has been committed under Subsection 112(b).

3. Subsection 113(e) establishes that an offense is committed by every person who manufactures or imports a substance in contravention of Paragraph 26(1)(b). Paragraph 26(1)(b) prohibits the manufacture and import of a substance that is not on the Domestic Substances List before the period for assessment has expired. The period of assessment applies to the information submitted by the regulatee under the notification requirements of CEPA.

   The New Substances Notification Regulations establish the time periods in which the information submitted by the regulatees must be assessed. If a regulatee imports or manufactures the micro-organism to which the notification provisions apply before the time periods established in the Regulations have elapsed, then Paragraph 26(1)(b) has been contravened and an offense under Subsection 113(e) has been committed.

4. Subsection 114(a) establishes an offense for every person who knowingly provides the Minister of Environment with any false or misleading information in purported compliance with Section 26, the notification provisions of CEPA.

   Any person who provides false or misleading information in meeting the requirements of the New Substances Notification Regulations and in purported compliance with Section 26 has committed an offense under Subsection 114(a). The false or misleading information must be submitted "knowingly". It is not enough in this offense just to submit such information but it must be done with a guilty mind; that is, it must be done with intent or a reckless disregard for consequences.

   Of particular interest from a compliance and enforcement perspective is Section 29.11 of the proposed amendments to the Regulations. This section provides that the Regulations would not apply to research and development micro-organisms that are:

   (a) imported to a contained facility in quantities of less than 50 ml or 50 g;

   (b) subject to paragraphs (c) and (d), manufactured in a contained facility, unless the micro-organisms require containment level 2, 3 and 4 as identified in the Laboratory Biosafety Guidelines:

   (c) manufactured in quantities less than 250 L in a contained facility and that require containment level 2 as identified in the Laboratory Biosafety Guidelines; or

   (d) human pathogens manufactured in quantities of less than 250 L in a contained facility and that require containment level 3 or 4 as identified in the Laboratory Biosafety Guidelines where an import permit or approval in writing to transfer has been granted in respect of the micro-organism under the Human Pathogen Importation Regulations.

   A person manufacturing or importing a micro-organism who meets the requirements in Section 29.11 does not have to notify but does have to ensure that the conditions in the section are met. Compliance and enforcement activities in regard to the Regulations would have to consider the regulatee's responsibilities under this section. A breach of the conditions in Section 29.11 would be an offense under Section 116 of CEPA.

A SECTION BY SECTION ANALYSIS OF THE MICRO-ORGANISM PROVISIONS OF THE NEW SUBSTANCES NOTIFICATION PROVISIONS

In conversations and correspondence with regulatees, these Regulations may be referred to as the New Substances Notification Regulations. This is the short title provided in Section 1 of the Regulations. Regulatees who import or manufacture micro-organisms will have particular interest in Part II.1, entitled New Substances that are Organisms, and the provisions within that Part that relate to micro-organisms.

SECTION 2 AMENDMENTS:

(2) Section 2 of the Regulations is amended by adding the following in alphabetical order:

Section 2 of the Regulations will be amended to provide legal definitions for several important words used throughout the Regulations in the micro-organism provisions. These definitions are used to avoid repetition and ambiguity. Where legally defined words are used in the Regulations as set out in this analysis, they are highlighted in bold and underlined. Reference can be made back to the definition in Section 2 when an underlined word highlighted in bold is spotted.

It should be noted that some words used in the Regulations have special scientific or technical meanings but are not defined in Section 2 or CEPA. These words are defined in this analysis on the basis of how they are commonly used in scientific publications.

Definition:

"confinement procedures" means any physical, chemical, operational or biological control, or combination thereof, to restrict the exit or dispersal of a **micro-organism**; (*méthodes de confinement*)

Legal Requirements for Regulatees:

The Regulations create information requirements, and assessment periods and an information provision date for micro-organisms to be manufactured or imported for introduction in accordance with confinement procedures. Regulatees must be clear on the definition of confinement procedures to determine if their intended manufacture or importation of a micro-organism falls within these requirements of the Regulations.

Regulatees may use any procedures or procedure listed in this definition but those procedures must function to restrict the exit or dispersal of a micro-organism.

This definition is relevant to:

- the information requirements in Paragraph 29.12(2)(b);
- the information provision dates in Paragraph 29.13(a)(ii);
- the assessment period in Subsection 29.14(a);
- the transitional information requirements in Paragraph 29.15(2)(b);
- the transitional information provision date in Section 29.16;
- the detailed information requirements in Schedule XV.

Definition:

"contained facility" means an enclosed building with walls, floor and ceiling, or an area within such a building, where the containment of a micro-organism is in accordance with the **Laboratory Biosafety Guidelines** or the "*Guidelines For Research Involving Recombinant DNA Molecules (NIH Guidelines) June 1994*" published by the United States Department of Health and Human Services, in the *Federal Register* (United States), Vol. 59, No. 127, on July 5, 1994, as amended from time to time; (*installation étanche*)

Legal Requirements for Regulatees:

The Regulations set out information requirements, an assessment period and an information provision date for micro-organisms to be manufactured or imported not for introduction outside a contained facility or for export only. The use of contained facilities is also imperative for exempting micro-organisms from notification as established in these Regulations. Regulatees must be clear on the definition of a contained facility to determine if their intended manufacture or importation of a micro-organism falls within these requirements of the Regulations or is exempted from notification by the Regulations.

This definition of contained facility means an enclosed building with walls, floor and ceiling or an area within such a building. In the case of either of these facilities, the regulatee must ensure that the containment is in accordance with the Laboratory Biosafety Guidelines or the "Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines), June 1994." The Laboratory Biosafety Guidelines are defined in Section 2 of the Regulations.

Both sets of Guidelines referred to in this definition may be amended from time to time and the regulatee should rely on the most recent version.

This definition is relevant to:

- the exemption provisions in Section 29.11;
- the information requirements in Subsection 29.12(4);
- the information provision date in Subsection 29.13(b);
- the assessment period in Subsection 29.14(b);
- the transitional information provision date in Section 29.16;
- the transitional information requirements in Section 29.15(4);
- the detailed information requirements in Schedule XVI.

Definition:

"ecozone" means one of the ecozones which are illustrated on the map entitled "*Land Ecozones and Ecoregions, Canada, 1994*" dated 26 August 1994 and having Catalogue Number CAS005, the boundaries of which are more particularly described in the National Soil Data Base (NSDB) of the Canada Soil Information System (CanSIS), developed by the Department of Agriculture and Agri-Food and the Department of the Environment, as amended from time to time; (*ecozone*)

Regulatory Requirements for Regulatees:

The Regulations create information requirements assessment periods and information provision dates for a proposed manufacture or importation of a micro-organism where it occurs naturally in an ecozone and where it does not occur naturally in an ecozone. Regulatees must be able to clearly identify the ecozone in which the manufacture or importation is to occur. This allows them to determine what provisions of the Regulations are applicable to them.

Proper identification of an ecozone is also important to the application of provisions in the Act that deal with importation and manufacturing on boundaries of ecozones. This definition provides that ecozones must be defined by reference to the map "Land Ecozones and Ecoregions, Canada 1994" and for more particular details, the National Soil Data Base of the Canada Soil Information Systems.

This definition is relevant to:

- the definition of indigenous in Subsection 2(1);
- the information requirements in Paragraphs 24.12(2)(a) and 29.12(2)(c);
- the ecozone boundary provision in Subsection 29.12(3);
- the information provision dates in Paragraph 29.13(a)(ii);
- the assessment periods in Subsection 29.14(a);
- the transitional information requirements in Paragraphs 29.15(2)(a) and 29.15(2)(c);
- the transitional ecozone boundary provision in Subsection 29.15(3);
- the transitional information provision date in Section 29.16;
- the detailed information requirements in Schedule XV.

Definition:

"experimental field study" means a study of a research and development substance that is a micro-organism, which study uses the minimum area, up to a maximum of 100 hectares, and the minimum quantity of the substance required to meet the objectives of the study; (*étude expérimentale sur le terrain*)

Regulatory Requirements for Regulatees:

These Regulations establish information requirements, an assessment period and an information provision date for micro-organisms that are imported or manufactured for introduction in an experimental field study. This definition allows regulatees to determine if these provisions apply to their activities.

An experimental field study as defined here has three components:

1. It must use a micro-organism that is a research and development substance. A research and development substance is defined in Subsection 2(1) of the Regulations as a substance that is undergoing 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 production process; or

(b) to determine the technical viability or performance characteristics of a product or process.

2. It must use the minimum area required to meet the objectives of the study. The area can be up to a maximum of 100 hectares.

3. It must use the minimum quantity of the substance to meet the objectives of the study.

This definition is relevant to:

- the information requirements in Subsection 29.12(5);
- the information provision date in Subsection 29.13(c);
- the assessment period in Subsection 29.14(c);
- the transitional information requirements in Subsection 29.15(5);
- the transitional information provision date in Section 26.16;
- the detailed information requirements in Schedule XVII.

Definition

"Laboratory Biosafety Guidelines" means the *Laboratory Biosafety Guidelines* established by the Department of National Health and Welfare and the Medical Research Council of Canada, published in 1990, as amended from time to time; (*Lignes directrices en matiére de biosécurité en laboratoire*)

Legal Requirements for Regulatees:

Laboratory Biosafety Guidelines must be adhered to in circumstances where micro-organisms are exempted from information requirements under the Regulations. The Guidelines also are the standard for containment in contained facilities. Regulatees must be clear on what the Guidelines are and what requirements they impose in order to adhere to the appropriate provisions in the Regulations.

The Laboratory Biosafety Guidelines set out the physical structures and operational procedures for containing the biohazards identified for groups of microbial agents.

This definition is relevant to:

- the definition of contained facility in Subsection 2(1);
- the exemptions to notification requirements in Subsections 29.11(b),(c)(d);
- the information requirements for contained facilities in Schedule XVI, Subsection 2(c).

Definition:

"indigenous" means in respect of a **micro-organism**, occurring naturally in the **ecozone** into which the **micro-organism** is intended to be introduced; (*indigène*)

Legal Requirements for Regulatees:

These Regulations establish of information requirements, assessment periods and information provision dates for micro-organisms that are indigenous and for micro-organisms that are not indigenous. The definition is key to determining a regulatee's responsibilities under the provisions of the Regulations.

Pursuant to this definition of indigenous, the micro-organism must occur naturally in the ecozone to which it is intended to be introduced. Ecozone is defined in Subsection 2(1). It should be noted that genetically modified micro-organisms are not indigenous because they have been modified by man. A micro-organism is naturally occurring when it occurs without intervention by man.

Definition:

"micro-organism" means an alive or killed microscopic organism that is

(*a*) classified in the Bacteria, the Archaea, the Protista, which includes protozoa and algae, or the Fungi, which includes yeasts,

(*b*) a virus, virus-like particle or sub-viral particle,

(*c*) a cultured cell of an animal or plant, other than a cell used to propagate an animal or a plant, or

(*d*) any culture other than a pure culture; (*micro-organisme*)

Legal Requirements for Regulatees:

This definition determines what organisms the micro-organism provisions in the Regulations apply to. The definition is key to all the duties imposed on regulatees under the Regulations. It allows regulatees to clearly distinguish the notification requirements under the Regulations for their substances from those requirements for other substances such as biopolymers and biochemicals.

This broad definition is relevant to all sections in the proposed amendment to the Regulations. It covers:

(a) the taxonomic designation of micro-organisms that are not viruses or are cultures derived from plants and animals;

(b) viruses, virus-like particles or sub-viral particles;

(c) plant or animal cell cultures excluding cells used to propagate an animal or plant;

(d) any culture other than a pure culture.

The definition relates to both formulations and consortia. A formulation is a deliberately formulated mixture of pure cultures. A consortium is a complex culture that is not a pure culture and that has not been deliberately formulated.

The definition also covers micro-organisms that have been genetically modified, as well as those that have been killed.

SECTION 3 AMENDMENTS:

2. Section 3 of the Regulations is replaced by the following:

3. These Regulations do not apply in respect of a substance

3. (*a*) that is loaded on a carrier outside Canada and moved through Canada to a location outside Canada, whether or not there has been a change of carrier during transit; or

Legal Requirements for Regulatees:

This exemption from the Regulations applies to regulatees transporting new micro-organisms through Canada. It applies, even if there is a change of carrier during transit. However, if the micro-organism is stored in Canada for subsequent distribution, the micro-organism would be subject to notification requirements.

3. (*b*) that is referred to in paragraph 26(3)(a) of the Act.

Legal Requirements for Regulatees:

Paragraph 26(3)(a) provides that the notification provisions of CEPA do not apply in respect of a substance that is manufactured or imported for a use that is regulated under any other Act of Parliament that provides for notice to be given prior to the manufacture, import or sale of the substance and for an assessment of whether it is toxic. This paragraph of the Regulations confirms that the Regulations do not apply to those substances that are also exempt from the notification requirements under Paragraph 26(3)(a).

Regulatees should determine if the micro-organism they propose to manufacture or import is exempted from notification under CEPA and the Regulations by consulting NSD on the application of this provision.

SECTION 29.11

29.11 This Part does not apply in respect of **micro-organisms** that are research and development substances and that are

Legal Requirements for Regulatees:

This section exempts certain new micro-organisms from the application of this part of the Regulations. These micro-organisms must be research and development substances as defined in Subsection 2(1) of the Regulations. In order to meet the definition, regulatees must be proposing to import or manufacture with a micro-organism that is undergoing systematic investigation or research by means of experimentation or analysis other than test marketing. The primary objectives of the investigation or research must be to:

(a) create or improve a product or process; or

(b) to determine the technical viability or performance characteristics of the product.

