CANADIAN INSTITUTE FOR ENVIRONMENTAL LAW AND POLICY
L'INSTITUT CANADIEN DU DROIT ET DE LA POLITIQUE DE L'ENVIRONNEMENT
Est. 1970

New Substances Notification Regulations Part II.1 Organisms

Draft CEPA Inspectors Manual

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for

The Office of Enforcement
Environment Canada

Contract #K2412-6-0043

October 1, 1996

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INTRODUCTION

Organisms are manufactured in or imported into Canada for a variety of uses and commercial applications. Like other substances, such as chemicals and polymers, organisms may be toxic to the environment and human health. Canada has a number of different federal acts and regulatory processes to assess the toxicity of organisms before they are imported or manufactured. However, the Canadian Environmental Protection Act (CEPA) and the New Substances Notification Regulations (the Regulations) are intended to protect Canadians and Canada's environment from new organisms that are toxic. CEPA and the Regulations may be viewed as a "safety net" that addresses the toxicity of organisms not dealt with under other federal acts.

The New Substances Notification Regulations under CEPA prescribe the process by which new substances are notified to and assessed by Environment Canada. The Regulations address notification procedures for chemicals, biochemicals and polymers. They have now been amended to apply to micro-organisms and organisms other than micro-organisms. These amendments come into force on July 1, 1997.

This manual focuses on how CEPA applies to micro-organisms and organisms other than micro-organisms. It provides an introduction to the amendments to the Regulations that apply to these organisms. This manual should be read in conjunction with the New Substances Notification Regulations, Revised CEPA Inspectors Manual which provides detailed information on the provisions of CEPA that require notification and assessment of new substances and the inspection procedures for substances that are chemicals and polymers. Some of the information contained in that manual is referenced or repeated here to assist inspectors in dealing with substances that are micro-organisms or organisms other than micro-organisms.

PART I: PROVISIONS IN THE NEW SUBSTANCES NOTIFICATION REGULATIONS FOR ORGANISMS (MICRO-ORGANISMS AND ORGANISMS OTHER THAN MICRO-ORGANISMS)

CEPA provisions and their application to new substances are fully explained in the New Substances Notification Regulations, Revised CEPA Inspectors Manual . It is unnecessary to repeat them in this manual. However, the relevant CEPA provisions will be referred to in a later discussion on the analysis required to be carried out by inspectors when dealing with a new substance that is an organism. The amendments to the New Substances Notification Regulations that apply organisms, that is to micro-organisms and organisms other than micro-organisms, are the particular focus of this part.

I.1 An overview of the provisions of the New Substances Notification Regulations that apply to organisms

Section 32 of CEPA provides for regulations to be made under the Act. In particular, under Paragraph 32(1)(a), regulations can be made establishing groups of biotechnology products for the purposes provision of information under CEPA. Biotechnology is defined in Subsection 3(1) 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 form. The New Substances Notification Regulations establishes groupings of biotechnology products as described in Paragraph 32(1)(a).

The New Substances Regulations consist of two parts; Part I which deals with chemicals that are new substances other than polymers and certain biotechnology products and Part II which deals with polymers including certain biotechnology products. Amendments to the Regulations create a New Part II.1 to deal with new substances that are organisms, including micro-organisms and organisms other than micro-organisms.

Part II.1 of the Regulations sets out in detail the obligations of manufacturers or importers of organisms under the Substances New to Canada section of CEPA (sections 25 to 32). In general the Regulations;

- incorporate definitions into the Regulation that are relevant to organisms.

- provide important exemptions for research and development micro-organisms and organisms other than micro-organisms that are manufactured or imported under defined conditions.

- establish groups of organisms for notification. and define the information requirements (set out in schedules) for these groups. the dates by which such information must be provided and the assessment period for each group of organisms. and

- set out special provisions for notification of organisms that are manufactured or imported during the transitional period (January 1. 1987 and June 30. 1994) and during the period between the end of the transitional period and the date that the amendments come into force (July 1. 1994 to June 30. 1997).

I.2 The definitions of micro-organisms and organisms other than micro-organisms

The Regulations apply to new substances that are micro-organisms and organisms other than micro-organisms. A micro-organism is defined in subsection 2(1) of the Regulations as 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 organisms not referred to in paragraphs (a) and (b). other than a cell used to propagate such organism; or

(d) any culture other than a pure culture.

An organism other than a micro-organism is not defined in the Regulations but includes all organisms not captured in the definition of micro-organism in subsection 2(1).

I.3 Provisions in the Regulations exempting certain organisms from notification

I.3.1 Exemption for organisms regulated under other federal acts

The Regulations set out important exemptions for new substances regulated under other federal acts. Subsection 3(1) eliminates the requirement for notification of a new substance that is manufactured or imported for another use that is regulated under another Act of Parliament. The other act must provide for notice to be given prior to the manufacture, import or sale of the substance and for an assessment of whether or not the substance is toxic. Subsection 3 (1) of the Regulation goes on to state that the other Acts of Parliament referred to in this subsection include the:

- Feeds Act.
- Fertilizers Act.
- Health of Animals Act.
- Pest Control Products Act. and
- Seeds Act.

This exemption repeats paragraph 26(3)(a) of CEPA but goes further to provide more detail on the acts that would be included in that paragraph.

I.3.2 Exemption for organisms in transit

The Regulations provide a special exemption for new substances in transit through Canada. Subsection 3(2) provides that the regulations do not apply to a substance that is loaded on a carrier outside Canada and moved through Canada to a location outside Canada. It does not matter whether or not there is a change of carrier during transit.

I.3.3 Exemptions for research and development organisms

New research and development substances are subject to special provisions in the Regulations. Subsection 2(1) of the Regulations defines a research and development substance as a substance undergoing systematic investigations or research by means of experimentation or analysis other than test marketing. The primary objectives of the investigation or research must be to create or improve a product or process or to determine the technical viability or performance characteristics of the product.

I.3.3.1 Exemptions for research and development micro-organisms

No notification need be provided for new micro-organisms that are research and development substances if the criteria set out in section 29.1 of the Regulations are met. This section requires that the micro-organism must also be imported to a contained facility. A contained facility is defined in subsection 2(1) of the Regulations as 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 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.

Trigger quantities also apply for these micro-organisms to be exempt from notification. If the micro-organism is not in risk group 2,3, or 4, of the Laboratory Biosafety Guidelines then the quantity must be less than 1000 liters. For all other micro-organisms the level of manufacture that triggers notification is 250 liters. Risk Group 3 and 4 micro-organisms have different trigger quantities. To be exempt form notification, micro-organisms in these groups must have an import permit for the micro-organism under Canada's Human Pathogen Importation Regulations or written permission to transfer the imported human pathogen granted under the same regulations. The volume triggers for exemption are maxima, inclusive of micro-organism and media and include both batch and continuous culture. Research and development micro-organisms imported to a contained facilities in a quantity of less than 50 ml or 50 g including micro-organisms and media are also exempt from notification.

I.3.3.2 Exemptions for research and development organisms other than micro-organisms

New organisms other than micro-organisms are also subject to an important exception under sections 29.16 and 29.19 of the Regulations This section requires that manufacturers or importers of organisms other than micro-organisms must provide the prescribed information unless the organism is a research and development substance and is imported to or manufactured in a facility from which there is no release, into the environment, of

(a) the organism;

(b) the genetic material of the organism; or

(c) material of the organism involved in toxicity.

1.4 Groups of organisms for notification

Section 26 of CEPA prohibits the import or manufacture of any substance not listed on the DSL unless the prescribed information is provided within the prescribed time and the period for assessing the prescribed information has expired. The Regulations create notification groups for micro-organisms and organisms other than micro-organisms.

1.4.1 Notification groups for micro-organisms

The notification groups, the information schedules required for each group, the prescribed time for notification and the assessment periods for micro-organisms are summarized in Appendix A. Section 29.11 of the Regulations establishes these notification groups for micro-organisms while section 29.12 sets out the prescribed time for notification and section 29.13 establishes the assessment periods.

The Regulations are written so that the notification group for "manufacture or introduction anywhere in Canada" outlined in subsections 29.11(1) specify the most comprehensive set of information requirements as prescribed in Schedule XV. The other subsections of 29.11 identify notification groups where other than the most comprehensive set of information requirements apply.

The Regulations also outline, in section 29.14, notification groups for micro-organisms manufactured or imported during the transitional period. Provisions for micro-organisms first manufactured or imported after the transitional period but before Part II.1 of the regulations came into force are subject to provisions in the Guidelines for the Notification of New Substances (the Guidelines). These provisions are discussed in detail in part I.6 of this manual.

I.4.2 The notification group for organisms other than micro-organisms

Section 29.16 the Regulations sets out the notification group for organisms other than micro-organisms. Subject to the exemption in this section, anyone manufacturing or importing a new substance that is an organism other than a micro-organism must provide the information as set out in Schedule XIX at least 120 days before the day on which manufacture or import begins. The assessment period is 120 days following receipt of the information.

Section 29.19 establishes a notification group for organisms other than micro-organisms that are first manufactured during the transitional period.

I.5 Provisions for organisms first manufactured or imported during the transitional period (January 1, 1987 to June 30, 1994)

Substances not listed on the DSL and manufactured or imported between January 1, 1987 and June 30, 1994 are subject to the transitional provisions of CEPA set out in subsection 26(2) unless exempted in subsection 26(3) or paragraph 32(1) of CEPA. Subsection 26(2) allows these substances to continue to be manufactured or imported after the notification regulations come into force, so long as the manufacturer or importer has provided the prescribed information to Environment Canada before January 1, 1998. The information that must be provided is set out in sections 29.14 (micro-organisms) and 29.19 (organisms other than micro-organisms) of the Regulations.

1.6 Provisions for organisms first manufactured or imported during the period between the end of the transitional period and the date that the amendments come into force (July 1, 1994 to June 30, 1997)

Under subsection 26(1) of CEPA. the manufacture or import of a substance is prohibited unless a notifier provides the prescribed information and the period for assessing the information has expired. Accordingly. for an organism first manufactured or imported after the transition period but before Part 11.1 of the Regulations came into force, a notification must have been provided and assessed before July1. 1997. This was required so that the manufacture or import of the organism could continue. subject to the results of the assessment. after July1. 1997. Six months between the date of publication of Part II.1 of the Regulations in the Canada Gazette. and the date on which Part II.1 came into effect (July 1. 1997) was provided to allow for the preparation submission and assessment of notification packages before July 1. 1997.

