CANADIAN INSTITUTE FOR ENVIRONMENTAL LAW AND POLICY

L'INSTITUT CANADIEN DU DROIT ET DE LA POLITIQUE DE L'ENVIRONNEMENT

*Est. 1970*

# OUTLINE OF AN ENFORCEMENT AND COMPLIANCE STRATEGY FOR THE MICRO-ORGANISM PROVISIONS,

# NEW SUBSTANCES NOTIFICATION REGULATIONS,

# CANADIAN ENVIRONMENTAL PROTECTION ACT

Prepared by:

Glennis M. Lewis, LL.B, Ph.D.
Research Associate

and

Mark S. Winfield, Ph.D.
Director of Research

for

Office of F[illegible]
Environm[illegible]



March 29, 1996
Contract #K2412-5-0125



517 College Street, Suite 400 • Toronto, Ontario • M6G 4A2 • Tel: (416) 923-3529 • Fax: (416) 923-5949
E-mail: cielap@web.apc.org • Home Page: http://www.web.apc.org/cielap

## Table of Contents

# Outline of an Enforcement and Compliance Strategy for the Micro-organism Provisions

## New Substances Notification Regulations
## Canadian Environmental Protection Act

## I. INTRODUCTION

New provisions proposed for the New Substances Notification Regulations under the *Canadian Environmental Protection Act* (CEPA) will extend the scope of the Regulations to micro-organisms. These provisions will require regulatees to notify Environment Canada prior to the importation or manufacture of any micro-organism new to Canada.

The Office of Enforcement of Environment Canada will implement an enforcement and compliance strategy for the new micro-organism provisions as they become law. The strategy was initiated with the completion of a section by section legal analysis of the proposed micro-organism provisions of the CEPA New Substances Notification Regulations in October 1995.[1]

The completion of this legal analysis was followed by a meeting held in Ottawa on December 14 and 15, 1995, attended by the authors and representatives of the Commercial Chemicals Evaluation Branch (CCEB), the Office of Enforcement (OOE), and Regional Environmental Protection Service Officials. The gathering canvassed the views of the participants on the development and implementation of a compliance and enforcement strategy for the proposed regulations.

This document provides an outline of the issues associated with an enforcement and compliance strategy for the micro-organism provisions. It also provides an overview of the strategies that could be taken to address these issues. The analysis is based on the comments made at the Ottawa meeting and the issues identified by the authors. The major components of the proposed enforcement and compliance strategy include:

* the identification of potential regulatees;

* the development and implementation of a communications plan with potential regulatees regarding contents and requirements of the regulations;

* the development of a training manual and the conduct of a training program for Environment Canada inspectors regarding the regulations, based on that developed for the CEPA New Substances Notification Regulations as they apply to chemicals and polymers;[2]

* the development and implementation of a plan for the coordination of activities within Environment Canada regarding the enforcement of the regulations, particularly between the Office of Enforcement, the Commercial Chemicals Evaluation Branch and Regional Offices of the Environmental Protection Service;

* the development and implementation of a plan for the coordination of the activities of Environment Canada and other government departments, particularly the Department of National Revenue (Canada Customs) and Health Canada, in the enforcement of the regulations; and

* the development of a strategy for ongoing education regarding changes in the application and requirements of the regulations for potential regulatees, Environment Canada officials, and officials of other affected government departments.

This document seeks to outline a full implementation strategy for the proposed regulations. Elements of the strategy may need to be modified or, in some cases eliminated depending upon the level of resources available within the Office of Enforcement and elsewhere in Environment Canada for its implementation.