Regulatees must also meet the conditions required in the paragraphs below if they are to be exempt under this section.

29.11(*a*) imported to a **contained facility** in quantities of less than 50 mL or 50 g;

Legal Requirements for Regulatees:

Regulatees can only be exempted under this paragraph if they import the new research and development micro-organism to a contained facility. The quantity of the micro-organism must be less than 50 ml or 50 g inclusive of the micro-organism and media.

29.11(*b*) subject to paragraphs (*c*) and (*d*), manufactured in quantities of less than 1 000 L in a **contained facility**, unless the **micro-organisms** require containment level 2, 3 or 4 as identified in the **Laboratory Biosafety Guidelines**;

Legal Requirements for Regulatees:

Regulatees that claim exemption for their micro-organism under this paragraph must manufacture it in quantities of less than 1,000 L in a contained facility. The 1,000 L limit may be in a batch or continuous volume. The limit of 1,000 L will not apply to micro-organisms that require containment levels 2, 3 or 4 as identified in the Laboratory Biosafety Guidelines. The containment levels established by the Laboratory Biosafety Guidelines, set out the physical structures and operational procedures to contain the biohazards related to defined groups of microbial agents.

Legal Requirements for Regulatees:

Regulatees who manufacture or import a micro-organism for introduction into any ecozone where it is indigenous must submit all of the information in Schedule XV except that in Subparagraphs 1(f)(i), (iii) and (iv) and Paragraphs 1(j) and 5(a).

Regulatees must also:

(1) identify the ecozone of intended introduction; and

(2) provide data that demonstrates that the micro-organism is indigenous to that ecozone.

29.12(3) A person who manufactures or imports a **micro-organism** for introduction into an **ecozone** at a point within 10 km of the boundary of an **ecozone** referred to in paragraph (2)(*a*) or (*c*), as the case may be, may elect to have the introduction of the **micro-organism** considered to be in that **ecozone** and not into the actual **ecozone** of introduction, in which case they shall provide a notice in writing of the election and the information required by that paragraph.

Legal Requirements for Regulatees:

A regulatee who is manufacturing or importing a micro-organism for introduction into an ecozone must determine if the micro-organism is indigenous to that ecozone. If it is not indigenous, then the information requirements identified in Paragraph 29.12(2)(a) apply. If it is indigenous, then the information requirements in Paragraph 29.12(2)(c) apply.

This provision gives an important election to a regulatee who is manufacturing or importing a micro-organism for introduction into an ecozone at a point within 10 km of the boundary with another ecozone. The regulatee may elect to have the introduction of the micro-organism considered to be in the other ecozone and not the actual ecozone of introduction. If such an election is made, the regulatee must provide a notice in writing and the information in Paragraph 29.12(2)(a) or (c), as the case may be.

29.12(4) A person who manufactures in a **contained facility** or imports to a **contained facility** a **micro-organism** that is not for introduction outside the **contained facility**, or is for export only, is not required to provide the information specified in Schedule XV, but shall provide the information specified in Schedule XVI.

Legal Requirements for Regulatees:

This provision applies to regulatees who are:

(1) manufacturing a micro-organism in a contained facility and the micro-organism is not for introduction outside that facility or is for export only; or

(2) importing a micro-organism to a contained facility and the micro-organism is not for introduction outside the contained facility or is for export only.

In both cases, the regulatees must submit the information in Schedule XVI.

29.12(5) A person who manufactures or imports a **micro-organism** for introduction in an **experimental field study** is not required to provide the information specified in Schedule XV, but shall provide the information specified in Schedule XVII.

Legal Requirements for Regulatees:

A regulatee who manufactures or imports a micro-organism for introduction in an experimental field study must submit the information in Schedule XVII.

29.12(6) A person who manufactures a **micro-organism** at the site from which it was isolated, for introduction into the same site, is not required to provide the information specified in Schedule XV, but shall provide the information specified in Schedule XVIII.

Legal Requirements for Regulatees:

A regulatee who manufactures micro-organism at the site from which it was isolated for introduction into the same site, must submit the information in Schedule XVIII.

Information Provision Dates

SECTION 29.13

29.13 The information referred to in section 29.12 shall be provided as follows:

29.13(*a*) for information

29.13(a)(i) specified in Schedule XV and referred to in subsection 29.12(1), at least 120 days before the day on which the person manufactures or imports the **micro-organism**,

Legal Requirements for Regulatees:

Regulatees, who are required under Subsection 29.12(1) of the Regulations to provide the information in Schedule XV, must provide the information on or before the prescribed date. This subparagraph prescribes that the information must be submitted at least 120 days before the day on which the regulatee manufactures or imports the micro-organism.

The Interpretation Act, R.S.C. 1985 c. I-21, has provisions that apply to interpreting time limitations. Under Section 26 of that Act, where the time limitation falls on a holiday, the regulatee may provide the information on the day next following that is not a holiday.

29.13(a)(ii) specified in Schedule XV and referred to in subsection 29.12(2), and the other information referred to in that paragraph, at least 120 days before the day on which the person manufactures or imports the **micro-organism** under conditions that trigger the requirement to provide the information, or

Legal Requirements for Regulatees:

Regulatees who are required under Subsection 29.12(2) of the Regulations to provide the specified information from Schedule XV and other information required under the subsection, must provide that information on or before the prescribed date. This subparagraph prescribes that the information must be submitted at least 120 days before the day on which the regulatee manufactures or imports the micro-organism under conditions that trigger the requirement to provide the information.

The Interpretation Act R.S.C. 1985 C. I-21, has provisions that apply to interpreting time limitations. Under Section 26 of that Act, where the time limitation falls on a holiday, the regulatee may provide the information on the day next following that is not a holiday.

29.13(a)(iii) referred to in subsection 29.12(3), at least 120 days before the day on which the person manufactures or imports the micro-organism under conditions that trigger the requirement to provide the information;

Legal Requirements for Regulatees:

Regulatees who have made an election under Subsection 29.12(3) of the Regulations must provide the appropriate information from Schedule XV and other information required on or before the prescribed date. This subparagraph prescribes that the information must be submitted at least 120 days before the day on which the regulatee manufactures or imports the micro-organism under conditions that trigger the requirement to provide the information.

The Interpretation Act R.S.C. 1985 c. I-21, has provisions that apply to interpreting time limitations. Under Section 26 of that Act, where the time limitation falls on a holiday, the regulatee may provide the information on the day next following that is not a holiday.

29.13(*b*) for information specified in Schedule XVI or XVIII, at least 30 days before the day on which the person manufactures or imports the micro-organism under conditions that trigger the requirement to provide the information; and

Legal Requirements for Regulatees:

Regulatees who are required under Subsections 29.12(4) and (6) of the Regulations to provide the information in Schedule XVI or XVIII, respectively, must provide that information on or before the prescribed date. This paragraph prescribes that the information must be submitted 30 days before the day on which the regulatee manufactures or imports the micro-organism under conditions that trigger the requirement to provide the information.

The Interpretation Act R.S.C. 1985 c. I-21, has provisions that apply to interpreting time limitations. Under Section 26 of that Act, where the time limitation falls on a holiday, the regulatee may provide the information on the day next following that is not a holiday.

29.13(*c*) for information specified in Schedule XVII, at least 90 days before the day on which the person manufactures or imports the **micro-organism** under conditions that trigger the requirement to provide the information.

Legal Requirements for Regulatees:

Regulatees who are required under Subsection 29.12(5) of the Regulations to provide the information in Schedule XVII must provide that information on or before the prescribed date. This Subsection prescribes that the information must be submitted 90 days before the day on which the regulatee manufactures or imports the micro-organism under conditions that trigger the requirements to provide the information.

The Interpretation Act R.S.C. 1985 c. I-21, has provisions that apply to interpreting time limitations. Under Section 26 of that Act, where the time limitation falls on a holiday, the regulatee may provide the information on the day next following that is not a holiday.

Assessment Periods

SECTION 29.14

29.14 The periods within which the Ministers shall assess the information referred to in Section 29.12 are as follows:

29.14(*a*) for information specified in Schedule XV and the other information referred to in Subsection 29.12(2), a period of 120 days following receipt of the information;

Legal Requirements for Regulatees:

The legal duty established under this provision falls on the Minister of the Environment and the Minister of National Health and Welfare under Subsection 28(2) of CEPA. They must assess the information properly submitted by the regulatee within a period of 120 days following the receipt of the information set out in Schedule XV and specified in Subsection 29.12(2) of the Regulations.

If the Ministers are of the opinion that further time is needed to assess the information, the Minister of the Environment, under Subsection 28(4) of CEPA, may extend the period for assessing the information subject to further conditions set out in the Act.

29.14(*b*) for Schedules XVI and XVIII, a period of 30 days following receipt of the information; and

Legal Requirements for Regulatees:

The legal duty established under this provision falls on the Minister of the Environment and the Minister of National Health and Welfare under Subsection 28(2) of CEPA. They must assess the information properly submitted by the regulatee within a period of 30 days following the receipt of the information set out in Schedule XVI or XVIII as the case may be.

If the Ministers are of the opinion that further time is needed to assess the information, the Minister of the Environment, under Subsection 28(4) of CEPA, may extend the period for assessing the information subject to further conditions set out in the Act.

29.14(*c*) for Schedule XVII, a period of 90 days following receipt of the information.

Legal Requirements for Regulatees:

The legal duty established under this provision falls on the Minister of the Environment and the Minister of National Health and Welfare under Subsection 28(2) of CEPA. They must assess the information properly submitted by the regulatee within a period of 90 days following the receipt of the information set out in Schedule XVII.

If the Ministers are of the opinion that further time is needed to assess the information, the Minister of the Environment, under Subsection 28(4) of CEPA, may extend the period for assessing the information subject to further conditions set out in the Act.

Transitional Period

SECTION 29.15

29.15(1) A person who manufactured or imported a **micro-organism** during the transitional period in any circumstance not described in subsections (2) to (6), and who manufactures or imports it, as the case may be, in any circumstance not described in those subsections, shall provide the information specified in Schedule XV.

Legal Requirements for Regulatees:

This Subsection establishes an overall duty for regulatees who have

(1) manufactured or imported a micro-organism during the transition period. and

(2) who are manufacturing or importing the micro-organism

to submit the information in Schedule XV. The specific information requirements in Schedule XV must be submitted in the circumstances set out in Paragraphs 29.15(2)(a) (b) and (c).

Schedules XVI, XVII and XVIII set out the information requirements for the activities described in Subsections 29.15(4), (5) and (6).

29.15(2) A person who manufactured or imported a **micro-organism** during the transitional period

29.15(2)(*a*) for introduction into one **ecozone** where it is not **indigenous** and who manufactures or imports it, as the case may be, for introduction into the same **ecozone**, shall provide the information specified in Schedule XV other than in paragraph 5 (*a*) thereof, and shall provide the identification of the **ecozone** of introduction and the data from tests conducted to determine the effects of the **micro-organism** on plant, invertebrate and vertebrate species likely to be exposed;

Legal Requirements for Regulatees:

The regulatee who has

(1) manufactured or imported a micro-organism during the transition period for introduction into one ecozone where it is not indigenous; and

(2) who now manufactures or imports that micro-organism for introduction into the same ecozone;

must submit the information in Schedule XV with the exception of Paragraph 5(a).

The regulatee must also submit

(1) the identification of the ecozone of introduction; and

(2) the data from tests conducted to determine the effects of the micro-organism on plant, invertebrate and vertebrate species likely to be exposed.

29.15(2)(*b*) for introduction in accordance with **confinement procedures** and who manufactures or imports it, as the case may be, for introduction in accordance with the same **confinement procedures**, shall provide the information specified in Schedule XV other than in paragraphs 5(*a*) and 6(*c*) and (*d*) thereof, and shall provide a description of those **confinement procedures** and their effectiveness in restricting the dispersal of the **micro-organism** from its locations of introduction; or

Legal Requirements for Regulatees:

The regulatee who has:

(1) manufactured or imported the micro-organism during the transition period for introduction in accordance with confinement procedures; and

(2) who now manufactures or imports that micro-organism in accordance with the same confinement procedures

must submit the information in Schedule XV with the exception of Paragraphs 5(a) and 6(c) and (d).

The regulatee must also submit a description of:

(1) those confinement procedures; and

(2) their effectiveness in restructuring the dispersal of the micro-organism from its locations of introduction.

29.15(2)(*c*) for introduction into any **ecozone** where it is **indigenous**, and who manufactures or imports it, as the case may be, for introduction into the same **ecozone**, shall provide the information specified in Schedule XV other than in subparagraphs 1(*f*)(i), (iii) and (iv) and paragraph 1(*j*) and 5(*a*) thereof, and shall provide the identification of the **ecozone** of introduction and data that demonstrates that the **micro-organism** is indigenous to that **ecozone**.

Legal Requirements for Regulatees:

The regulatee who:

(1) manufactured or imported a micro-organism during the transition period for introduction into any ecozone where it is indigenous; and

(2) now manufactures it for introduction into the same ecozone

must provide the information under Schedule XV with the exception of Subparagraphs 1(f)(i), (iii) and (iv) and Paragraph 1(j) and 5(a).

The regulatee must also provide:

(1) identification of the ecozone of introduction; and

(2) data that demonstrates that the micro-organism is indigenous to that ecozone.

