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Opened: 1997/11/01

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## Biotechnology - General Information

Departmental - General - Biotechnology  
Vol. 1 N

**FOLDER ID: 19977**

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GC 39.1 (91/10)

7540-21-904-5775

VOL. I IN

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Government of Canada  
Canadian Food Inspection  
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des aliments

# Facsimile Transmission

WESTERN SEED LABORATORY

301 - 421 Downey Road

SASKATOON, Saskatchewan

S7N 4L8

Facsimile Phone Number: (306) 975-6450

Telephone Number: (306) 975-5830 DATE: Dec 27/01TO: Stan Kirkland

Mike ✓

Louise ✓

FROM: Janine FYIShould we start a  
file for "GMO-free"  
requests? Stan

SUBJECT: \_\_\_\_\_

## Message:

as discussed.  
of the contract re  
seeds sent to us.

I agree with the  
suggested approach.

M. S.

FYI

From telephone conversa  
Janine was to reply that  
certification, can't ID a,  
all Canada's approved evs  
"no ~~regid~~ varieties of ---- regid in

Janine + I concluded &  
**Canada** require re-negoti

Kelly

New file requested:  
Certification requests "free-from"  
within a Biotechnology Primary.

Stan

ed  
ing

Government of Canada  
Canadian Food Inspection  
AgencyGouvernement du Canada  
Agence canadienne d'inspection  
des aliments

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Facsimile Phone Number: (306) 975-6450

Telephone Number: (306) 975-5830 DATE: Dec 27/01TO: Stan KirklandFROM: Janine FYI

SUBJECT: \_\_\_\_\_

Number of Pages  
(including cover)2 Short  
Long

## Message:

as discussed - FYI here is a copy  
of the contract memorandum SS Johnson  
seeds sent to us.

*Jan*

2001-12-27

FYI

From telephone conversation with Janine 2001-12-20  
Janine was to reply that we will not provide the requested  
certification, can't ID a private laboratory capable of testing  
all Canada's approved events; but we could provide the  
"no ~~regd~~ varieties of ---- regd in Canada" statement.

Janine + I concluded that the contract would likely  
**Canada** require re-negotiation.

*Stan*

Dec-27-01 10:23  
DEC 27 10:23

From-WESTERN SEED LAB  
FROM S.S. JOHNSON SEEDS

13068756450  
712048186601

T-038 P.02/02 F-725  
17000 F.UU/001 F-004



# JOHN ZUELZER & SON CANADA LTD.

"Representatives and Brokers in Seeds"

P.O. Box 550, Invermere, BC, Canada V0A 1K0

FAX: (250) 341-3448 • TELEPHONE: (250) 341-3444

## CONTRACT MEMORANDUM

No. 31-7536-12 (Page 2)

### QUALITY (cont'd.)

GMO free, as per acceptable test to be done by a mutually acceptable designated laboratory, to comply with EU Norms. The sample for this test is to be drawn by Agriculture Canada, or SGS Inspector, at Seller's option, according to ISTA Rules, and sent to the designated laboratory. The results of this analysis are to be final.

The Buyer has the option to take any quantity failing to meet the above described quality specifications at a mutually agreeable price. Any seed from the above production which is not acceptable to the Buyer because of quality, shall be disposed of as common mustard, without the variety name "SERVAL" being used.

ATTN: Janine

Direct Phone Line

204-376-3101

From S.S. Johnson  
seeds.

Dennis Jonsson

Thanks



Government  
of Canada

Gouvernement  
du Canada

Alan Goldrose / P.A. -  
K. Stolarik BIOTECH

# BIOTECHNOLOGY IN AGRICULTURE AND AGRI-FOOD

**A Consultation Document  
for the Renewal of the  
Canadian Biotechnology Strategy**

**February 1998**

*aussi disponible en français*

**Canada**

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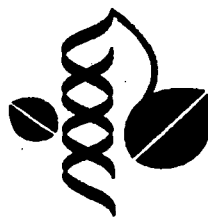
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# BIOTECHNOLOGY IN AGRICULTURE AND AGRI-FOOD

## A Consultation Document

*"For Canada to be a world leader in biotechnology and, through it,  
to enhance the quality of life of Canadians in terms of health, safety,  
the environment and economic development."*

*Proposed Vision for the Renewal of the  
Canada Biotechnology Strategy - January 1998*



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## INTRODUCTION

The federal government's National Biotechnology Strategy (NBS) was first introduced in 1983. The NBS had four policy goals:

- to focus on certain strategic areas (human and animal health, nitrogen fixation and plant strain development, cellulose utilization and waste management, and metal recovery and mineral leaching)
- to ensure an adequate supply of highly trained personnel
- to encourage research collaboration
- to create a climate conducive to investment

The federal government is updating its strategy to reflect current policy needs and strategic economic priorities. A federal interdepartmental Task Force has been organized to oversee the renewal process of the National Biotechnology Strategy, which is now called the Canadian Biotechnology Strategy (CBS). The Task Force is chaired by the Department of Industry and is responsible for a series of multi-stakeholder round-table consultations to be held in five centres across Canada during March-April 1998 (see Appendix I).

Proposed objectives of the CBS renewal are:

- to ensure that Canadians have access to, confidence in, and benefit from, safe and effective biotechnology-based products and services
- to position Canada as a responsible world leader in the development and sale of biotechnology products and services, domestically and internationally
- to develop suitable mechanisms to support Canada's economic and stewardship objectives (that is, health, safety, the environment and social and ethical matters) and to be a leader in promoting such mechanisms in the world arena

The new Canadian Biotechnology Strategy will build on the 1983 NBS policy framework, which recognized that Canada had an opportunity to use biotechnology to augment social and economic well-being.

Biotechnology, as defined in federal legislation, is the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms. This definition encompasses both the new biological tools of genetic engineering, cell fusion and protein engineering as well as the traditional techniques such as fermentation and classical plant and livestock breeding.

## Introduction

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Biotechnology is a technological tool with applications across a wide range of industries from health care to agriculture and agri-food, environment and the resource sectors. As such, Government policy calls for a science-based risk assessment and management approach to product regulation, under the powers of existing acts and regulations for specific product categories. This approach, along with knowledgeable and competent trained personnel, builds on Canada's established regulatory system which is designed to protect humans, plants, animals and the environment from potential adverse effects of all new products. This approach will be recognized in the development of the Canadian Biotechnology Strategy.

The Strategy must also reflect Canada's role as a trading nation, in supporting Canada's access to foreign markets while giving foreign products that meet Canadian standards access to Canadian markets. Agricultural exports totalled almost \$20 billion in 1996. This strong growth is expected to continue and, some suggest, could represent an estimated 4% of world export trade for agricultural products, a level last enjoyed in the 1970's. Biotechnology will have a significant role to play in achieving these export goals if the policy framework is well structured today. Finally, the Strategy must also capitalize and build on our competitive national business climate and predictable regulatory environment in order to attract new investment.

The unique role of the agricultural producer also needs to be highlighted in a biotechnology strategy. The agricultural biotechnology sector does not generally sell products directly to the consuming public. Instead, they provide the inputs to the producers who, for example, plant the seed and harvest the crop or vaccinate livestock to protect them from disease. The livestock or harvested crop, is then sold to processors for further processing before it reaches the consumer in the form of food products.

Recent polls indicate that the public wants access to accurate, understandable information on biotechnology, its products, and the government's role in this technology; to participate in and influence the development of policies; and to have meaningful fora to express moral and ethical concerns to the government.

The economic outlook for the sector suggests that the many years and dollars spent on research and development are finally yielding results and that the agri-biotechnology sector is poised for significant growth in the coming years as discoveries move to commercialization.



## Introduction

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From the policy foundation already in place and the issues that have arisen during ongoing discussion and consultations over the past several years, there emerge several broad policy objectives to be considered for agriculture and agri-food. These are:

- **To ensure the public has access to information regarding agricultural products derived from biotechnology**
- **To strengthen public confidence in the health, safety and efficacy evaluations conducted by government.**
- **To continue to build scientific knowledge and expertise for future regulation of biotechnology**
- **To provide the government with input into policy development through an advisory body and public participation.**
- **To foster expanded trade opportunities by sharing Canada's expertise and knowledge about biotechnology products, applications and regulation.**
- **To promote a climate conducive to investment in research, technology transfer and commercialization of agricultural products derived from biotechnology**

These objectives are set out for your consideration in the following three sections: *Meeting Public Needs, Market Access, and Strengthening Industry.*

## MEETING PUBLIC NEEDS

### Introduction

Public confidence in products of biotechnology, and in the safety and health of our food supply in general, are important issues facing governments and industry alike.

The application of biotechnology to agriculture and food production affects not only the developers and users of the technology, but also the consuming public. Whether biotechnology is used to produce new plant varieties that in turn become food ingredients, food processing enzymes, or commodities such as potatoes, tomatoes or fruit purchased at the retail level, the public has a stake in how the technology is introduced and managed. For its part, the government has a responsibility to develop and enforce regulations to protect human health and safety and the environment, while encouraging innovation and economic growth. An example of the synergy between these objectives is the trade opportunities afforded Canadian producers due to Canada's reputation for safe, wholesome food.

The federal government also endeavours to make decisions in an open and transparent way so as to keep the public informed of its activities. A variety of means have been used to provide transparency during the development of the regulatory regime for agricultural products, including stakeholder meetings, workshops, opportunities for written comments and public presentations. However, public advocacy representatives stress that more needs to be done to keep the public informed. There remains a fundamental challenge to communicate scientific information to non-scientists in the public domain and to maintain trust and confidence in that information.

### Providing Information

Given that we live in what has been identified by many as "the information age" it is not surprising that the public has an interest in obtaining more information about biotechnology. Information can be: commercial in nature, such as technical information about a new product; general, such as the role of biotechnology in agriculture and agri-food products; or descriptive, such as outlining the government's role in regulating those products.

Consumer groups have expressed a desire for more information on new food products and on biotechnology in general. A recent survey by the Canadian Institute of Biotechnology (CIB)<sup>1</sup> indicates that a wide variety of communication tools have been developed by the Canadian biotechnology community. These include the use of networks and other fora, regulatory consultations, inventories of expertise, conferences, workshops, presentations, documents, media articles and interviews, documentaries, newsletters, Internet sites, information kits, 1-800 numbers and surveys.

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<sup>1</sup> Canadian Institute of Biotechnology, *About Biotechnology: The Communications Experience in Canada*, October, 1997.

## Meeting Public Needs

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Federal and provincial governments, individual companies and industry associations, academia, non-governmental organizations and biotechnology associations have used the tools outlined above. The CIB documented some 250 different initiatives undertaken since 1992.

There is agreement that the availability of public information leads to better, more informed debate as the use of biotechnology evolves. Yet the CIB cautions that we must be careful to avoid duplicating previous efforts each time a new opportunity for debate and discussion occurs.

There is no clear consensus regarding the scope of information required to satisfy public needs. While some studies have suggested that the public needs more information about biotechnology and its various applications, others indicate that less detailed information is required on the scientific aspects of biotechnology and more is needed to increase the public's knowledge about the regulatory system for products of biotechnology.

Nor is there a clear understanding of the best ways to provide the public with information. Some have suggested that mandatory labelling of food products, to indicate they result from biotechnology or genetic engineering, could satisfy the consumer's desire for information.

Yet extensive consultations on the issue since 1993 have indicated that, although there is consensus that health, safety, nutritional or compositional change should be indicated, mandatory labelling may not be the best means of providing non-health and safety related information to consumers. One factor leading to this conclusion is that eventually most food products would be identified as "may contain" owing to the wide array of ingredients that are and will be derived through biotechnology. Point of sale information, 1-800 numbers and information via the media are options that are often seen as more effective alternatives (see Appendix III).

In a 1997 survey conducted for the Canadian Council of Grocery Distributors and the Food Marketing Institute, 88% of respondents felt that more information should be made available in supermarkets. The largest proportion (41%) cited pamphlets/brochures at point-of-purchase as being the most useful type of information, while only 2% cited the identification of biotechnology-based products.<sup>2</sup>

Consumer advocates stress that information must be available in a wide variety of forms, it must span the range of literacy levels in Canada, and the common core of terminology needs to be more consistent. Still more work with the public needs to be undertaken to determine information needs and the role that all stakeholders can play in more efficiently and effectively satisfying those needs.

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<sup>2</sup> Market Facts of Canada, *Trends in Canada: Survey of Consumer Shopping 1997*. 1997 Survey for the Canadian Council of Grocery Distributors and Food Marketing Institute

## Meeting Public Needs

While communications efforts are largely directed towards the public, it is important to recognize the information needs of others in the agri-food sector: farmers, producers, distributors, and retailers. In addition these groups are often called upon to provide the public with information on the products they use.

### **OBJECTIVE:**

**To ensure the public has access to information regarding agricultural products derived from biotechnology**

What kind of information would be helpful to the public and what are the most effective ways to disseminate it?

#### **Points to consider:**

- information needs of the public
- information sources used most frequently by the public
- information needs of farmers, food distributors, retailers, etc.
- examples of current information sources that are considered very effective and could serve as a model for future activities as well as benefitting from the experience of communications efforts to date
- broadening the focus of information dissemination by the agri-biotechnology community to incorporate more information for use in schools, by the media, and in other areas
- the role scientists and research institutions could play in increasing media and public knowledge of biotechnology
- co-ordination mechanisms that could be pursued with provinces, industry, universities, consumer groups and industry associations that can better inform the public and ensure previous efforts are not duplicated
- potential repositories for information pertaining to biotechnology

## **Regulation**

### **i) Framework**

The federal government has established a regulatory framework to ensure that the benefits of biotechnology products are realized in a way that protects health, safety and the environment (see Appendix II). Under the framework, the regulatory departments adopted six key principles for

## Meeting Public Needs

an efficient and effective approach to regulating biotechnology. One of these principles is to ensure that the development and enforcement of Canadian biotechnology regulations are carried out in an open manner and include consultation.

Clear and timely information on the regulatory processes, decisions, and enforcement activities, together with visible recognition of the importance of public input into regulatory policy development, have been suggested as important factors in public confidence. Yet focus groups have shown that the public is often unaware of the regulatory controls covering products of biotechnology.

### **OBJECTIVE:**

**To strengthen public confidence in the health, safety and efficacy evaluations conducted by government.**

How can we achieve greater awareness of the regulatory system, including its development and continued refinement?

#### **Points to consider:**

- appropriate roles of governments and industry to increase the public's awareness and understanding of the regulatory system for food products
- mechanisms to create greater transparency in regulatory activity

### **ii) Science Base**

An ongoing challenge for government is to ensure it has the necessary tools to maintain a strong science base on which to make regulatory decisions. Regulators take into consideration the nature of the organism or product and the characteristics of the environment into which it will be introduced. Characteristics considered in assessments include potential concerns such as pathogenicity, infectivity, allergenicity, weediness (for plants) and the likelihood of persistence, multiplication and dissemination. The development of the organism and any genetic changes and effects of these changes are also considered in detail.

As scientific innovation brings new products of biotechnology forward, new risk assessment and management tools have evolved, and must continue to do so, in order to support science-based regulation.



## Meeting Public Needs

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### iii) Human Resources

Government regulatory agencies, to maintain scientific parity with industry, will continue to require additional expertise and ongoing training to handle the demand for evaluations of new product types. For a regulatory system to function efficiently, effectively and with the public's confidence, the personnel carrying out the scientific reviews, as well as those interpreting and enforcing the regulations must be of the highest calibre, up to date with the current scientific advances, and available to federal regulatory departments.

Outside of those directly involved in new product evaluation and development, i.e., the regulators and the regulated industry, regulatory awareness is often lacking in Canada. Universities and research organizations, and the new scientists that they train, are frequently not aware of the regulatory system or new regulatory developments. A number of universities have courses with a small regulatory component, but full regulatory courses appear to be primarily targeted at legal students. The availability of careers in the regulatory field is not widely known to science graduates.

#### **OBJECTIVE:**

**To continue to build scientific knowledge and expertise for future regulation of biotechnology**

How should the government position itself to continue to have access to the most up-to-date scientific knowledge and best scientific expertise with which to make regulatory decisions?

#### **Points to consider:**

- use of collaborations among universities, governments and industry
- training programs, collaborations and processes that can be put into place to foster the human resources base
- establishment of permanent fora for sharing scientific knowledge across all participants in the sector

## Policy Development

### i) Public Participation

Just as with the availability of information, the public has a stake in policy development. There is opportunity for public comment and debate throughout policy development and the supporting legislative and regulatory process. The publication of proposed regulatory changes in the

## Meeting Public Needs

*Canada Gazette* and in consultation documents provide avenues for public input into the process. Consideration by Parliamentary committees, and formal, federal government-led consultations also provide opportunities for public input. In addition, the public makes its views known through correspondence with elected officials and the public service about issues of greatest concern. Public opinion surveys, government sponsored consultations, biotechnology community sponsored fora, conferences, workshops and presentations offer additional opportunities for input. Finally, various groups outside of government generate discussion as the influence of biotechnology on their interests has arisen.

There has been a significant amount of debate already on agri-biotechnology that has been prompted by government and that has generally been conducted in public arenas. These include government-sponsored consultations relating to both regulation and policy development, as well as discussions on broader issues surrounding biotechnology. However, participation remains confined to a few better-informed groups. It has been suggested that perhaps then, it is not a question of whether there are sufficient opportunities, but rather a broader question about representation and satisfaction in participation in government consultation.

### ii) Advisory Body to the Federal Government on Biotechnology

New technologies and products, as well as the jobs and growth resulting from these can clearly serve the public interest. However, the public's interest with respect to biotechnology is increasingly focussed on questions related to socio-economic and ethical issues raised by this technology. As such, the public needs continued opportunities to express the very real and legitimate interests that it has.

The National Biotechnology Advisory Committee (NBAC) is currently the only entity that provides advice to the federal government on a wide range of biotechnology matters. A number of federal departments and agencies have also undertaken new initiatives to formalize public involvement by creating advisory bodies that include representation of public interest organizations. In addition, both federal and provincial governments also have bodies addressing the ethical aspects of research and medical practices. However, none of these bodies uniquely addresses biotechnology. In its response to *Biotechnology Regulation in Canada: A Matter of Public Confidence. Report of the Standing Committee on Sustainable Development and the Environment*, the federal government stated:

"Given that this technology is and will continue to be part of Canadian life, the government recognizes that it needs the best possible advice on issues relating to the impact of this technology ... The government therefore agrees with the Standing Committee on the need for a more broadly-based body to provide advice to a group of ministers on the ethical, social, and regulatory aspects as well as the

## Meeting Public Needs

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economic, scientific, environmental and health aspects related to biotechnology consistent with the principles of sustainable development...”.

Findings from this and other consultations in the renewal of the Canadian Biotechnology Strategy will be used to put such an advisory body in place.

### **OBJECTIVE:**

**To provide the government with input into policy development through an advisory body and through public participation.**

How can the government obtain the best input into policy decisions from the Canadian public and an advisory body on biotechnology?

#### **Points to Consider:**

- mechanisms that recognize the right of Canadians to express their views and provide useful fora for Canadians to provide input into decisions on policy issues
- need to address socio-economic and ethical questions about agricultural products derived from biotechnology
- method of communication among agricultural stakeholders, including producers, companies and consumers to understand each other's interests and build on common goals
- adequate representation of the range of interests and diverse opinions of the public
- structure, membership and mandate of the Advisory Body

# MARKET ACCESS

## Introduction

Securing market access is fundamental to the successful commercialization of any product or process. There are two main issues pertaining to agricultural products derived from biotechnology in this domain: development of a harmonized body of international standards and regulations to facilitate the flow and acceptance of safe agri-biotechnology products in global markets; and, promoting co-ordination and co-operation among the federal and provincial governments and industry to develop marketing strategies to encourage other countries to recognize the quality and safety of our agricultural products developed using biotechnology.

Market access is more than the opening of export markets to Canadian goods and services -- it involves the accessibility of the Canadian market to foreign products while maintaining our high standards of health, safety, efficacy and environmental stewardship for Canadians.

## Harmonization of Standards and Regulations

Canada is a trading nation with considerable dependence on agricultural exports. A fundamental barrier to Canadian development of agricultural products derived from biotechnology can be access to foreign markets, which, in the absence of internationally harmonized standards, is

### International Fora

The federal government and stakeholders are currently engaged in a number of international fora to harmonize biotechnology standards including:

- the World Trade Organization (WTO) Committees on Technical Barriers to Trade (TBT), Sanitary and Phytosanitary Measures (SPS), and Trade Related Aspects of Intellectual Property (TRIPS);
- United Nations CODEX Alimentarius Commission
- Organization for Economic Cooperation and Development (OECD) Biotechnology Experts Group
- Office International des Épidémiologies (OIE)
- Technical Working Groups of the North American Free Trade Agreement (NAFTA)
- the proposed Biosafety Protocol to the United Nations Convention on Biological Diversity (under negotiation)
- Asia Pacific Economic Cooperation (APEC)
- North American Plant Protection Organization
- bilateral government to government discussions (Canada-European Union, Canada-Japan, Canada-United States etc.)

typically on a product-by-product, country-to-country basis. Already, Canadian commodities developed using the tools of biotechnology have faced barriers to foreign markets, notably the European Union.

In 1996, Canada achieved its goal of exporting nearly \$20 billion of agri-food products, \$10.3 billion of which was to the United States. That same year, Canada imported \$13.2 billion of agri-food products, with \$7.9 billion originating in the U.S. Canada's total agri-food exports included canola developed using biotechnology. Exports will soon include other crops with novel traits; these crops will form an important component of agricultural exports.

## Market Access

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Products of biotechnology are subject to the rights and obligations of international trade agreements such as the World Trade Organization agreement. Difficulties have arisen, however, because there are no specific international trade rules currently in place for products derived through biotechnology. Some countries have instituted their own regulatory regimes and risk assessment procedures, or are in the process of doing so. One multilateral initiative currently under negotiation is the United Nations' Biosafety Protocol (see Appendix III). The Protocol is intended to regulate the transboundary movement of organisms derived through modern biotechnology that could have an adverse effect on biological diversity.

For its part, Canada has developed a regulatory framework for biotechnology products. The principles of this framework and the regulatory practices used to support them have attracted the attention of such countries as Japan who have viewed the Canadian system as a model for putting biotechnology regulations into place. The Canadian approach may offer an opportunity to overcome potential variations in individual domestic regulations that could unduly hamper trade and market access for agricultural products developed using modern techniques of biotechnology. In addition this approach could provide real assistance to other countries in developing systems that safeguard human health and the environment.

Canada has actively supported the development of internationally harmonized standards to provide a basis for domestic regulations and risk assessments. In addition, Canada has advocated that any international standards must be based on scientific principles and procedures to protect health, animal and environmental safety. International cooperation among regulatory bodies also facilitates access to the world's best expertise, experience and information on which to base regulatory decisions. This cooperation can enhance our ability to make informed and efficient decisions, and can also facilitate the flow of agricultural products around the world.

International harmonization of regulatory systems is one approach that has been identified as a means of securing access to the best expertise and information, while at the same time facilitating international trade in agricultural products derived from biotechnology. Harmonization is a broad concept that could include a range of activities:

- Data exchange, e.g., inspection, enforcement and post market surveillance data
- Establishing common data requirements
- Setting procedures for data quality including data generation methods
- Common assessment of the generated data
- Acceptance of another jurisdiction's decision on products (including risk management strategies)
- Setting standards for regulatory outcomes, including the regulating process



## Market Access

- Bilateral mutual recognition agreements

Each step toward increased harmonization involves detailed work to establish commonality and agreement among jurisdictions. Harmonization may seem to be an extra step in the process of establishing domestic standards; ultimately, however, results of international work may mean increased knowledge and cost savings for both taxpayers and the regulated industry.

Canada has a unique opportunity to lead and influence the international direction of harmonization by sharing our internationally respected regulatory framework and experience with other jurisdictions. The potential for other countries to adopt similar systems could lead to further opportunities for harmonization and result in strategic advantages in marketing Canadian products abroad. This leadership could also contribute to both the growth of domestic biotechnology activities already geared to meeting our high domestic standards, as well as facilitating market access for Canadian-produced agri-biotechnology. As Canada continues to be active in discussing potential harmonization efforts in a number of international fora such as the Organization for Economic Cooperation and Development (OECD), the North American Plant Protection Organization (NAPPO), Office International des Épizooties (OIE), etc., our ongoing commitment to the principles of health, safety and environmental stewardship will be maintained.

### **Government Involvement in Marketing Strategies**

Government addresses domestic consumer needs in terms of information, human and environmental safety and efficacy, maintaining a healthy and stable economic and investment climate, and fostering domestic and international partnerships. The government also has a role in assisting the maturing of domestic industries to the point where firms attain export capacity.

Canadian governments have assisted the agri-food industry in marketing products throughout the world, through trade missions such as the Team Canada trade mission to China and South America. Canada has also placed agricultural experts in foreign embassies and posts. These efforts are focussed on marketing Canadian agri-food products in general, not specifically biotechnology, or products of biotechnology, although as noted previously the latter are increasingly being included in our agri-food exports.

To facilitate trade, federal and provincial governments are coordinating and cooperating with each other and with industry to develop marketing strategies. Many provinces already have strategies to facilitate the use of biotechnology to advance their economic competitiveness and others are in the process of developing strategies.

## Market Access

The Canadian government has the opportunity, through targeted market access efforts, to continue to advance and improve international trade in agricultural products including those derived from biotechnology.

### **OBJECTIVE:**

To foster expanded trade opportunities by sharing Canada's expertise and knowledge about biotechnology products, applications and regulation.

As Canada participates in international discussions on harmonization, how best can it achieve internationally agreed-upon standards and science-based risk assessment procedures to facilitate the flow of agricultural exports developed using biotechnology?

### **Points to Consider:**

- What opportunities exist for Canada to lead by example and use its experience to date in biotechnology regulation?
- What strategic government to government relations could be used to develop more global approaches? What are the most important fora for Canada to focus its efforts in this area (i.e., CODEX Alimentarius Commission, Office International des Épizooties, Asia Pacific Economic Cooperation, North American Plant Protection Organization, Organization for Economic Cooperation and Development, World Trade Organization)?
- Are bilateral approaches more fruitful in the short and medium term than multi-government approaches? Is the necessary infrastructure in place in key fora to support bilateral agreements? What level of international regulatory harmonization should Canada be seeking with its trading partners?
- Are there strategic markets for agri-biotechnology products where the government should focus its efforts? Are there strategic products (i.e., value-added traits) on which government should focus?
- Are there innovative ways to strengthen the industry/government partnership to increase the export of agri-biotechnology products?
- What opportunities will exist for the Canadian Biotechnology Strategy and provincial policy frameworks to be mutually supportive?

## STRENGTHENING INDUSTRY

### Introduction

Agriculture and agri-food is one of the top five industries in Canada, accounting for approximately 14.7% of employment or 1.9 million jobs. This sector produces 8% of the Gross Domestic Product (2% from farm-level agricultural production, 2% from food and beverage processing, and 4% from food-service and retail transactions). Exports continue to climb, reaching almost \$20 billion in 1996. Biotechnology is playing an increasingly important role in all aspects of this industry, and is anticipated to contribute to its ongoing economic success.

Canadian revenue from biotechnology products and services is estimated at around \$800 million. From 1995/96 industry data, Table 1 indicates the main product categories targeted by Canadian firms, with most of the activity consisting of traditional biotechnology (see Industry Canada section, Appendix III).