## II. ELEMENTS OF AN ENFORCEMENT AND COMPLIANCE STRATEGY

### 1. Identifying Potential Regulatees

The proposed amendments to the New Substances Notification Regulations will impose a new regulatory regime on individuals or companies who intend to manufacture or import micro-organisms that are new to Canada. A micro-organism is defined in the proposed provisions 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 animal or plant, other than a cell used to propagate an animal or a plant; or

(d) any culture other than a pure culture.[3]

However, the CEPA New Substances Notification Regulations will only apply to micro-organisms for which pre-manufacturing or importation notification and an assessment of whether the micro-organisms is capable of being "toxic" as defined by CEPA,[4] is not required under another Act of Parliament. This is due to the provisions of Subsection 26(3)(a) of CEPA. Micro-organisms which are intended to be used as pest control products and are regulated under the *Pest Control Products Act*, or which are fertilizers and are regulated under the *Fertilizers Act*, would, for example, be exempted from the requirements of the proposed CEPA regulations as a result of these provisions.

#### i) Potentially Affected Industrial Sectors

Notwithstanding the exemptions provided through Subsection 26(3)(a) of CEPA for micro-organisms whose use is regulated under other Acts of Parliament, the proposed CEPA regulations will apply to a diversity of industries and individuals importing or manufacturing micro-organisms which are new to Canada. This will include any company or person manufacturing or importing micro-organisms for such purposes as:

* the degradation of organic pollutants contaminating soils, groundwater, and sludges (bioremediation);

* waste treatment and conversion, including municipal waste treatment in sewage treatment plants, municipal solid waste composting or the conversion of agricultural wastes;

* the production of specialty chemicals such as dyes, enzymes and pharmaceuticals;

* ore and mineral leaching;

* cloud seeding;

* snow-making;

* wax and grease removal from oil and gas wells and other facilities or equipment;

* the production of biofuels such as ethanol, methane, and other hydrocarbons;

* the de-sulphurization of fossil fuels;

* enhanced oil recovery;

* biomass conversion (the conversion of plant biomass into commercially valuable products); and

* biomonitoring or the use of biosensors.[5]

The implementation strategy will have to identify all sectors of potential regulatees, as they will need to be informed of their obligations pursuant to CEPA and the regulations for micro-organisms. Potential regulatees may be identified through trade organizations representing potential importers, manufacturers or users of microbial products of biotechnology.

Associations of this nature include the Industrial Biotechnology Association of Canada (IBAC), the Canadian Environment Industries Association (CIEA), the Mining Association of Canada (MAC), Canadian Association of Petroleum Producers (CAPP), the Canadian Chemical Producers Association (CCPA), the Canadian Petroleum Products Institute (CPPI), Canadian Sections of the American Water Works Association, and others. Provincial economic development, environmental protection, and natural resources agencies may also be able to assist in the identification of companies and individuals involved in the importation or manufacturing of micro-organisms.

### ii) Potentially Affected Research and Development Activities

Individuals and organizations importing or manufacturing micro-organisms for research and development purposes may also be affected by the notification requirements of the proposed micro-organism provisions of the New Substances Notification Regulations. This will include research and development activities in private and university research facilities. Federal, provincial and territorial government laboratories are potentially subject to the requirements of the regulations as well, as CEPA is binding on the federal and provincial Crowns.[6]

In order to be exempted from the regulations, importers and manufacturers of microorganisms for research and development purposes must meet the following requirements specified in the Regulations:

1. they must be importing or manufacturing a research and development micro-organism. This is a micro-organism that is undergoing systematic investigation or research by means of experimentation or analysis other than test marketing; and

2. they must be manufacturing or importing the micro-organism below the trigger quantities for notification and meeting the specified operating procedures for contained facilities as set out in the *Laboratory Biosafety Guidelines, 1990*, developed by the Department of National Health and Welfare and the Medical Research Council of Canada.[7]

Individuals and organizations working with research and development micro-organisms who may be affected by the regulations could be identified through university biosafety offices, professional organizations such as the Canadian Society of Microbiologists, federal, provincial and territorial government agencies within which research involving micro-organisms occurs, and the industrial organizations noted earlier.

## 2. Communicating with Potential Regulatees

The proposed provisions for micro-organisms are very complex and will require clear explanation to ensure that all potential regulatees fully understand their responsibilities. A communications plan should be formulated and put in place to explain the new regulatory requirements to potential regulatees. The plan should include the following elements.