29.15(3) A person who, during the transitional period, manufactured or imported a **micro-organism** for introduction into an **ecozone** referred to in paragraph (2)(*a*) or (*c*), as the case may be, and who manufactures or imports the **micro-organism**, as the case may be, for introduction into an **ecozone** at a point within 10 km of the boundary of the **ecozone** of introduction during the transitional period, may elect to have the introduction of the **micro-organism** considered to be into the same **ecozone** of introduction as during the transitional period and not into the actual **ecozone** of introduction, in which case they shall provide a notice in writing of the election and the information required by that paragraph.

Legal Requirements for Regulatees:

A regulatee who, during the transition period, has manufactured or imported a micro-organism for introduction into an ecozone and now introduces the same micro-organism into the ecozone must determine if the micro-organism is indigenous to the ecozone. If it is not indigenous, then the information requirements identified in Paragraph 29.15(2)(a) apply. If it is indigenous, then the information requirements in Paragraph 29.15(2)(c) apply.

This provision gives an important election to regulatees who:

(1) during the transition period, manufactured or imported the micro-organism for introduction into an ecozone where it was or was not indigenous; and

(2) now manufacture or import the micro-organism, as the case may be, for introduction into an ecozone at a point within 10 km of the boundary of the ecozone of introduction during the transitional period.

Under these circumstances, the regulatee may elect to have the introduction of the micro-organism considered to be into the same ecozone of introduction as during the transition period and not into the actual ecozone of introduction. If such an election is made, the regulatee must provide a notice in writing and the information required in Paragraph 29.15(2)(a) or (c), as the case may be.

29.15(4) A person who, during the transitional period, manufactured in a **contained facility** or imported to a **contained facility** a micro-organism that was not for introduction outside the contained facility or was for export only, and who manufactures the **micro-organism** in the same contained facility or imports it to the same **contained facility**, as the case may be, which **micro-organism** is not for introduction outside the **contained facility** or is for export only, shall provide the information specified in Schedule XVI.

Legal Requirements for Regulatees:

This provision applies to regulatees who:

(1) during the transition period, manufactured in a contained facility, or imported to a contained facility, a micro-organism that was not for introduction outside that facility or was for export only; and

(2) now manufacture that micro-organism in the same contained facility or import it to the same contained facility.

They must submit the information in Schedule XVI.

29.15(5) A person who manufactured or imported a micro-organism for introduction in an **experimental field study**, during the transitional period, and who manufactures or imports the **micro-organism**, as the case may be, for introduction in the same **experimental field study**, shall provide the information specified in Schedule XVII.

Legal Requirements for Regulatees:

This subsection applies to regulatees who:

(1) during the transitional period, manufactured or imported a micro-organism for introduction in an experimental field study; and

(2) now manufacture or import that micro-organism for introduction into the same experimental field study.

They must submit the information in Schedule XVII.

29.15(6) A person who manufactured a **micro-organism** at the site from which it was isolated for introduction into the same site, during the transitional period, and who manufactures the **micro-organism** at that site for introduction into that site, shall provide the information specified in Schedule XVIII.

Legal Requirements for Regulatees:

This Subsection applies to regulatees who:

(1) manufactured a micro-organism at the site from which it was isolated for introduction into the same site; and

(2) now manufacture that micro-organism at that site for introduction into that site.

The regulatees must provide the information in Schedule XVIII.

SECTION 29.16

29.16 The information referred to in section 29.15 shall be provided on or before June 1, 1996.

Legal Requirements for Regulatees:

The regulatee must provide the information in Section 29.15 on or before June 1, 1996. This date is prescribed under Subsection 26(2) of CEPA.

SCHEDULE XV

(Subsections 29.12(1) and (2) and 29.15(1) and (2))

INFORMATION REQUIRED IN RESPECT OF **MICRO-ORGANISMS**

Legal Requirements for Regulatees:

Schedule XV sets out the information required under Subsections 29.12(1) and (2) where a regulatee intends to manufacture or import a micro-organism under the conditions specified in those subsections and where the micro-organism is not specified on the Domestic Substances List.

The information in Schedule XV is also required under Subsections 29.15(1) and (2) where a regulatee has manufactured or imported a new micro-organism during the transition period and under the conditions specified under those subsections. The regulatee now manufactures or imports the micro-organism under the same conditions.

Each information item specified in this Schedule is required to make an assessment of the micro-organism's toxicity under CEPA. Regulatees receive guidance on these notification requirements directly by contacting NSD and from Guidelines produced by NSD.

SECTION 1

1. The following information in respect of the **micro-organism**:

Legal Requirements for Regulatees:

This Section sets out the specific characteristics of the micro-organism that the regulatee must describe in the notification.

1. (*a*) the identification and the information substantiating the identification;

Legal Requirements for Regulatees:

The regulatee must provide the identification of the micro-organism and the information that substantiates that identification.

Special considerations should be given to identification in the following circumstances:

(1) where a formulation is to be or has been manufactured or imported, each micro-organism in the formulation must be identified by the regulatee;

(2) where a consortium is to be or has been manufactured or imported, regulatees should attempt to identify each micro-organism. Otherwise, the identification should be made according to the Guidelines produced by NSD; and

(3) where a genetically engineered organism is to be or has been manufactured or imported, the regulatee should identify the host micro-organism as well as the organisms that were the source of the genetic information.

1. (*b*) the synonyms and common and superseded names;

Legal Requirements for Regulatees:

The regulatee must submit names other than the taxonomic designation submitted in 1(a) that the micro-organism is known by or has been known by.

1. (*c*) the strain history;

Legal Requirements for Regulatees:

The regulatee must submit a strain history of the micro-organism. A strain is a micro-organism isolate or culture. The word "strain" is not defined in CEPA or the Regulations. A strain history would describe the development of the strain from its original source of isolation to final product development.

1. (*d*) a description of any modifications to the **micro-organism**, including

Legal Requirements for Regulatees:

The regulatee must submit descriptions of any modifications made to the micro-organism. Micro-organisms may be modified by physical or chemical means or by novel molecular techniques. The specific items to be included in a description of any modification are listed in the subparagraphs below. The regulatee may have to provide other relevant information on the modifications not listed in the subparagraphs.

1.(d)(i) the purpose of the modifications,

Legal Requirements for Regulatees:

The regulatee must submit information on the purpose of any modifications made to the micro-organism.

1.(d)(ii) the methods and steps taken to make the modifications,

Legal Requirements for Regulatees:

The regulatee must describe all methods and steps taken to make the modification.

1.(d)(iii) the phenotypic and genotypic changes that resulted from the steps referred to in subparagraph (ii),

Legal Requirements for Regulatees:

The regulatee must describe the genotypic and phenotypic changes that resulted from the steps in Subparagraph 1(d)(ii). A micro-organism's genotype is its genetic constitution with reference to a single trait or a set of traits. A genotype also means the sum total of all the genes present in an individual. A micro-organism's phenotype is its observable properties resulting from interactions between the genotype and the environment. The words genotype and phenotype are not defined in CEPA or the Regulations.

1.(d)(iv) the stability of the changes referred to in subparagraph (iii), and

Legal Requirements for Regulatees:

The regulatee must submit a description of the stability of the changes described under Subparagraph 1(d)(iii). This would consider if the genotype and phenotype of the modified micro-organism are passed on unchanged from one generation to another.

1.(d)(v) the nature, source and function of any inserted genetic material;

Legal Requirements for Regulatees:

The regulatee must provide information on the nature, source and function of any genetic material inserted into the modified micro-organism.

1. (*e*) a description of the methods that can be used to distinguish and detect the **micro-organism**;

Legal Requirements for Regulatees:

The regulatee must submit a description of the methods that can be used to distinguish and detect the micro-organism.

1. (*f*) a description of the biological and ecological characteristics of the **micro-organism**, including

Legal Requirements for Regulatees:

The specific items to be included in a description of the biological and ecological characteristics of the micro-organism are listed in the subparagraphs below. The regulatee may have to provide other relevant information on these characteristics not listed in the subparagraphs.

1.(f)(i) the life cycle,

Legal Requirements for Regulatees:

The regulatee must submit a description of the micro-organism's life cycle. A life cycle describes all the biological events that occur in the life of the micro-organism from beginning to end.

This information is not required where the regulatee:

(1) manufactures or imports a new micro-organism for introduction into an ecozone where it is indigenous (Paragraph 29.12(2)(c)); or

(2) manufactured or imported a micro-organism during the transition period for introduction into an ecozone where it is indigenous and manufactures or imports it, as the case may be, for introduction into the same ecozone (Paragraph 29.15(2)(c)).

1.(f)(ii) the infectivity, pathogenicity to non-human species, toxicity and toxigenicity,

Legal Requirements for Regulatees:

The regulatee must describe in the notification the infectivity, toxicity and toxogenicity of the micro-organism to all species. A description of pathogenicity to non-human species must be provided as well. Information on pathogenicity to humans would be submitted under Paragraph 6(a). The relevant definitions are presented below:

(1) Infectivity means the ability of pathogenic micro-organisms to invade a body and re-produce and multiply to cause disease. This word is not defined in CEPA or the Regulations.

(2) Toxicity means the ability of a micro-organism to be toxic. Section 11 of CEPA provides that a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions:

(a) having or that may have an immediate or long term effect on the environment;

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

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

(3) Toxogenicity means the ability of a pathogenic organism to cause disease through the production of toxins. This word is not defined in CEPA or the Regulations.

(4) Pathogenicity means the ability of the micro-organism to cause disease. This word is not defined in CEPA or the Regulations.

1(f)(iii) the resistance to antibiotics and tolerance to metals and pesticides,

Legal Requirements for Regulatees:

The regulatee must submit information on the micro-organism's resistance to antibiotics and tolerance to metals and pesticides. A micro-organism is resistant to an antibiotic if it is no longer susceptible to it. Likewise, micro-organisms are said to be tolerant to metals and pesticides if they are no longer susceptible to them.

This information does not have to be submitted by a regulatee who:

(1) manufactures or imports a new micro-organism for introduction into an ecozone where it is indigenous (Paragraph 29.12(2)(c)); or who

(2) manufactured or imported a micro-organism during the transition period for introduction into an ecozone where it is indigenous and manufactures or imports it, as the case may be, for introduction into the same ecozone (Paragraph 29.15(2)(c)).

1.(f)(iv) the involvement in biogeochemical cycling, and

Legal Requirements for Regulatees:

The regulatee is required to submit information on the micro-organism's involvement in biogeochemical cycling. The term "biogeochemical cycling" is not defined in CEPA or the Regulations. It refers to the cyclic path of an inorganic substance such as carbon or nitrogen through an ecosystem. Its geological components are the atmosphere, the crust of the earth and the oceans, lakes and rivers. Its biological components are producers, consumers and detritivors that break down dead and discarded organic matter.

This information does not have to be submitted by the regulatee who:

(1) manufactures or imports a micro-organism for introduction in an ecozone where it is indigenous (Paragraph 29.12(2)(c)); or who

(2) manufactured or imported a micro-organism during the transition period for introduction into an ecozone where it is indigenous and manufactures or imports it, as the case may be, for introduction into the same ecozone (Paragraph 29.15(2)(c)).

1.(f)(v) the conditions required for, and conditions that limit, survival, growth and replication;

Legal Requirements for Regulatees:

The regulatee must describe the conditions that are required for, and limit the micro-organisms' survival, growth and replication. The conditions described for this provision would be environmental parameters such as pH, temperature, salinity, oxygen and nutrient requirements.

1. (*g*) a description of the mode of action in relation to the intended use;

Legal Requirements for Regulatees:

The regulatee must describe in the notification the micro-organism's mode of action in relation to its intended use. The mode of action would include a description of the production of any toxic chemicals from the activity of the micro-organism in its intended use.

1.(*h*) the identification of any patent or any application for a patent, as the case may be;

Legal Requirements for Regulatees:

If a regulatee has applied for or been granted a patent in relation to the micro-organism, then that information must be submitted in the notification.

1.(*i*) a material safety data sheet, as defined in subsection 11(1) of the *Hazardous Products Act*, in respect of the micro-organism, if available;

Legal Requirements for Regulatees:

Where a material safety data sheet is available for the micro-organism, it must be submitted by the regulatee. Material safety data sheets are produced under the Hazardous Products Act R.S.C, 1985, c. H-3.

(*j*) the dispersal by gene transfer of traits of pathogenicity to non-human species, toxigenicity and resistance to antibiotics, including a description of

Legal Requirements for Regulatees:

The regulatee must provide information on the ability of the micro-organism to disperse specified traits by gene transfer. The traits of pathogenicity to non-human species, toxigenicity and resistance to antibiotics, would have been identified for the micro-organism in Subparagraphs 1(f)(ii) and (iii). The meaning of pathogenicity and toxicity have been considered in the analysis under Subparagraph 1(f)(ii). The meaning of resistance to antibiotics has been considered in the analysis under Subparagraph 1(f)(iii).

The information under this Paragraph does not have to be submitted by a regulatee who:

(1) manufactures or imports a new micro-organism for introduction into an ecozone where it is indigenous (Paragraph 29.12(2)(c); or who

(2) manufactured or imported a micro-organism during the transition period for introduction into an ecozone where it is indigenous and manufactures or imports it, as the case may be, for introduction into the same ecozone (Paragraph 29.15(2)(c).