<b>Table 1 Canadian Biotechnology: Products/Services Sales</b>	
<b>Area</b>	<b>*Estimated Sales by Area (\$ Cdn. Million)</b>
<b>Agri-Food</b>	<b>319</b>
<b>Aquaculture</b>	<b>59</b>
<b>Environment</b>	<b>38</b>
<b>Human biologicals</b>	<b>300</b>
<b>Human diagnostics</b>	<b>96</b>
<b>ALL AREAS</b>	<b>812</b>

\* Source: Industry Canada (see Appendix III). Some areas such as human diagnostics include significant sales of imported products for redistribution.

Shortages of qualified personnel are expected over the next five years as more companies mature and move from early stage research to commercial production. The Paget study<sup>3</sup> predicts that

<sup>3</sup> The Paget Consulting Group Inc., *Building Long Term Capacity Now*. Canadian Human Resources Study in Biotechnology. May 1996

## Strengthening Industry

industry growth will create 4000 new jobs by the year 2000: 1300 in research, technical and support activities, 2000 in commercialization, and 700 in management.

### Human Resources Council

The Biotechnology Human Resources Council (BHRC) is an industrial sector agency mandated to develop a strategy to meet the future skill requirements of the Canadian Biotechnology industry. Funding for the Council comes from the Sectoral Partnerships Initiative of Human Resources Development Canada and the biotechnology industry. It held its inaugural meeting April 30, 1997 (see Appendix III).

The challenges in this area are rooted in the fast pace of development of the technologies. Knowledge rapidly becomes outdated as new processes emerge. From a corporate viewpoint, the significant investments in research and development mean that experts in management, financial markets and strategic alliances are key components of growth.

## Financing/Investment

There are several elements required to create a climate conducive to further development and growth of knowledge-based sectors. Biotechnology is no different. Firms need substantial capital because of the research-intensive nature of biotechnology and the large amount of time required to bring a product to market. Companies will continue to survive and grow on the success of their biotechnology research and development efforts.

One impediment to the successful commercialization of any high technology has been the lack of investment/capital available during the early commercialization phases, for example, product market penetration. These phases of high technology business development often cannot achieve the accepted objectives of private venture capitalists for a 20-30% Return on Investment (ROI) within a 3-5 year time frame. In addition, the investment required at these stages is often relatively low. These conditions together pose significant problems for the private sector investor:

- Long time frame to achieve normal ROI targets;
- Expense of completing due diligence and managing the investment relative to the size of the investment is extremely high;

In addition, many private sector investor institutions emphasize financial analysis of an investment over technical analysis. Most companies in the early stages of commercializing a product have limited financial data on which to base a financial analysis. As a result, technical

## Strengthening Industry

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knowledge associated with early-stage products, with respect to technical feasibility, product scale-up, and potential market acceptance, becomes increasingly important.

In Canada, there is a potential for increased investment in biotechnology, because, overall, funds for knowledge-based technologies have become accessible with the growth of the public and private equity markets. In addition, federal and provincial governments are offering strategic funding through programs, such as, the federal government's new Technology Partnerships Canada program which offers financial support for innovative technologies at the near-market stage of development.

Between 1991 and 1995, investments in Canadian biotechnology companies amounted to \$1 billion, with private placements/venture capital accounting for 39%, initial public offerings 24%, and public offerings 31%. Ninety percent of that \$1 billion was directed to human health care while agriculture received 6%. As a result of the strong public equity market, the industry raised over \$1 billion in 1996 alone. The human health care sector received 98%.<sup>4</sup> Although it appears that investment is on the rise, the distribution of these investments across Canadian biotechnology market segments has shifted strongly to the human health care sector from the proportion invested in agriculture and other markets between 1991 and 1995. This reflects the same trend of financing and investment that has reported in the U.S. biotechnology industry<sup>5</sup>.

Another trend has been the recent takeovers of small, leading-edge U.S. agricultural biotechnology companies by larger businesses. Many are suggesting that the takeovers reflect a situation where only larger, global agricultural-based or chemicals-based companies can afford to nurture the development of agricultural products derived from biotechnology. A different set of issues, such as export markets for agricultural products derived from biotechnology, low returns on investment, etc. can affect the profitability of investment in agricultural biotechnology as compared to profits from the larger health-care biotechnology sector. One of the challenges facing companies in agricultural biotechnology is to secure a reasonable return, because prices or margins for many products are not necessarily higher than those for traditional products.

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<sup>4</sup> Cooper, Denys, *Capital Financing of Biotechnology - a Bonanza Year* in Canadian Biotechnology 1997. Contact Canada. January 1997.

<sup>5</sup> Ernst and Young LLP, *Biotech 97 Alignment - the 11th Industry Annual Report*. 1996

## Strengthening Industry

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### Intellectual Property

There are a number of basic issues relating to biotechnology concerning intellectual property:

- the management of Intellectual Property, i.e., how to recognize inventions and protect the investment, where to file patents and/or plant breeders rights, licensing agreements, and technology transfer provisions
- administrative issues, such as the cost and time investment of obtaining and maintaining patents and/or plant breeders' rights
- issues relating to the appropriateness of allowing the patenting of higher life forms

Research and development to bring biotechnology products to market typically represents a larger portion of a firm's costs than it does for other products, mainly because the real value of a biotechnology product or process is "intellectual capital". The management of that capital is a key determinant in the success of individual firms. Given its importance, the policy and legal framework concerning intellectual property rights influences in which countries/jurisdictions, and when, products will be developed/marketed.

The Canadian Patent Office permits claims for unicellular microorganisms (i.e. algae, bacteria, fungi, protozoa, and viruses) and cell lines, but has not approved protection for multi-cellular life forms. The decision by the Commissioner of Patents to reject patent claims for the Harvard onco-mouse has been appealed in the courts. It may take several years before the case is ultimately heard and ruled upon by the Supreme Court. The World Trade Organization (WTO) Agreement on Trade Related Aspects of Intellectual Property rights (TRIPS)(see Appendix III) and North America Free Trade Act (NAFTA) do not currently require Canada to patent higher life forms; if, as in the case of plants, protection for plant varieties is provided by an effective, alternate system. In Canada, this protection is provided by the Plant Breeders' Rights legislation. However, Canada will be discussing this issue with other countries as the WTO TRIPS provision on the patentability of higher life forms is reviewed in 1999.

### Research

The successes of biotechnology have been due largely to the strength of long term research activities at public institutions that have provided the foundation for Canadian agriculture. Over the past decade fundamental research on the application of cell and tissue culture techniques, molecular genetics and recombinant DNA methods to a wide variety of important crops has

## Strengthening Industry

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opened the door to a new era in crop production, quality and productivity. Canada's long term competitiveness in the international marketplace is enhanced by these varieties, and could be further strengthened with more research activity.

The widespread use of tissue culture methods has resulted in such advancements as the development of synthetic seeds from embryos grown in culture and the growth of genetically pure plants from developing pollen. Methods to quickly generate large numbers of stable genetically pure plants that can be used for breeding from developing microspores, pioneered by scientists at Canadian government and university laboratories, is a hallmark achievement. These methods are now fundamental tools employed by plant breeders throughout the world. Furthermore, when coupled to the techniques of recombinant DNA technology, a variety of tissue culture methods have been used as a platform for the transfer of genetic information between species that are not sexually compatible.

### Research Focus

In recent years, there has been a greater focus on research collaboration between academic, government and industry organizations. One visible commercial outcome of this type of collaborative effort is the overall importance and economic value of the canola crop.

New cultivars have been bred to allow farmers to control weeds effectively at lower cost with smaller quantities of chemicals. Recently, new canolas with tolerance to one of several types of herbicides that have been introduced into the marketplace made possible the environmentally beneficial practice of no-till agriculture. Use of crops with modified traits contributes to the appeal of adopting no-till practice by farmers resulting in a dramatic increase in the sale and planting of these varieties. In addition to the new canola varieties, new lines of corn and soybeans have been developed and are now poised to assume a significant role in the market place. New varieties such as these provide the potential for increased, high quality productivity and thus strengthened Canadian leadership in the production of high quality canola for domestic and international markets.

Examples of developments that will continue to add value to Canada's agricultural crop base include the identification of genes that impart:

- insect, bacterial or fungal disease resistance
- tolerance to stress such as cold or salt
- selective controls of plant development, e.g., fertility for hybrid seed production

## Strengthening Industry

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- a change in biochemical pathways to produce fruits, seeds and vegetables with altered composition, ripening characteristics and growth potential

Canadian researchers have isolated and are characterizing many examples of these genes and continue to work with the private sector to ensure these new genetic traits are available to the Canadian farmer.

Efforts to increase the overall economic value of crops will continue to be a driving force for industry. Canadian research has led the development of many value-added crops and processes, such as the development of specialty cosmetic ingredients from oats, now being used as a natural replacement for talc, specialty wheats with new characteristics such as high levels of vitamin A, specific starch profiles tailored for specialty products and other wheats selected for specific properties important in food production. As the food processing industry enters the next century there will be increasing demand for crops that can be used to produce "functional foods", such as high fibre, low fat and nutritionally enhanced foods, and "nutraceuticals".

With increased consumer interest in foods with health benefits, many believe that biotechnology will play a key role in developing functional foods and nutraceuticals (foods or medicinal products derived from food, respectively, that demonstrate physiological benefits and/or reduce the risk of chronic disease) will increase market opportunities for Canadian food products (see Appendix III). These products, which have the potential to be higher in value than traditional agri-food products, are considered a research priority, both domestically and internationally. Canada, therefore, is in an excellent position to compete in this market. With our scientific expertise and existing infrastructure, it should be possible to conduct the necessary research and development to benefit from these products.

In a practice known as molecular farming, recent advances allow scientists to modify plants to be used for the low cost production of proteins currently derived from different sources. These advances provide the threshold of a revolution in the production of important value-added products. Plants can now be used for the large scale manufacture of proteins of commercial value, such as enzymes, peptides of medicinal and pharmaceutical value, and vaccines for human health care and veterinary purposes.



## Strengthening Industry

### Patenting and Commercialization

The costs associated with obtaining the rights to use fundamental technologies can become a serious obstacle to the commercial viability of some biotechnology projects. Patent searches and commercialization plans are as important as literature reviews at the beginning of every new project

Examples of important plant transformation technologies controlled by non-Canadian interests and used in domestic research are as follows:

- Recombinant DNA: The use of recombinant DNA itself, regardless of how achieved, is controlled by the Cohen-Boyer patents from Stanford University.
- Composition of the Recombinant DNA: The individual genes and DNA sequences that comprise commonly used recombinant DNA molecules are also controlled by patents.
- Transformation Methods: Methods to transform individual species such as canola, soybean, or wheat are now controlled by patents issued to several corporations. The methods that have greatest general utility include: Agrobacterium based systems, the biolistic approach, microinjection, DNA uptake by protoplasts and needle-like whiskers.

Similarly, Canada can capitalize on its strengths in other industries that can better utilize the agricultural potential of this country. For example, the development of crops that can be used for meal production for aquaculture is a goal that could reduce the industry's dependence on imported fish meal. These crops could also be modified to contain vaccines and other animal growth-enhancing factors. The development of products such as these will enable Canada to capitalize on its resources and promote synergies between various sectors that can cooperate in generating economic growth.

Improvements in animal health care and husbandry have facilitated the growth of the Canadian livestock sector. Modified meals, improved

feed ingredients (e.g. modified grain meals) and biotechnology derived vaccines have and continue will continue to lead to increased productivity and higher-quality products. Advances in embryo technology and animal reproduction have allowed Canadian livestock producers to raise animals that are tailored to consumer demands. Canada will need to continue its efforts in the development of advanced technology for livestock production. New genetic strains of livestock that yield products with characteristics demanded by the Canadian consumer need to be developed. These products will include safer food and food with altered nutritional content, e.g., lower fat content. Additionally, livestock performance will be subject to new technologies and Canada needs to remain at the leading edge in this field.

Developments in cloning technology and animal transgenics may create more opportunities for agriculture in the future. Advancements in cloning technologies could allow the cloning of elite lines of animals - breeds with desirable traits such as increased egg production in chickens and leaner meats in sheep and pigs. In addition, with genetic engineering potentially easier to achieve, the introduction of new characteristics could be a closer reality e.g. the production of medically therapeutic proteins in an animal's milk.

## Strengthening Industry

### Remaining Competitive in Biotechnology Research

Despite the many advances that have been made and the products that have become a commercial reality, only a modest fraction of the potential of biotechnology has been realized to date. The international effort focussed on biotechnology is huge and continues to expand as products of research assume prominent positions in the international market place.

To take advantage of the momentum already gained in agricultural biotechnology, analysts have suggested that Canada needs to continue to foster the alignment of the private sector with the research community, and identify key areas of practical significance, such as commercialization. Already many organizations are racing to completely sequence and characterize the genome of commercially valuable crop species. Resulting discoveries will be protected by patents, and analysts suggest that Canadian industry faces a difficult period if it does not take similar steps to discover and protect important genetic components of crops valuable to it. The Canadian research community recognizes the need to discover and protect important genetic traits but knows that undertaking such a competitive initiative will not be a simple task. However, it is to the benefit of all Canadians to ensure that Canada has a prominent role in the new science of genomics.

#### U.S. Agriculture - Genome Strategy

The U.S. Department of Agriculture is developing a \$200-million National Food Genome Strategy. Over a 4 year period, a study of the DNA of plants, animals and microbes is proposed to "enhance the usefulness" of economically important species.

In addition, the U.S. government is expected to allocate a Plant Genome Initiative at the National Science Foundation (NSF) an estimated \$40 million for next year. The NSF program would focus on a wide range of plants, especially corn.

At a fundamental level, the key to the future of Canadian biotechnology is a continued and expanded pace of gene discovery and the technologies of genomics. Recent improvements in technology for rapid DNA sequencing and genome analysis has greatly accelerated the pace of gene identification and characterization to the level that entire genomes of individual species will be available in the coming years. The sequenced genome provides a data base to identify new genes and how they may be regulated. Knowledge of gene regulation provides the "tools" for the transfer of new genes into host species. The introduction of new genes into plant species is fundamental to competitive product development; new genes could be used to impart valuable traits that in turn improve the quality, performance or abilities of plants including forest trees.

The identification of new traits, or the modification of existing traits through genomic technologies, must be accompanied by preservation of wild and novel germplasms. This preservation will be important in the development of crops, fish, and other animals when

## Strengthening Industry

genomic technologies are at the point of providing the means to modify complex traits, including those from wild species.

Clearly, Canada faces many challenges in the coming years. The fundamental strength of Canada's research community (see Canadian Agri-Food Research Council, Appendix III) can help Canadian agriculture meet those challenges and remain a strong international presence.

### **OBJECTIVE:**

**To promote a climate conducive to investment in research, technology transfer and commercialization of agricultural products derived from biotechnology**

Does the federal government have a role to play in creating the climate necessary to stimulate financing/investment in the Canadian industry developing agricultural products derived from biotechnology?

What are the research, technology transfer, human resources and intellectual property rights components of a Canadian strategy on biotechnology that will ensure that Canada remains a competitive player in agri-biotechnology?

### **Points to Consider:**

- the transferral of technologies/processes developed in publicly funded institutions to the private sector
- specific areas of research and commercialization that should be established as priority for Canada to pursue
- sufficiency of Canada's foundation of basic scientific research to develop the knowledge required for future agricultural innovations
- policy concerning the patenting of whole plants and animals
- periods of a company's development where more or less government assistance is desirable or appropriate
- advantages and limitations of various types of government assistance – i.e., direct grants and subsidies, tax provisions such as Canadian R&D tax credits, promotion and development of markets

## APPENDIX I

### **Renewal of the Canadian Biotechnology Strategy (CBS): Interdepartmental Task Force Round-Table Consultations**

A federal interdepartmental Task Force has been organized to oversee the renewal process of the National Biotechnology Strategy, which is now called the Canadian Biotechnology Strategy (CBS). The Task Force is chaired by the Department of Industry and is responsible for a series of multi-stakeholder round-table consultations to be held in five centres (Vancouver, Saskatoon, Toronto, Montreal and Halifax) across Canada during March-April 1998.

These round-tables will focus on three objectives: developing a new broad policy framework; establishing an external advisory body specifically to advise the federal government on biotechnology issues; and identifying mechanisms for public input.

You may request copies of all CBS consultation documents and related materials from:

Canadian Biotechnology Strategy Task Force  
Room 799B, East Tower  
235 Queen Street, 7th Floor  
Ottawa, Ontario K1A 0H5  
Tel: (613) 946-2848  
Fax: (613) 946-2847  
E-mail: [cbstf@ic.gc.ca](mailto:cbstf@ic.gc.ca)  
Web site: <http://strategis.ic.gc.ca/cbs>

## APPENDIX II

### The Regulatory Framework – Maintaining Health, Safety and Efficacy

In its role as the regulator of agricultural products of biotechnology, the Canadian Food Inspection Agency (CFIA) conducts safety assessments of fertilizers, seeds, plants or plant products, animals, animal vaccines and feeds, and is responsible for enforcing portions of the *Food and Drugs Act*.

Health Canada is responsible for assessing the safety of novel foods, which include foods derived from biotechnology. That department, in conjunction with the CFIA, is also responsible for developing regulations concerning labelling. The Pest Management Regulatory Agency of Health Canada is responsible for regulating pest control products, including those developed through biotechnology, and evaluates health and environmental safety and value of products submitted for registration.

A description of biotechnology products and the acts under which they are regulated is set out in the table on the following page.

Canada's policy framework for regulating products of biotechnology was announced on January 11, 1993. It is based on several guiding principles that reflect the need to:

- maintain Canada's high standards for the protection of the health of workers, the general public and the environment
- use existing legislation and regulatory institutions to clarify responsibilities and avoid duplication
- develop clear guidelines for evaluating products of biotechnology that are in harmony with national priorities and international standards
- provide for a sound scientific database on which to assess risk and evaluate products
- ensure that the development and enforcement of Canadian regulations are open and include consultation
- contribute to the prosperity and well-being of Canadians by fostering a favourable climate for investment, development, innovation and adoption of sustainable Canadian biotechnology products and processes

These principles have been used by Environment Canada, Health Canada and the CFIA as they developed their regulatory systems. Both these principles and the regulatory practice used to

## Appendix II

support them have attracted considerable international attention as other nations strive to put in place their own regulatory systems.

Products Regulated	Federal Department(s)	Act	Regulations
Drugs, Cosmetics, Medical Devices, and Foods	Health Canada	<i>Food and Drugs Act</i>	<i>Food and Drugs Regulations, Medical Devices Regulations, Cosmetics Regulations</i>
Pest Control Products	Health Canada	<i>Pest Control Products Act</i>	<i>Pest Control Products Regulations</i>
Products for uses not covered under other federal legislation	Environment Canada, Health Canada	<i>Canadian Environmental Protection Act</i>	<i>New Substances Notification Regulations</i>
Feeds, including novel feeds	Canadian Food Inspection Agency	<i>Feeds Act</i>	<i>Feeds Regulations</i>
Fertilizer supplements, including novel microbial supplements	Canadian Food Inspection Agency	<i>Fertilizers Act</i>	<i>Fertilizers Regulations</i>
Veterinary Biologics	Canadian Food Inspection Agency	<i>Health of Animals Act</i>	<i>Health of Animals Regulations</i>
Plants, including plants with novel traits, including forest trees	Canadian Food Inspection Agency	<i>Seeds Act</i>	<i>Seeds Regulations</i>
Aquatic organisms (under development)	Fisheries and Oceans	<i>Fisheries Act</i>	<i>Fisheries Regulations</i>

### Contacts:

Canadian Food Inspection Agency (613) 225-2342 Environment Canada (613) 953-1678  
Fisheries and Oceans Canada (613) 990-0275 Health Canada (613) 957-3844

## APPENDIX III

*Throughout the agriculture and agri-food sector consultation document, there are references to the involvement of the federal government in other initiatives that have mandates to explore specific issues related to biotechnology. You may make your views known to, or obtain more information from, the following contacts:*

### **Biotechnology Human Resources Council (BHRC)**

The Biotechnology Human Resources Council (BHRC) was inaugurated on April 1, 1997, and is the sector council responsible for the development and implementation of a human resource strategy for the Canadian biotechnology industry. BHRC is supported by Human Resources Development Canada and BIOTECCanada.

Current and proposed BHRC activities include:

- **University and College Programs Review:** The collection of data about the biotechnology and biotechnology-related programs offered by Canadian colleges and universities.
- **Biotechnology Skills Inventory:** Preparation of an inventory of the skills required for a series of biotechnology job categories, including job descriptions.
- **Biotechnology Careers and Programs Reference Guide:** A national guide to list descriptions of career opportunities available.
- **Canadian Biotechnology Job Bank:** BHRC currently maintains a databank of resumes of skilled biotechnology employees and potential employees and available biotechnology positions and plans to expand this resource into a website
- **Training Program Series:** Developing specialized training programs to meet the immediate skills and human resources shortages of the biotechnology industry.

For more information, contact:

Biotechnology Human Resources Council (BHRC)  
130 Albert Street, Suite 420  
Ottawa, Ontario K1P 5G4  
Tel: (613) 235-1402  
Fax: (613) 233-7541  
<http://www.biotech.ca>

## Appendix III

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### **Canadian Agri-Food Research Council**

Canadian Agri-Food Research Council (CARC) was established in 1974 as a non-profit organization and incorporated in 1985. Its mission is to "provide leadership in coordination and networking of research and technology transfer and is a catalyst for building consensus on research prioritization in Canada. In this regard, research and technology transfer is directed to assist the agriculture and food industry to be: globally competitive, environmentally sustainable and socially responsible."

To assist in the renewal of the Canadian Biotechnology Strategy (CBS), CARC is consulting with the agricultural research community and contributing the results of these discussions to the process of the CBS renewal.

For more information, please contact:

Canadian Agri-Food Research Council (CARC)  
Heritage House, Bldg 60  
Central Experimental Farm  
Ottawa, Ontario K1A 0C6  
Tel: (613) 234-2325  
Fax: (613) 234-2330

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## Appendix III

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### **Industry Canada: Bio-Industries Information Products**

Industry Canada provides strategic information products and services to help industry sectors or sub-sectors identify competitive issues and opportunities. For example, an upcoming Bio-industries report, part of the Sector Competitiveness Frameworks series published by Industry Canada, contains statistical information about the industry and analyses of policy issues such as investment and financing, trade and export strategies, identification of growth prospects, etc.

In addition, Statistics Canada, Industry Canada and BIOTEC Canada are now working on a comprehensive survey of the Canadian biotechnology industry, to be conducted in 1998. This survey is intended to capture cross-sector information about the state of the biotechnology industry in Canada.

For more information, contact:

Bio-Industries Branch  
Industry Canada  
235 Queen Street.  
Ottawa, Ontario K1A 0H5  
Tel: (613) 954-3071  
Fax: (613) 952-4209

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### **Labelling Foods from Biotechnology and the CODEX Alimentarius Commission**

Health Canada is responsible for setting labelling policies on health and safety matters. The Canadian Food Inspection Agency is responsible for developing non-health and safety food-labelling regulations and policies, including those pertaining to new foods derived through biotechnology.

General principles for labelling foods from biotechnology have emerged from a series of multi-stakeholder consultations over the past four years. Specifically, there is support for labelling in the case of a health or safety concern such as allergenicity or a significant nutritional change in the food. Voluntary negative ("does not contain") or positive ("does contain") claims are permitted, providing the claims are truthful and not misleading. These principles are consistent with the *Food and Drugs Act and Regulations*.

## Appendix III

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Canada is a member of CODEX Alimentarius and works with the CODEX Committee on Food Labelling to arrive at a common international position on this matter.

For more information or to make your views known, please contact:

Biotechnology Strategies and Coordination Office  
Canadian Food Inspection Agency  
59 Camelot Drive  
Nepean, Ontario K1A 0Y9  
Tel: (613) 225-2342  
Fax: (613) 228-6604  
Website: [www.cfia-acia.agr.ca](http://www.cfia-acia.agr.ca)

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## Nutraceutical/Functional Food Project: Regulation

In a response to the strong interest from the food industry and consumers, the Therapeutic Products and Food Programmes of Health Canada have initiated a project to develop a federal policy on the appropriate regulatory framework for nutraceuticals/functional foods. The internal Health Canada Working Group is being assisted in this process by an External Advisory Panel of experts from the food and drugs industries, consumer groups, academia and practising health professionals. Workshops have also been held to consult with stakeholders on regulatory issues about nutraceuticals/functional foods. These discussions have resulted in a draft policy options analysis paper that examines the range of options available.

The draft policy options analysis document is available for all interested stakeholders by sending a request to:

Nutraceuticals/Functional Foods Project  
Bureau of Policy and Coordination  
Therapeutic Products Programme  
Health Canada, Address Locator 0702B1  
Tunney's Pasture  
Ottawa, Ontario K1A 0L2  
Tel: (613) 941-5057  
Fax: (613) 941-6458  
<http://www.hc-sc.gc.ca/hpb-dgps/therapeut> or  
<http://www.hc-sc.gc.ca/datahpb/datafood>

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## Appendix III

### **Nutraceutical and Functional Food Technologies Workshops (March-April 1998):**

The federal government is collaborating with food industry and biotechnology organizations on a series of regional workshops to be held in March and April 1998. The workshops will identify critical industry issues and barriers to the business development of the emerging nutraceutical/functional foods market segment.

For more information about this workshop, contact:

BIOTECanada  
130 Albert Street  
Suite 420  
Ottawa, Ontario K1P 5G4  
Tel: (613) 230-5585  
Fax: (613) 233-7541

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### **United Nations Convention on Biological Diversity - A Biosafety Protocol**

Negotiations are underway to develop a Biosafety Protocol under the United Nations Convention on Biological Diversity. This Protocol would aim to protect biological diversity from adverse effects that may result from the movement across borders of living modified organisms, including those derived through biotechnology.

For more information, or to make your views known, please contact:

Biodiversity Convention Office  
Environment Canada  
Place Vincent Massey  
351 St. Joseph Blvd., 5th Floor  
Hull Quebec K1A 0H3  
Tel: (819) 953-4374  
Fax: (819) 953-1765

### Appendix III

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## **World Trade Organization (WTO) Trade Related Aspects of Intellectual Property (TRIPS)**

Canadian patents have been issued for unicellular organisms, but no patent claims covering a plant or animal have been granted. The case of the Harvard onco-mouse patent application is still before the Federal Court awaiting a decision.

Through consultations, Industry Canada is preparing a position on the patenting of higher life forms in time for the upcoming 1999 World Trade Organization (WTO) reviews.