If these micro-organisms and organisms other than micro-organisms has not been notified. assessed and listed on the DSL by the time the Regulations came into force. they would have been considered new substances and their manufacture or import would have had to halt until a notification was provided and the assessment period had expired.

PART II : THE ANALYTICAL FRAMEWORK FOR INSPECTORS

Inspectors must clearly understand how CEPA and the New Substances Notification Regulations apply to micro-organisms and organisms other than micro-organisms. This is the starting point for addressing inquiries from the public. in assisting members of the regulated community comply with the regulations and in enforcing CEPA and the Regulations. A "Quick Reference" for the application of CEPA and the Regulations to micro-organisms and organisms other than micro-organisms is presented in Appendix B. This Appendix sets out the major decision points for inspectors as described in the text below.

II.1 Deciding if CEPA and the Regulations apply to an organism

II.1.1 Is the organism a "substance" under CEPA ?

The first decision that inspectors must make in an analysis of the application of CEPA and the Regulations lies in determining if the micro-organism or the organism other than a micro-organism is a substance under the Act. Subsection 3(1) of CEPA defines a substance as

> any kind of distinguishable kind of organic or inorganic matter. whether animate or inanimate. and includes
>
> > (a) any matter that is capable of being dispersed in the environment or of being transformed in the environment into matter that is capable of being so dispersed matter or that is capable of causing such transformations in the environment.

(b) any element or free radical,

(c) any combination of elements of a particular molecular identity that occurs in nature or as a result of a chemical reaction. or

(d) complex combinations of different molecules that originate in nature or are the result of chemical reactions but that could not practicably be formed by simply combining individual constituents.

This broad definition means that organisms are substances under CEPA, whether living or dead or genetically modified or derived from naturally occurring populations.

Some important exceptions to the definition of substances under CEPA are also provided in section 3(1). These also must be considered in an analysis of whether or not the micro-organism or organism is a substance. The following are not substances under CEPA .

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

It is important at this point for the inspector to know if the micro-organism and organism other than micro-organisms is a pure culture, a consortium or a deliberate formulation. Mixtures of organisms that are deliberately prepared formulations are not considered substances and, consequently do not require notification. However, if any constituent organism of a mixture is a new substance, that constituent is a notifiable substance.

Mixtures derived form natural sources that cannot be characterized because their composition is too complex or variable are considered single substances and, therefore, subject to notification. For example, a consortium of micro-organism, that is a complex natural mixture of micro-organisms, is considered a single substance for notification. However, a formulation deliberately mixed from pure cultures of micro-organisms is not a single substance. In this case, each individual pure culture in the formulation is a substance and may require notification.

(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.

In order to determine if this exemption applies, inspectors must inquire as to if the micro-organism or organism other than a micro-organism meet the above criteria: that is if the manufactured or imported item will possess a definite shape or design necessary to its final function. Shape defines the macro-structure (i.e. the physical three-dimensional structure of the final item).

An example would be an immobilized micro-organisms contained in a column for use in processing a chemical stream. The column would not be a notifiable substance but the

component micro-organisms would be. Similarly, the structural framework of a biofilter would not be considered a notifiable substance but the micro-organisms used in the filter may be.

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

Inspectors will need to know about the material that the organism may be a part of in order to determine if this exemption applies. If the material, including organisms and organisms other that micro-organisms is contained in effluents, emissions and wastes, it is excluded from the definition of substance. However, inspectors must be aware that any subsequent processing such as screening , selecting or promoting the growth of these organisms may qualify them as notifiable substances.

II.1.2 Is the organism on the Domestic Substances List?

The Domestic Substances List (DSL) is the sole basis for determining if an organism is new for the purposes of CEPA. Inspectors will have to verify if an organism is on the DSL to determine if notification is required. Appendix D provides details on how to obtain access to the DSL to verify that an organism has been listed.

Subsection 25 (1) of CEPA establishes the DSL. The DSL 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.

Under CEPA subsection 26 (1), any person is prohibited from importing or manufacturing an organism not on the DSL 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.

The listing of an organism on the DSL may describe the organism according to genus, species and, where applicable, strain and include other identifying information as well. In the case of micro-organisms, this could be the culture history, phenotypic characteristics or uses. Species that have been genetically engineered may also be described by the genetic modification. For example, a genetically engineered micro-organism on the DSL may be identified by genus and species as well as the description of the added or deleted gene. Inspectors may wish to seek guidance from CCEB (Commercial Chemicals Evaluation Branch) if there is confusion about the identification of any organism on the DSL.

Disclosing the explicit biological name of an organism on the DSL may reveal confidential business information. Subsection 19(1) of CEPA allows a person who provides information about a new substance to claim that the information be treated as confidential. Section 31 of CEPA provides for the implementation of regulations for the masking of substance names. These regulations are currently being developed.

A masked name is a name having one or more of the specific components identified in a manner which prevents the identification of the specific organism. For example, in the case of micro-organisms, the taxonomic name portion specific substance name/description to the species level may be masked. Thus "Bacillus species" may be listed on the DSL as a masked name for *Bacillus subtilis*. Other unique identifiers of an organism such as source, history and use of a micro-organism on the DSL could also be masked.

Inspectors will have to check with CCEB regarding the listing of an organisms on the confidential portion of the DSL. This will be required when a claim is made that an organism is on the DSL but under a masked name.

II.1.3 Does the organism meet the criteria for substances that do not require notification under CEPA subsection 26(3)?

Once a determination is made that an organism is a "substance" under CEPA and it is not on the DSL, the next step in the analytical framework is to determine if the organism is exempt from notification because of the application of CEPA subsection 26(3). This subsection establishes special criteria for new substances that are not subject to the Regulations. However, it must be noted that, while these exemptions apply to all substances, they may not all be relevant for micro-organisms and organisms other than micro-organisms. An organism does not require notification if the following criteria are met.

(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.

Subsection 3(1) of the Regulations further specifies that substances may be exempted from notification under the Regulations including those under the jurisdiction of the following federal acts:

- The Pest Control Products Act
- The Seeds Act
- The Fertilizers Act
- The Feeds Act
- The Health of Animals Act: and
- The Food and Drugs Act.

Inspectors may verify if an organism is regulated under these acts by calling the contacts listed in Appendix D.

Inspectors should keep in mind that micro-organism and organisms other than micro-organisms addressed by the federal acts and meeting the criteria in CEPA Subsection 26(3)(a). are. however, subject to notification under CEPA if used in applications other than those regulated by these acts. For example. a micro-organism used for pest control purposes is regulated under the Pest Control Products Act. Notification under the CEPA and the Regulations may be required before manufacture or import if the micro-organism is to be used for a different purpose such as bioremediation

(b) transient reaction intermediates that are not isolated and are not likely to be released to the environment.

Transient reaction intermediates are substances produced within a sequence of chemical reactions between the starting materials and the end product. Inspectors should consult with CCEB in considering if an organism is exempt from notification due to the application of this exemption.

(c) Impurities. contaminants and partially unreacted materials the formation of which is related to the preparation of a substance

Impurities and contaminants are substances found in minimal concentrations in the starting materials. or are the result of secondary reactions that occur during the manufacturing process. These substances and partial unreacted starting materials present in the final product. are the direct result of the preparation. are not necessary to the end use of the product. have not been intentionally added. and do not enhance the substance's commercial value. Inspectors should consult with CCEB before considering if an organism is exempt from notification due to the application of this provision.

(d) Substances produced when a substance undergoes a chemical reaction that is identical to the use to which the substance is put or that results form storage or from environmental factors.

Incidental reaction products include. for example. substances formed from exposure to environmental factors such as air. moisture and sunlight. Inspectors should consult with the CCEB before considering if an organism is exempt from notification due to the application of this provision.

(e) A substance that is manufactured or imported in a quantity that does not exceed the maximum quantity prescribed as exempt form this section.

Paragraph 32 (1) (b) of CEPA provides that regulations can be made to prescribe the maximum exempt quantities for the purpose of paragraph 26 (3) (e). Trigger quantities which apply only to micro-organisms are set out in Section 29.1 of the Regulations

There are a series of questions that might be asked in considering if notification is not needed for a new micro-organism as provided in this exemption.

(1) Is the micro-organism a research and development substance?

This exemption applies to a micro-organism that is a research and development substance, and is manufactured in or imported to a contained facility below these maximum prescribed quantities.

A research and development (R&D) substance is defined in Subsection 2(1) of the Regulations. To meet this definition the regulatee must be proposing to import or manufacture 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) determine the technical viability or performance characteristics of the product.

(2) Is the research and development micro-organism being imported or manufactured in contained facilities?

A research and development micro-organism must also be imported to a contained facility which is defined in Subsection 2(1) of the Regulations. A contained facility is 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 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. The Laboratory Guidelines referred to in this provision are those published by the Medical Research Council of Canada. Department of National Health and Welfare in 1990 and as amended from time to time (subsection 2(1) of the Regulations).

3. Is the micro-organism imported or manufactured in quantities less than trigger quantities and in accordance with the other requirements set out in section 29.1 of the Regulations?

Section 29.1 of the regulations provides exemptions for 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 paragraph (c) and (d), manufactured in quantities of less than 1 000 L in a contained facility unless the micro-organism require level 2, 3, or 4 as identified in the Laboratory Biosafety Guidelines:

(c) manufactured in quantities of 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 an approval in writing to transfer has been granted in respect of the micro-organism under the Human Pathogens Importation Regulations.

Table 1 summarizes the groups of research and development micro-organisms that do not require notification . It should be noted that the volume triggers for exemption are maxima, inclusive of micro-organism and media and include both batch and continuous culture. Research and development micro-organisms imported to a contained facility in a quantity of less than 50 ml or 50g are inclusive of micro-organisms and media.

Table 1. A summary of the provisions in section 29.1 of the Regulations

Regulation Provision	R & D organism	manufact-ured in a contained facility	Imported to a contained facility	trigger quantity	Biosafety Level
Paragraph 29.1 (a)	Yes	Yes	Yes	less than 50 mL or 50 gm	
Paragraph 29.1 (b)	Yes	Yes	No	less than 1 000 L	level other than 2,3 or 4
Paragraph 29.1 (c)	Yes	Yes	No	less than 250 L	level 2
Paragraph 29.1 (d)	Yes , human path-ogen	Yes	imported with permit or approval under Human Pathogen Importation Regulations	less than 250 L	level 3 or 4

A determination of exemption for research and development micro-organisms requires a thorough understanding of the Laboratory Biosafety Guidelines and the nature of research activities involving micro-organisms. If inspectors are confronted

with a situation where a claim is made that a micro-organism is exempt form notification under Section 29.1 of the Regulations, expert advise should be sought on the matter by consulting with CCEB and possibly experts in the field of laboratory biosafety and laboratory operations.