## i) The Development of Contact Lists

Contact lists for the distribution of information regarding the new regulations will need to be developed for the following sub-categories.

### a) Potential Regulatees

This category will include individuals, firms, and other private, government and university bodies engaged in the manufacture or import of microorganisms, including manufacture or import for research and development purposes. This contact list may be developed from the existing contact list for the proposed regulations which has been developed by the CCEB, and through contacts with the relevant professional and trade associations.

### b) Relevant Trade and Professional Organizations

This category may include such organizations as IBAC, CEIA, MAC, CAPP, CCPA, CPPI, Canadian Society of Microbiologists, Canadian Sections of the American Water Works Association, and others.

### c) Academic Institutions and other Research Organizations

This category would include university departments of microbiology, and of environmental and chemical engineering, and university, hospital and government laboratory biosafety offices. Health Canada may be of assistance in the development of a list of relevant contacts in these categories.

### d) Media

This would include general national media, and the relevant trade, professional and academic journals. National media contact lists should be available through Environment Canada's communications branch. However, lists of trade, professional and academic journals whose readership includes industries and researchers potentially affected by the CEPA biotechnology regulation may have to be developed.

### ii) The Distribution of Information and Educational Materials to Potential Regulatees

Ideally, all potential regulatees should be provided with a copy of the Regulations and the accompanying guidelines being developed by the CCEB. These materials should be accompanied by a plain language explanation of the application and requirements of the regulations. This explanatory document should be as brief and concise as possible, and give particular attention to the triggers for the application of notification requirements. It should attempt to make clear to potential regulatees the circumstances under which the regulations may apply to them, and when it may be appropriate to contact CCEB for clarification or more information.

In addition, the existing 1-800 service provided to regulatees by the CCEB with respect the chemical and polymer provisions of the CEPA New Substances Notification Regulations should be extended to deal with inquiries from individuals an organizations potentially affected by the new micro-organism provisions of the Regulations. Information on the proposed Regulations should also be placed on Environment Canada's Green Lane World Wide Web site.

### iii) The Presentation of Information Seminars and Workshops on the Regulations to Potential Regulatees

In addition to the distribution of written materials, seminars or workshops on the proposed regulation should be offered to potential regulatees. These could take the form of special purpose events organized and presented by Environment Canada or by non-governmental organizations or private firms experienced in the organization of such events, with the participation of Environment Canada staff. Environment Canada staff might also make presentations on the application and requirements of the regulations at special sessions during relevant trade, professional and academic meetings and conventions.

### iv) Outreach Through Media

The publication of the proposed regulations in *Canada Gazette II*, should be accompanied by a media release to the national environmental and business media, and to relevant trade, professional and academic journals. Arrangements for follow-up with the relevant trade, professional and academic journals should be made to ensure that coverage occurs. The placement of advertisements in such journals by Environment Canada regarding the coming into force of the new regulations and indicating where to get additional information regarding the regulations should also be considered.

### v) Ongoing Communications with Potential Regulatees

Provision will also have to be made for ongoing communications with potential regulatees, regarding new policies and practices, new interpretations of the meaning of provisions of the Regulations, and how situations unforseen at the time of the development and coming into force of the regulations should be dealt with.

The communication of information of this type will require the maintenance of a contact list of potential regulatees and representative associations. Specific communications materials and strategies will have to be developed on a case by case basis. A regular newsletter to regulatees from the CCEB may provide an effective means of keeping them up-to-date about the requirements and interpretation of the Regulations. Updates should also be provided on Environment Canada's World Wide Web site.

## 3. Producing a Training Manual for Inspectors and Conducting An Inspectors' Training Program

The proper training of inspectors to meet their responsibilities will be essential to the successful implementation a compliance and enforcement strategy for the Regulations. The training portion of the enforcement and compliance strategy for the proposed CEPA regulations for micro-organisms should consist of two elements:

i) the development a training manual for inspectors; and

ii) the delivery of an inspectors' training program.