For further information, please contact:

Intellectual Property Policy Directorate  
Industry Canada  
235 Queen Street.  
Ottawa, Ontario K1A 0H5  
Tel: (613) 952-2527  
Fax: (613) 952-1980

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Agriculture and  
Agri-Food Canada

Assistant Deputy Minister  
Policy Branch

Ottawa, Ontario  
K1A 0G5

Agriculture et  
Agroalimentaire Canada

Sous-ministre adjoint  
Direction générale des politiques

Ottawa (Ontario)  
K1A 0G5

Theresa / De Olson PA-BIOTECH

DEC 16 1997

DEC 16 1997

MEMORANDUM TO: Diane Fitton  
Jeanne D'Arc Durepos  
Jeannette Ladouceur  
Tina Pagliarello

Policy Branch Biotechnology Responsibilities

The purpose of this note is to inform you of the following  
division of responsibilities regarding the "Biotechnology" file  
within Policy Branch:

Canadian Biotechnology Strategy:	Christine Nymark
Departmental Discussion Paper:	Christine Nymark
rbST:	Doug Hedley
Higher Life Forms:	Doug Hedley
Regulations (Policy):	Doug Hedley
Canadian Environmental Protection Act (CEPA):	Environment Bureau
Biodiversity Convention:	Environment Bureau

It would be appreciated if we could forward incoming requests and  
correspondence on "Biotechnology" to the responsible contacts as  
listed above as well as inform them of relevant meetings as we  
are made aware of such meetings. Note that Strategic and  
Corporate Relations (SCR), Industry Performance and Analysis  
(IPA) and the Environment Bureau will share briefing material  
with each other.

  
Marc Meloche  
Executive Assistant

c.c. Christine Nymark  
Doug Hedley / Bill Boddie  
Michael Presley  
Deputy Minister's Office

Canada

Copies to Dr. Gravel  
1 ~~Dr. Gravel~~ B. Ray  
M. Kenny  
T. Iuliano

PA - 1510 - 5

## WHAT IS THE BIOSAFETY PROTOCOL ABOUT?

*To address the transboundary movement of any living modified organism resulting from modern biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity.*

What does this mean?

1. What is a Living Modified Organism (LMO)?  
- genetically engineered plants, vaccines
2. What is "modern" biotechnology?  
- altered by recombinant based genetic engineering
3. Is this only about biodiversity?
4. Is the Protocol to create an international biotechnology regulatory system or is it specific to LMOs that are adverse to biodiversity (e.g., similar to PIC)?  
Prior informed consent - Dangerous chemicals
5. How would one know *a priori* which LMOs could have adverse effects?
6. Perhaps the Protocol is for all LMOs, then find out about adverse effect potential in the risk assessment.
7. What is the difference between scope of the Protocol and scope of advance informed agreement (AIA)?  
→ which LMO's  
& may be interchangeable.

**From:** Stephen Yarrow  
**To:** OTTAWAEM1.MISBSJCB.MCALPINER, OTTAWAEM1.MISBSJCB.h...  
**Date:** 11/11/97 1:16pm  
**Subject:** AAFC/CFIA Retreat on the Biosafety Protocol - November 13, 1997.

The promised worksheet, containing the consolidated draft text with corresponding Canadian policy considerations, will now be supplied to you in hard copy form (it was being generated for another purpose by another group, who unfortunately use MS Word - I was not successful at converting this to WP6.1, so was not able to e-mail it to you - however, it is 96 pages, so may not have been too happy about printing this yourselves!). Ann will supply the AAFC participants with hard copies and I will supply the CFIA participants (Harvey, Ann will get you a copy, despite you being mistakenly listed as part of CFIA - I apologize!). We will aim to get these to your desks Wednesday Nov. 12th.

The worksheet will have three columns. The first will contain the consolidated draft legal text, from the October Montreal negotiating session, listing all the options generated for each of the 43 articles. You will have seen this already, in a different format, in the material that Ann e-mailed you last week. The second and middle column of the worksheet will contain either Canada's current policies on the article in question, or, in the absence of current policy, information on our current considerations. The third column will be blank, into which we will enter our proposed position (s), etc, resulting from the Thursday discussions. We will walk you through this material before we start on Thursday. When reviewing the worksheet, please concentrate on the following articles, that will form the basis of our discussions:

- Article 2 - Use of Terms (especially the terms, Living Modified Organism, Contained Use, Deliberate Release, Novel Traits)
- Article 3 - Advance Informed Agreement (AIA)
- Article 4 - Notification Procedure for AIA
- Article 5 - Response to AIA Notification
- Article 6 - Decision Procedure for AIA
- Article 7 - Review of Decision under AIA
- Article 8 - Notification of Transit
- Article 9 - Simplified Procedure for AIA
- Article 10 - Subsequent Imports
- Article 11 - Bilateral and Regional Agreements
- Article 12 - Risk Assessment
- Article 13 - Risk Management
- Article 17 - Handling, Transport, Packaging, and Labelling
- Article 19 - Information Sharing/Biosafety Clearing House
- Article 23 - Trade with Non-Parties
- Article 24 - Non-Discrimination
- Article 35 - Monitoring and Compliance

Please note that for Article 3, Advance Informed Agreement, there are actually 20 options, but these have been "clustered" into 6 groups. Each of the options, as in all the other articles, has been developed by a single country (the country name was removed during the consolidation in Montreal). All of the consolidated text in the first column was generated by the Secretariat in Montreal, so any typos or confusing use of square brackets has not been our responsibility!

Attached below is the agenda for the meeting. Please note that lunch is not being supplied. See you on Thursday.

CC: AGCAN.internet."betty.kennedy@sympatico.ca"



of Canada du CanadaMEMORANDUM NOTE DE SERVICE

Security - Classification - de Sécurité
Our File - Notre référence <b>1430-1-3-3</b>
Your File - Votre référence
Date  <b>November 3, 1997</b>

**Distribution:**

Rory McAlpine - Deputy Director - International Trade Policy (MISB, AAFC)  
Harold Hedley - Acting Director - Grains and Oilseeds Division (MISB, AAFC)  
Ross Reid - Grains and Oilseeds Division (MISB, AAFC)  
Sandra Needham - Environment Bureau (Policy Branch, AAFC)  
Dalia Kudirka - Special Advisor Biotechnology/International (Research Branch, AAFC)  
Brad Fraleigh - Special Advisor Biodiversity and Genetic Resources (Research Branch, AAFC)  
Garry Hewston - Senior Economist (Policy Branch, AAFC)  
Lucy LaRose - Horticulture and Special Crops Division (MISB, AAFC)  
Dave Trus - Animal Industry Division (MISB, AAFC)  
Daniel Burgoyne - Economist/International Affairs Division (CFIA)  
Stacy Charlton - Plant Biotechnology Office (CFIA)  
Harvey Voldeng - Ass Director, ECORC, Research Branch, (CFIA)  
Alan Goldrosen - Regulatory Affairs (CFIA)  
Trudy Werry - Plant Protection Program (CFIA)  
Francine Lord - Animal Health Program (CFIA)  
Jill Vaisey - (PFRA, AAFC - Regina)  
Alick Huebener - (Communications Branch, AAFC)  
Barbara Doan - Special Advisor on Biotechnology  
Betty Kennedy - Facilitator

cc (memo only): Stephen Yarrow (BSCO/CFIA)  
cc (memo only): Suzanne Vinet (ITPD/AAFC)

cc (memo only): Margaret Kenny (BSCO/CFIA)

Attachments:

- Agenda for the Retreat
- Biodiversity Secretariat's Report of the Negotiating Session in Montreal (October 13-17, 1997)
- Summary Table of Canada's Negotiating Positions (to be forwarded later)
- Report of Meeting of Agricultural Commodities Advisory Group (September 10, 1997)

I would like to invite you to a one-day retreat to prepare an Agriculture negotiating position@ on the Biosafety Protocol. The retreat will be held on **November 13, 1997** in the **AJoilette Room@** of the **Citadel Hotel** from **9:00 am - 5:00 pm**. I would appreciate if you would confirm your participation with me, **Ann Penner (759-7678)** by November 7, 1997.

Objective of the Retreat:

The objective of the retreat is to begin to develop an Agricultural negotiating position@ to reflect the concerns of AAFC and the CFIA with: (1) the Biosafety Protocol's potential trade implications for agricultural commodities; (2) meeting AAFC/CFIA's commitments under the Biodiversity Action Plan; and (3) maintaining the integrity of Canada's current regulatory system for approving genetically modified organisms for environmental release

Background:

Canada is currently participating in the negotiations of a Biosafety Protocol within the framework of the United Nations' Convention on Biological Diversity. The Protocol's objective is to regulate the transboundary movement of living modified organisms (LMOs), derived from modern biotechnology, that could have an adverse effect on biological diversity. At the heart of the proposed Protocol is the Advance Informed Agreement (AIA) - a process that would require assessment, approval, and consent by an importing country prior to the transboundary movement of an LMO.

Three negotiating sessions have been held on the Protocol, the most recent of which was held in Montreal from October 13-17, 1997. Officials from AAFC and the CFIA participated in the Montreal session. The purpose of the Montreal session was to develop a consolidated draft legal text from the submissions that participating Governments made in August, 1997. This consolidated text will be the subject of three more negotiating sessions (planned for February, August, November), in order that the Protocol is completed by December, 1998. The Biodiversity Secretariat's report of the Montreal Session is attached for your information.

Next Steps:

The next negotiating session of the Protocol is scheduled for February 9-18, 1998. Canada's delegation must develop negotiating positions on the consolidated draft legal text between now and February. Canada has begun to formulate positions on certain issues. However, Canadian positions have not been developed for a number of important issues. The current status of Canada's negotiating position is being summarized into a table and will be forwarded

to you later this week.

Canada's negotiating position will be developed by a federal inter-departmental working group between now and February, 1998. The working group is co-chaired by Environment Canada and the Department of Foreign Affairs and International Trade (DFAIT), and consists of representatives from AAFC, CFIA, Fisheries and Oceans, Health Canada, Industry Canada, Justice, Natural Resources Canada, and PCO. The working group must prepare a Memorandum to Cabinet (MC) by the end of November, 1997 to obtain negotiating authority for 1998.

It is therefore important that AAFC and CFIA officials develop an Agricultural negotiating position@ to reflect the interests of the agri-food sector within the broader inter-departmental exercise. The retreat will be used to go through the Protocol's draft legal text and Canada's current negotiating positions to determine which options are acceptable to AAFC/CFIA, and to identify holes where positions are needed.

Furthermore, the retreat will be used to consider the interests of interested stakeholders, and to determine how AAFC and CFIA officials should respond. Industry consultations will be conducted on two levels during November: (1) Biosafety Advisory Group - a group that consists of the federal inter-departmental working group and industry representatives from environmental non-governmental organizations, biotechnology industry associations, and two agri-food industry associations (Canadian Seed Trade Association, Canada Grains Council); and (2) Agricultural Commodities Advisory Group which consists of representatives from a wide-cross section on the agri-food industry and is co-chaired by AAFC and the CFIA. The Biosafety Advisory Group will be engaged over the next few weeks, leading to a meeting mid-January 1998. AAFC and CFIA officials are planning to hold a consultation session with the Agricultural Commodities Advisory Group in November, 1997, in Guelph, with the possibility of a second session in Winnipeg.

#### Overview of Industry Concerns:

To date, the agri-food industry has been primarily concerned about the potential ramifications of the Protocol's AIA process for the trade of agricultural commodities such as canola and wheat, as they are substituted and/or co-mingled with biotechnology derived varieties. Specifically, agri-food associations are fearful that the AIA will place excessive, unmanageable restrictions and information requirements on Canadian exporters when trading commodities that contain LMOs. Furthermore, they are concerned that the federal government has not given the views of the agricultural sector equal weight to those of environmental groups, even though they have recognized that the government has begun to address some of the problems associated with the inclusion of agricultural commodities in the Protocol.

Agricultural producers would like agri-food commodities to be exempt from the protocol, particularly where they are intended for human or animal consumption and will not enter the local environment (i.e., through cultivation). At the very least, they would like the protocol to include provisions to facilitate the flow of agri-food commodities that do/could contain LMOs but which pose no risk to biodiversity. Their concerns are legitimate in view of the rapid commercialization of genetically modified crops in Canada, the significance of Canada's exports of grains and oilseeds, and the thousands of trans-boundary movements of LMOs that occur each year, etc. It is particularly important to note that there is currently no segregation of genetically modified and traditional crops in Canada's bulk handling and export system and so

all of Canada's grains and oilseeds could be affected by the provisions of the protocol. A summary of industry concerns is provided in the report of the first meeting of the Agricultural Commodities Advisory Group in September, 1997 (attached).

**Retreat of AAFC and CFIA Officials -  
Agricultural Negotiating Positions on the Biosafety Protocol  
November 13, 1997  
Citadel Hotel**

8:45 am Coffee

9:00 am Welcome and Introductions

9:15 am Debrief of the Montreal Negotiating Session A. Penner, S. Yarrow

10:15 am Coffee

10:30 am Review of the Consolidated Draft Legal Text of the Biosafety Protocol

12:00 pm Lunch

1:00 pm Review of the Consolidated Draft Legal Text of the Biosafety Protocol (cont'd)

3:00 pm Coffee

3:15 pm Review of the Consolidated Draft Legal Text of the Biosafety Protocol (cont'd)

4:00 pm Industry Consultations

5:00 pm Adjournment



## CONVENTION ON BIOLOGICAL DIVERSITY

Distr.  
GENERAL

UNEP/CBD/BSWG/3/6  
17 October 1997

ORIGINAL: ENGLISH

ADVANCE UNEDITED COPY

OPEN-ENDED AD HOC WORKING  
GROUP ON BIOSAFETY  
Third Meeting  
Montreal, Canada  
13 to 17 October 1997

### REPORT OF THE THIRD MEETING OF THE OPEN-ENDED AD HOC WORKING GROUP ON BIOSAFETY

#### Introduction

1. The third meeting of the Open-ended Ad Hoc Working Group on Biosafety, established in accordance with decision II/5 of the Conference of the Parties to the Convention on Biological Diversity, was held in Montreal (Canada) from 13 to 17 October 1997.

#### I. ORGANIZATIONAL MATTERS

##### A. Opening of the meeting

2. The meeting was opened by Mr. Veit Koester (Denmark), in his capacity as Chairman of the Open-ended Ad Hoc Working Group, at 10.20 a.m. on Monday, 13 October 1997. In his opening statement, Mr. Koester welcomed all participants and expressed his satisfaction at what had been accomplished since the second meeting of the Open-ended Working Group,

in May 1997. He particularly highlighted the volume and scope of the government submissions of draft texts on selected items for inclusion in the draft protocol, and congratulated the secretariat on the preparation of the documentation available to the current meeting.

3. Recalling that decision III/20 of the Conference of the Parties requested the Open-ended Working Group to complete its work by 1998, he said that a lot of ground still had to be covered by the Group. To meet the target set, and to conform to paragraph 3 of Article 28 of the Convention, the Group was compelled to submit to the Conference of the Parties at its fourth meeting, in May 1998, a draft text of a protocol that all agreed constituted sufficient ground for the completion of the negotiating process and the adoption of the protocol before the end of 1998. That meant that all the options and elements should be contained in the consolidated draft in legal terms. There was no doubt that additional negotiations would be deemed necessary after May 1998.
4. The timetable required that there be another meeting of the Group before the fourth meeting of the Conference of the Parties, and possibly two meetings subsequent to it, in order to finalize the negotiations, based on the preliminary consolidated text submitted to the Conference of the Parties. The draft protocol would be submitted for official adoption at a special session of the Conference of the Parties in late 1998, which would be held in conjunction with the last meeting of the Group. The dates and venues of the further meetings of the Group would be discussed later at the current meeting. He concluded by thanking all those involved for their efforts in the progress made so far, and expressed the hope that the goodwill and cooperation shown in the previous meetings of the Group would enable it to make further progress in solving the tasks before it.
5. At the opening session of the meeting, the Working Group also heard statements from: Mr. Reuben Olembo, Deputy Executive Director of the United Nations Environment Programme (UNEP) and Mr. Calestous Juma, Executive Secretary of the Convention on Biological Diversity.
6. Mr. Olembo expressed his appreciation to Governments for their cooperation in submitting draft texts for inclusion in the protocol under negotiation and also congratulated the secretariat for its efforts in preparing the documentation for the meeting. He said that the current meeting of the Working Group provided an opportunity to achieve the results that the outside world was looking for. Given the rapid development in the use of biotechnology products and processes, it was important for an international agreement on safety in biotechnology to be speedily attained, taking into account the knowledge and experience

gained so far. He noted that the 1996 survey by UNEP on the implementation of the UNEP International Technical Guidelines for Safety in Biotechnology had indicated that the aspects of the Guidelines of most interest to Governments were those related to risk-assessment and risk-management principles, national regulatory mechanisms and capacity-building, as well as regional and international regulatory mechanisms. Other issues mentioned included lack of human resources, institutional capacities and the infrastructural facilities needed for an effective exchange of information on biosafety. High priority should therefore be given to initiatives aimed at supporting countries overcome these constraints. In conclusion, Mr. Olembo stressed the importance of taking into account the views of all stakeholders, including the biotechnology industry and civil society, through their effective participation at all stages of the protocol development process.

7. Mr. Juma said that the precautionary principle provided guidance in the development and application of international environmental law where there was scientific uncertainty. The core of the principle, which was still evolving, was reflected in the ninth preambular paragraph to the Convention on Biological Diversity. The decision of the Conference of the Parties to establish the Working Group had set in motion the implementation of the principle within the framework of the Convention and had marked a turning point for the Convention. The main elements of a draft protocol C advance informed agreement, risk assessment and risk management C were an elaboration of the precautionary principle, and the process would, once again, establish the Convention on Biological Diversity as an important rule-making and standard-setting environmental forum. Recalling that, according to its terms of reference, the Group should endeavour to complete its work in 1998, the Executive Secretary pledged the full support of the secretariat to the Group's work and urged participants to continue with the same spirit of cooperation that they had shown at previous meetings.

#### B. Attendance

8. The meeting was attended by representatives of the following States and regional economic integration organizations: Antigua and Barbuda, Argentina, Australia, Austria, Bahamas, Bangladesh, Belarus, Belgium, Bolivia, Brazil, Bulgaria, Burkina Faso, Burundi, Cameroon, Canada, Cape Verde, Central African Republic, Chad, Chile, China, Colombia, Comoros, Costa Rica, Cuba, Czech Republic, Democratic Republic of the Congo, Denmark, Dominican Republic, Ecuador, Egypt, Eritrea, Ethiopia, European Community, Fiji, Finland, France, Gabon, Gambia, Germany, Ghana, Greece, Grenada, Guinea, Haiti, Hungary, India, Indonesia, Iran (Islamic Republic of), Italy, Jamaica, Japan, Jordan, Kenya, Kiribati, Kuwait,

Lao People's Democratic Republic, Lebanon, Lesotho, Lithuania, Luxembourg, Madagascar, Malawi, Malaysia, Mali, Mauritania, Mexico, Mongolia, Morocco, Myanmar, Nepal, Netherlands, New Zealand, Niger, Norway, Papua New Guinea, Philippines, Poland, Portugal, Republic of Korea, Russian Federation, Saint Lucia, Samoa, Saudi Arabia, Seychelles, Singapore, South Africa, Spain, Saint Kitts and Nevis, Swaziland, Sweden, Switzerland, Thailand, Togo, Uganda, United Kingdom of Great Britain and Northern Ireland, United States of America, Venezuela, Viet Nam, Zambia and Zimbabwe.

9. The following United Nations bodies and specialized agencies were represented: Global Environment Facility (GEF), United Nations Environment Programme (UNEP), World Intellectual Property Organization (WIPO).
10. Representatives of the following intergovernmental organizations attended the meeting: Commission for Environmental Cooperation, Institut de l'Énergie Des Pays Ayant en Commun l'Usage du Français (IEPF), Organisation for Economic Cooperation and Development.
11. The following non-governmental organizations were also represented: American Seed Trade Association, American Soybean Association, ASSINSEL (International Association of Plant Breeders), Association of Biotechnology Industries of Denmark, Beveridge & Diamond, P.C., BIO, Biotechnology Industry Organisation, Biotechnology Working Group, Canada Grains Council, Canadian Broadcasting Corporation (CBC), Canadian Institute for Environmental Law and Policy, Canadian Institute of Biotechnology, Canadian Seedtrade, CBC Radio, Council for Responsible Genetics, Department of Foreign Affairs and International Trade, Ecoropa, Environmental Information Management Consulting, Forum Environment and Development Working Group on Biodiversity, Foundation for International Environmental Law and Development, Friends of the Earth International, German Working Group on Biodiversity, Green Industry Biotechnology Platform (GIBiP)/Assinsel, Greenpeace, Industrial Biotechnology Association, Institute for Agriculture and Trade Policy, International Service for the Acquisition of Agro-Biotech Applications (ISAAA), Japan Bioindustry Association, M.S. Swaminathan Research Foundation, McGill University, Monsanto-BIO, Musée Canadien de la Nature, Natural Agriculture Environment Committee (NAEC), Ontario Agri-food Technologies, Reportaje y Dialogo and Prensa Libre, Royal Ontario Museum, The Canadian Federation of Agriculture, The Edmonds Institute, Third World Network, Université de Montréal, Université du Québec à Montréal (UQAM), University of Montreal - Faculty of Law and York University.



#### C. Bureau

12. Pursuant to paragraph 1 (b) of decision III/20 of the Conference of the Parties to the Convention on Biological Diversity, the following representatives served as the Bureau of the Working Group at its third meeting:

Mr. Veit Koester (Denmark) (Chairman)  
Mr. Behren Gebre Egziabher Tewolde (Ethiopia)  
Mr. David Hafashimana (Uganda)\*  
Mr. Diego Malpede (Argentina)  
Mrs. Sandra Wint (Jamaica)  
Dr. Ervin Balazs (Hungary)  
Dr. Alexander Golikov (Russian Federation)  
Mr. Jose Maria A. Ochave (Philippines)\*\*  
Mr. Jong Ho Choi (Republic of Korea)\*\*\*  
Mr. David Gamble (New Zealand)

13. Dr. Alexander Golikov (Russian Federation) continued to serve as Rapporteur.

#### D. Adoption of the agenda

14. The Working Group adopted the following agenda on the basis of the provisional agenda that had been circulated under the symbol UNEP/CBD/BSWG/3/1:

1. Opening of the meeting.
2. Adoption of the agenda.
3. Organization of work.
4. Elaboration of a protocol on biosafety in accordance with decision II/5 of the Conference of the Parties to the Convention on Biological Diversity.
5. Dates and venues of meetings of the Open-ended Ad Hoc Working Group on Biosafety for 1998.
6. Adoption of the report.
7. Closure of the meeting.

#### E. Documentation

15. The following working documents were before the Working Group at the meeting: provisional agenda (UNEP/CBD/BSWG/3/1); annotated provisional agenda (UNEP/CBD/BSWG/3/1/Add.1); Chairman's review of items addressed by country submissions at the second meeting of the Open-ended Working Group (UNEP/CBD/BSWG/3/2); compilation of government submissions of draft text on selected items (UNEP/CBD/BSWG/3/3 and Add.1-3); compilation of draft text prepared by the Secretariat on selected items (UNEP/CBD/BSWG/3/4 and Add.1); government submissions (UNEP/CBD/BSWG/3/5 and Add.1)
16. The Working Group also had before it the following information documents: compilation of definitions and terms relevant to a biosafety protocol (UNEP/CBD/BSWG/3/Inf.1 and Add.1); background document on existing international agreements related to biosafety (UNEP/CBD/BSWG/3/Inf.2); Chairman's draft content of text of items, article 11 and articles 15-22 (UNEP/CBD/BSWG/3/Inf.4).

#### F. Organization of work

17. The Working Group decided to establish two open-ended sessional Sub-Working Groups: Sub-Working Group I, co-chaired by Dr. Eric Schoonejans (France) and Mrs. Sandra Wint (Jamaica), and Sub-Working Group II, co-chaired by Ms. Hira Jhamtani (Indonesia) and Mr. David Gamble (New Zealand).
18. It was decided that the Sub-Working Groups would meet concurrently, but not at the same time as plenary sessions. In addition, to help offset the problems faced by small delegations and to ensure adequate regional representation in both the Sub-Working Groups, it was decided that each regional group would designate four representatives to attend each Sub-Working Group. The following core representatives were designated:
  - (a) Sub-Working Group I:
    - (i) From the African Group: Ethiopia, Guinea, Kenya, Seychelles;
    - (ii) From the Asia and Pacific Group: India, Japan, Malaysia, Republic of Korea;
    - (iii) From the East and Central European Group: Belarus, Czech Republic, Hungary, Lithuania;
    - (iv) From the Latin America and Caribbean Group: Argentina, Bahamas, Brazil, Colombia;

- (v) From the Western European and Others Group: Australia, Canada, European Commission, Norway;
- (b) Sub-Working Group II:
  - (i) From the African Group: Egypt, Ghana, Mali, Zimbabwe;
  - (ii) From the Asia and Pacific Group: China, Iran (Islamic Republic of), Philippines, Singapore;
  - (iii) From the East and Central European Group: Bulgaria, Poland, Russian Federation;
  - (iv) From the Latin America and Caribbean Group: Brazil, Colombia, Costa Rica, Venezuela;
  - (v) From the Western European and Others Group: Canada, European Commission, United Kingdom of Great Britain and Northern Ireland, United States of America.

19. It was agreed that Sub-Working Group I would have the following mandate:  
"With the objective of developing a consolidated draft negotiating legal text for proposed articles numbers 3 to 14 inclusive, excluding article 11, as identified in the Secretariat compilation of government submissions (UNEP/CBD/BSWG/3/3),

"Working under the guidance of the Co-Chairs, and under a modus operandi developed by the Co-Chairs and accepted by the participating Governments in the Sub-Working Group,

"The participants of the Sub-Working Group shall:

"Taking into account the views of participants, review in the submissions of Governments, and any additional information, and attempt to reach consensus on the content of a consolidated text which may contain agreed options for each draft article.

"It is expected that the Sub-Working Group will discuss the views of the participants, and the content of the government submissions, to identify what could be included in the consolidated text.

"The main objective of the work is to achieve a consolidated text for negotiation.

"The draft consolidated text developed in the Sub-Working Group will be presented to plenary not later than Thursday evening by the Co-Chairs

for adoption for inclusion in the report of the meeting."

20. It was agreed that Sub-Working Group II would have the following mandate:

"With the objective of developing a consolidated draft negotiating legal text for proposed articles numbers 11 and 15 to 22 inclusive, as identified in the Secretariat compilation of government submissions (UNEP/CBD/BSWG/3/3),

"Working under the guidance of the Co-Chairs, and under a modus operandi developed by the Co-Chairs and accepted by the participating Governments in the Sub-Working Group,

"The participants of the Sub-Working Group shall:

"Taking into account the views of participants, review the submissions of Governments, and any additional information, and attempt to reach consensus on the content of a consolidated text which will contain agreed options for each draft article.

"It is expected that the Sub-Working Group will discuss the views of the participants, and the content of the government submissions, to identify the various options that could be included in the consolidated text.

"The main objective of the work is to achieve a consolidated text for negotiation.

"The draft consolidated text developed in the Sub-Working Group will be presented to plenary not later than Thursday evening by the Co-Chairs for adoption for inclusion in the report of the meeting."

21. The Open-ended Ad Hoc Working Group also decided to establish two open-ended Contact Groups, meeting outside normal working hours, and reporting back to the plenary: Contact Group 1, co-chaired by Mr. Willemse (South Africa) and Mr. Piet van der Meer (Netherlands), and Contact Group 2, co-chaired by Mr. John Ashe (Antigua and Barbuda) and a representative nominated by the Western European and Others Group.