The specific items to be included in a description of dispersal of traits by gene transfer are detailed in the following subparagraphs. The regulatee may have to submit other relevant information not covered by the subparagraphs

1.(j)(i) the genetic basis for pathogenicity to non-human species, toxigenicity and resistance to antibiotics,

Legal Requirements for Regulatees:

The regulatee must submit information describing the micro-organism's genetic basis for pathogenicity to non-human species, toxigenicity and resistance to antibiotics. The definitions of the words pathogenicity and toxigenicity are provided in the analyses of Subparagraph 1(f)(ii). The meaning of resistance to antibiotics is offered in the analysis under Subparagraph 1(f)(iii).

1.(j)(ii) the capability to transfer genes,

Legal Requirements for Regulatees:

The regulatee must provide a description in the notification of the micro-organism's capability to transfer genes to other organisms.

1.(j)(iii) the conditions that might select for dispersal of traits of pathogenicity to non-human species, toxigenicity and resistance to antibiotics, and whether the conditions are likely to exist at the locations of introduction or within the range of dispersal of the micro-organism; and

Legal Requirements for Regulatees:

The regulatee must submit two items of information under this subparagraph. These are:

(1) a description of the conditions that might select for dispersal of traits of pathogenicity to non-human species, toxigenicity and resistance to antibiotics. The definitions of the words pathogenicity and toxigenicity are provided in the analysis of Subparagraph 1(f)(ii). An explanation of antibiotic resistance is offered in the analysis under Subparagraph 1(f)(iii); and

(2) a determination whether the conditions described above are likely to exist at the locations of the introduction or within the range of dispersal of the micro-organism.

1. (*k*) a description of the geographic distribution of the micro-organism.

Legal Requirements for Regulatees:

The regulatee must submit a description of the geographic distribution of the micro-organism. If the micro-organism is ubiquitous, then the regulatee would need to submit information substantiating this.

SECTION 2

2. The following information in respect of the manufacture and importation of the micro-organism:

Legal Requirements for Regulatees:

This section defines the information that must be submitted by the regulatee concerning the manufacture and importation of the micro-organism.

2. (*a*) the identification of trade names and manufacturers, importers and vendors;

Legal Requirements for Regulatees:

The regulatee must identify the micro-organism's trade name if it has one. The manufacturers, importers and vendors of the micro-organism must also be identified.

2. (*b*) the identification of locations of manufacture in Canada;

Legal Requirements for Regulatees:

The locations of manufacture of the micro-organism in Canada must be identified in the regulatee's notification.

2. (*c*) the physical state of the formulation;

Legal Requirements for Regulatees:

The regulatee must submit a description of the formulation of the micro-organism if applicable. The physical state of a formulation may be powder, dust, solution, mist or vapour form. The word "formulation" is not defined in CEPA or the Regulations. It means a mixture of pure micro-organism cultures that have been deliberately formulated.

2. (*d*) the concentration of the micro-organism in the formulation;

Legal Requirements for Regulatees:

The regulatee must submit information on the concentration of the micro-organism in the formulation. The definition of formulation is provided in the analysis under Paragraph 2(c).

2. (*e*) the identification and concentration of other ingredients and of any contaminants in the formulation;

Legal Requirements for Regulatees:

The regulatee must submit an identification of other ingredients and contaminants in the formulation. The concentration of these substances in the formulation must also be described. The identification of formulation is provided in the analysis of Paragraph 2(c).

2. (*f*) the viability of the **micro-organism** in the formulation;

Legal Requirements for Regulatees:

The regulatee must submit information on the viability of the micro-organism. Viability means the ability of micro-organism to grow, develop and reproduce. A micro-organism is viable if it is alive. The definition of formulation is provided in the analysis of Paragraph 2(c).

2. (*g*) a description of any recommended storage and disposal procedures;

Legal Requirements for Regulatees:

The regulatee must include a description of recommended storage procedures for the micro-organism. A description recommended disposal procedures for unused micro-organisms must be included in the notification as well.

2. (*h*) an estimation of the quantity of the **micro-organism** that was or will be imported or manufactured in Canada, as the case may be;

Legal Requirements for Regulatees:

The regulatee must submit an estimation of the quantity of the micro-organism that was, or will be imported or manufactured in Canada.

2. (*i*) a description of the equipment and methods of manufacture and of quality control and quality assurance procedures;

Legal Requirements for Regulatees:

The regulatee has a duty under this Paragraph to:

(1) describe the equipment and methods of manufacture of the micro-organism; and

(2) describe the methods of quality control and quality assurance procedures used in manufacturing the micro-organism.

2. (*j*) a description of the location of manufacturing facilities in Canada;

Legal Requirements for Regulatees:

The regulatee must provide a description of the location of facilities that manufacture the micro-organism in Canada.

2. (*k*) a description of the nature of potential releases of the **micro-organism** from the manufacturing facilities in Canada or from facilities to which the **micro-organism** was or will be imported, as the case may be, and the procedures to control releases; and

Legal Requirements for Regulatees:

The regulatee must provide a description of the nature of potential releases of the micro-organism from manufacturing facilities in Canada. A description of potential release from facilities to which the micro-organism was or will be imported must be submitted where the micro-organism is being imported. In both cases, the procedures to control releases must be described as well.

2. (*l*) a description of the procedures for the treatment and disposal of wastes containing the **micro-organism** from the manufacturing facilities in Canada.

Legal Requirements for Regulatees:

The regulatee has a duty under this paragraph to provide a description of the procedures for the treatment of wastes containing the micro-organism from the manufacturing facilities in Canada.

SECTION 3

3. The following information in respect of the introduction of the **micro-organism**:

This section defines the information that must be submitted by the regulatee in regard to the introduction of the micro-organism.

3. (*a*) the intended and potential uses;

Legal Requirements for Regulatees:

The regulatee must describe both the intended and potential uses for the micro-organism in the notification.

3. (*b*) the history of use;

Legal Requirements for Regulatees:

The regulatee must provide the micro-organism's history of use in the notification. This history of use of micro-organisms subject to the transactional provisions would include a description of use during the transitional period, along with details of other historic uses.

3. (*c*) a comparison of the natural habitat of the **micro-organism** to the habitat at the potential locations of introduction of the **micro-organism**, and the nature of the selection that may operate on the **micro-organism** at the potential locations of introduction;

Legal Requirements for Regulatees:

The regulatee must submit a comparison of the natural habitat of the micro-organism to the habitat of the potential locations of introduction of the micro-organism. The nature of the selection that may operate on the micro-organism at the potential locations of introduction, must be described as well.

In order to meet the obligations under this Paragraph, the regulatee must:

(1) describe the natural habitat of the micro-organism;

(2) describe the habitat at potential locations of the introduction of the micro-organism; and

(3) make a comparison of the habitats described in 1 and 2.

The term "nature of selection" refers to an identification of the factors in the environment that cause differences in the net reproduction of the micro-organism, thus favouring it over, or giving it a disadvantage in relation to other micro-organisms. This term is not defined in CEPA or the Regulations.

3. (*d*) a description of the procedures for the introduction of the micro-organism, including

Legal Requirements for Regulatees:

The regulatee must describe the procedures used for introducing the micro-organism. The information to be submitted under this paragraph must include the information items listed in the subparagraphs below. However, other information on the procedures used for introducing the micro-organism may be required as well.

3.(d)(i) the method of application,

Legal Requirements for Regulatees:

The regulatee must provide a description of how the micro-organism is to be applied for introduction.

3.(d)(ii) the quantity, frequency and duration of application, and

Legal Requirements for Regulatees:

The regulatee must provide information on the quantity, frequency and duration of introduction of the micro-organism. The duration of the application refers to the overall period for application of the micro-organism.

3.(d)(iii) any activities associated with the introduction;

Legal Requirements for Regulatees:

The regulatee must submit information on other activities associated with the introduction. These would include activities such as the addition of surfactants, or amendments of nutrients, aeration or venting of oxygen, or mixing or killing.

3. (*e*) a description of any contingency plans for accidental release; and

Legal Requirements for Regulatees:

The regulatee must provide a description of contingency plans for the accidental release of the micro-organism.

3. (*f*) a description of any recommended procedures for terminating the introduction of the micro-organism.

Legal Requirements for Regulatees:

The regulatee must provide a description of any recommended procedures for terminating the introduction of the micro-organism.

SECTION 4

4. The following information in respect of the environmental fate of the micro-organism:

Legal Requirements for Regulatees:

This section defines the specific information that must be submitted on the environmental fate of the micro-organism. Environmental fate describes what happens to the micro-organism when it enters the environment.

4. (*a*) the identification of the plant and animal species likely to be exposed and, where infectivity, pathogenicity to non-human species, toxicity and toxigenicity have been identified pursuant to subparagraph 1(*f*)(ii), the identification of the receptor species likely to be exposed;

Legal Requirements for Regulatees:

The regulatee must identify the plant and animal species likely to be exposed to the micro-organism. The receptor species must be described where the regulatee has identified the micro-organism's infectivity, pathogenicity to non human species, toxicity and toxigenicity under Subparagraph 1(f)(ii). The words infectivity, pathogenicity, toxicity and toxigenicity are defined in the analysis of Subparagraph 1(f)(ii).

4. (*b*) a description of habitats where the micro-organism may persist or proliferate;

Legal Requirements for Regulatees:

The regulatee must describe the habitats where the micro-organism may persist or proliferate. This description is based on the habitat specificity of the micro-organism and the likelihood of it reaching suitable habitats where it will establish and reproduce.

4. (*c*) the estimated quantities of the micro-organism in the air, water and soil at the points of introduction, and the estimated population trends; and

Legal Requirements for Regulatees:

The regulatee must provide estimates of the quantities of the micro-organism in the air, water and soil at the points of introduction. Estimations of population trends must also be submitted. Population trends are the quantities of micro-organisms at time points after the time of application. The term "population trends" is not defined in CEPA or the Regulations.

4. (*d*) any other information on the environmental fate of the micro-organism.

Legal Requirements for Regulatees:

This paragraph places a duty on regulatees to supply any other information on the environmental fate of the organism. This obligation extends beyond the detailed provisions of this section.

SECTION 5

5. The following information in respect of the ecological effects of the micro-organism:

Legal Requirements for Regulatees:

This section specifies the information on ecological effects of the micro-organism that must be submitted by the regulatee.

5. (*a*) the data from tests conducted to determine the effects of the micro-organism on

Legal Requirements for Regulatees:

The information in this paragraph must only be submitted by the regulatee under the general requirements for submitting information under Subsections 29.12(1) and 29.15(1). It does not have to be submitted under the circumstances set out in Paragraphs 29.12(2)(a), (b) and (c) and Paragraphs 29.15(2)(a), (b) and (c).

5.(a)(i) aquatic plant, invertebrate and vertebrate species likely to be exposed, and

Legal Requirements for Regulatees:

The regulatee must submit data from tests conducted to determine the effects of the micro-organism on aquatic plants, invertebrate and vertebrate species likely to be exposed to the micro-organism.

5.(a)(ii) terrestrial plant, invertebrate and vertebrate species likely to be exposed;

Legal Requirements for Regulatees:

The regulatee must submit data from tests conducted to determine the effects of the micro-organism on terrestrial plants, invertebrate and vertebrate species likely to be exposed to the micro-organism.

5. (*b*) the involvement of the micro-organism in adverse ecological effects; and

Legal Requirements for Regulatees:

The regulatee must provide information on the involvement of the micro-organism in adverse ecological effects. This would include adverse effects on non-target organisms and ecological processes.

5. (*c*) the effects on biodiversity and any other ecological effects that result from the introduction of the micro-organism.

Legal Requirements for Regulatees:

The regulatee must submit information on the effects on biodiversity and any other ecological effects that result from the introduction of the micro-organism. "Biodiversity" is not defined in CEPA or the Regulations. It means the variety of species on earth and the ecological processes of which they are part. The components of biodiversity are ecosystems, species and genetic diversity.

The ecological effects referred to in this paragraph are effects other than adverse ones identified in Paragraph 5(a).

SECTION 6

6. The following information in respect of the human health effects of the micro-organism:

Legal Requirements for Regulatees:

This Section details the information required on the human health effects of the micro-organism that must be submitted by the regulatee.

6. (*a*) the documented involvement of the **micro-organism** in adverse human health effects and a description of the characteristics of the **micro-organism** that distinguish it from known pathogens;

Legal Requirements for Regulatees:

The regulatee must submit information on the documented involvement of the micro-organism in adverse human health effects. Documented involvement may be determined from literature searches of major relevant information sources.

A description of the characteristics of the micro-organism that distinguish it from known pathogens must also be provided. This information may have been submitted as the characteristics used to identify the micro-organism as required in Paragraph 1(a) or the Schedule. However, if the micro-organism could be a pathogen or appears closely related to a pathogen, more specific tests could be required under this paragraph.

Special consideration may need to be given to consortia under this paragraph. A consortium is a complex mixture of micro-organisms that has not been formulated deliberately from pure cultures. An example would be a culture of micro-organisms isolated from soil where it would be extremely difficult or impossible to characterize all micro-organisms. Data on the presence of indicator micro-organisms may be provided under this paragraph subject to guidance given by NSD.

6. (*b*) the data from tests of antibiotic susceptibility;

Legal Requirements for Regulatees:

The regulatee must submit data from tests of antibiotic susceptibility. Antibiotic susceptibility means the susceptibility of the micro-organism to being killed by the antibiotic. This term is not defined in CEPA or the Regulations.