### i) Producing An Inspector's Training Manual

The CEPA micro-organism regulations training manual for inspectors should follow the format of the training manual which as been developed for the CEPA New Substances Notification Regulations for chemicals, and polymers. It should include flow charts and diagrams, and attempt to explain the regulatory requirements in plain language. The manual could be organized to include the following sections.

**a) A General Overview of CEPA and the Regulations**

This section would provide the inspector with background information on CEPA and the Regulations.

**b) An Overview of the Role of Inspectors in the Implementation and Enforcement of the Regulations**

This section would provide an overview of the inspector's role in enforcement and compliance activities related to the micro-organism provisions. It could also review Environment Canada's general policies and practices regarding enforcement and compliance, including the use of auditing in promoting compliance, with respect to CEPA.

**c) An Explanation of the Relevant CEPA Provisions**

This section could begin with a description of the role and status of the Domestic Substances List (DSL) and the Non-domestic Substances List (NDSL), including the criteria by which micro-organisms are placed on these lists. These criteria are currently being developed by CCEB. The introductory portion of this section could also provide background information on the notification and assessment process required by the Act.

This section should focus on those provisions in CEPA that inspectors will need to understand in order to carry out their duties in relation to the micro-organism provisions of the New Substances Notification Regulations. Detailed explanations should be provided to inspectors regarding:

* why micro-organisms are classified as "substances" under CEPA. In particular, the application of the definition of "substance" under CEPA to formulations and consortia of micro-organisms should be explained fully;

* what activities constitute the "manufacture" of a micro-organism under CEPA. Practical examples would serve to illustrate how the isolation and culturing of a micro-organism is interpreted as "manufacturing" in the context of the Act;

* the circumstances under which CEPA does not apply to the manufacture and importation of micro-organisms. This section of the manual should set out and explain the provisions of Subsection

26(3)(a) of CEPA. These provisions provide that notification is not required for a micro-organism manufactured or imported for a use that is regulated under any other federal act that provides for notice to be given prior to the manufacture, import or sale of the substance and for an assessment of whether it is "toxic." This exemption would apply, for example, to micro-organisms that are subject to notification and assessment under the *Pest Control Products Act* or the *Fertilizers Act*. Inspectors will need a "regulatory road-map" for micro-organisms that fall under other federal acts and do not require notification under CEPA;

* how certain information requirements can be waived under Subsection 26(4) of CEPA. Inspectors may encounter regulatees who have been granted a waiver and, hence, have not submitted all the information required under the regulations; and

* how micro-organisms imported or manufactured may be subject to claims of confidentiality under CEPA. Inspectors may need to understand how to deal with regulatees who have made such claims under the confidentiality provisions of Section 19 of the Act.

## d) An Explanation of the New Substances Notification Regulations Provisions for Microorganisms

This section would introduce inspectors to the relevant micro-organism provisions in the New Substances Notification Regulations. The bulk of the provisions for micro-organisms consists of schedules of specific information requirements for regulatees. Inspectors would likely not benefit from a detailed description of these requirements. However, a brief introduction to the general workings of the micro-organism provisions and the risk assessment process undertaken by the CCEB would serve as important background information.

Most importantly, this section should equip inspectors with a detailed understanding of the following:

* a clear definition of regulatory scope including how the regulations apply to such activities as pharmaceutical production, waste water treatment and composting. The regulatory scope will be further clarified by CCEB;

* how notification is made and the time requirements for notification and assessment;

* how the transitional provisions apply to regulatees who have manufactured or imported a new micro-organism during the transitional and post-transitional periods. The transitional period is the period between January 1, 1987 and June 30, 1994, the date when the notification requirements of CEPA came into force.[8] The transitional provisions are set out in Subsection 26(2) of CEPA and they are particularly complex. They will require careful explanation to inspectors.