22. It was agreed that Contact Group 1 would have the following mandate:

"With the objective of developing a consolidated draft negotiating legal text of a protocol on biosafety,

"Working under the guidance of the Co-Chairs, and under a modus operandi developed by the Co-Chairs and accepted by the participating Governments

in the Contact Group, the participants in the Contact Group on Definitions and Annexes shall:

"Taking into account the views of participants, review the information in the submissions of Governments and any additional information and attempt to reach consensus on recommendations on the content of a consolidated text which will contain agreed options for both definitions and annexes.

"It is expected that the Contact Group will discuss the views of the participants and the content of the government submissions, to identify the various options that could be included in the consolidated text.

"The main objective of the work is to achieve a consolidated text (i.e. one definition per item with or without square brackets) for negotiation, rather than to negotiate a final text."

23. It was agreed that Contact Group 2 would have the following mandate:

"With the objective of providing advice to the Working group on issues related to institutional and financial matters, as well as final clauses, that would assist in the development of a consolidated draft negotiating legal text of a protocol on biosafety,

"Working under the guidance of the Co-Chairs, and under a modus operandi developed by the Co-Chairs and accepted by the participating Governments in the Contact Group,

"The participants of the Contact Group will consider the draft Articles contained in document UNEP/CBD/BSWG/3/4 and Add.1 as they pertain to financial and institutional matters.

"As a matter of priority, following initial review of the matters if the Contact Group identifies topics that need discussion, these items should be recommended for discussion to the plenary no later than the evening of Tuesday, 14 October 1997.

"Also as a matter of priority, the Contact Group should also consider, on the basis of the discussion in plenary of the work of the second meeting of the Working Group and the element paper contained in the report of that meeting (UNEP/CBD/BSWG/2/6 pp. 55-56) on monitoring and compliance, what recommendations to make to the plenary on how to progress on the work on this item.

"Taking into account the views of participants, the Contact Group shall review the submissions of Governments and any additional information,

and formulate recommendations to the Working Group on these items.

"It is expected that the Contact Group will discuss the views of the participants and the content of the government submissions, to identify the various options that could be included in the consolidated text.

"The main objective of the work is to achieve a consolidated text for negotiation.

"Any item that the Working Group recommends for discussion in the plenary should be contained in an aide-mémoire, identifying the specific questions that, in the Contact Group's opinion, should be put to the plenary."

24. The Working Group decided that the principle of the meetings of both Sub-Working Groups and the two Contact Groups to be open to the full participation by all, implied that any decision to limit the effective/full participation of all delegates (e.g., speaking rights, right to attend the meeting, or right to be a member of any drafting group) would need to build on a consensus decision by all governmental members of the relevant group.
25. The Working Group also decided that, where possible, all other outstanding items would be addressed by the plenary.

II. ELABORATION OF A PROTOCOL ON BIOSAFETY IN ACCORDANCE WITH  
DECISION II/5 OF THE CONFERENCE OF THE PARTIES TO THE  
CONVENTION ON BIOLOGICAL DIVERSITY

26. At its 3rd and 4th plenary sessions, on 14 and 15 October 1997, the Working Group took up the following issues pertaining to possible elements for inclusion in a draft protocol and which had not been referred to the Sub-Working Groups: socio-economic considerations; liability and compensation; non-Parties; illegal traffic; non-discrimination; objectives; general obligations; title; and preamble. In some cases, those issues had been the subject of draft texts already submitted to the Secretariat by Governments.
27. As far as the items on socio-economic considerations and liability and compensation were concerned, the Working Group agreed that, following the discussion, the issues would not be the subject of a further element paper but would be included in the consolidated text of draft articles (see annex I below), with the legal texts already submitted by Governments being set out as various options and with an additional option to the effect that the item should not be addressed in the Protocol. The Governments concerned would be free to amend their submissions and other Governments could submit new text at the appropriate time. The issues concerned would be subsequently taken up on an equal footing with those issues being discussed in the Sub-Working Groups and Contact Groups.
28. At the 4th and 5th sessions of the meetings, on 15 and 16 October 1997, the Working Group heard the reports of the Co-Chairs of Sub-Working Groups I and II and of Contact Groups 1 and 2. At its 4th meeting, the Working Group agreed that the draft articles prepared by the Groups would be included in the consolidated draft annexed to the present report.

Socio-economic considerations

29. Several representatives strongly believed that the protocol should contain an article with specific provisions on socio-economic considerations arising from the introduction of LMOs. The view was expressed that such considerations should be at the very heart of the protocol itself, since many developing countries, particularly least-developed countries, lacked the capacities and infrastructure to protect themselves from possible negative impacts of introduced LMOs, such as genetic erosion in centres of origin; negative health and environmental impacts; threats to ecosystems and to biodiversity;

- possible displacement of resource-use systems, particularly with respect to small-scale farmers; problems arising from the introduction into products of genetic material from sources considered to be unclean by certain religious groups; and other ethical considerations.
30. Other representatives said that, because socio-economic considerations covered very broad issues which varied from country to country and which were difficult to quantify, it was not possible to evaluate fully the potential socio-economic impact of introducing an LMO into a specific country's conditions. It was thus not appropriate for the protocol to contain an article setting out specific provisions for socio-economic considerations.
31. Several representatives considered that the elements of the protocol concerning risk assessment and risk management should not be based solely on scientific aspects, but should take into account socio-economic and ethical aspects which, it was pointed out, varied from country to country and even from community to community. One representative proposed that risk assessment should incorporate elements to mitigate negative impacts on an importing country. Another representative considered that risk assessment and risk management needed to be addressed, in particular, genetic erosion and its impacts.
32. One representative considered that risk assessment of an LMO should be carried out solely on the basis of scientific data, and should not take into account socio-economic considerations. Risk-assessment criteria, he said, were based on a harmonization of procedures, and that process would be degraded by including socio-economic considerations.
33. One representative said that if an importing country decided that an LMO would have harmful socio-economic repercussions, it would be possible for that country to prevent the import under existing trade-related treaties, without there being a need to include socio-economic considerations in the protocol. Another considered that, while socio-economic considerations were important, they should be addressed at the national level and at the level of bilateral agreements between importing and exporting Parties; the protocol was a technical tool to ensure the proper and harmonized use and transfer of LMOs and should not contain any specific provisions on socio-economic considerations.
34. Another representative said that it was expected that Parties would be free to take a decision regarding the importing of a technology. To that end, she said, suitable exceptions should be included in the non-discrimination section of the protocol.
35. Another representative, while holding no definite view on whether or not



the protocol should contain provisions on socio-economic considerations, considered it important to distinguish between measures that sought to protect a country's agriculture against economic losses resulting from introduced pests, diseases or other harm, and measures that sought to protect a country's agriculture against international competition. The latter were not relevant to the present protocol, but were appropriate to other forums. He said that he would be very reluctant to see the protocol become a new pretext for protectionism.

36. One representative believed that, since socio-economic considerations were linked to national issues, the protocol should address aspects of socio-economic considerations, but with the proviso that they were a national issue. In addition, only those socio-economic considerations that were unique to the LMOs in question should be addressed. On the basis of their own national assessments, countries should retain the right to decide whether or not to agree to import an LMO. Moreover, it was not necessary for the protocol to contain provisions governing specific impacts, e.g. genetic erosion, since Governments were free to set stricter standards if they so wished.
37. Another representative, pointing out that his country's national biosafety legislation took into account the particular requirements of its indigenous people, considered that the protocol should not exclude the possibility of countries introducing national provisions along such lines.
38. Some representatives said that, while it was not appropriate for the protocol to contain provisions governing socio-economic considerations, the protocol could contain a reference to such considerations, perhaps in its non-binding, preambular section.

#### Liability and compensation

39. A number of representatives said that the issue of liability and compensation was of crucial importance, was not adequately covered in Article 14, paragraph 2, of the Convention and should be addressed in the protocol. A number of them supported the view that Article 14, paragraph 2, was an enabling provision and could be used as a starting point for future work on the question as it specifically related to biosafety. One of those representatives said that, unlike the provisions of Article 14, paragraph 2, the issue under consideration involved not only damage to biological diversity but also to the human health. Another of those representatives said that the fact that Article 14, paragraph 2, provided for an exception in cases where the liability was a purely internal matter showed that the provision did not

cover all the issues related to liability and compensation. One representative suggested the establishment of an accident insurance scheme for commercial transactions related to the movement and use of living modified organisms to cover any damage that might arise.

40. Some representatives suggested that further consideration should be given to the question of liability and compensation within the context of the Conference of the Parties. One of those representatives suggested that the Conference of the Parties might wish to establish another group for that purpose, following the model of the Basel Convention on the Control of Transboundary Movements and their Disposal, while another representative, speaking on behalf of a regional economic integration organization and its member States, said that it would not be desirable at the current point to include any substantive provisions on liability and compensation in the protocol, since the task of harmonizing relevant national legal regimes and principles would be complex and lengthy and unlikely to be completed by the time of finalizing the protocol in 1998. Yet another representative said that, since the studies referred to in Article 14, paragraph 2, had not yet been carried out, it was not appropriate to include an article on liability and compensation in the draft protocol. Another representative, however, said that there was no need to wait for those studies to be finalized in order to address the issue in the protocol. Another representative said that the issue was adequately covered by Article 14, paragraph 2, and therefore need not be addressed in a separate protocol; the claims for compensation should only involve the exporting and importing entities and should be decided upon on a case-by-case basis.
41. A number of representatives expressed support for the idea that, in addressing the issue of liability and compensation, the protocol should draw on existing international agreements. Relevant agreements mentioned included: the European Convention on Civil Liability for Damage resulting from Activities Dangerous to the Environment; the International Convention on Civil Liability for Oil Pollution Damage; the Convention on Civil Liability for Nuclear Damage; the Convention on International Liability for Damage caused by Space Objects; the International Convention on Liability and Compensation for Damage in Connection with the Carriage of Hazardous and Noxious Substances by Sea.
42. Some representatives supported having criteria in the Protocol for assessing liability and compensation. One representative outlined a number of criteria to be included as follows: establishment of baseline parameters for liability; establishment of the measure of damage; identification of the person or persons against whom the claim is made;

establishment of who reports the damage; designation of the forum in which the claim is made; determination of possible alternative means of resolution; and provision for the availability of defence. Liability should include both State and civil liability. One representative had no strong views on the issue, while another representative supported having criteria mentioned as a general principle. A few representatives were opposed to any inclusion at all of criteria.

43. Some representatives said that the criteria should be listed in a separate annex to the protocol, while others said that they were open to this idea. Some representatives opposed the separate listing in an annex.
44. A few representatives supported the immediate formulation of annexes containing criterias for liability while one representative opposed it.
45. A number of representatives agreed that national legislation addressing liability and compensation should apply in cases of harm due to transboundary movements of LMOs, one stating that that would enable the implementation of the protocol to be monitored at the national and bilateral levels. Another of those representatives said that such application would depend on how the national legislation was drafted and that the real substance of an article on liability and compensation would lie in encouraging a commitment on the part of countries to the development of applicable international law. Another representative said that provisions of the protocol must be included in national legislation, in which case such legislation would apply. The view was also expressed that the applicability of national legislation could be considered on a case-by-case basis and that customary international law was also of relevance.
46. One representative said that the exporter should always be liable to compensate aggrieved parties on the understanding that the importer of the LMO should not claim compensation for accidents arising out of his/her own negligence; any third party negatively affected by an LMO should be fully compensated by either the exporter only, if the exporter did not provide enough information, leading to the subsequent accident, or the exporter and importer if they were both responsible for the accident in question.

#### Illegal traffic

47. One representative, speaking on behalf of a regional economic integration organization and its member States, expressed the view that illegal traffic must be understood to mean movement of LMOs in breach of

national legislation implementing the protocol. He believed that it should be the responsibility of each Party to introduce appropriate domestic legislation to prevent illegal traffic. At the same time the issue of illegal traffic should be related to the objective of the protocol which was to ensure an adequate level of protection in the field of biosafety. However, relevant available information concerning illegal traffic should be transmitted to affected parties without delay. Data concerning illegal traffic could be included in the information-exchange mechanism.

48. One representative felt that the issue of illegal traffic was to be enforced under national legislation and that the issue was not to be dealt with in the protocol.
49. Another representative said that Parties should introduce appropriate national legislation to prevent and punish illegal traffic. Additional penalties could be imposed for illegal traffic, as appropriate.
50. One representative suggested the inclusion of a strong provision on illegal traffic in the protocol, in view of the fact that the protocol would be legally binding. National legislation would then have to be established in order to implement the international agreement. The representative suggested that the protocol should contain a provision related to traffic between Parties and non-Parties so as to assure the compliance with the protocol, either on a bilateral or regional basis. Several representatives stressed the need for the inclusion of a clause on illegal traffic in the protocol, in order to enhance countries' capacity to address illegal traffic at the national level.
51. Supporting this view, another representative, speaking on behalf of a regional group, said that illegal traffic, by nature, was international. Thus, international action on illegal traffic was required. He further stressed, that national legislation alone would not suffice in dealing with this issue.
52. The Working Group agreed that the Secretariat would compile the main elements submitted by countries on illegal traffic and, based on that text as well as legal texts submitted by Governments (the African region, Australia, Malaysia and South Africa), request Sub-Working Group II to refine the elements and/or develop legal texts. The outcome of the work of the Sub-Working Group would then be included in the consolidated draft.

#### Non-Parties

53. A number of representatives and a non-governmental organization

considered that the issue of non-Parties should be addressed in the protocol. One of them pointed to the role and influence that non-Parties could have with regard to the handling and transfer of LMOs. Another observed that the problem of non-Parties would arise in any case, so it was necessary to include a provision on them in the protocol.

54. One representative said that the issue of non-Parties should not be addressed by the protocol.
55. One other representative was of the opinion that at the current stage of negotiations it was premature to include in the protocol any provisions on non-Parties.
56. A number of representatives considered that trade with non-Parties should be permitted. The representative of the African Group said that the Group was holding consultations on specific aspects of trade with non-Parties and would return to the Open-ended Working Group with specific provisions on the issue at a later time. One representative reminded the meeting of the recommendation of the Conference of the Parties at its second meeting that the protocol should be ratified by as many countries as possible, in order to establish a procedure for the transfer of LMOs and a framework to integrate non-Parties, rather than exclude them. The same representative said that bilateral, multilateral or regional agreements between Parties and non-Parties could be acceptable for the transfer of LMOs, where such an agreement was compatible with the protocol provisions on safe transfer, handling and use of LMOs. In order for there to be transparency, information on the conclusion of such agreements should be made available to all Parties. Another representative pointed out that some countries possessed relevant technologies needed by the developing countries; trade from non-Parties should therefore be permitted if the non-Party was in compliance with the protocol.
57. One representative, speaking on behalf of a regional economic integration organization and its member States, said it still needed to be seen to what extent it would be necessary, in order to achieve the objectives of the protocol, to include a provision for traffic with non-Parties. In principle, it should be more advantageous to join the protocol than to stay outside it and the protocol should aim at ensuring that the largest number possible of movements of LMOs would take place in effective compliance with the protocol. On that basis, he considered that the matter should be the subject of further consideration.
58. Several representatives said it was important that the protocol should

not impose restrictions on general trade between countries that were more stringent than those of WTO.

59. One representative believed that transfer of LMOs to non-Parties should not be permitted, even if those non-Parties were in compliance with the protocol.
60. A number of representatives were of the opinion that trade with non-Parties that were in compliance with the protocol should be permitted. One of them said that measures to ensure the safe transboundary movement of LMOs should be included under the section on arrangements in the protocol. Another representative stressed that non-Parties should fulfil the safety provisions that were to be set out in the protocol.
61. One representative considered that, if a provision on non-Parties was included, it would need to be flexible, allow trade with compliant non-Parties and not be overly restrictive.
62. One representative believed that it would be difficult to gauge a non-Party's actual level of compliance with the protocol at any given time, because such a country would not be legally bound by its provisions and could change its conduct to suit its needs.
63. Following the discussion, the Working Group agreed that an element paper reflecting the views expressed should be prepared for its consideration with a view to inclusion in the consolidated text. Governments would then be invited to submit text in legal language for the next meeting of the Working Group.
64. Pursuant to that agreement, the Chairman presented to the Working Group, at the 5th session of the meeting, on 16 October, a summary of elements identified in the plenary discussion on the subject. Having considered and introduced two amendments to the paper, the Working Group decided that it should be incorporated into the consolidated text of draft articles, together with the legal texts on the subject that had already been submitted by Governments.

#### Non-discrimination

65. On the question of whether the issue of non-discrimination should be addressed in the protocol, several representatives, one of them speaking on behalf of a regional economic integration organization and its member States, referred to the need for further work to clarify the meaning and scope of the term within the context of the protocol.

66. Some other representatives considered that the issue should be addressed in so far as it related to equal treatment between domestic and foreign products or between different foreign products and that no discrimination should be allowed under the protocol. One of those representatives said that he was concerned that the use of socio-economic parameters in risk assessment might lead to such discrimination. The same representative stressed the need for the protocol to be consistent with trade-related treaties, particularly those under the World Trade Organization. Another representative referred to the need to respect the most-favoured-nation principle and suggested that non-discrimination could be covered in the article on general principles.
67. A few representatives opposed the inclusion of a provision on non-discrimination, one of them stating that it was the sovereign right of the receiving State to decide on the transfer, handling and use of LMOs within its territory, and another saying that such a provision would force upon countries LMOs that could pose local dangers and would therefore immobilize the protocol by making its essential part non-functional. Another representative said that, should there be a provision on non-discrimination included in the protocol, there was a need to protect the sovereign right of States to take independent decisions on the import of LMOs and their products based on objective criteria, including socio-economic considerations. If trade in an LMO was refused on socio-economic grounds, the same treatment would be applied to that LMO from any other Party.
68. Following the discussion, the Working Group decided that an element paper should be prepared on the subject and submitted to Sub-Working Group II for further refinement, and its insertion in the consolidated text, and that Governments would be requested to submit proposals on the subject for consideration at the next meeting of the Working Group.

#### Objectives

69. One representative, speaking on behalf of a regional economic integration organization and its member States, said the objectives of the protocol should derive from the following considerations: the community at large could only fully exploit the potential of biotechnology if an adequate and transparent international framework for biosafety was in place; the international framework for biosafety should consist of a number of activities and mechanisms at the national, regional, multilateral and international level, which - in order to be effective and adequate - should complement, and not duplicate, each

other; and that decision II/5 directed the Working Group to focus the protocol on the transboundary movement of living modified organisms resulting from modern biotechnology that might have an adverse effect on the conservation and sustainable use of biological diversity.

70. A number of representatives agreed that the article on objectives should reflect the relevant language of decision II/5, several of them indicating that it should be made clear that biological diversity also covered human health or that it could be broadened to cover other aspects. One representative said that the Working Group should keep to the mandate provided by Decision II/5 and Article 19, paragraph 3, of the Convention, and it was therefore not necessary to include a reference to human health. Another representative said that the purpose of the protocol was to protect biological diversity per se.
71. Another representative said that the objectives of the protocol were the protection of human health, the environment and the socio-economic well-being of society from the potential risks of biotechnology, in particular those arising from the development, management, transfer, use and release of LMOs and the products thereof.
72. One representative said that the protocol should contain a separate article covering broad objectives and drew attention in that regard to the legal text submitted by her Government. Another representative, whose country was a member of a regional group that had submitted legal text on the subject, said that the objectives should be broadened to cover all the issues required to protect biological diversity, the environment, human and animal health and social well-being.
73. One representative said that the focus of the protocol should be on transboundary movements of LMOs and the prevention of adverse effects on the conservation and sustainable use of biological diversity and the protection of the environment and human health. Another representative said that the objectives of the protocol should be designed to protect biological diversity, the environment as a whole and human health.
74. Following the discussion, the Working Group agreed that, since there were legal texts on objectives already submitted by Governments (the African Group, Australia, Brazil, the European Community, Japan, Malaysia, Norway, South Africa, and Switzerland), there was no need for a separate element paper to be produced. It therefore decided that the Sub-Working Group II should consider those texts with a view to reducing the number of alternatives and developing a draft article with brackets, on the understanding that other Governments or groups of Governments could submit new text to Sub-Working Group II if they so wished. The



outcome of the work of the Sub-Working Group II would then be included in the consolidated draft.

#### General obligations

75. A number of representatives supported the idea that the General Obligations should state Parties' obligations to ensure adequate provisions for emergency plans in case of accidental or unintended transboundary movements.
76. Several representatives supported the inclusion under General Obligations of the obligation to take appropriate legal, administrative and other measures to implement and enforce the provisions of the protocol stressing that, without appropriate national measures, it would not be possible to implement and enforce the provisions of the protocol.
77. One representative, speaking on behalf of a regional economic integration organization and its member States, said that provisions for emergency plans would not necessarily have to be included under General Obligations since, in complying with their specific obligations under the protocol, parties would have to take appropriate measures at the national level. He also stressed that exchange of information relating to transboundary movement of LMOs was needed to ensure safe transport and appropriate action at the national level.
78. One representative was opposed to the inclusion in the General Obligations of both the obligation to ensure adequate provisions for emergency plans in case of accidental or unintended transboundary movements as well as being obliged to take appropriate legal, administrative and other measures under General Obligations since those obligations were specifically covered elsewhere in the draft protocol, while another did not see the need for its inclusion but would be open to the proposal if the majority felt so.
79. One representative expressed the view that the Precautionary Principle should be reflected in the protocol, either under a Principles section or under the General Obligations.
80. One representative suggested the inclusion under General Obligations of a provision requiring each Party to apply the AIA procedure with regard to the transboundary movement of any LMO. Due authorization should be furnished by the designated national authority of the receiving Party and information and notification of transboundary movements should be ensured confidentiality.

81. One representative suggested that the General Obligations contain a provision ensuring that Advance Informed Agreement measures for the import of an LMO are implemented in a transparent manner, based on scientific principles and supported by the best available scientific evidence. These measures should not be more restrictive than measures applied to the same LMO produced domestically or imported from other parties and should be applied in a manner which does not constitute a disguised restriction on international trade. The representative added that Parties may impose additional requirements provided that these would be consistent with the provisions of the protocol and accord with other relevant international agreements.
82. The Working Group agreed that the Secretariat would identify already received submissions by countries on General Obligations and, based on this texts, request Sub-Working Group II to either define elements or develop legal texts. These countries were identified by the Chair as: the African region, Australia, Brazil, Colombia, the European Community, Norway, South Africa and Switzerland. The outcome of the work of Sub-Working Group II would be reported to the plenary which would assess the need for further country submissions.

#### Title

83. The Working Group agreed that the titles already provided as well as other possible titles submitted to the Secretariat by Governments during the meeting would be included as options together with other options available in the consolidated draft for consideration at the fourth meeting of the Working Group in 1998.

#### Preamble

84. At the 5th plenary session of the meeting, the Working Group decided that the Chairman should prepare a draft preamble to the protocol for consideration by the Group at its fourth meeting. The elements identified and suggested by the Chairman, as well as all legal text for a preamble submitted by Governments would be included in the consolidated draft.

#### Articles 3-10 and 12-14 (Report of Sub-Working Group I)

85. At the 5th plenary session, on 16 October 1997, the Co-Chair of Sub-Working Group I, Mrs. Sandra Wint (Jamaica), speaking also on behalf of her fellow Co-Chair, Mr. Eric Schoonejans (France), reported on the outcome of the deliberations of the Sub-Working Group which, she said, had considered draft articles 3-10 and 12-14, based on the draft text contained in submissions made by Governments. In the report prepared by

the Sub-Working Group, all the draft articles had been set out using the required legal text format, except for article 3 (Advance Informed Agreement), for which the Sub-Working Group had prepared an element paper on the application of the AIA procedure. On behalf of the members of the Sub-Working Group, she recommended that the Group's report be incorporated into the draft consolidated text.

86. The Chairman thanked the members of Sub-Working Group I for their efforts and, after a brief exchange of views and an amendment from the floor to option one of the text on draft articles 4, 5, 6 and 8, the Open-ended Working Group agreed to include the draft text prepared by Sub-Working Group I in the consolidated draft.

Articles 11 and 15-22 (Report of Sub-Working Group II)

87. At its 5th plenary meeting, on 16 October 1997, the Co-Chair of Sub-Working Group II, Mr. David Gamble (New Zealand), speaking also on behalf of his fellow Co-Chair, Ms. Hira Jhamtani (Indonesia), reported to the Working Group on the outcome of the deliberations of the Sub-Working Group which, he said, had had two main tasks.
88. First, in accordance with its mandate, the Sub-Working Group had developed a consolidated draft negotiating legal text for proposed articles 11 (Confidential information), 15 (Minimum national standards), 16 (Unintentional transboundary movements), 17 (Emergency measures), 18 (Handling, transport, packaging and labelling), 19 (Competent authority/focal point), 20 (Information-sharing/biosafety clearing house), 21 (Capacity-building), 22 (Public awareness/public participation), as identified in the secretariat compilation of government submissions (UNEP/CBD/BSWG/3/3) and also on the basis of the Chairman's draft content of text of items (UNEP/CBD/BSWG/3/Inf.4). The text for each of the draft articles prepared by the Sub-Working Group set out options that provided working alternatives covering the range of possibilities that Parties would want and provided the necessary basis for the coming negotiations.
89. Second, following the plenary discussion of 15 October 1997, the Sub-Working Group had been charged with preparing a draft text on elements of four issues for possible incorporation in the protocol: principles/objectives; general obligations; non-discrimination; and illegal traffic. In that task, the Sub-Working Group had had before it draft texts that had already been received from some Governments and a summary of the discussions held in the plenary, and had distilled those into a draft text containing elements that Governments were invited to use as a basis for possible future submissions of draft legal texts.

90. Both of the sets of draft texts prepared by the Sub-Working Group were available in English only, except for the draft article on competent authority/focal point, which also contained terms in French. In that connection, the Co-Chair particularly wanted to thank representatives for their commitment in accepting to work in English only, at the difficult stage of producing the draft documents. On behalf of Sub-Working Group II, he recommended the draft texts for incorporation into the consolidated draft being prepared by the Open-ended Working Group.
91. The Chairman of the Open-ended Working Group thanked the members of the Sub-Working Group for their efforts. The Working Group agreed that the texts would be incorporated into the consolidated text.

Definitions and annexes (Report of the Co-Chairman of Contact Group 1)

92. At the 5th plenary session, on 16 October 1997, the Co-Chair of Contact Group 1, Mr. P. van der Meer (Netherlands), speaking also on behalf of the other Co-Chair Mr. G. Willemsse (South Africa), reported to the Working Group on the outcome of its deliberations. With regard to definitions, the Contact Group had concluded that the desired outcome of its work was to present a consolidated document to the plenary with, preferably, one definition per item (with or without square brackets or options). As a basis for its work, the Contact Group had used document UNEP/CBD/BSWG/3/Inf.1, complemented by several additional submissions. The Group had identified about 30 terms which would need to be defined as a priority, on the understanding that, in the course of negotiations, other terms could be identified which would also need to be elaborated.
93. The results of the work of the Contact Group on the issue of definitions were presented as part 1 in its document. The Co-Chairs wished to draw attention to the use of the term "LMO" in the document in the elaboration of many items, e.g. transboundary movement. It was recognized that further discussion might take place as to whether and to what extent that term could be replaced by "LMOs and products thereof". However, the Contact Group had decided that it was not within its mandate to enter into such a discussion at the current time.
94. Concerning annexes, the Contact Group recommended that the annexes contained in the Chairman's draft (UNEP/CBD/BSWG/3/Inf.4) on information required in order to obtain advance informed agreement; risk assessment parameters; risk management schemes; function of focal points/competent authorities; and information to be provided to the secretariat under information sharing/clearing-house, be included in the consolidated

draft text, with only one amendment C the removal of the chapeau in annex I. That joint decision had been taken by the Contact Group with the explicit understanding that those draft annexes might or might not form part of the protocol, that annexes and proposed annexes contained in all submissions would be considered for future inclusion and that the list of annexes and proposed annexes to be considered for the protocol would remain open for any future additions. The Contact Group also provided, in part 2 of its document, a further list of proposed annexes from government submissions which would remain on the agenda for future consideration. The Contact Group recommended that the results of its work be incorporated into the consolidated text of the Working Group.