II.1.4 Is the organism an organism other than a micro-organism and are the criteria for exemption set out in sections 29.16 and 29.19 of the Regulations met?

Subsection 32(1)(a) provides for the establishment of groups of substances for the purposes of provision of information under Sections 26 and 27 of CEPA. Sections 29.16 and 29.19 (the transitional provision) of the Regulations require notification for an organism other than a micro-organism unless:

(i) the organism is a research and development substance; and

(ii) there is no release from the facility to the environment of the organism, the genetic material of the organism or material from the organism involved in toxicity.

For the purposes of this exemption, genetic material that has been introduced into the genome or cells of the organism is considered to be part of the genetic material of the organism.

Organisms other than micro-organisms will likely be regulated under other federal acts and therefore will be exempted under subsection 3(1) of the Regulations. Inspectors should be aware of this provision and consider it in their analysis. However, in reality there will likely be no requirement for compliance and enforcement activities in this area.

II.1.5 Is the organism being transported through Canada?

The Regulations do not apply to a substance loaded on a carrier outside Canada and moved through Canada to a point outside Canada. This exemption, specified in Section 3 of the Regulations, applies even if there is a change of carrier during transit. However, if a substance is brought into Canada and stored for subsequent distribution, the substance is subject to notification under CEPA. In order to determine if this exemption applies, inspectors will have to understand the chain of events in transferring the organism in question through Canada.

II.1.6 Is the organism exempt because it is not "manufactured"?

Inspectors will have to consider if the activity being carried out with the organism is indeed a "manufacture". The following activities are listed in the Guidelines as being outside the scope of what is considered a manufacture. These are:

(a) *in situ* stimulation of organism growth by adding nutrients or altering by physical means such as tilling;

(b) municipal and industrial wastewater treatment that does not isolate and process the organisms: and

(c) composting and septic tank operations that do not isolate and process the organism from treated waste.

Organisms that are the subject of these activities will not need to be notified under CEPA and the Regulations

In summary. notification of an organism must be made if it is:

- a "substance" to which CEPA and the regulations apply.
- not listed on the DSL.
- not subject to the exemptions set out in the Act and Regulations.
- is not being transported through Canada in accordance with Regulations section 3 (2). and
- is not excluded from the scope of manufacture.
-

At the end of this analysis. inspectors should be able to determine if notification is required under CEPA and the Regulations for any organism.

II.2 Determining if an offense has been committed

Once a determination is made that notification is required for a micro-organism or an organism other than a micro-organism. a decision can be made if the Act and Regulations may have been contravened and appropriate action can be taken.

The list of offenses under CEPA is set out in Appendix E. Information on these offenses has been provided in the New Substances Notification Regulations. Revised CEPA Inspectors Manual . This manual focuses on offenses that inspectors will most likely encounter in relation to new organisms subject to CEPA and the Regulations.

The main types of offenses committed by importers or manufacturers of new organisms will likely be the following:

- failing to report a new organism.
- late reporting of a new organism.
- importing or manufacturing a new organism before the period for assessing information about the organism has expired.

- providing misleading or wrong information when reporting. or
- importing or manufacturing an organism in a contravention of a condition or prohibition.

Each of these offense are considered below

II.2.1 Has the manufacturer or importer failed to report a new organism?

The obligation to report new substances is found in section 26 (1) of CEPA which provides where a substance is not specified on the DSL and is not a transitional substance. no person shall manufacture or import the substance unless;

(1) The person has provided the Minister with the prescribed information on or before the prescribed date: and

(2) the period for assessing the information has expired.

It is an offense under CEPA section 112 not to provide the Minister with the information required in Section 26.

In considering a potential offense of this nature. inspectors will need to have a solid understanding of whether or not the organism requires notification under CEPA and the Regulations. In particular those micro-organisms subject to exemptions under certain trigger quantities and subject to the requirements of particular biosafety levels must be considered here. If the micro-organism is:

- no longer a research an development substance.
- no longer imported to or manufactured in a contained facility.
- manufactured or imported above the trigger quantity. or
- no longer subject to the required biosafety requirements set out in section 29.1 of the Regulations

then the micro-organism is subject to notification.

Likewise. for organisms other than micro-organisms. if the organism is

- no longer a research and development substance.

- no longer imported to or manufactured in a facility where there is no release to the environment of the organism, the genetic material of the organism or material from the organism involved in toxicity

then the organism is subject to notification. This of course is subject to the proviso that organisms other than micro-organisms are likely to be regulated under other federal acts and as such are exempt from notification under CEPA.

Note: The role played by inspectors in enforcement activities in relation to research and development substances needs to be determined.

Inspectors will also need to consider who might be charged with the offense under section 112. While the Regulations cover manufacturers or importers it may not always be clear who the importer or manufacturer may be. Any person with control over a new organism --truck drivers, customs brokers, persons who own organisms and persons who order organisms--is considered an importer under the Regulations. However, the level of due diligence will vary according to which person is involved. The due diligence would not be very great for a truck driver whereas it might be considerably higher for a person who imports the substance in order to sell it . A truck driver would not violate CEPA or the Regulation for failing to notify about the import of a new substance but the driver can be questioned at the border about the origins of the substance and its destination. Customs brokers who own or order the organisms have the main duty to notify.

Further complexities lie in dealing with substances imported from abroad. It is not necessary for the actual importer to file the notices required under CEPA and the regulation. For example, Company X (U.S.) may intend to export a new organism to Canadian customers via Company X (Canada), which acts as agent for the customers. The customers are the importers. Company X (U.S.) may file the notification: Company X (Canada) must then sign as the regulatee (EC will accept a notification from a foreign company only if someone in Canada --Company X (Canada) in this case ---signs off and becomes the regulatee). One notification therefore covers all Company X customers. The customers may simply report that Company X (U.S.) is filing the notification on their behalf.

Even if Company X (U.S) files the notice, the Canadian customers must be able to show due diligence in ensuring that Company X properly notifies the Minister: the customers therefore must have a paper trail to this effect. If Company X failed to notify the Minister, the Canadian customers (the importers) would be obliged to notify.

II.2.2 Has the manufacturer or importer reported the manufacture or import of a new organism on time?

Inspectors will have to understand the notification requirements for organisms manufactured or imported at various times. An overview of the dates for notification is provided in Appendix F.

The time requirements for notification of new organisms are linked to the time that the organism was first manufactured or imported. Organisms not listed on the DSL and manufactured or imported between January. 1987 and June 30. 1994 are subject to the transitional provisions in CEPA (Subsection 26(2)) unless exempted under Subsections 26(3) or 32(1) of CEPA. Subsection 26(2) of the Act allows these "transitional substances" to be continued to be manufactured or imported after the Regulations come into force as long as the prescribed information has been provided to Environment Canada before January 1. 1998. The information must be provided as prescribed in Regulations section 29. 14 (micro-organisms) and section 29.19 (organisms other than micro-organisms) of the Regulations.

Circumstances may arise where the organism is currently being imported or manufactured subject to a notification group other than that for which it was manufactured or imported during the transitional period. The organisms would be subject to notification under subsection 26(1) of CEPA and would not be a transitional substance. Notification would not be required if the manufacture or import of the organism were discontinued before July 1. 1997. the date in which Part II.1 of the Regulations came into force.

Under Subsection 26(1) of CEPA. manufacture or import of a substance is prohibited unless the prescribed information has been provided and the period for assessing the information has expired. Accordingly. for an organism first manufactured or imported after the transitional period but before Part II.1 of the Regulations came into force. a notification must have been provided and appropriately assessed before July 1. 1997. This was required so the manufacture or import of the organism could continue subject to the results of the assessment after July 1. 1997. The six months between the publication of Part II.1 of the Regulations in the Canada Gazette and the date on which Part II.1 comes into force (July1. 1997) allows manufacturers or importers time to prepare and submit their notification packages. It also allows assessment of that information before July 1. 1997.

If these micro-organisms and organisms other than micro-organisms had not been notified and assessed and listed on the DSL by the time Part II.1 came into force. they would have been considered new substance subject to section 26 (1) of CEPA and their manufacture or import would have to cease until a notification was provided and the assessment period had expired. Inspectors may undertake an inspection to verify that manufacture or import has ceased in these circumstances

II.2.3 Has a new organism been imported or manufactured before the period for assessing information about the organism has expired?

The Regulations establish assessment period for micro-organisms in section 29.13 and for organisms other than micro-organisms in section 29.18. The assessment periods for

micro-organisms are presented in Table 1 on Page 12. The assessment period for organisms other than micro-organisms is 120 days following receipt of the information

It is an offense under CEPA paragraph 113 (e) to manufacture or import an organisms before the period for assessing the information provided in the notification has expired. Inspectors will require information on the dates that notification was made for a new organism if they are to verify that manufacture or import has not occurred prior to expiration of the assessment period.

II.2.4 Has the manufacturer or importer provided misleading or wrong information when reporting?

The information that must accompany the notification of a new substance is extensive. However. it is an offense under paragraph 114 (a) for any person to knowingly provide the Minister with any false or misleading information in purported compliance with the notification provision. section 26.

The suspicion that false or misleading information has been provided for assessment will arise when the information is being reviewed by CCEB. These suspicions should be passed on to the regional offices where an inspection may be arranged to collect any evidence that the false or misleading information was knowingly submitted.

It should be noted that there is a requirement that this offense be committed "knowingly". A person submitting information may by mistake have submitted false or misleading information. In these circumstances. the person notifying is still under an obligation under CEPA subsection 26(6) to notify the Minister of any corrections to the information as soon as possible after learning of them. An offense is committed under paragraph 112 (a) of CEPA if such corrections are not made.

II.2.5 Has a condition or prohibition placed on the manufacture or import of a new organism been contravened?

Under paragraph 29 (1) (a) of CEPA where any information submitted in notification has been assessed by the Ministers and they have the suspicion that the substance is toxic. permission may be given to manufacture or import the substance subject to conditions specified by the Ministers. Paragraph 29 (1) (b) also provides. where a substance is suspected of being toxic. a person may be prohibited from manufacturing or importing the substance. These actions may be taken by the Ministers before the assessment period has expired.

Notification of any such conditions or prohibitions must be communicated from CCEB to the regional offices. Inspectors can then conduct inspections to verify that the conditions or prohibitions are complied with. If the notifying party is not complying with the conditions or is not adhering to the prohibition. then an offense has been committed under CEPA paragraphs 113 (c) and 113 (d).