* how the post-transitional notification requirements apply to substances manufactured in or imported into Canada between the end of the transitional period and the date the Regulations come into force. The application of these provisions must be clarified by CCEB and explained carefully to inspectors; and

* how the exemptions for research and development micro-organisms apply. Inspectors will have to be familiar with the trigger quantities and the biosafety operating procedures as required in the *Laboratory Biosafety Guidelines, 1990*. CCEB will determine how the Guidelines apply to micro-organisms that are not currently covered in that document.

* how field trials of micro-organisms involving open release into the environment are approved and monitored under the Regulations.

### e) Roles and Responsibilities in the Administration of the Regulations

The manual should explain clearly the roles and responsibilities of the different branches of Environment Canada (e.g. OOE, CCEB, and Regional Offices of the Environmental Protection Service) and of the other government departments and agencies (e.g. Health Canada and Canada Customs), involved in the implementation of the Regulations.

### f) Compliance Promotion and Monitoring, and Inspections and Investigations

The manual should identify the regulated community to inspectors and outline their role in educating interested parties and regulatees. It should also provide clear guidance on measures to be taken by inspectors to promote compliance. It should set out the possible offenses under CEPA and identify the likely and appropriate points of intervention for inspectors.

Inspectors will have to deal with regulatees who are either known or unknown to Environment Canada. Known manufacturers or importers will typically be those who have provided notification data for the import of manufacture of a micro-organism and who have been brought to the attention of inspectors by the CCEB. Manufactures or importers of this type may be encountered in one of the following circumstances:

* the importer or manufacturer has nominated a micro-organism for inclusion on the DSL but it has been rejected. Inspectors may need to monitor these manufacturers or importers to determine if they are manufacturing or importing without notification contrary to CEPA;

* an importer or manufacturer has notified of his or her intent to manufacture or use a micro-organism in a contained facility, under the appropriate Schedule in the Regulations. If the assessment by CCEB has occurred and permission has been granted, then manufacturing or importation can occur. Inspections of the importer or manufacturer's facilities may be required to ensure that they meet the definition of "contained facility" as provided in the Regulations;

* notification of the intended manufacture or import of the micro-organism has been made but manufacturing or importation occurs before the assessment period provided in the Regulations has elapsed;

* questions have arisen, most likely within the CCEB, regarding the possibility that a regulatee has submitted false or misleading notification information. Inspections may be required to collect evidence to verify this;

* corrections are required to information submitted in the notification process and questions arise as to whether those corrections have been made. Inspections may be required to collect evidence to verify this;

* inspections may be required to ensure that field tests of micro-organisms approved under the Regulations comply with any conditions imposed by Environment Canada; and

* inspections may be required to confirm compliance with any conditions or prohibitions imposed under Subsection 29(1) of CEPA on a biotechnology product where the product is "suspected of being toxic."

Inspectors may also be called to act upon tips regarding contravention of the Regulations by manufacturers or importers who are unknown to Environment Canada. This will involve circumstances where the micro-organism is not on the DSL and no notification has been made. Such situations may include:

* the importation or manufacturing of a micro-organism for commercial purposes for which notification has not been made under CEPA or another Act of Parliament;

* circumstances where the micro-organism is a research and development micro-organism and no notification is required if the conditions specified in the regulations are met. Inspection may be carried out to confirm that importation or manufacturing is occurring at or below the amounts specified in the regulations for exemptions, and that the biosafety procedures, as established by the *Laboratory Biosafety Guidelines, 1990*, are being adhered to as required by the Regulations.