95. The Chairman of the Working Group thanked the members of Contact Group 1 for their work in carrying out the difficult task. The Working Group agreed that the draft text of the Contact Group be inserted into the consolidated draft text.

Monitoring and compliance, institutional and financial matters and final clauses (Report of the Co-Chairman of Contact Group 2)

96. At the 4th plenary session, on 15 October 1997, the Co-Chairman of Contact Group 2, Mr. John Ashe (Antigua and Barbuda), reported to the Working Group on the outcome of the deliberations in the Contact Group, which had completed its consideration of the items entrusted to it. The Contact Group had prepared draft text containing its proposals on monitoring and compliance, institutional and financial matters and final clauses and, where there had been divergence of opinion, setting out alternatives. Some members of the Contact Group had expressed a desire to make a further contribution on some of the issues dealt with in the draft text at the next meeting of the Working Group, after the alternatives had been considered in their capitals. The Contact Group also recommended an examination of each of the Articles of the Convention, especially Articles 21-42, to address the extent to which provisions on institutional matters needed to be in the protocol. The Contact Group recommended that its draft text should be included, in its current form and with its alternatives, in the consolidated text prepared by the Open-ended Working Group, on the understanding that the text, as well as additional text submitted by Governments, would have to be revisited at its next meeting.
97. The Chairman of the Open-ended Working Group thanked the Contact Group for its efforts in preparing its draft text which, he stressed, should be considered as being entirely in square brackets, since all options were still open. After an exchange of views, the Working Group agreed that the detailed proposals on the issues considered by the Contact

Group submitted by the African Group and the proposed text for an article on assessment and review of procedures/annexes by the Government of Switzerland (UNEP/CBD/BSWG/3/5) should also be incorporated into the consolidated text.

Chairman's statement on the consolidated draft articles

98. At the 5th session of the meeting, on 16 October 1997, the Chairman expressed his views as to the purpose of the consolidated draft which would be prepared based on the outcome of the Sub-Working Groups and attached to the main report of the meeting. He explained that Article 28, paragraph 3, of the Convention on Biological Diversity required that the text of any proposed protocol be communicated to the Parties by the Secretariat at least six months before the meeting at which it was to be adopted. In his opening statement at the current meeting, the Chairman had defined "text of a proposed protocol" as "a draft text of a protocol that all Governments agree constitute sufficient ground for the completion of the negotiating process and the adoption of the protocol, meaning that all options and elements should be contained in the consolidated draft in legal terms".
99. By submitting the consolidated draft to the Conference of Parties at its fourth meeting, the Working Group would meet the requirement that the text be communicated to the Parties six months before the end of the deadline given to the Working Group, which is by end 1998. Additionally, the Working Group would need the assistance of the Conference of Parties for three reasons: to obtain its approval for the Sub-Working Group to have three meetings in 1998 instead of the two already agreed on; to seek additional financial resources for the third meeting, and to convene an extraordinary meeting of the Conference of Parties at the end of 1998 in order to have the final text of the protocol adopted. A decision to hold an extraordinary meeting could only be made by the Conference of Parties. Finally, the Chairman emphasized that the Conference of Parties at its fourth meeting in no way should consider the actual content of the consolidated draft.

Procedural elements for future work

100. The Working Group reviewed the question of procedural elements for future work as identified by the Chair, at the 5th session of the meeting, on 16 October 1997, including the points on the character of the consolidated draft, the continuation of the organizational structure of the current meeting, guidance to Governments with regard to their submissions and the basic documents for the fourth meeting of the Working Group, as well as the character of that meeting. As agreed by the Working Group, the document is attached as annex II to the present

report as a Chairman's draft.

101. One representative reserved its position in respect of maintaining the Sub-Working Groups for the next meeting of the Working Group.
102. One representative requested that some flexibility be exercised in respect of accepting, even at a later stage, certain components of elements that had been omitted in the present legal texts, due to time pressure. This was accepted by the Chairman.

Deadline for submission of legal texts for inclusion in the consolidated draft

103. The Chairman recalled that, at the current meeting, the Working Group had invited Governments to submit text or amendments to existing text for inclusion under the following headings in the consolidated draft articles: socio-economic considerations; liability and compensation; illegal traffic; non-Parties; non-discrimination; objectives; and general obligations. The Working Group decided that 1 December 1997 should be the deadline for such submissions. The Working Group also acknowledged that the deadline would make it difficult for the the compilation document, prepared by the Secretariat and based on the same structure as the consolidated draft, to be circulated in accordance with the six-week rule for the distribution of documentation for meetings of the Working Group. The Working Group also recognized that the 1 December deadline would mean that the production of official documents in the official languages would also not be possible within the normal timeframe laid down by United Nations procedures.

III. DATES AND VENUES OF MEETINGS OF THE OPEN-ENDED AD HOC  
WORKING GROUP ON BIOSAFETY FOR 1998

104. At the 6th session of the meeting, on 17 October 1997, the Working Group, after some discussion, agreed that it would require three meetings in order to complete the work assigned to it by the Conference of the Parties before the end of 1998:
  - (a) An eight-working-day meeting, from 9 to 18 February 1998, which would be held in Montreal;
  - (b) A two-week meeting in the second half of July 1998, the exact dates of which would be communicated to the Parties by the Secretariat, taking into account the general schedule of international environmental meetings and availability of conference facilities in Montreal for the end of August 1998 in Montreal. The duration of the meeting could be reduced in the light of the results achieved at the February meeting;

- (c) A one-week meeting, to be held at about the beginning of December 1998, followed by a two-day (Monday-Tuesday) extraordinary meeting of the Conference of the Parties, at a location to be determined.
105. On the recommendation of the Bureau, the Working Group approved the recommendations to the Conference of the Parties contained in annex III to the present report.
106. The Working Group also agreed that the Secretariat should send the estimated financial implications of the 1998 meeting schedule to all focal points, with a copy to heads of delegations, well in advance of the fourth meeting of the Conference of the Parties, at which the related budgetary decisions would be taken.
107. One representative speaking on behalf of a regional economic integration organization and its member States said that the working process adopted by the current meeting had proved effective, and a systematic use of drafting groups would be necessary to yield a favourable result at the next meeting of the Working Group. He encouraged delegations to consult during the coming weeks on merging or reducing the number of options and to report to the Chairman or to the Secretariat on the results of such consultations, which could be reflected in an appropriate way for consideration at future discussions. He also encouraged the Chairman of the Working Group and the Co-Chairs of the Sub-working Groups and Contact Groups to assist in the efforts to reduce the number of options. With regard to adequately servicing the meetings scheduled for 1998 and ensuring at least the same level of participation as at the current meeting, he said that significant additional funding was needed and the European Community and its member States would attempt to renew and, where possible, increase their support. He urged other Governments that were in a position to do so to make available appropriate contributions in an expeditious manner. That was especially necessary, given the proximity of the next meeting in February 1998.

#### IV. OTHER MATTERS

##### Statement by the representative of the World Intellectual Property Organization (WIPO)

108. At the 3rd session of the meeting, on 14 October 1997, a representative from the World Intellectual Property Organization (WIPO) drew attention to the 1977 Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, to which



there were now 40 Parties. Under the Treaty, a contracting State that, in the case of an invention involving a microorganism, allowed or required a deposit of the microorganism for the purpose of its patents procedure must recognize such a deposit with any depositary institution, in any State Party that had acquired the status of international depositary authority under the Treaty. On the basis of this principle, the Treaty established a system of deposit of microorganisms for the purposes of patent procedure, whereby microorganisms were transported from one contracting State to another for the purposes of deposit and furnishing of samples. He then drew the attention of the meeting to Article 5 of the Treaty, which read: "Each contracting State recognizes it is highly desirable that, if and to the extent to which the export from or import into its territory of certain kinds of microorganisms is restricted, such restriction should apply to microorganisms deposited, or destined for deposit, under this Treaty only where the restriction is necessary in view of national security or the dangers for health or the environment".

Statements by non-governmental organizations

109. At the closing session of the meeting, the representative of Third World Network, speaking on behalf of the Council for Responsible Genetics, the Californian Biotechnology Action Council, Ecoropa, Diverse Women for Diversity, Edmonds Institute, Friends of the Earth International, German Working Group on Biodiversity, Greenpeace International, the National Biosafety Council (United States), Washington Biodiversity Action Council and the Women's Environmental Network, expressed the view that there was scientific evidence of major hazards arising from current practices of genetic engineering. She was concerned, in particular, about the danger from horizontal gene transfer and recombination in generating and spreading virulence and antibiotic resistance. Existing regulatory regimes, she said, were grossly inadequate and were not based on known scientific evidence. Listing several examples of abuses, she said that industry was effectively being given carte blanche, while regulatory bodies were using public funds to allay legitimate public fears and opposition. It was her hope that a protocol on biosafety would set appropriate standards, based on scientific rationality, the precautionary principle, and equity and ethical values. On behalf of the public interest groups at the current negotiations, she reiterated their call for a moratorium on all releases of LMOs until an appropriate protocol on biosafety was in effect.
110. The representative of the Biotechnology Industry Organization (BIO) took issue with the statement made on behalf of Third World Network and associated environmental groups, particularly the assertion that

horizontal gene transfer from LMOs had resulted in negative consequences for health. Although there had been some very interesting scientific reports in recent years, he stressed that none of them supported the assertions made. Moreover, he denied that industry had enjoyed carte blanche with regard to its technology and said that no products of technology in the history of humanity had been subjected to more lengthy and intensive a priori reviews. He concluded by expressing his confidence that the Open-ended Working Group, after examining the evidence, would agree with the rigorous scientific judgement that had found the products of biotechnology to be safe.

111. A representative speaking on behalf of the Green Industry Biotechnology Platform (GIBIP) and the International Association of Plant Breeders (ASSINSEL), said that the initial endeavours of the Group at its first meeting had given rise to the hope that industry representatives would be able to participate in the Group's work, since the issues in question involved products put on the market by industry, and because industry possessed particular expertise with regard to factors pertaining to risk assessment and management. He was concerned and saddened to note that products resulting from modern biotechnology were perceived as being dangerous, that a virus-resistant potato was considered a danger to local populations, and that maize requiring no pesticides was a threat. For the breeders he represented, biotechnologies were seen as an opportunity to enrich genetic diversity, not to destroy it. On behalf of GIBIP, he reiterated the offer to participate in the programme to set up capacities, so that the door would not be closed on countries wishing to have access to biotechnologies.

#### V. ADOPTION OF THE REPORT

112. The present report was adopted by the Working Group at its closing session, on Friday, 17 October 1997, on the basis of the draft report contained in document UNEP/CBD/BSWG/3/L.1.

#### VI. CLOSURE OF THE MEETING

113. In his closing remarks, Mr. Calestous Juma, Executive Secretary of the Convention on Biological Diversity, expressed his appreciation to the Parties for their timely submission of draft legal texts and their good cooperation with the Secretariat in the work of the current meeting of the Open-ended Ad Hoc Working Group. He especially wished to thank the following Parties for their financial support: Australia; Austria; Canada; Denmark; European Community; Finland; Netherlands; Norway; Sweden; and Switzerland.

114. After the customary exchange of courtesies, the Chairman declared the third meeting of the Open-ended Ad Hoc Working Group closed at 1.30 p.m. on Friday, 17 October 1997.

**Minutes of Meeting of the Agricultural Commodity Sector**  
**on the Biosafety Protocol, September 10, 1997**  
**Winnipeg, Manitoba**

1. The meeting was co-chaired by **Dr. Stephen Yarrow** (Canadian Food Inspection Agency), and **Ann Penner** (Agriculture and Agri-food Canada). A list of participants is included in **Attachment A**.
2. **Yarrow** opened the meeting by providing the group with background information on the genesis of the Biosafety Protocol, the agricultural commodity issue (i.e., the potential ramifications of the Protocol on trade of agricultural commodities), and the current state of the Protocol's negotiations. **Bill Leask** (Canada Seed Trade Association) complemented Yarrow's presentation, by summarizing his views on the Protocol's Advanced Informed Agreement (AIA), and the potential implications of AIA for commodity trade. Information on the Protocol and the AIA is summarized in **Attachment B**.
3. A series of questions followed Yarrow's presentation. **Gord Pugh** (Prairie Pools) asked for an overview of the next international negotiating session and Canada's proposals for the upcoming discussions. **Yarrow** explained that the next negotiating session would take place in Montreal on October 13-17, 1997. He also noted that Canada had submitted a draft legal text on certain issues on August 1, 1997 (included as **Attachment C**). Canada's text was written in a very generic way, in order that Canada could engage in further discussions on certain issues (e.g., scope of AIA) before, during, and after the October session of negotiations.
4. A number of questions were asked about how the Protocol would come into force, and about its relationship to the World Trade Organization (WTO). **Rory McAlpine** (Agriculture and Agri-food Canada) explained that once negotiations were completed, a minimum number of countries would have to ratify the Protocol for it to have legal effect. He also noted that the WTO Agreements on Technical Barriers to Trade (TBT), and Sanitary and Phytosanitary (SPS) Measures were relevant to biotechnology-related trade issues. **Penner** explained that issues regarding the relationship between the WTO and environmental agreements such as the Protocol have not yet been resolved. They are still the subject of discussion in the WTO's Committee on Trade and Environment. Members of the WTO CTE and negotiating parties need to consider how an agreement might be enforced, and how disputes among members of the Protocol could be resolved. A representative of the Saskatchewan Wheat Pool questioned whether trade rules should be discussed within an environmental agreement, and argued that trade rules should only be discussed within the WTO.
5. **Dale Adolphe** (Canola Council of Canada) turned the discussion towards important definitions of the Protocol. He questioned whether other countries would accept Canada's view of a living modified organism (LMO) (i.e., an organism with novel traits to a species in a receiving country). Adolphe also questioned whether the Protocol would only apply to those LMOs that adversely affected biodiversity, or would include all LMOs. He also asked whether Canada's view of an LMO would include commodities. In the event that the Protocol only included those LMOs that adversely affected biodiversity, Adolphe asked if someone had provided a definition of Abiodiversity. @

Adolphe's concern was the other delegations might include socio-economic, cultural, and religious factors into the definitions of biodiversity and LMO, and thereby take away from a science-based, transparent approach to risk assessment.

In response to Adolphe's question of the definition of biodiversity, Article 2 of the Convention on Biological Diversity states that Biological diversity means the variability among living organisms from all sources including terrestrial, marine and other aquatic ecosystems and the ecological complexes of which they are part; this includes diversity within species, between species, and of ecosystems.@

6. The issue of segregation emerged out of the discussions of the definition of an LMO. **Yarrow** explained that the issue of segregating genetically modified (GM) crops from traditional crops had not been raised in the Protocol's negotiations. **Leask and Mutch** challenged Yarrow's assertion, by stressing that segregation was an implicit part of the Protocol. In their view, segregation was likely to be required in the event that an importing party refused to accept a shipment of an agricultural commodity if it contained a certain LMO or novel trait that threatened biodiversity.
7. **Yarrow** challenged participants to put aside their concerns about the Protocol, and to consider the current realities that face exporters of LMOs (or genetically modified commodities). He reminded participants that regulatory regimes are currently in place for the approval of LMOs around the world. For example, Yarrow asked how the participants, as exporters of commodities such as wheat, anticipated handling the approval processes of the 60-90 countries of import? He argued that Protocol could be extremely positive for exporters, because it could begin to harmonize domestic regulatory standards and approval processes. **McAlpine** noted that in the absence of a protocol, countries could still act unilaterally to block trade and hence, there was value in having an instrument to impose some multilateral discipline on, for example, environmental risk assessment criteria.
8. **Morgan, Leask, and Conor Dobson** (IBAC) built on the importance of international harmonization of standards and approval processes. They asked participants to consider the other side of the story@ of the Protocol, and to think about how Canada would likely act when importing an LMO. They concluded that Canada would likely hope that other countries would conduct a risk assessment within a similar regulatory framework to our own, and would take the necessary precautions for those LMOs which were harmful to our environment. Furthermore, they hoped that the Protocol would place the obligations for the AIA process of the importing government (and not on the exporting government), as is the case in Canada's domestic regulations. Finally, they hoped that mutual recognition agreements might emerge as domestic regulations were harmonized, in order that Asafe@ GM commodities could move freely around international markets.
9. **Adolphe** agreed that international harmonization was an important objective. However, he noted that there only a few countries currently have domestic regulations for biotechnology in place (Canada, U.S., EU, and Japan). Therefore, he was concerned that 136 other countries (with no domestic regulations or procedures in place) were negotiating the Biosafety Protocol, and could thereby affect how LMOs/commodities were traded. Furthermore, he was concerned that an LMO which could be environmentally safe when handled by Canada, the U.S., the EU, and Japan, could be

very dangerous when countries without regulatory frameworks did so (i.e., in terms of containing the commodity between shipping and processing).

10. Assuming the Protocol did come into effect and was ratified by Canada, the EU, and Japan, **Pugh** asked whether parties to the Protocol would be required to change their domestic regulatory frameworks. Furthermore, Pugh questioned why the Protocol in general, and AIA in particular, was necessary in light of the fact that certain countries already had domestic regulatory systems in place to gather information about imported LMOs. **Yarrow** responded by explaining that Canada's existing regulatory scheme would likely satisfy the necessary conditions for ratifying the protocol. In addition, he noted that Canada believes that AIA should only apply to the first transboundary movement of an LMO. In other words, it was Canada's position that an LMO would not be subject to the Protocol if it had already been approved within a domestic regulatory system. For example, given that certain varieties of transgenic canola have been approved in the U.S., Japan, and Mexico, Canadian exporters would not be required to proceed through the AIA process when exporting those particular varieties because they would not be the first transboundary movement of those products (i.e., they would no longer be novel in those markets).
11. **Pugh** asked whether countries with sophisticated regulatory systems could be explicitly exempted from the Protocol (AIA). **Penner** explained that the U.S., Switzerland, Japan, EU, and Australia submitted proposals in August, 1997 to allow parties to conclude bilateral/multilateral agreements with each other to facilitate trade. These agreements would allow certain countries to by-pass the AIA system, once their first transboundary shipment of a particular LMO had been approved within the importing country's regulatory system. Canada has also been considering the benefits of using bilateral/multilateral agreements to reduce the scope of AIA, but did not include the proposal in its submission in August as the other countries did.
12. **Leask** posed two questions which were not discussed. He asked how the Protocol could impact food aid, and whether AIA would slow and/or restrict the process of supplying foodstuffs (which could contain LMOs) to those in need. Furthermore, he asked how the AIA process would affect transit trade that moved through a third country.
13. **Bob Friessen** (Canadian Federation of Agriculture) demanded that Canada must put trade concerns at the top of its priority list when negotiating the Protocol. He was concerned that the Protocol would automatically create technical barriers to trade, and thereby have an adverse affect on Canada's grain and horticulture producers.
14. **Yarrow** turned the discussion to some of Canada's proposals on certain elements of the Protocol.  
(A) *Scope of AIA: For the First Transboundary Movement of an LMO*

In addition to Canada's view that AIA should only apply to the first transboundary movement of an LMO, the Biosafety Advisory Body has considered a number of questions that could further reduce the scope of AIA, and ensure that the Protocol only focused on those LMOs which were a risk to biodiversity. These factors include:

- Is the importing country the centre of origin for a species?

- Is the LMO known to be pathogenic?
- Is the LMO known to be infective?
- Is the LMO known to be invasive?
- Is the LMO known to be toxigenic?

In the event that all of the factors were negative (e.g., in the case of commodities), the LMO would not be subject to AIA. However, if one or more of the factors was positive, AIA would apply. Furthermore, if more information was required about any of the factors, AIA would apply as well.

**Adolphe** responded to the list of factors by noting that it could be feasible for grain producers, but might not apply to the horticulture and animal breeding sectors. He argued that factors regarding seeds and animal breeding techniques be added to the list if it was used in the future. Adolphe also questioned whether an exporter or importer would be held liable in the event that information about these factors proved to be false. He was concerned that a LMO which had been deemed Asafe@ according to the list of factors could have an adverse effect on the environment at a later date, thereby subjecting the exporter/importer to liable.

**McAlpine** noted that the Europeans have raised the liability issue in the context of food waste. They have considered whether a restaurant owner could be liable for food waste, some of which could contain an LMO.

**Dobson** responded to the list of factors by questioning whether it was possible to conclusively establish that an LMO posed a risk to biodiversity. Furthermore, Dobson put forward the view that regulatory authorities should consider approval orders that had been released for substantially equivalent LMOs when considering the above-mentioned factors in the AIA process.

**Yarrow** concluded the discussion by noting that certain members of the Biosafety Advisory Body had concerns with this Afactor-based@ approach to AIA because of the difficulties involved in providing conclusive, scientific evidence about the factors. In other words, some members of the Advisory Body concluded that an importer might not be able to provide enough information about these factors to allow any LMOs to be exempted from the AIA process. Consequently, all LMOs (and commodities) would continue to be subject to AIA.

*(B) Bilateral, Multilateral or Regional AParty-to-Pary AIA-Type Agreements for Exemptions*

**Yarrow** recalled that certain countries had proposed bilateral/multilateral agreements as a means to narrow the scope of AIA. He underscored that any such agreements under the Protocol would have to be transparent, science-based, and open to other members in the event that they could meet the agreed upon standards. Yarrow explained that similar bilateral agreements are currently in place between Canada and the U.S. for greenhouse plants, and Canada and Mexico for seed potatoes. **McAlpine** noted that the WTO Agreement on Sanitary and PhytoSanitary (SPS) Measures permits WTO members to conclude bilateral equivalence agreements that go beyond their WTO obligations (e.g., Canada-EU Veterinary Equivalence Agreement). He asked whether the SPS Agreement could provide some direction for negotiators of the

Protocol.

**Yarrow** set out the pros and cons of using bilateral/multilateral agreements to narrow the scope of AIA. Agreements could be positive in that: (1) they took the burden of the AIA process off exporters/importers, and placed it onto governments; (2) agreements would help to promote harmonization of regulatory approaches and promote a scientifically-based system of substantial equivalence. However, bilateral/multilateral agreements could be problematic in the event that 1000s were established over time as new LMOs were developed.

© *ADobson Plan@ for the First Transboundary Movement of an LMO*

**Yarrow** noted that **Dobson** (IBAC) had developed a proposal to narrow the scope of AIA. In the event that an LMO was an agricultural commodity, the ADobson Plan@ proposed that the exporting government should be required to notify other governments that it had approved the LMO within its regulatory framework. The notification would be placed on an internationally accessible web-site (clearing house), and would allow importing governments to determine whether the LMO had already been approved. A transboundary shipment of the approved LMO would be allowed to proceed without AIA, unless the importing government felt that a risk assessment was necessary to protect its country's biodiversity.

The positive aspects of the ADobson Plan@ include: (1) commodities could be exempted from AIA while ensuring that importing governments had the opportunity to initiate an inquiry in the event that biodiversity was threatened; (2) the plan balances transparency, science-based risk assessments, trade, notification, and the preservation of biodiversity. The negative aspects of the ADobson Plan@ include: (1) a legal obligation is placed on the exporting government - this is contrary to Canada's current regulatory system where the obligation is placed on the importing government; (2) the WTO TBT Agreement includes a notification system where Members are legally obligated to notify the TBT Committee of their technical regulations. WTO Members have not always complied with their legal obligations under the TBT Agreement and have not submitted notifications on time. A requirement that parties to the Biosafety Protocol would have to publish approvals on an international web-site could encourage the same Anon-compliance@ problem, and render the notification system meaningless.

## Next Steps

15. **Yarrow** asked that participants consider whether future consultations were needed on the Biosafety Protocol. He also asked that participants consider which organizations should be included in future consultations, and whether other agricultural organizations should be represented on the Biosafety Advisory Body.

**Friessen and Higginson** (Canadian Federation of Agriculture-CFA) stressed that it was imperative that a representative of primary agriculture producers be placed onto the Biosafety Advisory Body to ensure that the sector's concerns were sufficiently represented. They also stated that another environmental association should not automatically be added to the Advisory Body in the event that an agricultural representative was permitted to represent the sector's interests. They disagreed with the Advisory Body's current approach that industry representatives and



non-governmental organizations had to be balanced.

**Dobson** argued that representatives of the agricultural commodities sector (as represented at the meeting) should be called together as a group to discuss the Protocol as it evolved. He suggested that a meeting be held before the fourth negotiating session in February, 1998.

**Morgan** agreed that the consultative process should be enhanced. He noted that the commodities sector was not represented adequately on the Biosafety Advisory Body, and must be in the future. He asked the co-chairs to continue seeking industry views as required, and to develop the process of dialogue. He also asked that members of the exporting industry (e.g., Canadian Exporting Association, Western Elevators Association) be invited to any future consultation sessions.

16. **Morgan** asked when Canada's position would be formulated and finalized. **Yarrow** responded that Canada, along with other parties, submitted a draft legal text for the Biosafety Secretariat on August 1, 1997. He expected that the October negotiating session would allow delegations to review the submissions, and begin to put together a draft legal text on essential elements of the Protocol (e.g., AIA). **Yarrow** agreed to present the results of the October session to the agricultural commodities industry and invite their views on how Canada should proceed. These views could then be integrated into Canada's position for the February session of negotiations.
17. **Morgan** asked that a 1-2 page brief on the Protocol be prepared for the industry. **Leask** noted that documents about the Protocol are available on the CSTA's web-site (<http://www.hookup.net/-csta>).
18. **Yarrow** announced that an information session on commodities trade will be held on the margins of the negotiating session (evening of October 13, 1997). Three speakers, one of whom will be A. Douglas Mutch (Canada Grains Council), are to provide information on the realities of trade for commodities such as wheat. It is expected that the two other speakers will be from the developing world, in order to inform delegates that the Protocol could impact trade of commodities such as coffee and tropical nuts as well. Given that there has often been a disconnect between trade and environment ministries in many of the countries participating in the negotiations, the information session is hoped to be a way to educate delegates on commodity trade as it stands today, and to illustrate some of the complexities that the Protocol could introduce to global trade.

**Yarrow** asked participants to suggest names of possible speakers who could explain how commodities from developing countries (e.g., coffee, nuts) are traded. **Leask** suggested Maria Dubois from Buenos Aires.

19. **Adolphe** asked whether industry representatives could attend the Information Session on Commodities Trade on October 13, 1997. **Leask** and **Yarrow** thought that interested parties would be able to attend, and advised **Adolphe** to check the Biodiversity Secretariat's web-site to obtain an application form.

#### **Points of Agreement Reached during the Meeting**

20. Participants agreed that representatives of the agricultural commodities sector should

continue to meet as the Protocol develops to ensure that their views are represented fully in Canada's position.