PART III: DEFINING ROLES AND RESPONSIBILITIES FOR INFORMATION FLOW IN COMPLIANCE AND PROMOTION

An effective compliance and enforcement strategy for the New substances Notification Regulations will require clear definition of roles and responsibilities. Appendix G provides a list of parties responsible for CEPA and the Regulations within Environment Canada

Note: this section requires a determination of how information is currently transferred between CCEB. Office of Enforcement and Regional Offices. It also should contain information on MoUs signed with Health and Welfare Canada or Customs Canada.

PART IV: COMPLIANCE PROMOTION AND VERIFICATION

Due to the complexity of the regulations and the numerous parties involved in their application and administration. the role of the inspector must be clearly defined. At its most basic. the role of the inspectors under CEPA and the Regulation is:

- to determine if someone has imported or manufactured a new organism under conditions and in quantities that require the importer or manufacturer to notify Environment Canada
- to determine if that person notified Environment Canada under the Regulation of their intent to import or manufacture and awaited the end of the assessment period before they began to import or manufacture in commercial quantities. and
- to verify compliance with any conditions or prohibitions imposed on the importation or manufacturing
-

The role of the inspector is discussed here in terms of the role played in identifying the regulated community. compliance promotion and compliance verification.

IV.1 Identifying the regulated community

Inspectors must identify the regulated community in order to determine who should be targeted for compliance promotion and inspections. It is important that inspectors know the potentially affected industrial sectors and how to obtain information on the activities of those sectors

The sectors that are potentially affected by the Regulations fall into two categories: the industrial sector which uses micro-organisms or organisms other than micro-organisms and the research and development sector that carries out research on and the development of products that are

micro-organisms or organisms other than micro-organisms. These sectors may not be mutually exclusive as manufacturers may carry out research and development. Likewise research institutions may operate pilot plants for industrial applications.

There are a wide range of activities that micro-organisms and organisms othan micro-organisms can be used in. Micro-organisms. in particular, may have application in environmental cleanup. waste treatment. mining. oil and gas production, manufacturing. climate control and pulp and paper industries. Environment Canada has assigned use codes for categorization of substances nominated to the Domestic Substances List. These are set out in the New Substances Advisory Note #02-96. Notification of Biotechnology Substances to the Domestic Substances List. The uses and codes that may be relevant to the manufacture or import of micro-organisms are listed in Table 2

Table 2. Use Codes for DSL Report Forms That May Apply to Micro-organisms.

Codes	Use
B1	Biodegredation
B2	Bioremediation
B3	Climate control
B4	Environmental probes
B5	Mineral leaching
B6	Pulp bleaching
04	Adhesive/ binder/ sealant/ filler
06	Antifreeze/coolant/deicer
14	Defoamer/emulsion breaker
15	Drilling mud additive/oil recovery agent/oil well treating agent
19	Flocculating/precipitating/clarifying agent
46	Surfactant - detergent/emulsifier/wetting agent/ dispersant
67	Industrial gas production
94	Textile manufacture
97	Water and waste treatment
98	Other than above (specify on an attachment)

It is difficult to categorize all the uses that a micro-organisms may be put to. Research and development activities in this area continue to use these organisms in new and innovative ways. Furthermore. since the potential regulated community is very diverse. there are numerous sources of information on the regulated community. These sources are listed below.

IV.1.1 Government data bases

Federal and provincial government departments may have data bases identifying companies and institutions manufacturing or importing micro-organisms. The New Substances Divsion of Environment Canada has identified members of the regulated community who have been informed of the new regulatory requirements for micro-organisms. Industry Canada, provincial economic development, environmental protection and natural resources agencies also may have lists of potentially affected parties.

IV.1.2 Biosafety committees and biosafety officers at universities, research facilities and companies

Universities, research facilities and companies often have biosafety committees established to ensure that the MRC Laboratory guidelines are adhered to and that research carried in contained facilities meet the required safety standards. Biosafety officers are employed to carry out the technical work required by the biosafety committee and advises the committee of plans, concerns and problems arising from research in contained facilitates. The chairs of biosafety committees and biosafety officers can be contacted directly regarding information on research and development activities carried out within research institutions and companies.

IV.1.3 Professional associations

Professional associations such as the Canadian Society of Microbiologists and the Canadian Association of Chemical Engineers may be able to provide lists of their members and the activities that they are involved in.

IV.1.4 Trade Associations/Promotional Organizations

Trade associations and promotional organizations such as the Canadian Environmental Industries Association, provincial environmental services associations such as the Environmental Services Association of Alberta, the Industrial Biotechnology Association of Canada, theToronto Biotechnology Initiative, the B.C. Biotechnology Initiative and the Canadian Institute of Biotechnology may be able to provide lists of their members identified by sector.

IV.1.5 Directories

Directories are an important means of obtaining information on members of the regulated community. Printed directories such as the Canadian Biotechnology directory, Environmental Services Association of Alberta Directory and other environmental industry directories, Dunn and Bradstreet and the British Columbia Directory of Biotechnology Capabilities are readily available for inspectors to consult. Electronic data bases identifying companies which may be members of the regulated community include Scotts Selectrory, the Info Biotech Canada company data base, AgWest Biotech's Directory of Saskatchewan Biotechnology Companies and Canadian Biotechnology 1996 in electronic format.

IV.1.6 Trade journals. trade shows, industry advertisements

Trade journals may contain articles on products which contain micro-organisms or processes that use micro-organisms. The companies involved in these activities may also be highlighted in the article.

Companies who are members of the regulated community also may promote their products at conferences and trade shows. These shows present an opportunity to communicate directly with manufacturers or importers or companies selling the products.

Company advertisements also appear in trade journals and advertising materials may be made available at trade shows. The Yellow Pages list companies that provide site remediation services under the heading "Environmental consultants".

IV.1.7 Customs brokers

A printed list of customs brokers in Canada is available from Customs and Excise. The list is sorted by municipality. It should be noted that documents in the office of a customs broker may be subject to inspection if there is reasonable grounds to believe the documentation is relevant to the administration of CEPA.

IV.1.8 Other government agencies

Provincial government departments may have some regulatory authority in relation to the regulated community. For example, licenses are required for biotechnology manufacturing plants pursuant to the Alberta Environmental Protection and Enhancement Act. Alberta Environment may be able to provide information on biotechnology manufacturing plants in that province.

Other federal government departments may have information on members of the regulated community. Industry Canada may be able to provide information on the biotechnology industry in Canada.

Environment departments of foreign governments may be contacted in relation to information on organisms being imported. The product may be subject to approval within the country of origine. For example, micro-organisms may have been subject to approval by the U.S. EPA if they required regulatory approval for testing or commercial manufacture in that country. The EPA can also provide information on enforcement actions that have been taken against companies and individuals in the US.

IV.1.9 Third party information

Third party information may come from competitors, and concerned individuals such as labor unions and environmental organizations. These "tips" may increase as the Regulations become better known to industry and the public.

IV.1.10 Contact with end users and their associations

Many companies may purchase micro-organisms to use in particular applications. These companies are not be the manufacturer or importer of the organism but they may be able to supply information on the companies that they obtain such products from. These end users may be easily contacted through their associations as listed below:

- provincial environmental services associations.
- Canadian Environmental Industries Association.
- Canadian Manufacturers Association.
- Mining Association of Canada.
- Canadian Petroleum Producers.
- Canadian Pulp and Paper Producers
- Canadian Chemical Producers.
- Canadian Petroleum Products Institute, and
- Canadian Sectors of the American Water Works Association.

Note: Who is responsible for collecting, analyzing and managing the information and for evaluating if the information is accurate and useful should be determined and identified in this part.

IV.2. Compliance promotion

Compliance may be an important activity for inspectors with the exception of those regions where program staff carry out this work. Those inspectors who are involved in compliance activities should consider the most time and cost effective means of compliance promotion. This means avoiding duplication of compliance activities carried out by CCEB and the Office of Enforcement.

Many members of the regulated community have been notified by the New Substances Division of Environment Canada regarding new regulations that will apply to them. Some have been involved in the consultations on the Regulations or participated in workshops on the Regulations offered by the Department.

However, there may be two important focus points for compliance promotion by inspectors. These are very small manufacturers or importers who may be unaware that they have obligations under CEPA and importers and manufacturers of research and development substances.

Small importers and manufacturers may be carrying out these activities in association with other businesses. Inspectors should take the opportunities to meet in person with representatives from such companies. Such meetings may take place at trade shows where small companies often promote their products. This allows inspectors to provide copies of the regulations and explain the obligations contained therein.

Importers and manufacturers of micro-organisms which are research and development substances and are exempt from notification may need special efforts in meeting their compliance obligations. Inspectors should ensure that biosafety officers and/or biosafety committees are notified directly of their need to comply with CEPA and the Regulations.

In carrying out compliance promotion, records of contacts should be maintained by inspectors to verify that companies have received compliance information. This should include the following:

- to whom information about the regulations was sent, and on what date
- a record of any conversations with the importer or manufacturer, including the name of the person and the date.

IV.3 Compliance verification

Compliance verification is an important component of the activities undertaken by inspectors. Under CEPA and the Regulations compliance verification may be required in a wide range of circumstances. These may arise where:

(1) the person, substance or situation is known to Environment Canada

(2) the person, substance and situation is unknown to Environment Canada.

For substances that are new chemicals and polymers the focus for compliance verification was on importers rather than manufacturers. It is not clear that that focus is applicable to new substances that are organisms. Both manufacturing and importation will likely require attention for compliance verification.

IV.3.1 Monitoring and compliance verification where the person, substance or situation is known to Environment Canada

Persons, substances or situations become known to Environment Canada in several ways. Firstly theses may have become known to Environment Canada during the development of the regulations. Secondly, they may become known if attempts have been made to submit organisms

for listing on the DSL or to notify the organism as a new substance. CCEB should provide information about these persons. substances and situations directly to regional offices.

IV.3.1.1 Targets for inspections

(a) Substances nominated to the DSL and rejected

A company may nominate an organism to the DSL and have it rejected. If the company wishes to continue to manufacture or import the substance. they should nominate the organism as a transitional substance. If the substances have not been so notified than the inspector may verify that the manufacture or import has ceased.

CCEB can provide regional offices with a list of persons or companies whose submissions have been rejected and for which substances Environment Canada has received no notification.