## g) Inspection Procedures

This section would set out the procedures for inspectors to follow during inspections. It could serve as a checklist to guide an inspector through an inspection. Such a checklist could, for example, direct the inspectors to consider the following actions:

* determining if the micro-organism is regulated under CEPA;

* verifying if notification has been submitted by calling the CCEB or examining the acknowledgement letter received by the regulatee from the CCEB;

* sending compliance information materials to regulatees;

* verifying compliance with containment requirements for micro-organisms notified under the "contained facility" Schedule of the regulations;

* verifying compliance with any conditions or prohibitions imposed on micro-organisms "suspected of toxicity" through Subsection 29(1) of CEPA;

* checking for compliance with control letters issued by CCEB after assessment period has lapsed(30 to 120 days) and checking to determine if assessment period has been extended by the Minister of Environment;

* verifying importation or manufacturing below the notification trigger quantities by research and development facilities, and verifying the compliance of such facilities with the requirements of the *Laboratory Biosafety Guidelines, 1990*;

* verifying the compliance of field trials of micro-organisms with any conditions imposed by Environment Canada; and

* collecting evidence as necessary, including documentary evidence and samples of substances.

A common reporting format for inspections should also be included in this section.

Particular attention should be paid to the question of the collection of evidence and the obtaining of product analyses by inspectors. In this context, the Office of Enforcement (OOE) must determine its approach to these issues in terms of:

* the difficulties inherent in obtaining and maintaining the integrity of samples of living organisms;

* the difficulties in obtaining an analysis to identify organisms in light of the limited number of experts in the field and their likely inexperience in handling samples as evidence;

* the occupational health and safety concerns of inspectors during inspections and in the taking of samples of unknown micro-organisms;

* the application of the *Transportation of Dangerous Good Act* or the equivalent provincial legislation to the transportation of samples from the site of their collection to a facility able to conduct the required analyses.

## h) Representative Case Studies

Case studies should be included in the manual to illustrate a range of circumstances which inspectors may encounter and appropriate applications of the proposed regulations to these circumstances. Possible case study examples include:

* dealing with regulatees who are manufacturing or importing formulations and consortia of micro-organism to illustrate how the regulations address formulations and consortia;

* the application of the regulations to micro-organisms that are waste products;

* the treatment of micro-organisms which require notification under other acts of Parliament, such as the *Fertilizers Act* or the *Pest Control Products Act*;

* conducting an inspection of micro-organisms being manufactured or used in a "contained facility;"

* conducting an inspection of a field test of a micro-organisms;

* conducting an inspection of a facility where a micro-organism which is being imported or manufactured for research and development purposes, and where the *Laboratory Biosafety Guidelines, 1990* apply;

* dealing with the import of manufacture of micro-organisms which fall under the transitional or post-transitional provisions of the regulations.

## i) Contacts

This section of the manual would identify the individuals within Environment Canada, particularly the CCEB, from whom inspectors can obtain further information on reporting requirements and procedures under the CEPA biotechnology regulations. It should also indicate to whom regulatees can be referred for further information and supporting documentation.

### ii) Training Programs for Inspectors

#### a) Initial Program

Once the training manual has been completed a training program for inspectors will need to be designed and delivered to inspectors, based on the contents of the manual. The training program should be very practical in its approach. It should be delivered by individuals that have a through understanding of CEPA and the Regulation, as well as the needs and concerns of inspectors. The elements of the training program should include:

* visits to sites where microbial products of biotechnology are, or may be in use, such as bioremediation sites, "contained" industrial facilities and research and development facilities subject to the requirements of the *Laboratory Biosafety Guidelines, 1990*; and

* a biosafety training component, to deal with occupational health and safety issues which may arise during inspections and the collection and handling of evidence.

Opportunities for coordination with training for the chemical and polymer provisions of the CEPA New Substances Notification Regulations should be examined.

#### b) Continuing Education for Inspectors

In addition to an initial training course for inspectors, provision will also have to be made for the ongoing training of inspectors and the updating of the inspector's manual. This may include the provision of information on new applications of micro-organisms which are covered by the CEPA Regulation. Changes in inspection procedures and other activities which become necessary as a result of the outcomes of enforcement actions and other events will also have to be communicated to inspectors.

## 4. The Coordination of Activities within Environment Canada

The Office of Enforcement (OOE) should work to coordinate efforts within Environment Canada in regard to enforcement and compliance activities. Particular attention should be given to the following.