Participants agreed to consider whether other industry organizations should be included in a future consultation session, and whether an agricultural organization should be represented on the Biosafety Advisory Group. Suggestions should be forwarded to Stephen Yarrow by fax (613-228-6604) or email (yarrow@em.agr.ca) or Ann Penner by fax (613-759-7503) or email (pennera@em.agr.ca).

Participants agreed that they would consider how the AIA process could be refined in order to balance the goals of the preservation of biodiversity and the facilitation of commodities trade. Views should be submitted to Stephen Yarrow by fax (613-228-6604) or email (yarrow@em.agr.ca) or Ann Penner by fax (613-759-7503) or email (pennera@em.agr.ca).

Participants agreed to submit names of possible candidates for the Information Session on Commodity Trade to Stephen Yarrow by fax (613-228-6604) or email (yarrow@em.agr.ca) during the next couple of weeks.

### **Attachment A - List of Participants**

Name	Organization
Dale Adolphe	Canola Council of Canada
Vahid Aidun	Industry Canada (conference call)
Bill Anderson	Ag-West Biotech
Robynne Anderson	Canadian Seed Trade Association
Marlin Beever	Canadian Cattleman's Association
Conor Dobson	IBAC
Tom Edge	Environment Canada
Ken Edie	Manitoba Pool Elevators
Jason Flint	IBAC
Sheila Forsyth	NAEC (conference call)
Bob Friessen	Canadian Federation of Agriculture
Rony Gravelines	Canada Grains Council
Harold Hedley	Agriculture and Agri-food Canada
Jennifer Higginson	Canadian Federation of Agriculture
Lorraine Hope	Canadian Wheat Board
Susan Iler	Ontario Soyabean Growers' Marketing Board
Bruce Kirk	Agriculture and Agri-food Canada
Bill Leask	Canadian Seed Trade Association
Rory McAlpine	Agriculture and Agri-food Canada
Bob Morgan	Saskatchewan Wheat Pool
A. Douglas Mutch	Canada Grains Council
Tom Nowicki	Canadian Grain Commission
Ann Penner	Agriculture and Agri-food Canada
Gord Pugh	Prairie Pools
Rhona Redick	Canadian Horticulture Council (conference call)
David Seston	Saskatchewan Wheat Pool
Victoria Watson	Canada Grains Council
Stephen Yarrow	Canadian Food Inspection Agency

**Retreat of AAFC and CFIA Officials**  
**Agricultural Negotiating Positions on the Biosafety Protocol**  
**November 13, 1997**  
**Joliette Room, Citadel Hotel, Ottawa**

**Retreat Objective :**

To prepare a federal agricultural negotiating position on the Biosafety Protocol

**Parameters:**

Our negotiating position must:

- Reflect the interests of the agri-food sector;
- Address potential trade implications for agricultural commodities;
- Meet commitments under the biodiversity action plan;
- Maintain the integrity of Canada's current regulatory system for approving genetically modified organisms for environmental release;
- Recognize Canada in the world trade and environmental context

**Scope of discussions:**

Of the approximately 40 articles in the draft legal text, the discussions for this retreat will be focused on the following four (4) groups of articles:

- 1) Use of Terms -Article # 2
- 2) Advance Inform Agreement (AIA) -Articles # 3, 4, 5, 6, 7, 8, 9, 10, 12, 13
- 3) Trade -Articles # 11, 17, 23, 24
- 4) Institutions -Articles # 19, 35

**AGENDA FOR THE DAY**

**9:00 OPENING**

- Welcome and Introductions
- Background & Debrief of Montreal Negotiating Session, Industry Concerns and Consultations

Chairs

- Retreat Objective/Parameters/Discussion Scope
- Agenda/Process/Ground Rules/Roles

Facilitator

**9:45 INTRODUCTION TO DISCUSSIONS**

Facilitator

- Introduction of roles/representatives
  - Clarify the role and representation of the various interest groups around the table (i.e. trade, environment, research, policy, grains & oilseeds, regulatory affairs, biotechnology, plant breeders, etc.)
- Outline discussion process for the day

## **AGENDA FOR THE DAY (cont'd)**

**10:15 REFRESHMENT BREAK**

**10:30 DISCUSSIONS**

Draft Legal Text - Use of Terms (Article 2)

Participants/  
Facilitator

**11:00 Draft Legal Text -AIA (Articles # 3, 4, 5, 6, 7, 8, 9, 10, 12, 13)**

Participants/  
Facilitator

**12:00 LUNCH BREAK**

**1:00 Draft Legal Text -AIA (cont'd)**

Participants/  
Facilitator

**2:45 REFRESHMENT BREAK**

**3:00 Draft Legal Text -Trade (Articles # 11, 17, 23, 24)**

Participants/  
Facilitator

**3:45 Draft Legal Text -Institutions (Articles # 19, 35)**

Participants/  
Facilitator

**4:15 WRAP-UP**

Recap and what's next

Round table session evaluation

Participants

Closing remarks

Chairs  
Facilitator/

Chairs

**4:40 SESSION ADJOURNS**

November 11, 1997

## **INDUSTRY CONCERNS**

### **re. THE BIOSAFETY PROTOCOL:**

1. Do not see a need for a Biosafety Protocol.
2. Agri-food sector fear that exports of agricultural commodities such as canola and wheat, as they are substituted and/or co-mingled with LMO-types could be caught up by excessive, unmanageable restrictions and information requirements to meet AIA.
3. Research and development could be inhibited as "exchanges" of experimental material are also caught up by excessive, unmanageable restrictions and information requirements to meet AIA.
4. The Protocol will stimulate developing countries to develop their own national biotechnology-related regulations, to meet the Protocol requirements. Canadian biotechnology companies will then have to obey the laws and regulations of these countries. Currently they do not have to, since there are no laws to obey.
5. Do not share the view that the Protocol will encourage harmonization of international biotechnology-related import regulations.
6. Feel that the Protocol is being driven by extreme environmental interest groups.
7. Advance informed agreement will contain "socio-economic" evaluation criteria.

ALAN

BIOSAFETY PROTOCOL WORKSHEET - draft November 10, 1997  
CANADIAN POLICY CONSIDERATIONS AND PREFERRED LEGAL TEXT FOR PROPOSED ARTICLES

Biosafety Protocol Consolidated Text from October 13-17, 1997	Canadian Policy Considerations	Preferred Legal Text
<p><b><u>TITLE</u></b></p> <p><b>Option 1</b> Protocol on Biosafety."</p> <p><b>Option 2</b> "Protocol for the Safe Transfer, Handling and Use of Living Modified Organisms."</p> <p><b>Option 3</b> "Biosafety Protocol."</p> <p><b>Option 4</b> Protocol for the Safe Transfer, Handling and Use of Living Modified Organisms;</p> <p><b>Option 5</b> Protocol for the Manipulation, Use, Transboundary Movement and Release into the Environment of Living Modified Organisms;</p>	<p>Canadian view submitted to Secretariat (January 1997):</p> <p>Canada suggests that the title could be "International Protocol for the Safe Transfer, Handling and Use of Living Modified Organisms."</p>	<p>3. Deliberate use</p> <p>4. Novel traits</p>
<p><b><u>PREAMBLE</u></b></p> <p><b>Option 1</b></p> <p>The Parties to this Protocol:</p> <p>Being Parties to the Convention on Biological Diversity,</p> <p>Mindful of their obligation under Article 8 (g) of that Convention to establish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity, including risks to human or animal health,</p>		

Biosafety Protocol Consolidated Text from October 13-17, 1997	Canadian Policy Considerations	Preferred Legal Text
<p>Considering the rapid expansion of modern biotechnology and the growing public concern over its potential adverse effects on human or animal health, biological diversity, the environment, and social and economic welfare,</p> <p>Recognizing the need to establish a minimum condition of safety and a procedure for the assessment and management of the potential risks arising from the development, use, release and transfer of living modified organisms and products thereof,</p> <p>Mindful of the obligation imposed by Article 19, paragraph 4, of the Convention on Biological Diversity on any Contracting Party, directly or by requiring any natural or legal person under its jurisdiction, to provide any available information about the use, the potential adverse impacts and the safety regulations required by that Contracting Party in handling such organisms to the Contracting Party into which those organisms are to be introduced,</p> <p>Taking into account the limited capabilities of many countries, particularly developing countries, to cope with the nature and scale of known and potential risks associated with living modified organisms resulting from biotechnology,</p> <p>Noting that States should make sure that the user of living modified organisms or products thereof should conduct its activities with respect to the development, handling, transport, use, release and transfer of living modified organisms in a manner that is consistent with the safety of human health and animal health, biological diversity, the environment, and social and economic welfare,</p> <p>Acknowledging that any State has the sovereign right to ban the entry or release of living modified organisms into its territory,</p> <p>Considering the importance of promoting international cooperation in the exchange of information on the transboundary transfer and release of living modified organisms and the development of appropriate containment measures and emergency plans required to deal with accidents,</p> <p>Noting that, in accordance with the precautionary principle, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize risk where such a risk is posed by living modified organisms resulting from biotechnology,</p> <p>Noting also that safety measures and decisions on the development, use, handling, release and transfer of living modified organisms and products thereof need to be based on up-to-date and most comprehensive technical and scientific knowledge available,</p> <p>Recalling chapter 16 of Agenda 21 adopted by the 1992 United Nations Conference on Environment and Development which provides for the "Environmentally Sound Management of Biotechnology", and which further seeks to ensure safety in biotechnology development, application, exchange and transfer through international agreement,</p>		



Biosafety Protocol Consolidated Text from October 13-17, 1997	Canadian Policy Considerations	Preferred Legal Text
<p>Desirous of affirming the responsibility of States to fulfil their obligations under Article 19, paragraph 3, of the Convention on Biological Diversity in setting out appropriate procedures, in particular advance informed agreement, in the field of the safe transfer, handling and use of living modified organisms resulting from biotechnology,</p> <p>Recalling also the commitment taken by the Parties to the Convention on Biological Diversity under the same provision of the Convention referred to above to consider the need for, and modalities of a protocol in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity,</p> <p>Determined to control through the use of established procedures of assessment, management and notification of risks associated with living modified organisms and through rules of liability and compensation for damage or loss arising from these organisms and products thereof,</p> <p>Have agreed on the following:</p> <p><b>Option 2</b></p> <p>The Parties to the Protocol,</p> <p>Recalling Article 19, paragraph 3, of the Convention on Biological Diversity,</p> <p>Recognizing the link between paragraphs 3 and 4 of Article 19 of the Convention,</p> <p>Recognizing also the link between Article 8 (g) and Article 19, paragraph 3, of the Convention,</p> <p>Recalling decision II/5 of the Conference of the Parties to the Convention on Biological Diversity to develop a protocol on biosafety, specifically focusing on transboundary movement of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, setting out for consideration, in particular, appropriate procedure for advance informed agreement,</p> <p>Recognizing that the framework includes national, regional, multilateral and international activities on risk assessment, risk management, information exchange, regulations, guidelines, capacity-building and international agreement,</p> <p>Affirming its support for a two-track approach through which the promotion of the application of the UNEP International Technical Guidelines for Safety in Biotechnology can contribute to and complement the implementation of the Protocol,</p>		

Biosafety Protocol Consolidated Text from October 13-17, 1997	Canadian Policy Considerations	Preferred Legal Text
<p>Noting the United Nations Recommendations on Transport of Dangerous Goods,</p> <p>Noting that the provisions of the Protocol should contribute to protection in the field of biosafety, based on scientific risk assessment and the precautionary principle,</p> <p>Recognizing that the interaction between living modified organisms (LMOs) resulting from modern biotechnology and the environment, in particular in centres of origin and genetic diversity, is of a very complex nature not always fully elucidated by adequate scientific knowledge,</p> <p>Aware that some applications of modern biotechnology may have adverse effects on the environment, also taking into account human health,</p> <p>Recognizing that, while properly addressing the risks from living modified organisms resulting from modern biotechnology, the Protocol should avoid causing unnecessary delays to the benefits that biotechnology could bring for health, agriculture and environment,</p> <p>Recognizing that the Protocol should not create unwarranted administrative requirements for transboundary transfer of LMOs for contained use,</p> <p>Recognizing that to be effective and workable, the Protocol should be based on science and up-to-date experience, and include mechanisms to ensure adequate flexibility, such as provisions for exemptions and for rapid adaptation to scientific and technical progress,</p> <p>Recognizing also that the Protocol should not duplicate other comparable existing legal instruments,</p> <p>Have agreed as follows:</p> <p><b>Option 3</b></p> <p>Recalling Article 19, paragraph 3, of the Convention on Biological Diversity,</p> <p>Recognizing the link between paragraphs 3 and 4 of Article 19 of the Convention,</p> <p>Recognizing also the link between Article 8 (g) and Article 19, paragraph 3, of the Convention,</p> <p>Considering that, although there exist international agreements of relevance to the impact of LMOs resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, there are no legal instruments which specifically address the transboundary movements of such LMOs,</p> <p>Recognizing also that, although considerable knowledge is gained, significant gaps in knowledge have been identified, specifically in the field of interaction between the environment and living modified organisms (LMOs), resulting from modern biotechnology, taking into account the relatively short period of experience with</p>		

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<p>releases of such organisms, the relatively small number of species and traits used, and the lack of experience in the range of environments, specifically those in centres of origin and genetic diversity,</p> <p>Noting also the advantages that lie in the potential of modern biotechnology to contribute to sustainable development,</p> <p>Noting also that where there is a threat of significant reduction or loss of biological diversity, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize such a threat,</p> <p>Recognizing that the safe transfer, handling and use of living modified organisms should be based on a step-by-step and case-by-case approach,</p> <p>Recognizing that the Protocol should not create unwarranted administrative requirements for transboundary transfer of LMOs for contained use provided that appropriate safety measures are applied,</p> <p>Recognizing that the production and use of living modified organisms should take place in an ethically and socially justifiable way, in accordance with the principle of sustainable development and without adverse effects on human health and the environment,</p>		
<p><b><u>ARTICLE 1- PRINCIPLES/OBJECTIVES</u></b></p> <p>The Article may take into account the following elements, as appropriate:</p> <ol style="list-style-type: none"> <li>1. The Protocol should contain a separate Article on objectives and it should be a broad objective;</li> <li>2. The objective should reflect the language in this field from decision II/5 of the Conference of the Parties;</li> <li>3. The objective should be broad and enable the Protocol to cover all the issues required to protect biodiversity, the environment and human [and animal] health [and social well being];</li> </ol> <p><b>GOVERNMENT SUBMISSIONS</b></p> <p><b>Option 1</b> The objective of this Protocol, to be pursued together with the relevant objectives and provisions of the Convention, is to safeguard human and animal health, the environment, biological diversity and the socio-economic welfare of societies from the potential risks of biotechnology, particularly modern biotechnology involving the development, handling, transfer, use and release of living modified organisms and products thereof.</p> <p><b>Option 2</b></p>	<p><b>Canadian view submitted to Secretariat (January, 1997):</b></p> <p><b>Canada suggests the Protocol may benefit from a Principles section. One possible inclusion would be reference to the precautionary principle as defined in the Convention.</b></p>	

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<p>The objective of this Protocol is to promote the safe transboundary movement of living modified organisms resulting from modern biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity, including through exchange of information and a scientifically-based and transparent system of advance informed agreement.</p> <p><b>Option 3</b> The objective of this Protocol is to promote the safe transboundary movement of all living modified organisms, and products thereof, resulting from modern biotechnology which may have an adverse effect on the conservation and sustainable use of biological diversity, taking also into account the risks to human health.</p> <p><b>Option 4</b> The objective of this Protocol is to contribute to ensuring an adequate level of protection in the field of biosafety, specifically focusing on transboundary movement, of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health.</p> <p><b>Option 5</b> The objective of this Protocol is to ensure the safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effect on the environment, in particular, the conservation and sustainable use of biological diversity, socio-economic imperatives, and the risks to agriculture and human health.</p> <p><b>Option 6</b> The objective of the Protocol is to ensure safe transfer, handling and use of living modified organisms (LMOs) resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity taking into account the risks to human health. The objective is also to ensure that these activities take place in accordance with the principle of sustainable development and in an ethically and socially justifiable way.</p> <p><b>Option 7</b> The objective of the Protocol is to ensure the safe transfer, handling and use of living modified organisms (LMOs) which result from modern biotechnology and which may have adverse effects on the conservation and sustainable use of biological diversity. Risks to human and animal health should be duly taken into account, and it should further be ensured that these activities take place in accordance with the principle of sustainable development, and in a socially and economically justifiable way.</p> <p><b>Option 8</b> The objective of this Protocol is to promote shared responsibility and cooperative efforts among the Parties to achieve an appropriate level of safety for the transboundary movement of living modified organisms that may have adverse effect on the conservation and sustainable use of biological diversity, taking also into account the risks to human health, by promoting and facilitating information exchange and providing for appropriate procedures.</p>		

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<p><b><u>ARTICLE 1 bis - GENERAL OBLIGATIONS</u></b></p> <p>The Article may take into account the following elements, as appropriate:</p> <ol style="list-style-type: none"> <li>1. Parties should be obligated to ensure adequate provisions for emergency plans in case of accidental or unintended transboundary movement;</li> <li>2. Parties should be obligated to take appropriate national legal, administrative and other measures [exchange of information and non-discrimination] to implement and enforce the provisions of this Protocol;</li> <li>3. Parties should ensure the AIA procedure be implemented in a transparent manner based on scientific methods;</li> <li>4. There should be no disguised restrictions on international trade;</li> <li>5. Parties should recommend relevant bodies to take appropriate action;</li> <li>6. Parties should employ a precautionary principle when dealing with the transboundary movement of LMOs;</li> <li>7. Parties should be obligated as to ensure that the Protocol is employed on a case by case basis;</li> </ol> <p><b>GOVERNMENT SUBMISSIONS</b></p> <p><b>Option 1</b></p> <ol style="list-style-type: none"> <li>1. The Parties to the present Protocol undertake to implement the provisions of the Protocol and the Annexes hereto which shall constitute an integral part of the present Protocol.</li> <li>2. Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms or products thereof are undertaken in a manner that prevents or reduces to acceptable levels of risks to human and animal health, biological diversity, the environment and socio-economic welfare of societies.</li> <li>3. Parties shall prohibit the export of living modified organisms or products thereof unless they obtain an advance informed agreement in writing from the State of import for the specific import.</li> <li>4. Parties shall prohibit the export of any living modified organisms or products thereof to the Parties which</li> </ol>		

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<p>have prohibited the import of such organisms or products. Parties exercising their right to prohibit the import of living modified organisms or products thereof shall inform the Secretariat and the Biosafety Clearing-House of their decision.</p> <p>5. No Party shall export or import living modified organisms or products thereof to or from non-Parties.</p> <p>6. Parties shall cooperate among themselves in order to achieve an environmentally sound system of management of the potential risks of living modified organisms and products thereof.</p> <p>7. Each Party shall take the appropriate measures to:</p> <p>(a) Ensure safety in biotechnology, especially in the transboundary transfer and release of living modified organisms resulting from modern biotechnology;</p> <p>(b) Ensure that persons involved in the development, handling, transfer, use or release of living modified organisms and products thereof take such steps as are necessary to avoid unacceptable risks to human and animal health, biological diversity, the environment and the socio-economic welfare of societies;</p> <p>(c) Require that information about a proposed transboundary transfer of any living modified organisms or products thereof be provided to the States concerned according to the appropriate procedures of notification set out in Article 7 of this Protocol;</p> <p>(d) Prohibit the export of any living modified organisms or products thereof to a State or group of States belonging to a regional economic integration organization that includes Parties which have prohibited imports by their legislation, or if it has reason to believe that the organisms or products in question will not be managed in an environmentally sound manner, according to criteria to be decided on by the Parties at their first meeting;</p> <p>(e) Cooperate with other Parties and may involve interested organizations as appropriate, directly and through the Secretariat and the Biosafety Clearing-House, with respect to the necessary measures for safety in biotechnology, including the dissemination of information on living modified organisms or products thereof, in order to ensure the environmentally sound management of such organisms and products and to achieve the prevention of illegal traffic and unintended releases;</p> <p>8. Furthermore, each Party shall:</p> <p>(a) Prohibit all persons under its national jurisdiction from developing, transferring, using or releasing living modified organisms or products thereof unless such persons are authorized to perform such types of activities or deal with such types of products;</p> <p>(b) Require that living modified organisms or products thereof that are to be the subject of transfer or a</p>		

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<p>transboundary transfer be packaged, labelled, and transported in conformity with the rules and requirements to be set out by the Secretariat and the competent authorities of the States concerned;</p> <p>(c) Require that living modified organisms and products thereof be accompanied by a transfer document from the point at which a transfer and transboundary transfer commences to the point of use or release.</p> <p>9. The Parties agree that failure to provide all the necessary information available about the living modified organisms or products thereof and any illegal traffic are criminal.</p> <p>10. Each Party shall take appropriate legal, administrative and other measures to implement and enforce the provisions of this Protocol, including measures to prevent and punish conduct in contravention of the Protocol.</p> <p>11. The obligation under this Protocol of States in which the living modified organisms or products thereof have been developed and in which they have originated is to require that those organisms or products are managed in an environmentally sound manner and may not under any circumstances be transferred to the States of import.</p> <p>12. Nothing in this Protocol shall prevent a Party or group of Parties from imposing additional requirements that are consistent with the objective and provisions of this Protocol and are in accordance with the rules of international law, in order to better protect human and animal health, biological diversity, the environment and the socio-economic welfare of societies.</p> <p><b>Option 2</b></p> <p>1. Parties shall take all necessary measures to comply with the provisions set out in this Protocol for the safe transboundary movement of living modified organisms resulting from modern biotechnology.</p> <p>2. Parties shall introduce, as necessary, implement and enforce national provisions in order to ensure compliance with the advance informed agreement procedures set out in Articles 6-11 of this Protocol.</p> <p>3. Parties shall ensure that advance informed agreement measures for the import of a living modified organism:</p> <ul style="list-style-type: none"> <li>(a) are implemented in a transparent manner, based on scientific principles and supported by the best available scientific evidence;</li> <li>(b) are not more restrictive than measures applied to the same living modified organism produced domestically or imported from other Parties, and;</li> <li>(c) are applied in a manner which does not constitute a disguised restriction on international trade.</li> </ul> <p>4. Parties may impose additional requirements for the safe transboundary movement of living modified</p>		

<p>organisms resulting from modern biotechnology, provided that they are consistent with the provisions of this Protocol and accord with other relevant international agreements.</p> <p><b>Option 3</b></p> <p>1. Each Party shall, in accordance with its particular conditions and capabilities:</p> <ul style="list-style-type: none"><li>a) develop an institutional framework for the execution of the provisions set out in this Protocol;</li><li>b) develop national strategies, plans or programmes for the provisions set out in this Protocol or adapt, for this purpose, existing strategies, plans or programmes;</li><li>c) integrate, as far as possible and as appropriate, the provisions set out in this Protocol into relevant national strategies, plans or programmes.</li></ul> <p>2. Importing Parties may impose additional requirements, for the safe transboundary movement of living modified organisms, and products thereof, provided that they are:</p> <ul style="list-style-type: none"><li>a) based on scientific principles and supported by the best available scientific evidence</li><li>b) detailed in national laws and regulations of the importing Party; and</li><li>c) consistent with the provisions of this Protocol and in accord with other relevant international agreements.</li></ul> <p><b>Option 4</b></p> <p>1. Each Party shall apply the AIA procedure provided under Article (AIA) with regard to the transboundary movement of any LMO.</p> <p>2. Each Party shall ensure that any LMO leaving its territory shall be furnished with due authorization of the designated national authority of the receiving Party.</p> <p>3. Parties which receive information and notifications of transboundary movements under the present Protocol shall ensure the confidentiality of the information of that nature which they have received.</p> <p><b>Option 5</b></p> <p>1. Nothing in this Protocol shall affect in any way the sovereignty of States over their territorial sea established in accordance with international law, and the sovereign rights and the jurisdiction which States have in their exclusive economic zones and their continental shelves in accordance with international law, and the exercise by ships and aircraft of all States of navigational rights and freedoms as provided for in international law and as reflected in relevant international instruments.</p> <p>2. Each Party shall ensure that the measures taken by it to implement this protocol do not create unnecessary obstacles to and do not constitute a means of arbitrary or unjustifiable discrimination or disguised restrictions on</p>		
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<p>international trade.</p> <ol style="list-style-type: none"> <li>3. The Parties shall, in accordance with this Protocol, exchange information relating to transboundary movement of LMOs.</li> <li>4. Without prejudice to compliance with relevant international requirements for transport operations, the Parties shall, where appropriate, ensure that LMOs within the scope of this Protocol and subject to intentional transboundary movement are accompanied by relevant information on LMOs, as specified in Annex II, and that the exporter shall be able to prove that the movement is in conformity with the requirements of the protocol.</li> <li>5. Transport of LMOs shall be carried out under safe conditions in order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.</li> </ol> <p><b>Option 6</b></p> <ol style="list-style-type: none"> <li>1. Parties exercising their right to prohibit the import of LMOs resulting from modern biotechnology shall inform other Parties thereof.</li> <li>2. Parties shall prohibit or shall not permit the export of LMOs resulting from modern biotechnology to Parties which have prohibited the import of such LMOs.</li> <li>3. Parties shall ensure adequate provisions for emergency plans in case of accidental or unintended transboundary movements.</li> <li>4. Parties shall take appropriate legal, administrative and other measures to implement and enforce the provisions of this Protocol, including measures to prevent and punish conduct in contravention of the Protocol.</li> </ol> <p><b>Option 7</b></p> <ol style="list-style-type: none"> <li>1. The Parties to the Protocol undertake to implement the provisions of the Protocol and its Annexes which constitute an integral part thereof.</li> <li>2. Parties shall ensure that the development, handling, transport, use, transfer and release of any LMOs are undertaken in a manner that prevents, or reduces to acceptable levels, risks to biological diversity, the environment and human and animal health.</li> <li>3. Subject to the provisions in Art. 7.1, Parties shall not approve or allow the export of LMOs until such time as an advance informed agreement (AIA), with explicit consent, has been obtained in writing, from the State of import for that specific import.</li> </ol>		

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<p>international trade.</p> <ol style="list-style-type: none"> <li>3. The Parties shall, in accordance with this Protocol, exchange information relating to transboundary movement of LMOs.</li> <li>4. Without prejudice to compliance with relevant international requirements for transport operations, the Parties shall, where appropriate, ensure that LMOs within the scope of this Protocol and subject to intentional transboundary movement are accompanied by relevant information on LMOs, as specified in Annex II, and that the exporter shall be able to prove that the movement is in conformity with the requirements of the protocol.</li> <li>5. Transport of LMOs shall be carried out under safe conditions in order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.</li> </ol> <p><b>Option 6</b></p> <ol style="list-style-type: none"> <li>1. Parties exercising their right to prohibit the import of LMOs resulting from modern biotechnology shall inform other Parties thereof.</li> <li>2. Parties shall prohibit or shall not permit the export of LMOs resulting from modern biotechnology to Parties which have prohibited the import of such LMOs.</li> <li>3. Parties shall ensure adequate provisions for emergency plans in case of accidental or unintended transboundary movements.</li> <li>4. Parties shall take appropriate legal, administrative and other measures to implement and enforce the provisions of this Protocol, including measures to prevent and punish conduct in contravention of the Protocol.</li> </ol> <p><b>Option 7</b></p> <ol style="list-style-type: none"> <li>1. The Parties to the Protocol undertake to implement the provisions of the Protocol and its Annexes which constitute an integral part thereof.</li> <li>2. Parties shall ensure that the development, handling, transport, use, transfer and release of any LMOs are undertaken in a manner that prevents, or reduces to acceptable levels, risks to biological diversity, the environment and human and animal health.</li> <li>3. Subject to the provisions in Art. 7.1, Parties shall not approve or allow the export of LMOs until such time as an advance informed agreement (AIA), with explicit consent, has been obtained in writing, from the State of import for that specific import.</li> </ol>		