6. (*c*) the data from tests of pathogenicity that are valid for related **micro-organisms** that are pathogenic to humans;

Legal Requirements for Regulatees:

The regulatee must provide the data from tests of pathogenicity that are valid for related micro-organisms that are pathogenic to humans. The word pathogenic has been defined in the analysis under Subparagraph 1(f)(ii).

The data referred to in this paragraph does not have to be submitted by regulatees who:

(1) manufacture or import a new micro-organism for introduction in accordance with confinement procedures (Paragraph 29.12(2)(b)); or who

(2) manufactured or imported a micro-organism during the transition period for introduction in accordance with confinement procedures and who manufacture or import it, as the case may be, in accordance with the same confinement procedures (Paragraph 29.15(2)(b)).

6. (*d*) the potential for adverse immunologic reactions in persons exposed to the **micro-organism**; and

Legal Requirements for Regulatees:

The regulatee must submit information on the potential for adverse immunological reactions in persons exposed to the micro-organisms. An immunological reaction is a highly specific defensive reaction of a body to invasion by a foreign substance.

The information referred to in this paragraph does not have to be submitted by regulatees who:

(1) manufacture or import a new micro-organism for introduction in accordance with confinement procedures (Paragraph 29.12(2)(b)); or who

(2) manufactured or imported a micro-organism during the transition period for introduction in accordance with confinement procedures and who manufacture or import it, as the case may be, in accordance with the same confinement procedures (Paragraph 29.15(2)(b)).

6. (*e*) the estimated number of persons that may become exposed and the degree of exposure to the **micro-organism**.

Legal Requirements for Regulatees:

The regualtee must submit information on the estimated number of people who may be exposed to the micro-organism and their degree of exposure. The estimated number of people exposed would conclude people in the general population and in occupational settings at all stages in the life cycle of the micro-organism. The degree of exposure of various individuals in a population would be provided at each stage in the life cycle of the micro-organism as well.

SECTION 7

7. All other information and test data in respect of the micro-organism that are relevant to identifying hazards to human health and the environment and that are in the person's possession or to which the person ought reasonably to have access.

Legal Requirements for Regulatees:

This section places a broad duty on the regulatee to provide all other relevant information and test data in respect to the micro-organism. The information and test data must be relevant to identifying hazards to human health and the environment.

The information and test data required here must be in the regulatee's possession. If the information and test data are not in the regulatee's possession, the regulatee must still submit it if it exists in circumstances whereby the regulatee ought reasonably to have access to it.

SECTION 8

8. The identification of other government agencies, either abroad or within Canada, that the person has notified of the manufacture or importation of the micro-organism, and the purpose of such notification.

Legal Requirements for Regulatees:

The regulatee must identify other government agencies, either abroad or in Canada, that have been notified off the manufacture or importation of the micro-organism. The purpose of the notification must be provided as well.

SECTION 9

9. A description or specification of the test procedures followed in developing the test data, including test methods, reference substances and quality control and quality assurance procedures.

Legal Requirements for Regulatees:

A regulatee must submit a description or specification of test procedures followed in developing the test data for the information requirements under this Schedule. This must include information on test methods, reference substances and quality control and quality assurance procedures.

SCHEDULE XVI
(Subsections 29.12(4) and 29.15(4))

INFORMATION REQUIRED IN RESPECT OF **MICRO-ORGANISMS** NOT FOR INTRODUCTION OUTSIDE A **CONTAINED FACILITY** OR FOR EXPORT ONLY

Schedule XVI sets out the information requirements for regulatees proposing to manufacture, in a contained facility or to import to a contained facility, a new micro-organism that is not for introduction outside the contained facility or is for export only. (Subsection 29.12(4))

The information in Schedule XVI is also required for regulatees who have, during the transitional period, manufactured in a contained facility or imported to a contained facility a micro-organism that was not for introduction outside the contained facility or was for export only and who manufacture the organism in the same contained facility or import it to the same contained facility as the case may be. (Subsection 24.15(4))

Each information item specified in this Schedule is required to make an assessment of micro-organism's toxicity under CEPA. Regulatees receive guidance on these notification requirements directly by contacting NSD and form Guidelines produced by NSD.

SECTION 1

1. The following information in respect of the **micro-organism**:

Legal Requirements for Regulatees:

This Section sets out the specific characteristics of the micro-organism that the regulatee must describe in the notification.

1. (*a*) the identification and the information substantiating the identification;

Legal Requirements for Regulatees:

The regulatee must provide the identification of the micro-organism and the information that substantiates that identification.

Special considerations should be given to identification in the following circumstances:

(1) where a formulation is to be or has been manufactured or imported, each micro-organism in the formulation must be identified by the regulatee;

(2) where a consortium is to be or has been manufactured or imported, regulatees should attempt to identify each micro-organism. Otherwise, the identification should be made according to the Guidelines produced by NSD; and

(3) where a genetically engineered organism is to be or has been manufactured or imported, the regulatee should identify the host micro-organism as well as the organisms that were the source of the genetic information.

1. (*b*) the synonyms and common and superseded names;

Legal Requirements for Regulatees:

The regulatee must submit names other than the taxonomic designation submitted in 1(a) that the micro-organism is known by or has been known by.

1. (*c*) the strain history;

Legal Requirements for Regulatees:

The regulatee must submit a strain history of the micro-organism. A strain is a micro-organism isolate or culture. The word "strain" is not defined in CEPA or the Regulations. A strain history would describe the development of the strain from its original source of isolation to final product development.

1. (*d*) a description of any modifications to the **micro-organism**, including

Legal Requirements for Regulatees:

The regulatee must submit descriptions of any modifications made to the micro-organism. Micro-organisms may be modified by physical or chemical means or by novel molecular techniques. The specific items to be included in a description of any modification are listed in the subparagraphs below. The regulatee may have to provide other relevant information on the modifications not listed in the subparagraphs.

1.(d)(i) the purpose of the modifications,

Legal Requirements for Regulatees:

The regulatee must submit information on the purpose of any modifications made to the micro-organism.

1.(d)(ii) the methods and steps taken to make the modifications,

Legal Requirements for Regulatees:

The regulatee must describe all methods and steps taken to make the modification.

1.(d)(iii) the phenotypic and genotypic changes that resulted from the steps referred to in subparagraph (ii),

Legal Requirements for Regulatees:

The regulatee must describe the genotypic and phenotypic changes that resulted from the steps in Subparagraph 1(d)(ii). A micro-organism's genotype is its genetic constitution with reference to a single trait or a set of traits. A genotype also means the sum total of all the genes present in an individual. A micro-organism's phenotype is its observable properties resulting from interactions between the genotype and the environment. The words "genotype" and phenotype are not defined in CEPA or the Regulations.

1.(d)(iv) the stability of the changes referred to in subparagraph (iii), and

Legal Requirements for Regulatees:

The regulatee must submit a description of the stability of the changes described under Subparagraph 1(d)(iii). This would consider if the genotype and phenotype of the modified micro-organism are passed on unchanged from one generation to another.

1(d)(v) the nature, source and function of any inserted genetic material;

Legal Requirements for Regulatees:

The regulatee must provide information on the nature, source and function of any genetic material inserted into the modified micro-organism.

1. (*e*) a description of the methods that can be used to distinguish and detect the **micro-organism**;

Legal Requirements for Regulatees:

The regulatee must submit a description of the methods that can be used to distinguish and detect the micro-organism.

1. (*f*) a description of the biological and ecological characteristics of the **micro-organism**, including

Legal Requirements for Regulatees:

The specific items to be included in a description of the biological and ecological characteristics of the micro-organism are listed in the subparagraphs below. The regulatee may have to provide other relevant information on these characteristics not listed in the subparagraphs.

1.(f)(i) the infectivity, pathogenicity to non-human species, toxicity and toxigenicity, and

Legal Requirements for Regulatees:

The regulatee must describe in the notification the infectivity, toxicity and toxogenicity of the micro-organism to all species. A description of pathogenicity to non-human species must be provided as well. Information on pathogenicity to humans would be submitted under Paragraph 4(a). The relevant definitions are presented below:

(1) Infectivity means the ability of pathogenic micro-organisms to invade a body and reproduce and multiply to cause disease. This word is not defined in CEPA or the Regulations.

(2) Toxicity means the ability of a micro-organism to be toxic. Section 11 of CEPA provides that a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions:

(a) having or that may have an immediate or long term effect on the environment;

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

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

(3) Toxogenicity means the ability of a pathogenic organism to cause disease through the production of toxins. This word is not defined in CEPA or the Regulations.

(4) Pathogenicity means the ability of the micro-organism to cause disease. This word is not defined in CEPA or the Regulations.

1.(f)(ii) the conditions required for, and conditions that limit, survival, growth and replication;

Legal Requirements for Regulatees:

The regulatee must describe the conditions that are required for, and limit the micro-organisms' survival growth and reproduction. The conditions described for this provision would be environmental parameters such as pH, temperature, salinity, oxygen and nutrient requirements.

1. (g) a description of the known mode of action in relation to the intended use;

Legal Requirements for Regulatees:

The regulatee must describe in the notification the micro-organism's known mode of action in relation to intended use. The mode of action would include a description of the production of any toxic chemicals from the activity of the micro-organism in its intended use.

1.(f)(i) the infectivity, pathogenicity to non-human species, toxicity and toxigenicity, and

Legal Requirements for Regulatees:

The regulatee must describe in the notification the infectivity, toxicity and toxogenicity of the micro-organism to all species. A description of pathogenicity to non-human species must be provided as well. Information on pathogenicity to humans would be submitted under Paragraph 4(a). The relevant definitions are presented below:

(1) Infectivity means the ability of pathogenic micro-organisms to invade a body and reproduce and multiply to cause disease. This word is not defined in CEPA or the Regulations.

(2) Toxicity means the ability of a micro-organism to be toxic. Section 11 of CEPA provides that a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions:

(a) having or that may have an immediate or long term effect on the environment;

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

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

(3) Toxogenicity means the ability of a pathogenic organism to cause disease through the production of toxins. This word is not defined in CEPA or the Regulations.

(4) Pathogenicity means the ability of the micro-organism to cause disease. This word is not defined in CEPA or the Regulations.

1.(f)(ii) the conditions required for, and conditions that limit, survival, growth and replication;

Legal Requirements for Regulatees:

The regulatee must describe the conditions that are required for, and limit the micro-organisms' survival growth and reproduction. The conditions described for this provision would be environmental parameters such as pH, temperature, salinity, oxygen and nutrient requirements.

1. (*g*) a description of the known mode of action in relation to the intended use;

Legal Requirements for Regulatees:

The regulatee must describe in the notification the micro-organism's known mode of action in relation to intended use. The mode of action would include a description of the production of any toxic chemicals from the activity of the micro-organism in its intended use.

2. (*c*) the containment level for each manufacturing facility in Canada or for each facility to which the micro-organism was or will be imported, as the case may be, determined in accordance with the physical and operational requirements set out, as the case may be, in the **Laboratory Biosafety Guidelines** or Appendix K of the "*Guidelines For Research Involving Recombinant DNA Molecules (NIH Guidelines) June 1994*" published by the United States Department of Health and Human Services, in the *Federal Register* (United States), Vol. 59, No. 127, on July 5, 1994, as amended from time to time;

Legal Requirements for Regulatees:

The regulatee must provide information on the containment levels for the manufacturing facilities in Canada. If the regulatee is importing the micro-organism, information must be provided on the confinement levels for each facility to which the micro-organism was or will be imported, as the case may be.

Containment levels are determined in accordance with the physical and operational requirements in:

(1) the Laboratory Biosafety Guidelines; or

(2) Appendix K of the Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines).

The regulatee must ensure that the containment levels established in accordance with these documents are based on the most recent amended version of the document.

2. (*d*) an estimation of the quantity of the **micro-organism** that was or will be imported or manufactured in Canada, as the case may be;

Legal Requirements for Regulatees:

The regulatee must submit an estimation of the quantity of the micro-organism that was or will be imported or manufactured in Canada.

2. (*e*) a description of the equipment and methods of manufacture and of quality control and quality assurance procedures;

Legal Requirements for Regulatees:

The regulatee has a duty under this paragraph to:

(1) describe the equipment and methods of manufacture of the micro-organism; and

(2) describe the methods of quality control and quality assurance procedures used in manufacturing the micro-organism.

2. (*f*) a description of any recommended storage procedures.

Legal Requirements for Regulatees:

The regulatee must submit a description of any recommended storage procedures.

SECTION 3

3. The following information in respect of the introduction of the **micro-organism**:

Legal Requirements for Regulatees:

This section defines the information that must be submitted by the regulatee in regard to the introduciton of the micro-organism.

3. (*a*) the intended and potential uses; and

Legal Requirements for Regulatees:

The regulatee must describe both the intended and potential uses for the micro-organism in the notification.

3. (*b*) the history of use.

Legal Requirements for Regulatees:

The regulatee must provide the micro-organism's history of use in the notification. This history of the use of micro-organisms subject to the transitional provisions would include a description of use during the transitional period along with details of other historic uses.

SECTION 4

4. The following information in respect of the human health effects of the **micro-organism**:

Legal Requirements for Regulatees:

This section details the human health effects information about the micro-organism that must be submitted by the regulatee.

4. (*a*) the documented involvement of the **micro-organism** in adverse human health effects and a description of the characteristics of the **micro-organism** that distinguish it from known pathogens; and

Legal Requirements for Regulatees:

The regulatee must submit information on the documented involvement of the micro-organism in adverse human health effects. Documented involvement may be determined from literature searches of major relevant information sources.