### i) Regional Offices of the Environmental Protection Service

Any implementation strategy must clearly identify what the roles and responsibilities of the CCEB, OOE and regional offices of the Environmental Protection Service. The lines of communication and responsibilities between these entities should be clearly defined regarding the implementation of the regulations.

### ii) Commercial Chemicals Evaluation Branch

CCEB is working to produce supporting documentation for the Regulations such as guidelines and ecozone maps. The application of the biosafety standards in the *Laboratory Biosafety Guidelines, 1990* to micro-organisms not identified in the *Guidelines* will need to be clarified. CCEB will also need to determine the requirements for micro-organisms to be placed on the DSL and procedures for dealing with post transitional substances. This information will need to be incorporated into the implementation strategy as appropriate.

Arrangements will also need to be for ongoing communications among the relevant branches of Environment Canada regarding new developments among the types of products affected by the Regulations and new interpretations of the Regulations and Guidelines.

## 5. The Coordination of Activities with Other Government Departments

The roles and responsibilities of other federal government departments should be clarified and opportunities for coordination of regulatory activities should be examined. Particular attention should be given to the need for coordination with the following agencies.

### i) Canada Customs

A memorandum of understanding (MOU) currently exists between Environment Canada and Canada Customs regarding the application of the CEPA New Substances Notification Regulations for chemicals and polymers to the importation of chemicals. The enforcement and compliance implementation strategy for the CEPA biotechnology Regulation should include consideration of extending the Environment Canada-Customs Canada MOU to include provisions for micro-organisms.

In the event that this option is pursued, Customs agents may require training sessions to be made aware of the forms in which micro-organisms could be transported into the country and the relevant prohibitions under CEPA. Training on the safe handling of micro-organisms in transit should also be provided.

### ii) Health Canada

OOE could investigate the possibility of entering into a MOU with Health Canada regarding the provision specialist advice in enforcement actions related to biosafety procedures. The role of Health Canada in the enforcement of the *Laboratory Biosafety Guidelines, 1990*, component of the proposed regulations should also be clarified.

As is the case within Environment Canada, arrangements will need to be made for ongoing communications among the Departments involved in the enforcement of the regulations regarding new developments in products potentially regulated through the regulations, and with respect to new interpretations of the Regulations and Guidelines.

## III. CONCLUSIONS

This document has presented an outline for a compliance and enforcement implementation strategy which will be undertaken by the Office of Enforcement of Environment Canada as the proposed micro-organism provisions of the New Substances Notification Regulations become law. The strategy encompasses identification of regulatees, establishment of a communication plan for informing regulatees of their responsibilities under CEPA and the Regulations, production of a training manual for inspectors, implementation of a training program for inspectors, coordination within Environment Canada and coordination with other departments. The final implementation strategy while based on this outline should also incorporate any other items as determined through ongoing input from inspectors, Environmental Protection Service regional offices and the CCEB.

## ENDNOTES

1.G.M. Lewis, Section-bySection Legal Analysis of the Proposed Micro-Organism Provisions of the New Substances Notification Regulations (Toronto: Canadian Institute for Environmental Law and Policy, October 1995).

2.The Recommendations for an organizational plan for an inspector's manual follows that of a draft document entitled Inspector's Manual - New Substances Notification Regulations authored by Eugene Oscapella.

3.Draft *New Substances Notification Regulations Part III - Biotechnology Products,* October 1994 draft, section 1.

4.See CEPA, s.11.

5.For a detailed summary of potential applications of microbial products of biotechnology see Clement International Corporation Issue Paer: Development of Ecological Tier Testing Schemes for Microbial Biotechnology Application (Fairfax, V.A.: USEPA (OPPT/HERD/EEB) and Environment Canada (CCEB), December 1993).

6.CEPA, Section 4.

7.Ibid., s.30(2).

8.Draft *New Substances Notification Regulations Part III - Biotechnology Products* October 1994 draft, Sections 34 and 35.