(b) Transitional substances and substances manufactured between July 1. 1994 and 1997

If the first manufacture or import of an organism has taken place between January 1. 1987 and June 30. 1994 notification will have to take place before January 1.1998. For organisms first manufactured or imported between July 1. 1994 and June 30, 1997. notification must take place before July 1997.

It is important to remember that in the case of transitional substances no infraction has occurred if manufacture or import has cease before July 1. 1994. Likewise. in the case of substances first manufactured or imported between July 1. 1994 and June 30 1997. no infraction has occurred if import or manufacture has ceased before June 30 1997.

Inspectors may wish to verify that the first manufacture or import occurred when the company claimed that it did. Furthermore. inspectors may wish to verify that once these the notification deadlines have been passed. manufacture or import has ceased.

(c) Substances subject to pre notification consultations but never notified

The New Substances Division of Environment Canada encourages manufacturers and importers to discuss the notification of a new substance with them prior to submission. Pre-notification packages may also be submitted to determine if waivers of information will be accepted and if Environment Canada has concerns that would result in prohibition of the substance. Inspections of some companies submitting pre-notification packages may be necessary to verify that the organisms not subject to further full notification are not being manufactured or imported.

(d) Substances falling under particular notification groups

Inspectors may wish to confirm that the notification group under which an organism has been notified is correct. For example. an organism may be notified under subsection 29.11 (6) of the regulations as a micro-organism manufactured at the site from which it was isolated for

introduction to the same site. CCEB should inform the regional offices of the identity of the organism. the identity of the manufacturer and the site in which manufacture is to take place so that inspectors can verify the manufacturer is in compliance.

(e) Wavier granted under 26(4)(b) check compliance with waiver conditions

Where waivers have been granted inspectors need to verify compliance with the conditions and situations that led to the waiver. Inspectors will likely need to inspect regarding the waiver justifications advanced by the company. CCEB will provide regional offices of the organism and the company for which a waver has been granted.

(f) Additional information required. conditions attached to import and manufacture. prohibition

CEPA paragraph 29 allows the Ministers to attach conditions to manufacture or importation of a substance. prohibit the importation or manufacture of a substance and request further information from a notifier or to request that the results of additional testing be provided. Inspectors may wish to verify that notifiers are complying with these requirements.

(g) Request for extension of assessment information

The Minister may extend the assessment period under CEPA subsection 28(4). Inspectors may wish to verify that manufacture or importation has not occurred in these circumstances.

(h) Suspect companies

Inspectors may informed of company activities that contravene CEPA and the Regulations and inspections will be carried out to verify information.

(i) Injunction from Minister

Inspection for compliance may be required for companies where the Minister has asked a court to issue an injunction to stop an importer or manufacturing from doing something or to get them to do something. Inspectors may conduct an inspection to verify that the injunction is being complied with.

IV.3.1.2 Inspections

Inspections of companies involving known persons. substances and situations will be relatively straight forward. CCEB should provide identification of the substance. the company name and contact information as the basis for any such inspection. Documentation such as copies of correspondence with the company will also be provided to the company. The inspector will arrange to go to the company premises where he or she will determine what activities related to the substance are occurring. Since the inspector will have determined what infraction may have occurred. the inspector can focus on the elements of the particular offense.

IV.3.2 Monitoring and compliance verification where the person. substance or situation is unknown to Environment Canada

Inspectors may have no knowledge about an importer or manufacturer of a new organism. However. the importer or manufacturer may be one that traditionally involves new organisms. Such information can be derived from activities undertaken to identify the regulated community.

Enforcement activities in relation to unknown person. substances and situations require a strategy for intelligence gathering. coordination with other government departments and agencies and clear lines of communication within Environment Canada. Coordination with other departments may involve formal arrangements (MoUs) or informal agreements with inspectors from other departments such Agriculture and Agri- foods Canada.

CCEB should provide information to regional offices on the companies from which notifications have been received. This can be used in conjunction with information on the regulated community to determine which companies have not provided notifications. This can assist inspectors in determining which companies have not notified Environment Canada and perhaps should have.

IV.3.2.1. Customs monitoring

Customs monitoring has been identified as being difficult for new chemicals and polymers. The same difficulties apply to organisms. An MoU may be considered with Customs Canada to obtain information on organisms being imported into Canada. However. the practicality of this needs to be examined in greater detail to determine the value of the information that may be obtained.

IV.3.2.2 Retailers and distributors

The inspector may conduct a "blind inspection by simply going to the manufacturer or importer and inspecting the premises. The inspector may then ask for a list of products and the components of these products. If the inspector plans to take a sample of the products. consideration must be given to the nature of the product and if sampling expertise is required.

The inspector will the have to carry out the analytical steps outline in Part II. It is important that every effort be made to determine the correct identity of the organism. Identification could include its taxonomic status. including genus. species and strain. common name. synonymous names. The number from the culture collection (for example. the American Type Culture Collection number) would also be of importance. If the organism is on the confidential list then the company should be able to supply the masked name that has been assigned to the organism. The inspector can then verify this with Environment Canada.

In some cases. the importer and those involved in the importation (truckers. customs brokers) may not know whether a product is a new organism. It may be necessary to go to the original manufacturer and ask for a detailed description of the product. There is no way to compel an out-of country manufacturer to supply such information. However, it may be in the manufactures commercial interest to cooperate.

IV.3.2.3 Research and development organisms exempt from notification

Research and development micro-organisms are exempt from notification where manufacture or import occurs below a certain quantity and under certain operating conditions. Organisms other than micro-organism also are exempt under certain conditions. Inspectors may verify that the manufacturer or importer is in compliance with the Regulations and the exemption from notification applies. Otherwise, the manufacturer or importer may have committed an offense by failing to notify a substance new to Canada.

IV.3.2.4. Product analysis

The degree of difficulty in identifying an unknown organism varies with the organism. Plants and animals (organisms other than micro-organisms) may be easier to identify then micro-organisms. All organisms can be identified by competent taxonomists to a certain level. However. micro-organisms may pose particular challenges for identification. If the organism is genetically altered (for example through recombinant DNA techniques) the identification of the genetic modification becomes exceedingly expensive and so difficult as to be impossible. There may be further difficulties in taking an appropriate sample and preserving the organism so that identification can be made. Inspectors should rely on other means of identifying the organism that can be obtained during the inspection.

PART IV: INSPECTION PROCEDURES

IV.1 Practical preparations for an inspection

Prior to carrying out an inspection the following issues must be carefully considered

1. how many people should participate in the inspection

2. what skills should these people bring to the inspection. For example. are experts on biosafety required for particular purposes.

3. what materials should be brought to the inspection.

computers
DSL
sampling equipment
cameras

tape recorder

4. which company records to ask for and why

5. how to react when the company does or does not supply information

IV.2 Support services available to inspectors while they develop region-specific inspections

1. the 1-800 number for the New substances Notification Division (CCEB)

2. a Notification Division program officer who will accompany inspectors on the inspection to assist in biosafety procedures and calculations. In the case where inspection is carried out in a laboratory where micro-organisms are research and development substances that are exempt from notification. the accompanying individual may require expertise in the MRC Guidelines and laboratory operating procedures.

3.one visit per year by a forensic accountant who will accompany inspectors. probably through a manufacturing facility to search through records to verify existence of new micro-organisms or calculate amounts imported in one calendar year.

IV.3 Inspection data required

Inspectors should acquire the following information about a micro-organism when conducting an inspection

the identity of the micro-organism. genus species and strain. common names culture collection number.

if the micro-organism is on the DSL and or if notification has been made

the use being made of the organism

what amounts have been imported or manufactures (to determine if trigger quantities have been exceeded)

when the amounts were imported or manufactured

various pieces of forensic and site intelligence

To perform these tasks. inspectors will need a general knowledge of accounting and they will need to know which records to ask for and why.

IV.4 The need for healthy skepticism

It is essential for inspectors to be somewhat skeptical when conducting inspections since it is relatively easy for members of the regulated community to mislead inspectors, even those who understand accounting and the scientific and technical aspects of manufacturing or importing organisms. Even documents that appear legitimate can be falsified. Inspectors must be skeptical of management, employees and sampling done by the company.

Inspectors must have an investigative mentality and must enter a company with a good knowledge of its type of business. They must seek out the best evidence, look for alternative sources of information and interview people. In deciding whether a company has exceeded a trigger quantity, for example, inspectors should use their powers of observation and common sense, rather than relying on accounting or laboratory records that they may not fully understand. They must go beyond the surface and beyond the obvious. However, the most important attribute of an inspector in dealing with the Regulations as they apply to organisms lies in recognizing when expert advice and assistance is required.

IV.5 Identifying relevant records

The inspector (or the forensic accounting specialist helping the inspector) must look for relevant records. Which records are relevant will depend on the nature of the companies operation and whether or not they are manufacturing or importing or if they are dealing with a research and development organism.

IV.5.1 Records associated with the manufacturing process:

The following is a partial list of documents related to the manufacturing process that may be relevant for an inspection.

(1) purchase orders: these are created by the purchaser

(2) a flow chart of the manufacturing process

(3) a recipe for the product (product specifications) the recipe is the best place to start

(4) receiving records to show that the ordered material has been received

(5) production scheduling, work schedules (especially for companies that may produce a certain micro-organism at a certain time): production scheduling is very important, because concern is how much was produced during a given period.

(6) how much of each type of inventory the company has (raw materials, work in progress, finished goods): If the company uses a perpetual inventory system, inventory figures are

more likely to be accurate (assuming the company is being honest). Inspectors should always look at inventory figures for the beginning of the year and the end of the year.

(7) waste/spoilage/inefficiencies that may cause loss of inventory: the company may have an internal reporting mechanism for this, but inspectors must remember that these figures are easy for the company to exaggerate

(8) sales records : invoices for product or sales orders even sales ledgers -- anything that indicates how much of a particular product is sold; inspectors should cross-check sales figures against production figures

(9) a company's annual report may give some idea about the nature of the company business but is not critical for an inspection; in any event, only public companies are required to file annual reports and many companies are private.

These records will help inspectors determine the identity of the organism produced, the time period when it was produced and the manufacturing conditions it was produced under.

IV.5.2 Records associated with importation

The following is a partial list of documents related to importation that may be relevant for an inspection.

(1) US/Canada Customs documents: these documents can be a good source of information because they are prepared by an independent third party; however, these documents may often be inaccurate

(2) bills of lading/weigh bills: these are transportation records; they provide information similar to that on customs records; they indicate where the substance is delivered

(3) customs brokers records: these can be checked to ensure that they correspond to customs documents

(4) invoices and shipping/recieving records: these are likely the most accurate documents because customs records are often vague or inaccurate

(5) reports made to government under other legislation

(6) inspection records (i.e. relating to dangerous goods)

(7) sales records

(8) manufacturing records: however the company might not manufacture it might simply ship the substance out after importing it. If the substance is used in the manufacturing process, inspectors may need to look at the documents outlined above for manufacturing.