A description of the characteristics of the micro-organism that distinguish it from known pathogens must also be provided. This information may have been submitted as the characteristics used to identify the micro-organism as required in Paragraph 1(a) of the Schedule. However, if the micro-organism could be a pathogen or appears closely related to a pathogen, more specific tests could be required under this paragraph.

Special consideration may need to be given to consortia under this paragraph. A consortium is a complex mixture of micro-organisms that has not been formulated deliberately from pure cultures. An example would be a culture of micro-organisms isolated from soil where it would be extremely difficult or impossible to characterize all micro-organisms. Data on the presence of indicator micro-organisms may be provided under this paragraph subject to guidance given by NSD.

4. (*b*) the data from tests of antibiotic susceptibility;

Legal Requirements for Regulatees:

The regulatee must submit data from tests of antibiotic susceptibility. Antibiotic susceptibility means the susceptibility of the micro-organism to being killed by the antibiotic. This term is not defined in CEPA or the Regulations.

SECTION 5

5. All other information and test data in respect of the **micro-organism** that are relevant to identifying hazards to human health and the environment and that are in the person's possession or to which the person ought reasonably to have access.

Legal Requirements for Regulatees:

This section places a broad duty on the regulatee to provide all other relevant information and test data in respect to the micro-organism. The information and test data must be relevant to identifying hazards to human health and the environment.

The information and test data required here must be in the regulatee's possession. If the information and test data are not in the regulatee's possession, the regualtee must still submit it if it exists in circumstances whereby the regualtee ought reasonably to have access to it.

SECTION 6

6. The identification of other government agencies, either abroad or within Canada, that the person has notified of the manufacture or importation of the **micro-organism**, and the purpose of such notification.

Legal Requirements for Regulatees:

The regulatee must identify other government agencies either abroad or in Canada that have been notified of the manufacture or importation of the micro-organism. The purpose of the notification must be provided as well.

SECTION 7

7. A description or specification of the test procedures followed in developing the test data, including test methods, reference substances and quality control and quality assurance procedures.

Legal Requirements for Regulatees:

A regulatee must submit a description or specification of test procedures followed in developing the test data for the information requirements under this Schedule. This must include information on test methods reference substances and quality control and quality assurance procedures.

SCHEDULE XVII
(Subsections 29.12(5) and 29.15(5))

INFORMATION REQUIRED IN RESPECT OF **MICRO-ORGANISMS**
FOR INTRODUCTION IN AN **EXPERIMENTAL FIELD STUDY**

Legal Requirements for Regulatees:

Schedule XVII sets out the information that a regulatee must submit before the regulatee can manufacture or import a new micro-organism for introduction in an experimental field study. (Subsection 29.12(5)) This information must also be provided by a regulatee who manufactured or imported a micro-organism for introduction in an experimental field study during the transitional period and who manufactures or imports the micro-organism, as the case may be, for introduction in the same experimental field study. (29.15(5))

Each information item specified in this Schedule is required, to make an assessment of the micro-organism's toxicity under CEPA. Regulatees receive guidance on these notification requirements directly by contacting NSD and from Guidelines produced by that division.

SECTION 1

1. The following information in respect of the micro-organism:

Legal Requirements for Regulatees:

This Section sets out the specific characteristics of the micro-organism that the regulatee must submit in the notification.

1. (*a*) the identification and the information substantiating the identification;

Legal Requirements for Regulatees:

The regulatee must provide the identification and information substantiating identification.

Special considerations should be given to identification in the following circumstances:

(1) where a formulation is to be or has been manufactured or imported, each micro-organism in the formulation must be identified by the regulatee;

(2) where a consortium is to be or has been manufactured or imported, regulatees should attempt to identify each micro-organism. Otherwise, the identification should be made according to the Guidelines produced by NSD; and

(3) where a genetically engineered organism is to be or has been manufactured or imported, the regulatee should identify the host micro-organism as well as the organisms that were the source of the genetic information.

1. (*b*) the synonyms and common and superseded names;

Legal Requirements for Regulatees:

The regulatee must submit names other than the taxonomic designation submitted in 1(a) that the micro-organism is known by or has been known by.

1. (*c*) the strain history;

Legal Requirements for Regulatees:

The regulatee must submit a strain history of the micro-organism. A strain is a micro-organism isolate or culture. The word "strain" is not defined in CEPA or the Regulations. A strain history would describe the development of the strain from its original source of isolation to final product development.

1. (*d*) a description of any modifications to the micro-organism, including

Legal Requirements for Regulatees:

The regulatee must submit descriptions of any modifications made to the micro-organism. Micro-organisms may be modified by physical or chemical means or by novel molecular techniques. The specific items to be included in a description of any modification are listed in the subparagraphs below. The regulatee may have to provide other relevant information on the modifications not listed in the subparagraphs.

1.(d)(i) the purpose of the modifications,

Legal Requirements for Regulatees:

The regulatee must submit information on the purpose of any modifications made to the micro-organism.

1.(d)(ii) the methods and steps taken to make the modifications,

Legal Requirements for Regulatees:

The regulatee must describe all methods and steps taken to make the modification.

1.(d)(iii) the phenotypic and genotypic changes that resulted from the steps referred to in subparagraph (ii),

Legal Requirements for Regulatees:

The regulatee must describe the genotypic and phenotypic changes that resulted from the steps in Subparagraph 1(d)(ii). A micro-organism's genotype is its genetic constitution with reference to a single trait or a set of traits. A genotype also means the sum total of all the genes present in an individual. A micro-organism's phenotype is its observable properties resulting from interactions between the genotype and the environment. The words "genotype" and "phenotype" are not defined in CEPA or the regulations.

1.(d)(iv) the stability of the changes referred to in subparagraph (iii), and

Legal Requirements for Regulatees:

The regulatee must submit a description of the stability of the changes described under Subparagraph 1(d)(iii). This would consider if the genotype and phenotype of the modified micro-organism are passed on unchanged from one generation to another.

1.(d)(v) the nature, source and function of any inserted genetic material;

Legal Requirements for Regulatees:

The regulatee must provide information on the nature, source and function of any genetic material inserted into the modified micro-organism.

1. (*e*) a description of the methods that can be used to distinguish and detect the **micro-organism**;

Legal Requirements for Regulatees:

The regulatee must submit a description of the methods that can be used to distinguish and detect the micro-organism.

1.(*f*) a description of the biological and ecological characteristics of the **micro-organism**, including

Legal Requirements for Regulatees:

The specific items to be included in a description of the biological and ecological characteristics are listed in the subparagraphs below. The regulatee may have to provide other relevant information on these characteristics not listed in the subparagraphs.

1.(f)(i) the infectivity, pathogenicity to non-human species, toxicity and toxigenicity,

Legal Requirements for Regulatees:

The regulatee must describe in the notification the infectivity, toxicity and toxogenicity of the micro-organism to all species. A description of pathogenicity to non-human species must be provided as well. Information on pathogenicity to humans would be submitted under Paragraph 7(a) The relevant definitions are presented below:

(1) Infectivity means the ability of pathogenic micro-organisms to invade a body and reproduce and multiply to cause disease. This word is not defined in CEPA or the Regulations.

(2) Toxicity means the ability of a micro-organism to be toxic. Section 11 of CEPA provides that a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions:

(a) having or that may have an immediate or long term effect on the environment;

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

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

(3) Toxogenicity means the ability of a pathogenic organism to cause disease by the production of toxins. This word is not defined in CEPA or the Regulations.

(4) Pathogenicity means the ability of the micro-organism to cause disease. This word is not defined in CEPA or the Regulations.

1.(f)(ii) the conditions required for, and conditions that limit, survival, growth and replication;

Legal Requirements for Regulatees:

The regulatee must describe the conditions that are required for and limit the micro-organisms' survival growth and replication. The conditions described for this provision would be environmental parameters such as pH, temperature, salinity, oxygen and nutrient requirements.

1(f)(iii) the life cycle, where the **micro-organism** is not indigenous,

Legal Requirements for Regulatees:

The regulatee must submit a description of the micro-organism's life cycle. A life cycle is all the biological events that occur in the life of the micro-organism from beginning to end.

This information is required when the micro-organisms not indigenous. It does not have to be submitted for a micro-organism that is indigenous.

1(f)(iv) the resistance to antibiotics and tolerance to metals and pesticides, where the **micro-organism** is not **indigenous**, and

Legal Requirements for Regulatees:

The regulatee must submit information on the micro-organism's resistance to antibiotics and tolerance to metals and pesticides. A micro-organism is resistant to an antibiotic if it is no longer susceptible to it. Likewise, micro-organisms are said to be tolerant to metals and pesticides if they are no longer susceptible to them.

This information is required where the micro-organism is not indigenous. It does not have to be submitted for a micro-organism that is indigenous.

1.(f)(v) the involvement in biogeochemical cycling, where the **micro-organism** is not **indigenous**;

Legal Requirements for Regulatees:

The regulatee is required to submit information on the micro-organism's involvement in biogeochemical cycling. The term "biogeochemical cycling" is not defined in CEPA or the Regulations. It refers to the cyclic path of an inorganic substance such as carbon or nitrogen

through an ecosystem. Its geological components are the atmosphere, the crust of the earth and the oceans, lakes and rivers. Its biological components are producers, consumers and detritivors that break down dead and discarded organic matter.

This information is required where the micro-organism is not indigenous. It does not have to be submitted where the micro-organism is indigenous.

1. (*g*) a description of the known mode of action in relation to the objective of the **experimental field study**;

Legal Requirements for Regulatees:

The regulatee must describe in the notification, the micro-organism's known mode of action in relation to the objective of the experimental field study. Information on the known mode of action could include a description of toxic chemicals from the activity of the micro-organism.

It should be noted that the reference here is to the "known" mode of action. This means information that is known about the micro-organism. Experimental data needs not be generated to meet the requirements of this paragraph.

1. (*h*) the identification of any patent or any application for a patent, as the case may be;

Legal Requirements for Regulatees:

If a regulatee has applied for or been granted a patent in relation to the micro-organism, then that information must be submitted in the notification.

1. (*i*) a material safety data sheet, as defined in subsection 11(1) of the *Hazardous Products Act*, in respect of the micro-organism, if available;

Legal Requirements for Regulatees:

Where a material safety data sheet is available for the micro-organism, it must be submitted by the regulatee. Material safety data sheets are produced under the Hazardous Products Act R.S.C., 1985, c. H-3.

1. (*j*) where the **micro-organism** is not **indigenous**, the dispersal by gene transfer of traits of pathogenicity to non-human species, toxigenicity and resistance to antibiotics, including a description of

Legal Requirements for Regulatees:

The regulatee must provide information on the ability of the micro-organism to disperse specified traits by gene transfer. The traits of pathogenicity to non human species, toxigenicity and resistance to antibiotics would have been identified for the micro-organism in Subparagraphs 1(f)(i) and (iv). The meaning of pathogenicity and toxicity have been considered in the analysis

under Subparagraph 1(f)(i). The meaning of resistance to antibiotics has been considered in the analysis under Subparagraph 1(f)(iv).

This information must be provided where the micro-organism is not indigenous. It does not have to be submitted where the micro-organism is indigenous.

The specific items to be included in a description of dispersal of traits by gene transfer are detailed in the following subparagraphs. The regulatee may have to submit other relevant information not covered by the subparagraphs.

1.(j)(i) the genetic basis for pathogenicity to non-human species, toxigenicity and resistance to antibiotics,

Legal Requirements for Regulatees:

The regulatee must submit information describing the micro-organism's genetic basis for pathogenicity to non-human species, toxigenicity and resistance to antibiotics. The definitions of the words pathogenicity and toxigenicity are provided in the analyses of Subparagraph 1(f)(i). An definition of antibiotic resistance is offered in the analysis under Subparagraph 1(f)(iv).

1.(j)(ii) the capability to transfer genes,

Legal Requirements for Regulatees:

The regulatee must provide a description in the notification of the micro-organism's capability to transfer genes to other organisms.

1.(j)(iii) the conditions that might select for dispersal of traits of pathogenicity to non-human species, toxigenicity and resistance to antibiotics, and whether the conditions are likely to exist at the site of the **experimental field study** or within the range of dispersal of the micro-organism; and

Legal Requirements for Regulatees:

The regulatee must submit two items of information under this subparagraph. These are:

(1) a description of the conditions that might select for dispersal of traits of pathogenicity to non-human species, toxigenicity and resistance to antibiotics. The definitions of the words pathogenicity and toxigenicity are provided in the analysis of Subparagraph 1(f)(i). an explanation of antibiotic resistance is offered in the analysis under Subparagraph 1(f)(iv); and

(2) a determination whether the conditions described above are likely to exist at the site of the experimental field study.

1. (*k*) a description of the geographic distribution of the micro-organism.

Legal Requirements for Regulatees:

The regulatee must submit a description of the geographic distribution of the micro-organism. If the micro-organism is ubiquitous, then the regulatee would need to submit information substantiating this.

SECTION 2

2. The following information in respect of the manufacture and importation of the micro-organism:

Legal Requirements for Regulatees:

This section defines the information that must be submitted by the regulatee concerning the manufacture and importation of the micro-organism.

2. (*a*) the identification of trade names and manufacturers, importers and vendors;

Legal Requirements for Regulatees:

The regulatee must identify the micro-organism's trade name if it has one. The manufacturers, importers and vendors of the micro-organism must also be identified.