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<p>4. Parties shall not approve or allow the export of any LMOs to those Parties which have prohibited the import of such organisms. Parties exercising their right to prohibit the import of LMOs shall inform the Secretariat and the Clearing House of their decision. <i>[For the purpose of this Protocol, the Secretariat and Clearing House of the Convention on Biological Diversity will also fulfil those functions for the Protocol.]</i></p> <p>6. Parties shall cooperate among themselves in order to develop an environmentally sound risk management system for LMOs.</p> <p>7. Each Party shall take appropriate legal, administrative and other measures to:</p> <ul style="list-style-type: none"> <li>(a) Ensure safety in biotechnology, especially in the handling, use, release and transboundary transfer of LMOs resulting from modern biotechnology.</li> <li>(b) Ensure that persons involved in the development, handling, transfer, use or release of LMOs take the necessary steps to avoid unacceptable risks to biological diversity, the environment and human and animal health.-</li> <li>(c) Require that information on intended transboundary transfers of any LMO be provided to the States concerned according to the procedures of notification set out in Article 6 of this Protocol.</li> <li>(d) Prohibit the export of any LMOs to a State, or group of States belonging to a regional economic integration organisation that includes Parties, which have prohibited the import of such LMOs through legislation</li> <li>(e) Cooperate with other Parties and involve appropriate organisations, directly or through the Secretariat and the Clearing House, in taking measures aimed at ensuring safety in biotechnology, including the dissemination of information on living, modified organisms.</li> <li>(f) Ensure that appropriate national authorisation is required for all activities, including experimental, involving development, handling,, use, transfer and release of LMOs.</li> <li>(g) Require that living, modified organisms which are to be transferred, either internally or across boundaries, be packaged, labelled, and transported in conformity with the rules and requirements laid down by the Parties and the competent authorities of the States concerned.</li> <li>(h) Require that living, modified organisms be accompanied by a transfer document front the point at which a transfer and transboundary transfer commences to the point of use or release.</li> </ul> <p>8. Nothing in this Protocol shall prevent a Party or group of Parties from imposing additional requirements that are consistent, with the objectives and provisions of this Protocol, other agreements legally binding on those Parties and in accordance with the principles of international law.</p>		

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<p><b>Option 8</b></p> <ol style="list-style-type: none"> <li>Each Contracting Party shall take appropriate legislative and/or administrative measures in order to achieve the objectives of this Protocol.</li> <li>The Contracting Parties shall, in accordance with this Protocol, exchange information on living modified organisms in order to contribute to the environmentally sound management of biotechnology.</li> </ol> <p>The Contracting Parties shall ensure that measures taken for the oversight of transboundary movement of living modified organisms do not create unnecessary obstacles to, and/or constitute a means of arbitrary or unjustifiable discrimination or disguised restrictions on international trade.</p>		
<p><b><u>ARTICLE 2 - USE OF TERMS</u></b></p> <p><b><u>ACCIDENTAL RELEASE</u></b> Accidental release is any incident involving an [significant and] unintended release of a LMO in the course of its [contained use] [contained handling, transfer of use] [natural setting] which [could] [may or may not] [adversely affect] [present an immediate or delayed hazard to] the conservation and sustainable use of biological diversity, taking also into account [risk to] [adverse effects on] human health.</p> <p><b><u>COMPETENT AUTHORITY</u></b> Competent authority means any national [or intergovernmental] [authority] [agency] [possessing sufficient relevant scientific capacity] designated by a Party to be responsible for:</p> <p><b>option 1:</b> the implementation of the Protocol;</p> <p><b>option 2:</b> the handling [,issuing and receiving] of [notifications] [AIA] of transboundary movement [or release] of LMOs and any information related to it] [and to execute the functions of issuing and withdraw of approval for handling and use of LMOs];</p> <p><b>Option 3:</b> to regulate [biotechnology and] [biosafety], [intellectual property rights] [and other relevant aspects].</p> <p><b><u>CONTAINED USE</u></b> Contained use means any [<del>limited, experimental, non-commercial</del>] activity in which LMOs are cultured, stored, transported, destroyed, disposed of or used in any other way whereby the contact with [or their impacts on] the</p>	<p>"contained facility" (CEPA - microorganisms)</p>	

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<p>environment <del>[including humans]</del> is <del>[prevented]</del> [limited] by <del>[specific containment measures]</del> <del>[physical barriers or a combination of physical, chemical and/or biological barriers]</del> <del>[operational requirements]</del>.</p> <p><b><u>DELIBERATE RELEASE</u></b> Deliberate release</p> <p><b>Option 1:</b> means any intentional introduction into the environment of LMOs [which is not contained use] [without specific containment measures] [without provisions for containment such as physical barriers or a combination of physical barriers together with chemical and/or biological barriers used to [limit] [prevent] their contact with the general population and the environment]. [ This may take the form of a field trial or a general release].</p> <p><b>Option 2:</b> means any production and use [or activity or incident] of LMOs that is not [a] [approved as] contained use.</p> <p><b><u>EXPORT AND IMPORT</u></b> Export and import mean, in their respective connotations, the movement from one Party [or State] to another Party [or State], but exclude mere transit operations.</p> <p><b><u>EXPORTER</u></b> Exporter means any legal or natural person under the jurisdiction of the exporting Party [or State], who arranges for LMOs to be exported.</p> <p><b><u>FIELD TRIAL</u></b> Field trial means the [deliberate] introduction [release] of an LMO into the environment [for the purpose of testing] with provisions for limiting the potential for [and monitoring for the] uncontrolled dissemination or persistence of the LMO [or its genetic material] in the environment, [under conditions where the degree of dissemination of the LMOs is limited by physical and/or chemical and/or biological barriers which prevent the survival of such organisms in the environment].</p> <p><b><u>FOCAL POINT</u></b> Focal point means any [national] body [institutional component] designated by a Party [competent authority] [to be responsible for providing and collecting information on the implementation of the protocol at the national level and communication between the Parties about the implementation of the Protocol] to receive and supply [relevant] information [and assist communication] related to transboundary movements of LMOs, [and other information concerning biosafety].</p> <p><b><u>ILLEGAL TRAFFIC</u></b> Illegal traffic means any transboundary movement or transfer without notification to, or advance informed agreement of, all Parties concerned; pursuant to the provisions of this protocol; or with advance informed agreement obtained from Parties concerned through falsification, misrepresentation or fraud; or with advance informed agreement which does not conform in a material way with the documents submitted or which results in</p>	<p>means an enclosed building with walls floor and ceiling, or an area within such a building , where containment of a microorganism is in accordance with Canadian Laboratory Biosafety Guidelines (1990) or Appendix K of the U.S. NIH Guidelines (1994) as amended from time to time.</p> <p>“containment” (Health of Animals Act - vet biologics regs) means containment in accordance with Canadian Laboratory Biosafety Guidelines (1990) and as amended from time to time.</p> <p>“release” (Seeds Act - plants with novel traits regs) means any discharge or emission of seed into the environment or exposure of seed to the environment and includes the growing and field testing of plants.</p> <p>“release” (Health of Animals Act - vet biologics regs) means any discharge or emission of a veterinary biologic into the environment.</p> <p>“experimental field study” (CEPA -NSNregs) means a study of a research and development substance that is a microorganism, which study uses the minimum area, up to a maximum of 100 hectares, and the minimum quantity of the substance required to meet the objectives of the study.</p>	

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<p>the deliberate release of living modified organisms in contravention of this protocol and of general principles of international law [and of general principles of international law].</p> <p><b>IMPORTER</b> Importer means any legal or natural person under the jurisdiction of the Party [or State] of import [receiving Party] who arranges for LMOs to be imported.</p> <p><b>LIABILITY</b> Liability shall mean the quality or state of being legally obligated or responsible.</p> <p><b>LIVING MODIFIED ORGANISM (LMO)</b></p> <p>LMO means:</p> <p><b>option 1:</b> any organism or part thereof which is capable of regenerating itself on its own or in the body or cell of another organism and whose genetic material has been modified by modern biotechnology in a way which does not occur naturally by mating or recombination, [or any living organism or part thereof which had been a fossil but has been resuscitated through modern biotechnology].</p> <p><b>Option 2:</b> <i>→ living</i> any organism that has been deliberately modified to exhibit one or more traits, that do not exist in/are novel to the species in the receiving country, not excluding when the LMO is a modified form of an organism that is a new species (exotic) to the receiving country.</p> <p><b>Option 3:</b> any organism in which the genetic material [including both DNA and RNA] has been altered in a way that does not occur naturally by mating and/or natural recombination.</p> <p><b>Option 4:</b> any organism produced through genetic modification and whose genetic make-up is unlikely to occur in nature, including any genetic material intended for use to produce LMOS, and products derived therefrom. These include subcellular particles such as plasmids, DNA fragments and vectors.</p> <p><b>Option 5:</b> any organism whose genome [have been altered by the insertion of] [contains] foreign DNA (or RNA). The DNA (or RNA) insert is gene construction created through chemical manipulations with certain DNA fragments isolated from different sources (organisms, taxa) or synthesized artificially. [In the context of the Protocol the term "LMO" also covers products thereof (food, feed and pharmaceutical ones)].</p> <p><b>NOTIFICATION</b></p>	<p>Canadian view submitted to Secretariate (January, 1997):</p> <p>We propose a definition of LMO (not including humans in this context) as follows: " living organisms that have been deliberately modified to exhibit one or more traits, that do not exist in/are novel to the species in the receiving country, not excluding when the LMO is a modified form of an organism that is a new species (exotic) to the receiving country. Novel traits are defined as: characteristics in an organism that have been created or introduced through a specific genetic change and that make the organism different from the unmodified organism. Deliberately modified means: altered by any means." We note that Canada also includes non-modified exotic species in its domestic safety assessment schemes.</p> <p>- a very narrow process-based definition of LMO could exclude from the scope of the Protocol, organisms that are currently within the scope of Canada's biotechnology regulatory scheme. The Protocol could include a safeguard to enable countries to maintain broader more product-based scope approaches.</p>	

*Novel / advanced effects.*

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<p>Notification means:</p> <p><b>option 1:</b> the presentation of documents containing the requisite information to the competent authority(ies)/focal point;</p> <p><b>option 2:</b> the express written notification by the country/person to the [Party of import or] affected country prior to any proposed/intended transboundary movement/release/activity into/within the [Party of import or] affected country which may affect/have an impact on the potentially [Party of import or] affected country. [It may also entail notification to third parties, as appropriate.] [Notification will be necessary whether or not the intended/proposed transfer represents a threat to the [Party of import or] affected country].</p> <p><b>NOVEL TRAITS</b> Novel traits are characteristics in an organism that have been created or introduced through a specific genetic change [using modern biotechnology or techniques specified in the definition of LMOs] [or by mating with initial LMOs] and that make the LMO different from the unmodified organism.</p> <p><b>ORGANISM</b> An organism is [the active, infective, or dormant stage or life form of] any biological [acellular, unicellular or multi cellular] entity capable of [replication] [reproducing itself] or of transferring genetic material. [This definition covers plants, animals, fungi, mycoplasmas, [mycoplasma-like organisms,] micro-organisms, viruses and viroids, including cell and tissue cultures, germinal cells, seeds, pollen and spores]] [other than human or human embryo].</p> <p><b>PARTY OF EXPORT</b> Party of export means a Party from which a transboundary movement is planned to be initiated or is initiated.</p> <p><b>PARTY OF IMPORT</b> Party of import means a Party to which a transboundary movement is planned to take place or is made.</p> <p><b>PARTY OF TRANSIT</b> Party of transit means any Party, other than Party of export or import, through which a movement is planned or takes place.</p> <p><b>PARTY CONCERNED</b> Party concerned means any Party of export, import, transit and affected Parties or non Parties.</p> <p><b>PARTY OF ORIGIN</b> Party of origin means the Party or Parties to this protocol from whose jurisdiction a transboundary [release or transfer] [movement] of LMO has taken place or is envisaged to take place.</p> <p><b>POTENTIAL RECEIVING ENVIRONMENT</b></p>	<p>"microorganism" (CEPA - NSNregs) means an alive 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 organism not referred to in a) or b), other than a cell used to propagate such an organism, or d) any culture other than a pure culture.</p>	

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<p>Potential receiving environment is an ecosystem or habitat, including humans and animals, which is likely to come in contact with released organism.</p> <p><b>PRODUCT</b> Product means anything made by or from, or derived from LMOs or a combination of LMOs, living or dead [, which is placed on the market].</p> <p><b>RECEIVING PARTY</b> Receiving Party means the Party or Parties to this protocol to whose jurisdiction a transboundary [release or transfer] [movement] of LMO has taken place or is envisaged to take place.</p> <p><b>TRANSBOUNDARY MOVEMENT</b></p> <p><b>option 1:</b> Transboundary movement means any movement from an area under the national jurisdiction of one Party to or through an area under the national jurisdiction of another Party to or through an area not under the natural jurisdiction of any Party (meaning any land, marine area or airspace within which a Party exercises administrative and regulatory responsibility in accordance with international law in regard to the protection of human health or the environment), provided at least two Parties are involved in the movement.</p> <p><b>Option 2:</b> Transboundary movement means any intended [and/or unintended] movement of LMOs [or genetic material] across [one or more national borders] [across the area under national jurisdiction].</p> <p><b>Option 3:</b> Transboundary movement is any intentional and/or unintended physical movement/transport of any LMO or products derived therefrom, across national boundaries, including, without limitation to, organisms that are produced, through genetic modification, and products derived therefrom, within the national boundaries of a Party, by persons (legal or natural). Transboundary movement also entails the behaviour of the LMOs, in particular in the receiving country, i.e. in R&amp;D, in handling, transfer, use and disposal of the LMOs.</p> <p><b>TRANSBOUNDARY RELEASE</b> Transboundary release means any unintended release of LMOs from the jurisdiction of one Party [or State] to the other or to areas beyond the limits of a national jurisdiction or control.</p> <p><b>UNCONFINED RELEASE</b> Unconfined release means the use of a LMO that is not subject to [provisions to limit the uncontrolled spread or persistence of that LMO] and physical [or biological] isolation from the natural or agricultural environment, site inspections, post-harvest land use restrictions and/or restricted use of seed and progeny.</p> <p><b>UNINTENDED RELEASE</b> Unintended release means any release of living modified organisms or products thereof which is not a deliberate</p>	<p>“confined release” (Seeds Act - plants with novel traits regs) means release under conditions intended to minimize the establishment and spread, in the environment, of seed or of genetic material from</p>	



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<p>release.</p> <p><b>UNINTENDED TRANSBOUNDARY MOVEMENT</b></p> <p>Unintended transboundary movement is the [natural or] accidental movement of LMOs [or genetic material] across national borders</p>	<p>plants derived from the seed, and the interaction of the seed or genetic material with the environment.</p> <p>“unconfined release” (Seeds Act - plants with novel traits regs) means release on an unrestricted basis.</p>	
<p><b>ARTICLE 3 - APPLICATION OF THE AIA PROCEDURE - ELEMENT PAPER</b></p> <p>1) All LMOs subject to AIA</p> <p>Option A: This Protocol applies to the transboundary movement of living modified organisms resulting from modern biotechnology that may have an adverse effect on the conservation and sustainable use of biological diversity, including human health.</p> <p>Option B: A Party shall permit the export of living modified organisms or products thereof only when it confirms that the agreement of the State of import has been obtained in advance based on the necessary information that the State of import has received in accordance with the provisions of Article (4) and Annex (I).</p> <p>Option C: Each Party shall apply the PIC procedure provided under article (PIC) with regard to the transboundary movement of any LMO.</p> <p>Option D: Each Party shall apply the Advance Informed Agreement procedure with respect to all living modified organisms defined in this Protocol.</p> <p>No intending country Party shall transfer, handle or use LMOs to or within a receiving country Party without first obtaining the receiving Party's consent. Any Party exercising jurisdiction over an individual person or entity shall ensure that no such person or entity shall transfer, handle or use LMOs to or within the receiving country Party without first obtaining the receiving Party's consent, through the receiving Party's National Competent Authority.</p> <p>Option E: To effect a transboundary movement, the exporter must submit an application, in the official format used by the importing country, to the competent authority of the importing country and before shipping the product, with all the information required by that competent authority and in accordance with the</p>	<p>Canadian view submitted to Secretariat (January, 1997):</p> <p>Canada proposes that AIA be required for the first intended transboundary movement (importation) to the importing party of a subject LMO. Subsequent AIA action on a particular LMO would depend on national requirements and on the results of the assessment by the national authority in the importing Party.</p> <p>Canadian legal text (footnote) submitted to Secretariat (July, 1997):</p> <p>The range of LMOs subject to AIA procedures are the LMOs that may have adverse effect on the conservation and sustainable use of biological diversity, including human health; therefore the expression “subject to AIA” is intended to provide a shorthand reference to those LMOs. The protocol should also recognize that LMOs that have been previously assessed by Parties prior to the coming into force of the Protocol and reported under Article 6(1)c would not be considered “first” transboundary movements.</p> <p>- Canada's current proposal is to exclude certain LMOs from AIA with a risk-based approach using exposure-related concepts like contained use and restraintment/confinement.</p>	

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<p>national law in force in the importing country.</p> <p>Option F: No transboundary movement of LMOs or products derived from them shall be allowed without the Advance Informed Agreement of the importing country.</p> <p>Option G: Each Party shall apply the Advance Informed Agreement to LMOs and products thereof that come under its jurisdiction as defined in this Protocol.</p> <p>Option H: It is established an advance informed agreement procedure on Living Modified Organisms subject to international trade which may have adverse effects on human health and the environment. In their first meeting, the Parties will establish the scope, the documents and the mechanisms for the information and previous consent procedure and the criteria to select the Living Modified Organisms which would be included in the previous fundamental consent procedure.</p> <p>Option I: "Advance informed agreement" means an agreement by the competent authority of the State of import to the transfer of any living modified organisms or products thereof based on the information supplied by the competent authority of the State of export with the understanding that the information is accurate and complete. The scope of AIA procedure will cover all the LMOs and their products and all the first and subsequent transfers of all LMOs and their products subject to the Articles of the Protocol.</p> <p>Option J: The advanced informed agreement is a means of providing official information on LMOs and products thereof, which are to be introduced into a particular country.</p>	<p>- the New Substances Notification Regulations under CEPA currently exempt some LMO imports from notification as follows:</p> <p>1) import of microorganisms that are R&amp;D substances to a "contained facility" (see definition in article 2 above) in quantities of less than 50mL or 50g;</p> <p>2) import of organisms other than microorganisms that are R&amp;D substances to a facility from which there is no release, into the environment, of a) the organism; b) the genetic material of the organism; or c) material from the organism involved in toxicity.</p> <p>- under some Acts, notification of an LMO is required before any "release" into the environment. Some LMO imports could be exempt from notification if they are considered "substantially equivalent" to an organism previously assessed. Some LMO imports could be exempt from notification as follows:</p> <p>1) import of plant seeds to be grown in containment in such a manner that there is no release into the environment of any genetic material from the plants derived from the seed;</p>	
<p>2) All first time transboundary movements of LMOs</p> <p>Option A: All initial transfers of LMOs to another country shall be subject to the AIA procedure. No transboundary transfer of LMOs shall be allowed without the AIA. The State of Export shall not allow the export and the State of Import shall not allow the import of LMOs until the Exporter has received the AIA. Explicit consent should be a requirement for initial shipment of all LMOs. Implicit consent shall apply to subsequent shipments of LMOs. In that case transboundary transfer of the LMOs shall be carried out according to the common procedure adopted in the State of Import for transboundary transfer of organisms which are not LMOs.</p> <p>Option B: Explicit Advanced Informed Agreement shall be required for the first import of living modified organisms, and/or products thereof, resulting from modern</p>	<p>2) import of a veterinary biologic for release under "containment" or in accordance with "confinement procedures" in a manner that prevents the dissemination of any genetic material from the veterinary biologic into the environment;</p> <p>3) import of fertilizer supplements for experimental purposes that will not result in release to the environment.</p>	

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<p>biotechnology, which may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account human health.</p> <p>Option C: All initial transboundary movements of LMOs shall be subject to AIA. This article does not apply to LMOs:</p> <ol style="list-style-type: none"> <li>1. imported into contained/confined facilities (imported for contained/confined use); or</li> <li>2. subject to bilateral, multilateral or regional agreements or arrangements as provided in Article (12).</li> </ol> <p>Option D: Subject to Article (9 paragraph 1), all initial transfers of LMOs to another country which is Party to this Protocol, will be subject to the AIA procedure.</p> <p>Option E: All first intentional transboundary movements of a specific LMO for specific purposes or uses into a new country, shall be subject to the procedure for Advance Informed Agreement (hereafter referred to as AIA). The State of import may, however, declare that low-risk micro-organisms and other low-risk research organisms intended for contained use shall not be covered by the AIA procedure.</p> <p>3) All LMOs except those explicitly excluded and exempted</p> <p>Option A: 1. Without prejudice to paragraphs 2 and 3, (this Protocol)(these procedures) shall apply to transboundary movement of living modified organisms resulting from modern biotechnology (LMOs).</p> <p>2. (This protocol )(these procedures) shall not apply to :</p> <ul style="list-style-type: none"> <li>- the transboundary movement of LMOs not likely to have an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as specified in Annex (I);</li> <li>- requirements for transport operations.</li> </ul> <p>3. (The protocol)(these procedures) shall neither apply to the transboundary movement of LMOs destined for subsequent contained use, nor to the transit of LMOs, except as regards Articles (4) (on general provisions) and (11) (on unintentional transboundary movement).</p> <p>Option B: 1. LMOs Subject to the AIA Procedure;</p> <p>(a) All transboundary transfers of LMOs resulting from modern biotechnology, except those mentioned in # 2 and 3 below, shall be within the scope of the application of the AIA procedures.</p>		

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<p>(b) Organic materials which are components of LMOs but are not self-reproducible in the environment, such as DNA or RNA segments, plasmids and peptides, shall, by definition, not be regarded as LMOs and be thus excluded from the application of the AIA procedures.</p> <p>(c) LMO products which do not contain live cells shall also be excluded from the application of the AIA procedures.</p> <p>2. Exclusion from the Application of the AIA procedures;</p> <p>(a) The LMOs which are subject to any other international agreement related to transboundary transfer of LMOs shall be excluded from the application of the AIA procedures.</p> <p>(b) The LMOs requested to be imported by the competent authority of the recipient Contracting Party for the purpose of carrying out risk assessment as a process of the AIA procedures stipulated in this Protocol shall be excluded from the application of the AIA procedures.</p> <p>(c) Those LMOs shall be excluded from the application of the AIA procedures if they are to be used, such as for experimental purposes, exclusively under confined conditions defined in this Protocol and if it is established by the Conference of the Parties to the Protocol that there does not exist any risk to the environment and human health by the use of those LMOs under the conditions so defined.</p> <p>3. Exemption from the Application of the AIA procedures. If it is established that there does not exist any risk by the use and release of certain LMOs on the basis of the best available scientific knowledge and experience, as well as relevant information, a recipient Contracting party by means of unilateral declaration or bilateral, regional or multilateral agreement or arrangement, may exempt such LMOs from the application of the AIA procedures, by which no explicit agreement by the competent authority of the recipient Contracting party is required.</p> <p>4) Importing State decides whether exporter should apply national regulations or Protocol.</p> <p>Option A: All first intentional transboundary movements of a specific LMO for specific purposes or uses into a new country, shall be subject to the procedure for Advance Informed Agreement (hereafter referred to as AIA). The State of import may, however, declare that low-risk micro-organisms and other low-risk research organisms intended for contained use shall not be covered by the AIA procedure.</p> <p>5) LMOs included based on criteria listed in an annex</p>		

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<p>Option A: The LMOs to be included will be based on criteria listed in an annex.</p> <p>6) LMOs intended for field testing, or first field growth or banned / no regulatory decision</p> <p>Option A: 1. <u>Scope</u>. An LMO is subject to the AIA where:</p> <ul style="list-style-type: none"> <li>(a) The LMO is intended for field testing in the importing country; or</li> <li>(b) (1) The LMO has not been imported into the importing Party and the LMO is not being produced in the importing Party, and               <ul style="list-style-type: none"> <li>(2) The LMO is one:                   <ul style="list-style-type: none"> <li>(i) that is intended for first field growth in the importing Party, including in particular first field growth in a center of origin or genetic diversity for that product;</li> <li>(ii) that has been banned or refused approval in the exporting Party because of potential adverse effect on the conservation and sustainable use of biodiversity that were identified during the review process;</li> <li>(iii) for which approval is in the process of being sought in the exporting Party;</li> <li>(iv) for which approval in the exporting Party would have been required had the LMO been intended for domestic commercialization, field testing, or field growth in the exporting Party;</li> <li>(v) or which approval in the exporting Party would have been required had the LMO been intended for domestic commercialization or growth in the exporting Party but for which an application or request for approval was withdrawn; or</li> </ul> </li> <li>(c) The LMO has been imported into the importing Party, but subsequent to such import, the exporting Party has banned or refused approval of the LMO because of potential adverse effects on the conservation and sustainable use of biodiversity, and the importing Party has not approved the LMO for import or growth since such exporting Party ban of refusal of approval.</li> </ul> </li> </ul>		
<p><u>ARTICLE 4 - NOTIFICATION PROCEDURE FOR AIA</u></p> <p style="text-align: center;"><u>ARTICLES 4,5,6,7</u></p>	<p>Canadian proposed legal text submitted to the Secretariat (July, 1997):</p> <p>1. Each Party of import shall require notification to be given, by the importer, to</p>	

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<p align="center"><u>ADVANCE INFORMED AGREEMENT PROCEDURE</u></p> <p>(Notification Procedure For AIA; Response To AIA Notification; Decision Procedure For AIA; Review Of Decision Under AIA)</p> <p><i>a)</i> Notification / application (Article 4)</p> <ul style="list-style-type: none"> <li>The State of export(Party of origin)</li> </ul> <p>Option 1: The State of export shall notify, or shall require the exporter to notify by application in writing, through the channel of the competent authority of the State of export, the competent authority of the states concerned of any proposed transboundary transfer of living modified organisms or products thereof. Such application shall contain the declarations and information specified in Annex I, written in a language acceptable to the State of import. One application or notification shall be sent to each of the States concerned and to the Biosafety Clearing House.</p> <p>Option 1b The State of export shall require the exporter to supply either through the channel of, or by providing a copy to the competent authority of the State of export the information included in Annex I to the State of import, prior to the first intentional transboundary movement of LMOs.</p> <ul style="list-style-type: none"> <li>The exporter as required by the State of export or the State of import(receiving Party)</li> </ul> <p>Option 2: For the intentional transboundary movement of LMOs, the exporter shall notify in advance the party of import in writing of that movement and shall only proceed with such movement in compliance with Articles 5 and 6 (these articles address Acknowledgment of Receipt, Procedures and AIA). Information to be provided in the notification is specified in Annex I.</p> <ul style="list-style-type: none"> <li>The State of export or the exporter as required by the state of export or import</li> </ul> <p>Option 3: The AIA procedure shall be triggered by the Exporter. The application shall be submitted to the competent authority/focal point in the State of Import. The Exporter has to supply all the information about the LMO necessary for implementation of adequate risk assessment.</p>	<p>the Party of import<sup>1</sup> of the first proposed transboundary movement of a living modified organism (LMO) subject to AIA<sup>2</sup> before it is imported<sup>3</sup>.</p> <p>2. The notification referred in Article 1(1) regarding LMOs subject to AIA shall include the following:</p> <ul style="list-style-type: none"> <li>(a) the name of the exporter and importer;</li> <li>(b) information about the LMO, including source and characteristics</li> <li>(c) available information about the potential adverse effects of the LMO on the conservation and sustainable use of biological diversity, including within the Party of import;</li> <li>(d) intended use; and,</li> <li>(e) available information about any notification to other governments regarding the import or development of the living modified organism, and the purpose thereof;</li> </ul> <p>4. Each Party shall make its importers responsible for the accuracy of the information provided in a notification and</p>	

<sup>1</sup> For the purpose of carrying out the administration of this paragraph, each Party of Import shall designate one or more responsible entities.