IV.5.4 Records from companies importing or manufacturing research and development organisms

The records described above may in some instances be relevant in obtaining evidence in an inspection of a company dealing manufacturing or importing a research and development organism. However, in these circumstances, it will be important to review laboratory records and notebooks kept by researchers as well. The information contained in these records may be very technical so inspectors will likely require assistance in interpreting them.

IV.6 Border inspections and inspections within Canada

Inspections can occur in two main places -- at the border and in the interior of Canada. At the border point, if an inspector sees something that contains a micro-organsism, the inspector can ask to see the micro-organism. Border inspection rights are not very complicated; in essence an inspector can inspect any substance at the border.

Inspector's powers are more difficult to explain and apply for materials already in Canada. Here an inspector need reasonable grounds to inspect.

IV.6.1 Reasonable grounds to conduct an inspection

The reasonable grounds necessary to carry out an inspection differ from the reasonable grounds needed to conduct a search warrant or send a letter of warning. To obtain a search warrant there must be reasonable grounds to believe that proof of an infraction is located in the location to be searched. To send a letter of warning there must be reasonable grounds to believe that a crime has been committed.

To carry out an inspection, the inspector must have reasonable grounds to believe that the area is controlled and that it contains a regulated substance or pertinent information with regard to enforcing the law.

The fact that a biotechnology company is importing micro-organisms for example, does not constitute reasonable grounds to conduct an inspection. the Canadian Charter of rights and Freedoms and court interpretations of it do not permit "fishing expeditions" by law enforcement authorities in carrying out their duties. The purpose of requiring inspectors to have reasonable grounds before they inspect is because of the Charter right of everyone to be secure against unreasonable search or seizure. This helps protect a person's reasonable expectation of privacy.

IV.6.2 Grounds for inspections at border points

At border points, inspections are carried out based on less information than would be available for an inspection carried out within Canada. Courts have repeatedly indicated that privacy expectations are very limited at border points. For this reason, an inspector authorized under

CEPA may inspect any thing that may contain an organism regulated by the Regulations and any related information.

IV.6.3 Grounds for inspections within Canada

An inspection may be carried out anywhere in Canada if the inspector has reasonable grounds to believe that a micro-organism regulated by CEPA or information relating to the enforcement of CEPA is present (s.100(1)(a) and (f)). the expression "reasonable grounds" is interchangeable with the expression "reasonable likelihood". As a result an inspection may take place in any area under the control of individuals who import. distribute (retail or wholesale). use or manufacture products for which there is a reasonable likelihood that micro-organisms regulated under the regulations are present.

The best way for an inspector to determine if reasonable grounds to inspect exist is to be aware of substances and information present in that area. The inspector can acquire that knowledge in several ways: through personal contacts. through plausible information obtained through a third party (the official in charge of that area. an outside collaborator or a colleague from the Ministry) or other means (for example advertising. product labels or various documents).

It is not the subjective belief of the inspector. but an objective assessment by the inspector of the facts that is necessary to determine whether there are reasonable grounds to inspect. Inspectors must determine whether the information and the sources of the information are credible. The information may be communicated to inspectors in writing or orally. Inspectors must consider the totality of the circumstances in determining whether reasonable grounds exist.

Examples of information that may constitute reasonable grounds are:

an anonymous tip that has been corroborated to ascertain its credibility

credible information from law enforcement agencies

credible information from public servants

credible information from foreign governments

credible information from Canada Customs records

credible information from third parties such as customs brokers or competitors

credible information from employees or managers of the regulatee (For example it is permissible to ask an employee of a company about the company's activities. the answer may provide reasonable grounds to enter a place and inspect.

credible information obtained from manufacturers. suppliers. distributors transporters. etc.

credible information obtained from other inspectors

credible information obtained by observations of inspectors

credible information obtained from departmental records

credible information obtained from trade journals

When inspectors rely on information from an informer, it is not necessary to confirm every detail of the informer's information, as long as the sequence of events actually observed conforms sufficiently to the anticipated pattern to remove the possibility of innocent coincidence. On the other hand, the level of verification required may be higher where inspectors rely on an informant whose credibility cannot be assessed or where fewer details are provided and the risk of innocent coincidence is greater. How informers acquired the information may also be important.

Since the regulations cover many substances, it will be difficult for inspectors to develop the expertise to determine if there are reasonable grounds to justify an inspection. Inspectors and the Office of Enforcement should consult with the New Substances Notification Division to list priority micro-organisms and activities which warrant inspection.

IV.7 Generic inspection procedures for blind inspections

Blind inspections refer to situations where the inspector does not know if a violation has been committed and therefore must consider all possibilities. In short, any substance is open to inspection if reasonable grounds exist for the inspection.

At places other than retail stores, which are considered public, inspectors will need reasonable grounds to believe a new substance has been imported or manufactured in the facility, or that a violation of the Regulations has occurred. The legal requirements of "reasonable grounds" were discussed above.

The analysis that inspectors must carry out in a blind inspection is set out in Part II of this manual.

PART V: CASE SCENARIOS

Case Scenario # 1: Substance regulated under another federal act

A small company in Manitoba plans to offer a new product to their clients. This product consists of a micro-organism which has not been sold before in Canada. The owner of the company calls the Environment Canada regional office to inquire what his obligations are upon importing the product. Upon inquiry as to the identity of the micro-organism, the caller states that it is a strain of Hirsutella sphaerospora that is very effective in controlling mealy bugs on fruit trees.

Response:

The inspector responding to this call should

(a) confirm that the micro-organism does meet the criteria for being considered a substance under CEPA

(b) check the DSL to determine that the micro-organism is not listed and check the possibility it may be listed under a masked name.

(c) determine that the organism is a pest control product and confirm this with the Pest Management Regulatory Agency, Health Canada.

(d) explain to the caller that the micro-organism is not subject to notification under CEPA paragraph 26(3)(a) and Regulation section 3(1). The caller should be referred to the appropriate contact in Health Canada

Case Scenario #2: Manufacturing a research and development micro-organism not in accordance with MRC guidelines

An inspector is meeting with a biosafety officer at a University to discuss compliance issues. On the way to the meeting, the inspector passes a micro-biology laboratory where there has recently been a fire. The inspector is aware that it is the research laboratory of a well known molecular biologist who is conducting research on genetically engineered micro-organisms. The lab is still in operation but many of the facilities seem to be awaiting repair.

Response:

1. The inspector should provide the biosafety officer with an explanation of the requirements under the Regulations section 29.1. The inspector should also make it clear that if the requirements of this section are not complied with then the manufacturer or importer will have committed an offense under CEPA of failing to notify a new substance.

(2) the biosafety officer should be asked to attend the lab with the inspector to obtain a description of the organisms being manufactured or imported and their quantities.

(3) the inspector may wish to return to conduct an inspection of the laboratory. The inspection should be carried out with the assistance of experts who can evaluate the containment facilities and if the appropriate procedures for containment under the Laboratory Biosafety Guidelines are being observed. Laboratory records may be examined and personnel may be interviewed.

(4) on the basis of the inspection, a determination can be made if there has been an offense committed under CEPA.

Case Scenario #3: Manufacturing before the assessment period has expired

A company intends to manufacture and sells a micro-organism to mining companies for treating mine waste. The company notified the New Substances Notification Division of its intent to manufacture and submits the required information set out in Schedule XV on July 3. 1996 . The company has a major customer who wishes a large supply of the product so manufacture starts on August 14. 1996. New Substances Notification Division has concerns that the company has started manufacture.

Response:

(1) the regional office should have received information from CCEB regarding the notification made by the company. Since notification occurred on July 3. 1996 and the assessment period . as provided in Regulation subsection 29.11 (1). is 120 days.

(2) the concerns raised by New Substances Division warrant an inspection of the company to determine if manufacture has commenced.

(4) the inspector should collect relevant evidence of the identity of the micro-organism from records. interviews. Evidence of manufacture may be obtained from the records and further determined in interviews with personnel. Photographs should be taken of the machinery in operation at the plant as well.

(5) the outcome of the inspection will determine if an offense has been committed under subsection 118 (e).

Case Scenario # 4: Verification of conditions for an experimental field trial

An Environment Canada regional office has been informed by CCEB that a company has received approval to conduct an experimental field trial of the fungi. Candida. which has shown some promise for degrading hydrocarbons in soils. The trial must be carried out according to a number of conditions. A list of those conditions have been forwarded to the regional office.

Response:

(1) CCEB should inform the regional office of the field trial and the conditions attached to it

(2) the inspector should become familiar with the conditions set out for the field trial and ask for guidance if the conditions are highly technical

(3) an inspection could be carried out to confirm that the conditions are being adhered to

Case Scenario # 5

A caller complains to an inspector that his neighbor has a massive compost pile which smells bad and attracts flies. The neighbor has heard that new regulations under the Canadian Environmental Protection Act will cover micro-organisms. He knows that micro-organisms have something to do with composting and he wonders if Environment Canada can force his neighbor to get rid of the compost pile.

Response:

(1) the caller should be informed that while CEPA does require notification and assessment of micro-organisms new to Canada, the activities of composting do not fall within the scope of manufacture under CEPA and the Regulations. Composting is *in situ* stimulation of micro-oranisms.

(2) the inspector receiving the call, however, may wish to inspect the premises where the composting is taking place to ensure that composting is the only activity being carried out. If the organisms are being isolated and cultured then a manufacture of a new organism may be taking place and notification may be required.