2. (*b*) the physical state of the formulation;

Legal Requirements for Regulatees:

The regulatee must submit a description of the formulation of the micro-organism if applicable. The physical state of a formulation may be powder, dust, solution, mist or vapour form. The word "formulation" is not defined in CEPA or the Regulations. It means a mixture of pure micro-organism cultures that have been deliberately formulated.

2. (*c*) the concentration of the micro-organism in the formulation;

Legal Requirements for Regulatees:

The regulatee must submit information on the concentration of the micro-organism in the formulation. The definition of formulation is provided in the analysis under Paragraph 2(c).

2. (*d*) the identification and concentration of other ingredients and of any contaminants in the formulation;

Legal Requirements for Regulatees:

The regulatee must submit an identification of other ingredients and contaminants in the formulation. The concentration of these substances in the formulation must also be described. The definition of formulation is provided in the analysis of Paragraph 2(b).

2. (*e*) the viability of the **micro-organism** in the formulation;

Legal Requirements for Regulatees:

The regulatee must submit information on the viability of the micro-organism. Viability means the ability of micro-organism to grow, develop and reproduce. A micro-organism is viable if it is alive. The definition of formulation is provided in the analysis of Paragraph 2(b).

2. (*f*) a description of any recommended storage and disposal procedures;

Legal Requirements for Regulatees:

The regulatee must include a description of recommended storage procedures for the micro-organism. A description of recommended disposal procedures for unused micro-organisms must be included in the notification as well.

2. (*g*) an estimation of the quantity of the **micro-organism** that was or will be imported or manufactured in Canada, as the case may be;

Legal Requirements for Regulatees:

The regulatee must submit an estimation of the quantity of the micro-organism that was, or will be imported or manufactured in Canada.

2. (*h*) a description of the equipment and methods of manufacture and of quality control and quality assurance procedures;

Legal Requirements for Regulatees:

The regulatee has a duty under this paragraph to:

(1) describe the equipment and methods of manufacture of the micro-organism; and

(2) describe the methods of quality control and quality assurance procedures used in manufacturing the micro-organism.

2. (*i*) a description of the location of manufacturing facilities in Canada;

Legal Requirements for Regulatees:

The regulatee must provide a description of the location of facilities that manufacture the micro-organism in Canada.

2. (*j*) a description of the nature of potential releases of the **micro-organism** from the manufacturing facilities in Canada or from facilities to which the **micro-organism** was or will be imported, as the case may be, and the procedures to control releases; and

Legal Requirements for Regulatees:

The regulatee must provide a description of the nature of potential releases of the micro-organism from manufacturing facilities in Canada. A description of potential release from facilities to which the micro-organism was or will be imported, must be submitted where the micro-organism is being imported. In both cases, the procedures to control releases must be described as well.

2. (*k*) a description of the procedures for the treatment and disposal of wastes containing the micro-organism from the manufacturing facilities in Canada.

Legal Requirements for Regulatees:

The regulatee has a duty under this paragraph to provide a description of the procedures for the treatment of wastes containing the micro-organism from manufacturing facilities in Canada.

SECTION 3

3. The following information in respect of the site of the experimental field study:

Legal Requirements for Regulatees:

This Section defines the information on the experimental field study site that must be submitted by the regulatee.

3. (*a*) the location and a map;

Legal Requirements for Regulatees:

The regulatee must clearly describe the location of the experimental field study site and indicate its location on a map.

3. (*b*) the size;

Legal Requirements for Regulatees:

The regulatee must describe the size of the experimental field study site in the notification. Size would be measured in terms of length, width and depth of site.

3. (*c*) the distance to populated areas;

Legal Requirements for Regulatees:

The regulatee must provide a measure of the distance from the experimental field study site populated areas. Populated areas could be cities, towns or villages.

3. (*d*) the distance to any protected areas;

Legal Requirements for Regulatees:

The regulatee must submit a measure of the distance form the experimental field study site. Protected areas could be national parks, provincial parks, wildlife reserves and migratory bird sanctuaries.

3. (*e*) a description of the geological landscape at the site and surrounding the site;

Legal Requirements for Regulatees:

A description of the geological landscape at the site and surrounding the site must be described by the regulatee in the notification. The geological landscape could include a description of bedrock geology, physiography and surficial geology.

3. (*f*) a description of the biological diversity found at the site and surrounding the site, including

Legal Requirements for Regulatees:

The regulatee must submit information on the biological diversity found at the site and surrounding the site. Biological diversity would mean the variety of species present at the site and surrounding the site.

The information to be included in this paragraph is set out in the subparagraphs. However, the regulatee may be required to submit other information on the biological diversity found at the site and surrounding the site.

3.(f)(i) the identification of the endangered or threatened species, and

Legal Requirements for Regulatees:

The regulatee must identify endangered or threatened species found at the site or surrounding the site.

3.(f)(ii) where infectivity, pathogenicity to non-human species, toxicity and toxigenicity have been identified in subparagraph 1(*f*)(i), the identification of the receptor species;

Legal Requirements for Regulatees:

The regulatee may have identified infectivity pathogenicity to non-human species, toxicity and toxigenicity for the micro-organism under Subparagraph 1(f)(i). This subparagraph requires the regulatee to identify receptor species for those identified traits.

The words infectivity, pathogenicity, toxicity and toxigenicity are defined in the analysis under Subparagraph 1(f)(i).

3. (*g*) a comparison of the natural habitat of the **micro-organism** to the habitat at the site of the **experimental field study**, and the nature of the selection that may operate on the **micro-organism** at that site; and

Legal Requirements for Regulatees:

The regulatee must submit a comparison of the natural habitat of the micro-organism and the habitat at the site of the experimental field study. The nature of the selection that may operate on the micro-organism at that site must be described as well.

In order to meet the obligations under this paragraph, the regulatee must:

(1) describe the natural habitat of the micro-organism;

(2) describe the habitat at the site of the experimental field study; and

(3) make a comparison of the habitats described in 1 and 2.

The term "nature of selection" refers to an identification of the factors in the environment that cause differences in the net reproduction of the micro-organism, favoring it over, or giving it a disadvantage relative to other micro-organisms. This term is not defined in CEPA or the Regulations.

3. (*h*) where the micro-organism is **indigenous**, data to demonstrate that it is **indigenous**.

Legal Requirements for Regulatees:

The regulatee must submit data to demonstrate that a micro-organism is indigenous to the experimental field study site.

SECTION 4

4. The following information in respect of the experimental field study:

Legal Requirements for Regulatees:

This section defines the information that the regulatee must provide in respect of the experimental field study.

4. (*a*) the objectives of the experimental field study;

Legal Requirements for Regulatees:

The regulatee must state the objectives of the experimental field study in the notification.

4. (*b*) the history of use of the **micro-organism**;

Legal Requirements for Regulatees:

The regulatee must describe the history of use of the micro-organism. For transitional notifications, the history would include a description of use during the transitional period.

4. (*c*) the start date and duration;

Legal Requirements for Regulatees:

The regulatee must provide information on the start date and duration of the experimental field study.

4. (*d*) a description of the procedures for transporting the **micro-organism** to and from the site of the **experimental field study**;

Legal Requirements for Regulatees:

The regulatee must provide information on the procedures used for transporting the micro-organism to and from the experimental field study.

4. (*e*) a description of the procedures and design for the **experimental field study**, including

Legal Requirements for Regulatees:

This paragraph requires the regulatee to submit a description of the procedures and design for the experimental field study. The subparagraphs set out the information items to be included in its description. However, the regulatee may be required to submit other information, describing the procedures and design for the experimental field study.

4.(e)(i) the method of application of the **micro-organism**,

Legal Requirements for Regulatees:

The regulatee must describe the method of applying the micro-organism to the experimental field study.

4.(e)(ii) the quantity, frequency and duration of application of the **micro-organism**, and

Legal Requirements for Regulatees:

The regulatee must describe the quantity, frequency and duration of application of the micro-organism to the experimental field study. The duration of the application refers to the overall period for application of the micro-organism.

4.(e)(iii) any activities associated with the **experimental field study**;

Legal Requirements for Regulatees:

The regulatee must describe any activities associated with the experimental field study. These activities could be the addition of surfactants or amendments of nutrients, aeration or venting of oxygen or mixing or tilling.

4. (*f*) a description of any procedures for monitoring the **micro-organism** and its ecological effects at the site of the **experimental field study**, during and after the **experimental field study**;

Legal Requirements for Regulatees:

The regulatee is required to:

(1) describe any procedures for monitoring the micro-organism at the site of the experimental field study; and

(2) describe any procedures for monitoring the micro-organism's ecological effects at the experimental field study.

These procedures must be in place during and after the experimental field study.

4. (*g*) a description of the security measures at the site of the **experimental field study**;

Legal Requirements for Regulatees:

The regulatee must describe the security measures taken at the site of the experimental field study. This would include measures for controlling access to the site by humans and by potential animal vectors.

4. (*h*) a description of any contingency plans for accidental release;

Legal Requirements for Regulatees:

The regulatee must describe any contingency plans for accidental release of the micro-organism.

4. (*i*) a description of any recommended procedures for terminating the **experimental field study**; and

Legal Requirements for Regulatees:

The regulatee must describe any recommended procedures for terminating the experimental field study.

4. (*j*) a description of any confinement procedures and biosafety conditions for the **micro-organism** at the site of the **experimental field study**, and a description of their effectiveness.

Legal Requirements for Regulatees:

The regulatee must describe:

(1) any confinement procedures and biosafety conditions for the micro-organism at the site of the experimental field study; and

(2) the effectiveness of these confinement procedures and biosafety conditions.

"Biosafety conditions" means the conditions adopted to ensure the safe application of the micro-organism. This term is not defined in CEPA or the Regulations.

SECTION 5

5. The following information in respect of the environmental fate of the **micro-organism**:

Legal Requirements for Regulatees:

This section defines the specific information that must be submitted on the environmental fate of the micro-organism. Environmental fate describes what happens to the micro-organism when it enters the environment.

5. (*a*) a description of habitats where the **micro-organism** may persist or proliferate;

Legal Requirements for Regulatees:

The regulatee must describe the habitats where the micro-organism may persist or proliferate. This description is based on the habitat specificity of the micro-organism and the likelihood of it reaching suitable habitats where it will establish and reproduce.

5. (*b*) the estimated quantities of the **micro-organism** in the air, water and soil at the points of introduction and the estimated population trends; and

Legal Requirements for Regulatees:

The regulatee must provide estimates of the quantities of the micro-organism in the air, water and soil at the points of introduction. Estimations of population trends must also be submitted. Population trends are the quantities of micro-organisms at time points after the time of application. The term "population trends" is not defined in CEPA or the Regulations.

5. (*c*) any other information on the environmental fate of the **micro-organism**.

Legal Requirements for Regulatees:

This paragraph places a duty on regulatees to supply any other information on the environmental fate of the organism. This obligation extends beyond the detailed provisions of this section.

SECTION 6

6. The following information in respect of the ecological effects of the **micro-organism**:

Legal Requirements for Regulatees:

This section specifies the information on ecological effects of the micro-organism that must be submitted by the regulatee.

6. (*a*) the involvement of the **micro-organism** in adverse ecological effects; and

Legal Requirements for Regulatees:

The regulatee must provide information on the involvement of the micro-organism in adverse ecological effects. This would include adverse effects on non-target organisms and ecological processes.

6. (*b*) the effects on biodiversity and any other ecological effects that result from the **experimental field study**.

Legal Requirements for Regulatees:

The regulatee must submit information on the effects on biodiversity and any other ecological effects that result from the introduction of the micro-organism. Biodiversity is not defined in CEPA or the Regulations. It means the variety of species on earth and the ecological processes of which they are part. The components of biodiversity are ecosystems, species and genetic diversity.

The ecological effects referred to in this paragraph are ecological effects other than the adverse ones identified in paragraph 6(a).

SECTION 7

7. The following information in respect of the human health effects of the **micro-organism**:

Legal Requirements for Regulatees:

This Section detail the information required on the human health effects of the micro-organism that must be submitted by the regulatee.

7.(*a*) any documented involvement of the **micro-organism** in adverse human health effects and a description of the characteristics of the **micro-organism** that distinguish it from known pathogens;

Legal Requirements for Regulatees:

The regulatee must submit information on the documented involvement of the micro-organism in adverse human health effects. Documented involvement may be obtained form literature searches of major relevant information sources.

A description of the characteristics of the micro-organism that distinguish it from known pathogens must also be provided. This information may have been submitted as the characteristics used to identify the micro-organism as required in Paragraph 1(a) of the Schedule. However, if the micro-organism could be a pathogen or appears closely related to a pathogen, more specific tests could be required under this paragraph.

Special consideration may need to be given to consortia under this paragraph. A consortium is a complex culture of micro-organisms that has not been formulated deliberately from pure cultures. An example would be a culture of micro-organisms isolated from soil where it would be extremely difficult or impossible to characterize all micro-organisms. Data on the presence of indicator micro-organisms may be provided under this paragraph subject to guidance given by NSD.

7. (*b*) the data from tests of antibiotic susceptibility; and

Legal Requirements for Regulatees:

The regulatee must submit data from tests of antibiotic susceptibility. "Antibiotic susceptibility" means the susceptibility of the micro-organism to being killed by the antibiotic. The term is not defined in CEPA or the Regulations.

7. (*c*) the estimated number of persons that may become exposed and the degree of exposure to the **micro-organism**.

Legal Requirements for Regulatees:

The regualtee must submit information on the estimated number of people who may be exposed to the micro-organism and their degree of exposure. The estimated number of people to the micro-organism. The estimated number of people exposed would include people in the general population and in occupational settings at all stages in the life cycle of the micro-organism. The degree of exposure of various individuals in a population would be provided at each stage in the life cycle of the micro-organism as well.

SECTION 8

8. All other information and test data in respect of the **micro-organism** that are relevant to identifying hazards to human health and the environment and that are in the person's possession or to which the person ought reasonably to have access.

Legal Requirements for Regulatees:

This Section places a broad duty on the regulatee to provide all other relevant information and test data in respect to the micro-organism. The information and test data must be relevant to identifying hazards to human health and the environment.

The information and test data required here must be in the regulatee's possession. If the information and test data are not in the regulatee's possession, the regulatee must still submit it if it exists in circumstances whereby the regulatee ought reasonably to have access to it.

SECTION 9

9. The identification of other government agencies, either abroad or within Canada, that the person has notified of the manufacture or importation of the **micro-organism**, and the purpose of such notification.

Legal Requirements for Regulatees:

The regulatee must identify other government agencies either abroad or in Canada that have been notified of the manufacture or importation of the micro-organism. The purpose of the notification must be provided as well.

SECTION 10

10. A description or specification of the test procedures followed in developing the test data, including test methods, reference substances and quality control and quality assurance procedures.

Legal Requirements for Regulatees:

A regulatee must submit a description or specification of the test procedures followed in developing the test data for the information requirements under this Schedule. This must include information on test methods, reference substances and quality control and quality assurance procedures.

SCHEDULE XVIII
(Subsections 29.12(6) and 29.15(6))

INFORMATION REQUIRED IN RESPECT OF **MICRO-ORGANISMS** FOR INTRODUCTION INTO THE SITE FROM WHICH THEY WERE ISOLATED

Legal Requirements for Regulatees:

Schedule XVIII sets out the information that regulatees must submit when propsosing to manufacture a new micro-organism at the site from which it was isolated and proposing to introduce the micro-organism into the same site. (Subsection 29.12(6))

The information in Schedule XVIII must also be submitted by a regulatee who manufactured a micro-organism at the site from which it was isolated for introduction into the same site during the transitional period, and who manufactures the micro-organism at that site for introduction into that site.

Each information item specified in this Schedule is required to make an assessment of the micro-organism's toxicity under CEPA. Regulatees receive guidance on these notification requirements directly by contacting NSD and from Guidelines produced by that division.

SECTION 1

1. The following information in respect of the **micro-organism**:

Legal Requirements for Regulatees:

This Section sets out the specific characteristics of the micro-organism that the regulatee must describe in the notification.

1. (*a*) the identification and the information substantiating the identification;

Legal Requirements for Regulatees:

The regulatee must provide the identification and information substantiating identification. The regulatee must provide the identification of the micro-organism and the information that substantiates that identification.

Special considerations should be given to identification in the following circumstances:

(1) where a formulation is to be or has been manufactured or imported, each micro-organism in the formulation must be identified by the regulatee;

(2) where a consortium is to be or has been manufactured or imported, regulatees should attempt to identify each micro-organism. Otherwise, the identification should be made according to the Guidelines produced by NSD; and

(3) where a genetically engineered organism is to be or has been manufactured or imported, the regulatee should identify the host micro-organism as well as the organisms that were the source of the genetic information.

1. (*b*) the infectivity, pathogenicity to non-human species, toxicity and toxigenicity; and

Legal Requirements for Regulatees:

The regulatee must describe in the notification the infectivity, toxicity and toxigenicity of the micro-organism to all species. A description of pathogenicity to non-human species must be provided as well. Information on pathogenicity to humans would be submitted under Paragraph 6(a). The relevant definitions are presented below:

(1) Infectivity means the ability of pathogenic micro-organisms to invade a body and reproduce and multiply to cause disease. This word is not defined in CEPA or the Regulations.

(2) Toxicity means the ability of a micro-organism to be toxic. Section 11 of CEPA provides that a substance is toxic if it is entering or may enter the environment in a quantity or concentration or under conditions:

(a) having or that may have an immediate or long term effect on the environment;

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

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

(3) Toxigenicity means the ability of a pathogenic organism to cause disease by producing toxins. This word is not defined in CEPA or the Regulations.

(4) Pathogenicity means the ability of the micro-organism to cause disease. This word is not defined in CEPA or the Regulations.

1. (*c*) a description of the known mode of action in relation to the intended use.

Legal Requirements for Regulatees:

The regulatee must describe in the modification the micro-organism's mode of action in relation to its intended use. The mode of action would include a description of the production of any toxic chemicals from the activity of the micro-organism in its intended use.

SECTION 2

2. The following information in respect of the manufacture of the micro-organism:

Legal Requirements for Regulatees:

This section defines the information that must be submitted by the regulatee concerning the manufacture of the micro-organism.

2. (*a*) data to demonstrate that the micro-organism was isolated from the site of introduction;

Legal Requirements for Regulatees:

The regulatee must provide data to demonstrate that the micro-organism was isolated from the site of introduction.

2. (*b*) the physical state of the formulation;

Legal Requirements for Regulatees:

The regulatee must provide information on the physical state of the formulation.

The physical state may be powder, dust, solution, mist or vapour form. The word formulation is not defined in CEPA or the Regulations. It means a mixture of pure micro-organism cultures that have been deliberately formulated.

2. (*c*) the concentration of the micro-organism in the formulation;

Legal Requirements for Regulatees:

The regulatee must submit information on the concentration of the micro-organism in the formulation. The definition of formulation is provided in the analysis under Paragraph 2(b).

2. (*d*) the identification and concentration of other ingredients and of any contaminants in the formulation;

Legal Requirements for Regulatees:

The regulatee must submit an identification of other ingredients and contaminants in the formulation. The concentration of these substances in the formulation must also be described. The definition of formulation is provided in the analysis of Paragraph 2(b).

2. (*e*) the viability of the micro-organism in the formulation;

Legal Requirements for Regulatees:

The regulatee must submit information on the viability of the micro-organism. Viability means the ability of the micro-organism to grow, develop and reproduce. A micro-organism is viable if it is alive. The definition of formulation is provided in the analysis of Paragraph 2(b).

2. (*f*) an estimation of the quantity of the micro-organism that was or will be manufactured, as the case may be;

Legal Requirements for Regulatees:

The regulatee must submit an estimation of the quantity of the micro-organism that was or will be manufactured in Canada.

2. (*g*) a description of the equipment and methods of manufacture and of quality control and quality assurance procedures; and

Legal Requirements for Regulatees:

The regulatee has a duty under this Paragraph to:

(1) describe the equipment and methods of manufacture of the micro-organism; and

(2) describe the methods of quality control and quality assurance procedures used in or that were used in manufacturing the micro-organism.

2. (*h*) a description of the procedures for the treatment and disposal of wastes containing the micro-organism.

Legal Requirements for Regulatees:

The regulatee has a duty under this paragraph to provide a description of the procedures for the treatment of wastes containing the micro-organism from the introduction.

SECTION 3

3. The following information in respect of the site of introduction of the micro-organism:

Legal Requirements for Regulatees:

This section defines the information on the site of introduction of the micro-organism that must be submitted by the regulatee.

3. (*a*) the location and a map;

Legal Requirements for Regulatees:

The regulatee must clearly describe the location of the site of introduction and indicate its location on a map.

3. (*b*) the size; and

Legal Requirements for Regulatees:

The regulatee must describe the size of the site of introduction in the notification. Size would be measured in terms of length, width and depth of the site.

3. (*c*) the distance to populated areas.

Legal Requirements for Regulatees:

The regulatee must provide a measure of the distance from the site of introduction to populated areas. Populated areas could be cities, towns or villages.

SECTION 4

4. The following information in respect of the introduction of the **micro-organism**:

Legal Requirements for Regulatees:

This section sets out the information on the introduction of the micro-organism that must be submitted by the regulatee

4. (*a*) the intended use;

Legal Requirements for Regulatees:

The regulatee must state what the intended use is or was of the micro-organism being introduced.

4. (*b*) the history of use;

Legal Requirements for Regulatees:

The regulatee must include a history of use of the micro-organism. For micro-organisms used during the transition period, the use during that period as well as other historical uses should be included.

4. (*c*) the start date and duration;

Legal Requirements for Regulatees:

The regulatee must provide information on the start date of the micro-organism's introduction. The duration of the introduction must be described as well.

4. (*d*) a description of the procedures for the introduction of the **micro-organism**, including

This paragraph requires that the regulatee submit a description of the procedures used for the introduction of the micro-organism. The subparagraphs detail the information items that must be provided under this paragraph. However, regulatees may be required to provide other information on the procedures used for the introduction.

4.(d)(i) the method of application,

Legal Requirements for Regulatees:

The regulatee must describe the method of applying the micro-organism in the introduction.

4.(d)(ii) the quantity, frequency and duration of application, and

Legal Requirements for Regulatees:

The regulatee must describe the quantity, frequency and duration of application of the micro-organism. The duration of the appreciation refers to the overall period for application of the micro-organism.

4.(d)(iii) any activities associated with the introduction;

Legal Requirements for Regulatees:

The regulatee must submit information on other activities associated with the introduction. These would include activities such as the addition of surfactants, or amendments of nutrients, aeration or venting of oxygen, or mixing or killing.

4. (*e*) a description of any **confinement procedures** and biosafety conditions for the **micro-organism** at the site of introduction, and a description of their effectiveness.

Legal Requirements for Regulatees:

The regulatee must describe:

(1) any confinement procedures and biosafety conditions for the micro-organism at the site of introduction, and

(2) the effectiveness of those confinement procedures and biosafety conditions.

"Biosafety conditions" means the conditions adopted to ensure the safe application of the micro-organism. This term is not defined in CEPA or the Regulations.

SECTION 5

5. The following information in respect of the ecological effects of the **micro-organism**:

Legal Requirements for Regulatees:

This Section specifies the information on ecological effects of the micro-organism that must be submitted by the regulatee.

5. (*a*) the involvement of the **micro-organism** in adverse ecological effects; and

Legal Requirements for Regulatees:

The regulatee must provide information on the involvement of the micro-organism in adverse ecological effects. This would include adverse effects on non-target organisms and ecological professes.

5. (*b*) the effects on biodiversity and any other ecological effects that result from the introduction of the **micro-organism**.

Legal Requirements for Regulatees:

The regulatee must submit information on the effects on biodiversity and any other ecological effects that result from the introduction of the micro-organism. "Biodiversity" is not defined in CEPA or the Regulations. It means the variety of species on earth and the ecological professes of which they are part. The components of biodiversity are ecosystems, species and genetic diversity.

The ecological effects referred to in this are not adverse effects as those identified in Paragraph 5(a).

SECTION 6

6. The following information in respect of the human health effects of the **micro-organism**:

Legal Requirements for Regulatees:

This Section details the information required on the human health effects of the micro-organism that must be submitted by the regulatee.

6. (*a*) any documented involvement of the **micro-organism** in adverse human health effects and a description of the characteristics of the micro-organism that distinguish it from known pathogens; and

Legal Requirements for Regulatees:

The regulatee must submit information on the documented involvement of the micro-organism in adverse human health effects. Documented involvement may be determined from literature searches of major relevant information sources.

A description of the characteristics of the micro-organism that distinguish it from known pathogens must also be provided. This information may have been submitted as the characteristics used to identify the micro-organism as required in Paragraph 1(a) of the Schedule. However, if the micro-organism could be a pathogen or appears closely related to a pathogen, more specific tests could be required under this paragraph.

Special consideration may need to be given to consortia under this paragraph. A consortium is a complex mixture of micro-organisms that has not been formulated deliberately from pure cultures. An example would be a culture of micro-organisms isolated from soil where it would be extremely difficult or impossible to characterize all micro-organisms. Data on the presence of indicator micro-organisms may be provided under this paragraph, subject to guidance given by NSD.

6. (*b*) the estimated number of persons that may become exposed and the degree of exposure to the **micro-organism**.

Legal Requirements for Regulatees:

The regulatee must submit information on the estimated number of people that may be exposed and the degree of exposure to the micro-organism. The estimated number of people exposed would include people in the general population and in occupational settings at all stages in the life cycle of the micro-organism. The degree of exposure of various individuals in a population would be provided at each stage in the life cycle of the micro-organism as well.

SECTION 7

7. All other information and test data in respect of the **micro-organism** that are relevant to identifying hazards to human health and the environment and that are in the person's possession or to which the person ought reasonably to have access.

Legal Requirements for Regulatees:

This section places a broad duty on the regulatee to provide all other relevant information and test data in respect to the micro-organism. The information and test data must be relevant to identifying hazards to human health and the environment.

The information and test data required here must be in the regulatee's possession. If the information and test data are not in the regulatee's possession, the regulatee must still submit it if it exists in circumstances whereby the regulatee ought reasonably to have access to it.

SECTION 8

8. The identification of other government agencies, either abroad or within Canada, that the person has notified of the manufacture or importation of the **micro-organism**, and the purpose of such notification.

Legal Requirements for Regulatees:

The regulatee must identify other government agencies either abroad or in Canada that have been notified of the manufacture or importation of the micro-organism. The purpose of the notification must be provided as well.

SECTION 9

9. A description or specification of the test procedures followed in developing the test data, including test methods, reference substances and quality control and quality assurance procedures.

Legal Requirements for Regulatees:

A regulatee must submit a description or specification of test procedures followed in developing the test data for the information requirements under this Schedule. This must include information on test methods, reference substances and quality control and quality assurance procedures.