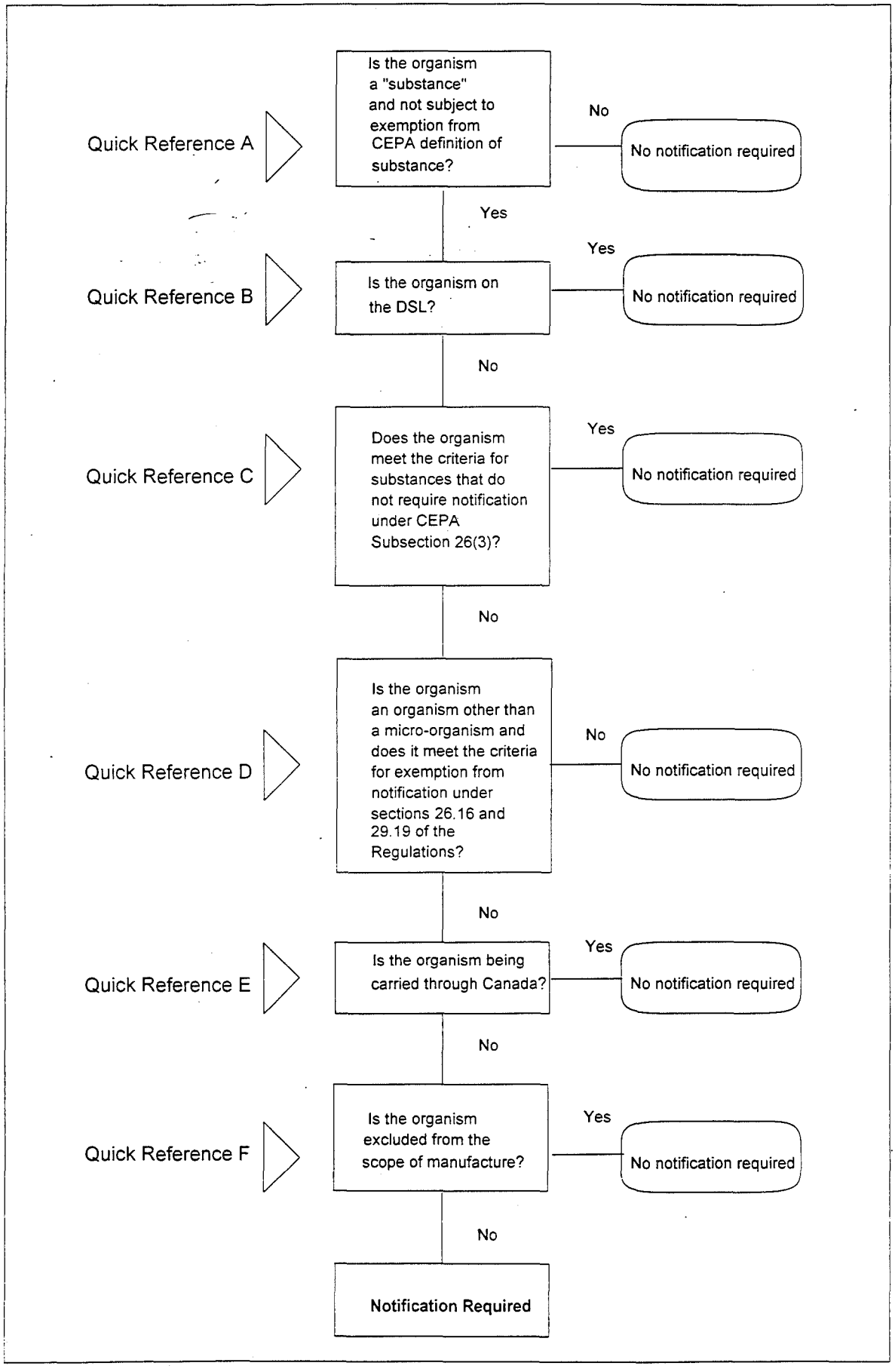
Appendix A

A Summary of Notification Groups Established for Micro-organisms in the New Substances Notification Regulations Part II.1

Notification group	Information Schedule	Notification not less than	Assessment period
manufacture or import for introduction anywhere in Canada	Schedule XV	120 days before the day on which person manufactures or imports	120 days
manufacture or import for introduction in one ecozone where it is not indigenous	Schedule XV except information in Paragraph 5(a)	120 days before the day on which person manufactures or imports under trigger conditions	120 days
manufacture or import for introduction in accordance with confinement procedures	Schedule XV except information in Paragraphs 5(a),6(c) and 6(d)	120 days before the day on which person manufactures or imports under trigger conditions	120 days
manufacture or import for introduction in any ecozone where it is indigenous	Schedule XV except information in Subparagraphs 1(f)(i),(iii) and (iv) and Paragraphs 1(i) and 5(a)	120 days before the day on which person manufactures or imports under trigger conditions	120 days
manufacture in a contained facility or import to a contained facility and not for introduction outside a contained facility, or for export only	Schedule XVI	30 days before the day on which person manufactures or imports under trigger conditions	30 days
manufacture or import for introduction to an experimental field study	Schedule XVII	90 days before the day on which person manufactures or imports under trigger conditions	90 days
manufacture and introduction at the same site from where isolated	Schedule XVIII	30 days before the day on which person manufactures or imports under trigger conditions	30 days

Appendix B

Quick Reference Flow Chart


Quick Reference A
Is the organism a "substance" and not subject to exemption from CEPA definition of substance?
No
No notification required
Yes
Quick Reference B
Is the organism on the DSL?
Yes
No notification required
No
Quick Reference C
Does the organism meet the criteria for substances that do not require notification under CEPA Subsection 26(3)?
Yes
No notification required
No
Quick Reference D
Is the organism an organism other than a micro-organism and does it meet the criteria for exemption from notification under sections 26.16 and 29.19 of the Regulations?
No
No notification required
No
Quick Reference E
Is the organism being carried through Canada?
Yes
No notification required
No
Quick Reference F
Is the organism excluded from the scope of manufacture?
Yes
No notification required
No
Notification Required

Quick Reference A

Is the organism a "substance" and not subject to exemption from the CEPA definition of substance ?

Substance is defined in CEPA section 3 as:

any distinguishable kind of organic or inorganic matter, whether animate or inanimate, and includes

(a) any matter that is cap able of being dispersed in the environment or of being transformed in the environment into matter that is capable of being so dispersed or that is capable of causing such transformations in the environment,

(b) any element or free radical.

(c) any combination of elements of a particular molecular identity that occurs in nature or as a result of a chemical reaction,

(d) complex combinations of different molecules that originate in nature or are the result of chemical reactions but that could not practicably be formed by simply combining individual constituents.

Important Exceptions to the CEPA Definition of "substance"

CEPA section 3 also limits the definition of substance
No notification is required for

(a) any mixture that is a combination of substances and does not itself produce a substance that is different from the substances that were combined,

(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, or

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

Quick Reference B

Is the organism on the DSL?

Substances may be included on the DSL if:

(a) they were in commercial use in Canada between January 1, 1984 and December 31, 1986 (subsection 25(1) CEPA); or

(b) the government has received all the prescribed information under section 26 of CEPA, and an assessment by the departments has determined that no controls should be imposed and that the import or manufacture has exceeded the quantities prescribed under section 30 of CEPA

Quick Reference C

Does the organism meet the criteria for substances that do not require notification under CEPA subsection 26(3) ?

CEPA subsection 26(3) establishes criteria for new substances that do not require notification. These are

(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 toxicity,

(b) transient reaction intermediates that are not isolated and are not likely to be released into the environment,

(c) impurities, contaminants and partially unreacted materials the formation of which is related to the preparation of a substance,

(d) substances produced when a substance undergoes a chemical reaction that is incidental to the use to which the substance is put or that results from storage or from environmental factors

(d) a substance that is manufactured or imported in a quantity that does not exceed the maximum quantity prescribed as exempt from this section.

Quick Reference D

Is the organism an organism other than a micro-organism and does it meet the criteria for exemption from notification under sections 29.16 and 29.19 of the Regulations?

A micro-organism is defined in subsection 2(1) of the Regulations as 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 organisms not referred to in paragraphs (a) and (b), other than a cell used to propagate such organism; or

(d) any culture other than a pure culture.

An organism other than a micro-organism is not defined in the Regulations but includes all living organisms not captured in the definition of micro-organism in subsection 2(1).

Sections 29.16 and 29.19 of the Regulations provide that no notification is required for organisms other than micro-organisms if

(a) the organism is a research and development substance, and

(b) there is no release from the facility to the environment of the organism, the genetic material of the organism or material from the organism involved in toxicity

Quick Reference E

Is the organism being carried through Canada?

Section 3 of the Regulations provide and exemption for new substances loaded on a carrier outside of Canada and moved through Canada.

Quick Reference F

Is the organism excluded from the scope of manufacture?

An organism not isolated from its environment and processed is some way is not considered a "manufacture " under CEPA. Therefore the following activities do not require notification

(a) *in situ* stimulation of organism growth by adding nutrients or altering by physical means such as tilling,

(b) municipal and industrial wastewater treatment that does not isolate and process the organism, and

(c) composting and septic tank operations that do not isolate and process the organism from the treated waste.

Appendix C

Information on the Domestic Substances List

The Domestic Substances List (DSL) and the Non-domestic Substances List (NDSL) are available are in hard copy. standard 5 ¼ "diskette (MS-DOS. ASCII file) and CD-ROM. Organisms appearing on the DSL and NDSL may be identified by genus and species and strain and other identifying information. Confidential organisms are identified on the DSL using masked identities named in a manner prescribed by the Confidential Information Disclosure Regulations.

The original DSL and NDSL were published on January 26. 1991 as a supplement to Canada Gazette Part I . Substances notified as new substances remain new substances (and thus notifiable for a second party) until they are published as a supplement to the DSL in the Canada Gazette. Supplements to the Gazette will be published when required and quarterly updates to the DSL will be available on CD-ROM.

The Canada Gazette is available in subscribing libraries and institutions as well as Environment Canada regional offices and district offices. Importers and manufacturers can buy published formats of the list through the following suppliers.

In Canada:

Canada Communication Group Publishing
Ottawa. Ontario. Canada K1A 0S9
Tel: (819) 956 -4802
Fax: (819) 994-1498

In the USA:

International Specialized Book Services Inc.
5602 NE Hasslo St..
Portland. Oregon.
USA. 97213

Tel: (800) 547 - 7734
Fax: (503) 284 - 8859

In Europe:

Books Express
P.O. 10
Saffron Walden
Essex CB11 4EW
England
Tel: (0799) 513726
Fax: (0799) 513248

The following information must be included with the order

Non-domestic Substances List Cat # EN40-398-1991

Importers and manufacturers can telephone or fax the NSN line to obtain standard 5 ¼ " diskette (MS-DOS. ASC11 file) versions of the DSL and NDSL (check this)

The DSL and NDSL on CD-ROM can be obtained from the CCINFO service. Canadian Center for Occupational Health and safety. 250 Main Street East. Hamilton. Ontario L8N 1H6. 1-800-263-8340.

Appendix D

Contacts in other federal departments

The following contacts allow inspectors to determine if a micro-organism or an organism other than a micro-organism is regulated under another federal act and hence exempt from notification under CEPA.

Organisms	**Federal Act**	**Contact**
Pesticides	The Pest Control Products Act	Pest Management Regulatory Agency, Health Canada Tel: 1-800-267-6315
Plants	The Seeds Act	Plant Biotechnology Office Food Inspection Directorate Agriculture and Agri-Food Canada Tel:(613) 952-8000
Fertilizers	The Fertilizers Act	Fertilizers Section Food Inspection Directorate Agriculture and Agri-Food Canada Tel:(613) 952-8000
Animal Feeds	The Feeds Act	Feeds Section Food Inspection Directorate Agriculture and Agri-Food Canada Tel:(613) 952-8000
Veterinary biologics	The Health of Animals Act	Veterinary Biologics and Biotechnology Section Animal and Plant Health Directorate Agriculture and Agri-Food Canada Tel:(613) 952-8000
Food, drugs, cosmetics, medical devices	Food and Drugs Act	Office of Biotechnology, Food Directorate (food, food additives, veterinary drugs) Tel: (613) 952-5137 Directors Office Bureau of Biologics, Drugs Directorate, Health Canada (drugs for human use) Tel: (613) 957-8065 Director's Office, Environmental Health Directorate, Health Canada (medical devices) Tel: (613) 957-4786

Appendix E

Offenses under CEPA and the Regulations

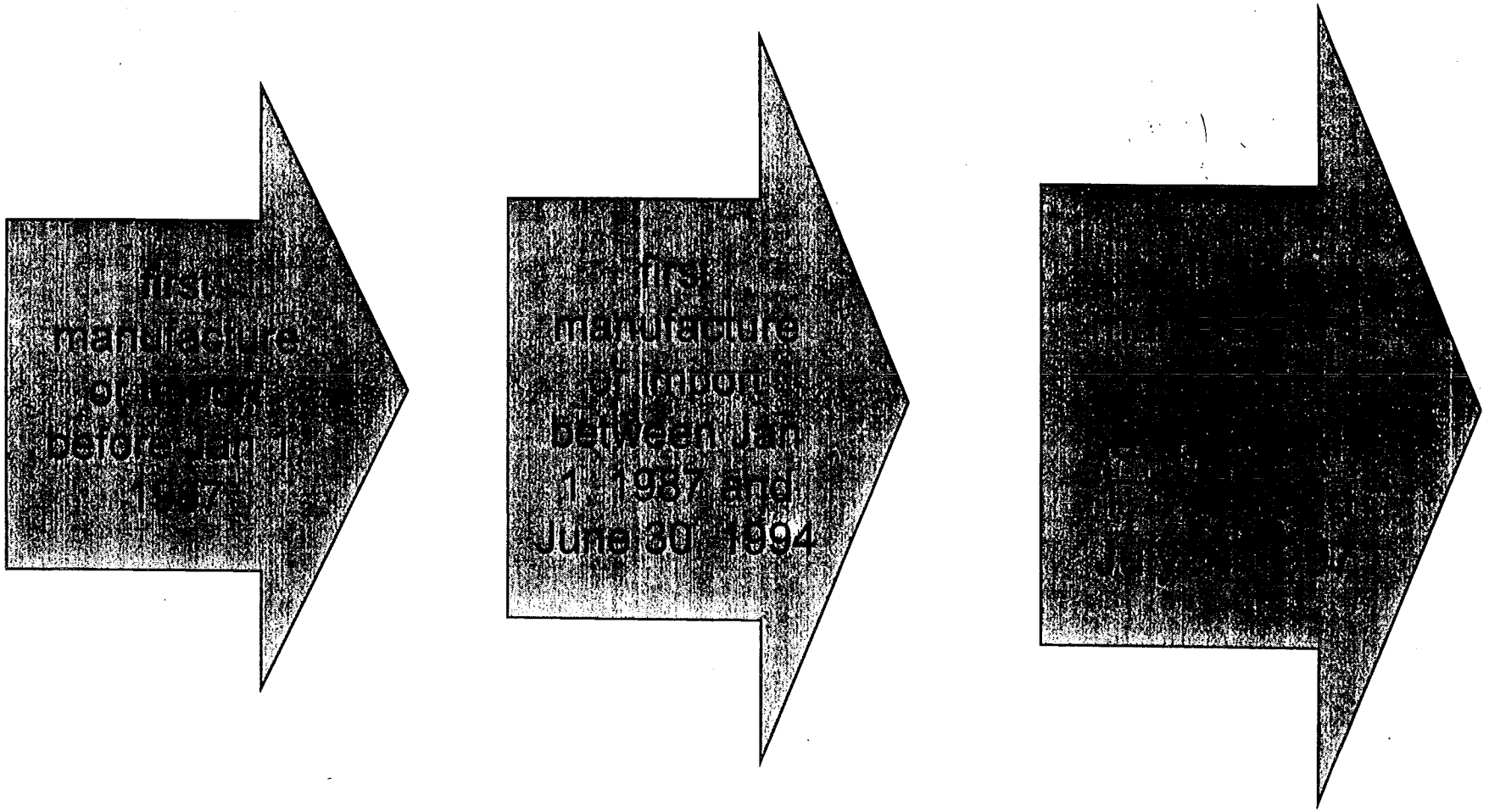
Violation	of CEPA section	under CEPA section
Importing or manufacturing a new substance without having provided the prescribed information	26(1)(a)	112(a)
Importing or manufacturing a new substance before the expiration of the assessment period	26(1)(b)	113(e)
Importing or manufacturing a transitional substance without providing the necessary information prior to the prescribed date	26(2)	112(a)
Failure to notify the Minister of corrections to the information provided	26(60	112(b)
Failure to notify the Minister that the prescribed quantity for inclusion into the DSL has been exceeded within 30 days	26(7)	112(b)
Failure to provide information requested by the Minister following a violation of Subsection 26(1)	27(1)	112(a)
Resuming activities prior to the expiration of the assessment period after activities have been prohibited and information has been requested by the Minister following a violation of 26(1)	27(1)	113(i)
Resuming activities prior to providing the required information after actvities have been prohibited by the Minister following an infraction to subsection 26(2)	27(2)	112(a)
Contravening the conditions of importation or manufacture as specified by the Minister	27(2)	112(a)
Contravening the prohibition on importation or manufacture imposed by the Minister	29(1)(b)	113(d)
Manufacturing or importing a substance without submitting the information requested under Section 29(1)(c)	29(2)(a)	113(e)
Manufacturing or importing a new substance prior to the expiration of the assessment period of the additional information requested under Section 29(1)(c)	29(2)(b)	113(e)
Contravention to any regulations or prohibitions made by the Minister following a determination that the new substnace is toxic	34 and any such regulations	113(f)
Providing false or misleading information to the Minister	26.27. 27(1)(c)	114(a)
Failing to give inspector all reasonable assitance to enable inspector to carry out functions and duties under CEPA. or Failing to provide inspector with information with respect to the administration of CEPA and the regulations that the inspector may require	102	111(a)

Violation	**of CEPA section**	**Under CEPA section**
Knowingly making a false or misleading statement. either orally or in writing. to an inspector carrying out duties under CEPA (section 103(a). or otherwise hindering or obstructing an inspector carrying out duties under CEPA section 103(b)	103 (a) and (b)	111(b)
Removing. altering or interfering in any way with any thisn siezed and detained by an inspector under section 104(1) or 101(2)	104(6). 116	116
Failing to provide the minister with information or samples as required under CEPA section 16 or 18(1)(b)	16.18(1)(b)	112(a)
Failing to notify the Minister that the person is engaged in an activity involving a substance that is toxic or is capable of becoming toxic	18(1)(a)	112(b)
Failing to conduct the toxicological and other tests that the Minister may specify in the notice or failing to submit the test results to the Minister	18(1)(c)	112(c)
Failing to provide information to the Minister forthwith where the person has obtained information that reasonably supports the conclusion that the substance is toxic or is capable of becoming toxic	17	113(a)
Conducting a false or misleading test in purported compliance with a notice under 18(1)(c)	18(1)(c)	113(b)
Failure to comply with the conditions imposed in a waiver under section 26(4)	26(4)	116
Knowingly giving a false or misleading statement to an inspector.	111(b)	111(b)
Knowingly giving the Minister false or misleading Information	114	114
Intentionally or reclessly causing an environmental disaster	115(1)(a)	115(1)(a)
Showing wanton or reckless disregard for the lives or safety of others. causing risk of death or harm	115(1)(b)	115(1)(b)
Showing wanton or reckless disregard for the lives or safety of others and actually causing death or bodily harm	115(2) and Criminal Code sections 220 and 221	115(2) and Criminal Code sections 220 and 221

Violation	of CEPA section	Under CEPA section
Failing to permit a person carrying out a search under section 101: (a) to use or cause to be used any computer system at the place to search any data contained in or available to the computer system for data from which a record that the person named in the warrant is authorized to search for or may be produced, or (b) to obtain a physical copy of the record, or (c) to use or cause to be used any copying equipment at the place to make copies of the record	101 (2)	116
contravening any provision of CEPA, other than provisions referred to in sections 111 to 115, or contavening any regulation made under CEPA	116	116

Appendix F

Time Requirements for Notification



nominate to the DSL
if criteria met under
CEPA subsection 25 (1)

notify under appropriate schedule in
Regulations sections 29.14 or 29.19

information must be submitted by
Jan 1, 1998 for manufacture or import to
continue

notify under appropriate schedule

information must be submitted and
assessed before
July 1, 1997 for manufacture or
import to continue

Appendix G

Contacts within Environment Canada

Information and assistance for the inspector is available from several groups and/or offices within Environment Canada.

New Substances Division
Commercial Chemicals Evaluation Branch
Environment Canada
Ottawa , Canada
K1A 0H3

Toll free Number: 1-800-567-1999 (Within Canada)
Hot-line Number: (819)953 - 7156
Fax: (810) 953-7155

Center	Contact	Contact Numbers
Atlantic Region	David Aggett Chief, Enforcement Division	(902) 426-5048
Quebec Region	Paul Laramee Chef, Section des inspections	(514) 283-7000
Ontario Region	Mark Vanderlaan Head, Inspection and Technical Services	(416) 739-5861
Prairie and Northern Region	Robert Patzer Chief, Regulatory Enforcement and Investigations Section	(403) 468-8075
Pacific and Yukon Region	Bruce Kay Head, Inspections	(604) 666-6711
New Substances Division	Danie Dube Head, New Substances Notification Section	(819) 997-3202
Chemical Control Division	Scott Howarth, Head, Use Patterns Selection	(819) 953-1665