<sup>2</sup> The range of LMOs subject to AIA procedures are the LMOs that may have adverse effect on the conservation and sustainable use of biological diversity, including human health; therefore the expression "subject to AIA" is intended to provide a shorthand reference to those LMOs. The Protocol should also recognize that LMOs which have been previously assessed by Parties prior to the coming into force of the Protocol and reported under Article 6(1)(c) would not be considered "first" transboundary movements.

<sup>3</sup> Canada recognizes that the importer may need to have the exporter or owners of proprietary knowledge that they are not privy to, (but which is needed for the review for import,) supply information directly to the Party of Import. This exchange of information is subsumed under the heading of importer.

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<ul style="list-style-type: none"> <li>The importer</li> </ul> <p>Option 4: Each Party of import shall require notification to be given, by the importer, to the Party of import of the first proposed transboundary movement of a living modified organism (LMO) subject to AIA before it is imported.</p> <ul style="list-style-type: none"> <li>The state of export or the exporter</li> </ul> <p>Option 5: Each exporting Party shall notify, or require a natural or legal person under its jurisdiction to notify, in writing, the importing Party through the importing Party's national focal point prior to the first export to the importing party of an LMO that is subject to the AIA (those LMOs which may present risks to the conservation and sustainable use of biodiversity). The notification need be sent to only one focal point in the importing Party concerned. The notification shall include the information contained in the annex to this Protocol.</p> <ul style="list-style-type: none"> <li>The exporter through its own CA</li> </ul> <p>Option 6: <u>The exporter must notify in writing the competent national authority of the importing country regarding his intention to export, through his own competent national authority.</u></p> <ul style="list-style-type: none"> <li>In writing</li> </ul> <p>Option 7: The exporting Party shall notify, or shall require that notification be given to, in writing, the Focal Point of the importing Party, intent to export a LMO (for the first time)(that is subject to AIA).</p> <p>Option 7b: The exporting Party shall notify, or shall require that notification be given to, in writing, the Focal Point of the importing Party, intent to export a living modified organism for the first time into an importing Party. The information to be provided with the notification is set out in Annex I to this Protocol.</p> <ul style="list-style-type: none"> <li>(Party of origin)</li> </ul> <p>Option 8: <u>The PIC procedure shall be triggered by notification of a request for transboundary movement of any LMO by the designated national authority of the Party of origin addressed to the designated national authority of the receiving Party and, where applicable, to the designated</u></p>	<p><b>for any new information provided pursuant to this Article.</b></p> <p>- Canada's current proposal is that Parties of Import would require notification from the importer of the first transboundary movement of an LMO. This proposal reflects our domestic regulatory regime and places notification obligations on importers rather than exporters. The intent is to require someone subject to Canadian law to bear responsibility for the import.</p> <p>- Canada recognizes that the importer may need to have the exporter or owners of proprietary knowledge that they are not privy to, (but which is needed for the review for import) supply information directly to the Party of Import. This exchange of information is subsumed under the heading of importer.</p> <p>- to place notification obligations on exporters to provide a notification to a Party of Import or to receive AIA prior to exporting an LMO could require legislative changes in Canada.</p>	

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<p><u>national authority of the Party of transit.</u></p> <ul style="list-style-type: none"> <li>(Receiving Party)</li> </ul> <p>Option 9: Any Party who intends to transfer, handle or use any LMO to or within any receiving country Party shall give prior notice to, through its National Competent Authority, the National Competent Authority of the receiving country Party, by application in writing of its intention to do so. Each Party shall ensure that any individual person or entity under its jurisdiction who intends to undertake any transfer, handling or use of LMOs to or within any receiving country Party shall give prior notice to the National Competent Authority of the receiving country Party by application in writing, of its intention to do so.</p> <p>Option 10: Explicit Advanced Informed Agreement shall be required for the first import of living modified organisms, and/or products thereof, resulting from modern biotechnology, which may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account human health.</p> <p><i>b)</i> Information requirements for the notifications/applications</p> <ul style="list-style-type: none"> <li>Annex I including or excluding risk assessment</li> </ul> <p>Option 1: (The exporting Party) (Importer/exporter) (intending Party) shall submit (declaration and ) the information identified in Annex I, in writing, to (the importing Party) (receiving Party).</p> <ul style="list-style-type: none"> <li>List of information required as adopted and reviewed by COP</li> </ul> <p>Option 2: The information to be provided to the competent authorities of the recipient Contracting Party for the implementation of the AIA procedures shall be specified and enumerated in a list by the Conference of the Parties to the Protocol. The list shall be reviewed, by the Conference of the Parties to the Protocol, periodically in the light of the most recent and best available scientific knowledge and experience, as well as other relevant information. The Conference of the Parties to the Protocol may establish a technical advisory body with the task of providing the Contracting Parties with scientific backgrounds for reviewing the list.</p> <ul style="list-style-type: none"> <li>No specific requirements</li> </ul> <p>Option 3: The AIA procedure shall be triggered by the Exporter. The application shall be submitted to the competent authority/focal point in the State of Import. The Exporter has to supply all the information about the LMO necessary for implementation of adequate risk assessment.</p> <ul style="list-style-type: none"> <li>Under national requirements of the importing Party</li> </ul>		



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<p>Option 4: The competent authority/focal point in the State of Import shall provide information to the Exporter concerning its laws, regulations, guidelines, legal and administrative procedures and other requirements related to the biosafety.</p> <p>c) Responsibility for the accuracy of the information</p> <ul style="list-style-type: none"> <li>Any new information</li> </ul> <p>Option 1: The National Competent Authority of the intending country Party shall attest to the accuracy of the information stated above.</p> <ul style="list-style-type: none"> <li>Responsibility for the accuracy of the information</li> </ul> <p>Option 2: The State of export shall, through its competent authority, examine the conformity to the notification under paragraphs 1 and 2 above with the requirements of this Protocol and the State of import, and shall stand surety for the accuracy and completeness of the information supplied by the exporter, on the basis of which the advance informed agreement is made.</p> <p>Option 2b: Parties shall introduce, as necessary, implement and enforce national provisions in order to ensure the compliance with the AIA procedures, including the provision of accurate information.</p> <p>Option 2c: Each Party shall make its ( exporter ) responsible for the accuracy of the information provided in a notification and for any new information provided.</p> <p>Option 3: No provision on responsibility for the accuracy of the information is necessary.</p>		
<p><b><u>ARTICLE 5 - RESPONSE TO AIA NOTIFICATION</u></b></p> <p>d) Acknowledgment of receipt (Article 5)</p> <ul style="list-style-type: none"> <li>No acknowledgment</li> </ul> <p>Option 1: No acknowledgment is required.</p> <ul style="list-style-type: none"> <li>Acknowledgment</li> </ul>	<p>Canadian proposed legal text submitted to Secretariat (July, 1997):</p> <p>5. Each Party of import shall acknowledge to the importer, not later than 30 days after receiving the notification under this Article, that the notification contains prima facie the information described under Article 1.2. Such acknowledgement does not limit the possibility to require further scientific information under Article 2(2)(d).</p>	

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<p>Option 2: The designated national authority of the receiving Party shall review the content of the request and, if found in order, shall within X days following notification, communicate such finding in writing to the designated national authority of the Party of origin.</p> <p>In the event that the request is found not to be in order, the designated national authority of the receiving Party may request within the period specified above, the missing information, in which event the deadlines specified for these purposes shall be suspended until the requested information is provided.</p> <ul style="list-style-type: none"> <li>Acknowledgment in writing within X (10/30) days or a reasonable period of time</li> </ul> <p>Option 3: Each Party of import shall acknowledge (in writing) to the importer, (not later than X days) (in a reasonable time) on after receiving the notification under this Article, (that the notification contains prima facie the information described under Annex I) (the date of the receipt of the notification) (or with a request for further information). Such acknowledgment does not limit the possibility to require further scientific information under Article 13.</p> <p>Option 3b: The receiving country shall acknowledge in writing to the intending country within X days after receipt of the application by the national competent authority of the receiving country.</p> <p>e) Information to notifier</p> <p>Option 1: The Party of import shall within the period referred to in Article 6 (Acknowledgment of Receipt) (30 days of the date of receipt of the notification) inform the notifier to proceed according to:</p> <ul style="list-style-type: none"> <li>a) either its regulatory framework implementing Article 8(g) of the CBD, provided the framework includes a control mechanism for transboundary movement consistent with the protocol;</li> <li>b) or the procedure provided for in Article 4 (AIA).</li> </ul> <p>f) Time Frames</p> <ul style="list-style-type: none"> <li>in due time</li> </ul> <p>Option 1: The importing Party will communicate its decision to the exporting Party in due time</p> <ul style="list-style-type: none"> <li>within a reasonable period of time</li> </ul>	<p>- Canada should strive to prevent the Protocol prescribing assessment periods within which a decision must be communicated that are shorter than prescribed Canadian periods.</p> <p>- assessment periods are prescribed in the New Substances Notification Regulations under CEPA and range from 30 to 120 days.</p>	

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<p>Option 2 The importing Party shall acknowledge the notification, in writing, within a reasonable period of time. This acknowledgment shall include:</p> <ul style="list-style-type: none"> <li>A. advice that a risk assessment has been or is to be carried out; and</li> <li>B. a request, as necessary, for any further information which remains to be provided in accordance with this Article.</li> </ul> <ul style="list-style-type: none"> <li>• within x (30/90/120/150/180) days,</li> </ul> <p>Option 3 The Party of import shall within the period referred to in Article 6 (30 days of the date of receipt of the notification) communicate to the exporter:</p> <ul style="list-style-type: none"> <li>a) that, unless it has not, with justification, asked for additional information, imposed conditions or refused permission for the notified movement within 150 days after the date of receipt of the notification, the movement may proceed;</li> <li>b) or that the movement may proceed only after the Party of import has given its written consent, with or without conditions. The Party of import shall decide within 150 days after the date of receipt of the notification.</li> </ul> <p>Option 3b The competent authority in the state of import (shall be obliged to respond to the State of export)(shall take appropriate legislative and/or administrative measures to ensure response to the exporter and the Secretariat) within X days after the date of acknowledging the receipt of notification.</p> <p>Option 3c An importing Party shall respond to notification of an intention to export to the importing Party LMO that is subject to the AIA as soon as possible , but not later than 180 days after transmission of such notification.</p> <ul style="list-style-type: none"> <li>• extension of time frame</li> </ul> <p>Option 4the period of response should be extended by the period of time awaiting requested information; the period of time for conducting field trials; or by a request for additional time no longer than 60 days</p> <p>Option 4b The Party of import may inform the notifier with justification that this period (150 days) is extended by a defined period no longer than 60 days. When calculating the period referred to in paragraph 1, the number of days for which the Party of import is waiting for additional information which it has requested from the notifier shall not be taken into account.</p> <p>Option 4c The number of days for which the importing Party is waiting for additional information which it has requested from the notifier, shall not be taken into account.</p>		

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<ul style="list-style-type: none"> <li>• as long as necessary</li> </ul> <p>Option 5      Notwithstanding paragraph 1 above, the receiving country Party shall be allowed as much time as is necessary to assess the information it has received from the intending country Party so as to enable it to reach an informed decision on the application and make its own risk assessment decisions on the transfer, handling or use of the LMO.</p> <ul style="list-style-type: none"> <li>• Agreed</li> </ul> <p>Option 6:      Decisions regarding import should be made within a time frame agreed between the importing and exporting Parties.</p> <p>g)      Interim Response</p> <ul style="list-style-type: none"> <li>• No provision for interim response</li> </ul> <p>Option 1</p> <ul style="list-style-type: none"> <li>• interim decision pending final decision</li> </ul> <p>Option 2      <u>The response of the designated national authority of the receiving Party to a request for transboundary movement can take the following form;</u></p> <p><u>An interim response which:</u></p> <ul style="list-style-type: none"> <li>(i) <u>States the need to conduct a risk assessment;</u></li> <li>(ii) <u>Requests additional information.</u></li> <li>(iii) requests for extended period of time to respond</li> </ul>		
<p><b><u>ARTICLE 6 - DECISION PROCEDURE FOR AIA</u></b></p> <p>h) Decision by importing state (Article 6)</p> <ul style="list-style-type: none"> <li>■ yes, yes with conditions, or no</li> </ul> <p>Option 1      The State of import shall respond to the notifier in writing:</p>	<p><b>Canadian proposed legal text submitted to Secretariat (July, 1997):</b></p> <p><b>2. On or before the expiration of the period in Article 2.1 and based on the result of the science-based risk assessment conducted under Article 2.1, the competent authority of the Party of import shall:</b></p> <p><b>(a) allow the import,</b></p>	

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<p>1. consenting to the intended movement with or without conditions or</p> <p>2. deny permission for the movement.</p> <p>■ basis for the decision: whether the decision applies to other imports; and subsequent imports</p> <p>Option 2 The importing Party shall provide full details to the exporting Party or exporter, in writing, and the Clearing House on:</p> <p>1. the basis for the decisions (to deny imports) including full details of risk assessments; (or)</p> <p>2. whether the decision applies, either in whole or in part, to other potential imports of the same living modified organism; (and) (or)</p> <p>3. whether notification is required for subsequent imports of the same living modified organism, in accordance with (Article 10) (Notification for Subsequent Imports).</p> <p>The importing Party shall make all import decisions. Decisions shall be based on scientific principles and supported by the best available scientific evidence. Decisions shall consist of:</p> <p>(a) approval to import, without conditions, or;</p> <p>(b) approval to import, with specified conditions, or;</p> <p>(c) prohibition of import.</p> <p>Option 2b All decisions by the Party of import shall be based on scientific risk assessment of the adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health.</p> <p>Option 2c The State of import shall communicate in its response to the State of export whether an AIA procedure with explicit consent or implicit consent is required for subsequent imports of the same LMO or whether a simplified notification in accordance with Article XX shall be applied.</p> <p>Option 2d The (importing parties) (receiving country) shall make all decisions on the basis of, inter alia, risk assessment, socio-economic imperatives, and social and ethical considerations.</p> <p>Option 2e A final decision shall be accompanied by information describing the legislative and/or administrative measures on which the decision is based. The same conditions, if any, shall apply to the imported and domestic produced living modified organisms.</p> <p>Option 2f The importing state shall make decisions based on scientific, social, economic and cultural</p>	<p>or decide to:</p> <p>(b) allow the import, subject to conditions;</p> <p>(c) prohibit the import; or</p> <p>(d) request from the importer further scientific information reasonably required before allowing or prohibiting the import.</p> <p>3. The competent authority of the Party of import shall provide an importer, subject to decisions under Article 2.2(b), (c) or (d), with reasons for such decisions.</p> <p>- Canada's current proposal is designed to allow two kinds of legal schemes to implement AIA procedures for LMOs: an explicit consent scheme and a tacit consent scheme. Under explicit consent, an LMO importation cannot proceed until it has been expressly agreed to by the Party of Import. Under tacit consent, an LMO importation is allowed unless the Party of Import communicates otherwise within a set period of time.</p> <p>- a number of Canadian Acts are based upon an explicit consent scheme while the Canadian Environmental Protection Act and aspects of the Food and Drugs Act are based upon tacit consent.</p> <p>- a Protocol requirement for a scheme based solely on explicit consent could require changes to Canadian legislation.</p>	

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<p>criteria.</p> <p>Option 2g In cases where the State of import considers that the documentation provided by the state of export is not sufficient in order to determine the potential adverse effects of an LMO, the State of import has the right to prohibit import of the LMO in question.</p> <p>Option 2h Decisions under the Protocol shall be based on scientific grounds and experience</p> <p>■ Competent Authority Decision; yes, with conditions, or no</p> <p>Option 1: On or before the expiration of the period in Article 6 and based on the result of the science-based risk assessment conducted under Article 13, the competent authority of the Party of import shall:</p> <ul style="list-style-type: none"> <li>(a) allow the import,</li> <li>or decide to:</li> <li>(b) allow the import, subject to conditions;</li> <li>(c) prohibit the import; or</li> <li>(d) request from the importer further scientific information which the competent authority reasonably requires before allowing or prohibiting the import.</li> </ul> <p>• explicit consent, or request for further information</p> <p>Option 1 Upon receipt of the application by the National Competent Authority of the receiving country Party, the receiving country Party can indicate to the National Competent Authority of the intending country Party can indicate either;</p> <ul style="list-style-type: none"> <li>(a) the request for additional information if the receiving Party feels that the information provided by the intending Party is incomplete; or</li> <li>(b) upon satisfactory completion of the assessment of the information supplied to it by the intending Party, the consent to the transfer, handling or use of the LMO with or without conditions.</li> <li>(c) reject the application absolutely or provisionally.</li> </ul> <p>i) Consequences of failure to respond (in a given time frame)</p> <p>■ Implicit/explicit</p> <p>Option 1 If the importing Contracting Party fails to transmit a final decision or an interim response within the period of (120 days) of receiving the application, the living modified organism concerned shall not be exported without the explicit consent of the importing Contracting</p>		

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<p>Party.</p> <p>Option 1b Should competent authorities of the recipient Contracting Party fail to reply to the Exporter within the period mentioned in (X) above, the competent authorities are deemed to have given to the Exporter an implicit agreement to the import of the LMOs concerned.</p> <p>Option 1c The Parties shall cooperate with a view to deciding, as soon as possible, to what extent in relation to the procedures, and in which cases, to be specified in Annex (es), the intentional transboundary movement cannot proceed without an explicit consent.</p> <p>■ implicit refusal</p> <p>Option 2 If the receiving Party does not provide any response in 60 days, it shall be deemed to be a rejection of the application.</p> <p>■ No response</p> <p>Option 3 If the importing Party fails to submit a final decision within 180 days, the transboundary movement is no longer governed by the terms of this Protocol and the exporting Party shall have no further obligations under this Protocol with respect to such transboundary movement.</p> <p>j) Responsibility of Contracting Parties</p> <p>Option 1</p> <ol style="list-style-type: none"> <li>1. The State of export shall, through its competent authority, examine the conformity to the notifications under paragraphs 1 and 2 above with the requirements of this Protocol and the State of import, and shall stand surety for the accuracy and completeness of the information supplied by the exporter, on the basis of which the advance informed agreement is made.</li> <li>2. No transboundary transfer of living modified organisms or products thereof shall be allowed without the advance informed agreement of the State of import. The State of export shall not allow the exporter to commence the transboundary transfer until it has received written confirmation that the applicant has received the advance informed agreement of the State of import.</li> <li>3. Any transboundary transfer shall be covered by insurance, bond or other guarantee as may be required by the States Concerned and/or recommended by the Biosafety Clearing House.</li> <li>4. The Parties shall, whenever it comes to their knowledge, ensure in the case of any unintended or deliberate release or any accident occurring during or subsequent to the transboundary transfer of</li> </ol>		

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living modified organisms, which are likely to present risks to human and animal health, biological diversity, the environment or the socio-economic welfare of societies in other States, that those states are immediately informed.		
<p><b>ARTICLE 7 - REVIEW OF DECISION UNDER AIA</b></p> <p>k. REVIEW OF DECISIONS UNDER AIA (Article 8)</p> <p>■ new information available</p> <p>Option 1 If, at any time before, during or after the transboundary transfer, the Competent Authorities or the exporter become aware of relevant new information on the LMO, which may have significant consequences for the associated risks, the competent authorities of the States concerned and the Secretariat and Clearing House will be informed within 30 days of such information becoming available.</p> <p>Option 1b If, subsequent to the intentional transboundary movement, the exporting Party has gained new experience or has become aware of relevant new information that causes the exporting Party to ban or refuse approval of the LMO because of the potential adverse effects on the conservation and sustainable use of biodiversity, and the importing Party has not approved the LMO for import or growth since such exporting Party ban or refusal of approval, the LMO will again be subject to the AIA, and the exporter will provide notice prior to export. New scientific information concerning the LMOs potential adverse impact on the conservation and sustainable use of biodiversity shall be submitted to the Clearing House within a reasonable time.</p> <p>■ Exporter/exporting State may request importing party to review its decision</p> <p>Option 2 Exporters/Exporting Party may request importing Parties to review import decisions in cases where exporting Parties consider that;</p> <p>a) a change in circumstances has occurred which may influence the outcome of the risk assessment; or</p> <p>b) additional relevant scientific or technical information has become available.</p> <p>■ C/A of importing State shall be informed by exporting State/exporter on new information within X days.</p> <p>Option 3 If at any time before, during or after the transboundary movement, the party of Export/Import becomes aware of relevant new information on the LMOs in question, which could have significant consequences on the accompanying risks, the Competent Authorities of the Parties concerned shall be informed immediately and the terms of the Advance Informed Agreement</p>	<p>Canadian proposed legal text submitted to the Secretariat (July, 1997):</p> <p>3. Each Party of import shall require importers to immediately, and in no case later than thirty days, after learning of such information, notify the Party of import of:</p> <p>(a) any new available information regarding potential adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, including within the Party of import, and</p> <p>(b) new information on change in use, containment or conditions of release.</p>	



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<p>be changed accordingly.</p> <p>■ Exporter/Exporting State shall be informed by the importer/importing State on new information within X days</p> <p>Option 4      If at any time before, during or after the intentional transboundary movement the State of export or import has gained new experience or becomes aware of relevant new information related to the LMO in question, which could have consequences for the risks, the States concerned shall be informed within 30 days and the AIA decision may be changed accordingly.</p> <p>Response to request to review decision</p> <p>Option 5      Exporting Parties may request importing Parties to review import decisions, in cases where exporting Parties consider that:</p> <ol style="list-style-type: none"><li>1.      a change in circumstances has occurred which may influence the outcome of the risk assessment; or</li><li>2.      there is reasonable evidence that the decision has not been based on scientific principles and supported by the best available scientific evidence; or</li><li>3.      additional relevant scientific or technical information has become available.</li></ol> <p>Exporting Parties may provide any additional information which they consider relevant to a review of the import decision.</p> <p>Importing Parties shall respond to such requests, in writing, within a reasonable period of time, and provide full details on the basis for their decision.</p> <p>Option 5b      The Party of Origin shall only be able through its designated national authority, to request the receiving Party to conduct a risk assessment with a view to reviewing its decision. In this case, the receiving Party shall be able to call for payment of all of the costs of the assessment.</p> <p>Lack of response implies implicit refusal</p> <p>Option 6      Importers lack of response to a request to review a decision from exporter, will substantiate an implicit refusal.</p> <p>■ New information may cause review by importing party</p> <p>Option 7      A receiving country Party may at any time in light of new information or evidence, unilaterally review its decisions on any transfer, handling or use of LMOs into its country and employ any</p>		

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<p>review mechanism established through its national legislation or any other national procedures.</p> <p>■ exporting state may apply to importing state to review decision</p> <p>Option 8      In light of new scientific evidence and information made available to the receiving country Party, a new application may be submitted in respect of a previously rejected application.</p> <p>New information available</p> <p>Option 9      Each Party of import shall require importers to immediately, and in no case later than 30 days, after learning of such information, notify the Party of import of:</p> <p>                  (a) any new available information regarding potential adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, including within the Party of import, and</p> <p>                  (b) new information on change in use, containment or conditions of release.</p> <p>■ New information</p> <p>Option 10      Each party of export shall require the exporters to immediately notify and no later than 15 days in any case, of any new information about the adverse impacts of the LMO and/or products thereof on the environment, biological diversity, human and animal health and agriculture, or of any new use of the LMO or product thereof. The party of export will be responsible for the accuracy and adequacy of the information.</p> <p>I.      Safeguard clause</p> <p>Option 1      If at any time a Party has reason to believe, taking into account available scientific information, that LMOs for which an intentional transboundary movement may proceed on the basis of the Articles 5 to 9 are likely to cause adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, that Party may then prohibit such and any such subsequent movements to its territory, or specify conditions under which all such subsequent movements have to take place. In such a case, that Party must promptly inform notifiers who have previously notified movements of such LMOs in accordance with this Protocol with the reason of its decision.</p>		

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Option 2      No provision regarding a safeguard clause is necessary		
<p><b>ARTICLE 8 - NOTIFICATION OF TRANSIT</b></p> <p>Requirements</p> <p>Option 1      Parties may require notification, in writing, through their Focal Points, of other Parties' intent to transit a living modified organism through their territory. Where such notification is required, Parties (shall)(should) provide information to the Clearing House on:</p> <p style="padding-left: 40px;">a) details of the categories of living modified organisms for which notification is required, and; information to be provided with the notification, based on that set out in Annex I.</p> <p>Option 2      1. Parties may require notification, in writing, of other Parties' intent to transit a living modified organism or product through their territory.</p> <p style="padding-left: 40px;">2. Parties that require notification of intent to transit living modified organisms, or products thereof, through their territory shall stipulate to the Clearing House:</p> <p style="padding-left: 80px;">a) details of the categories of living modified organisms, and products thereof, for which notification is required; and b) information to be provided with the notification.</p> <p>Option 3      <u>The Party effecting the export must obtain the necessary permits from Party and non-party countries through which the LMOs will be in transit, as well as assuming responsibility for any cases of accidental release in those countries.</u></p> <p>Option 4      1. <u>Any LMO or products derived from it may be located in transit between the country of export and country of import, provided that this status is accepted in writing.</u></p> <p style="padding-left: 40px;">2. <u>All the requirements in labelling, packaging and transportation shall be met.</u></p> <p>Option 5      Provided prior notification, consent and labelling is given, and subject to the national laws, regulations and procedures, each Party undertakes to facilitate the transit of LMOs through its territory. For the purposes of this Article, transit shall mean the temporary stop-over of an LMO which is on a continuous journey to another destination. For the avoidance of doubt, transit shall not mean the transfer to another Party of LMOs used for field testing, which is bound for another destination after the field testing.</p>	<p>The New Substances Notification Regulations under CEPA would not apply to an LMO loaded on a carrier outside of Canada and moved through Canada to a point outside Canada. This exemption would apply even if there is a change in carrier during transit. However, if the LMO is brought into Canada and stored for subsequent distribution, the LMO would be subject to notification.</p>	

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<p>Option 6</p> <p>1. The State of export shall require the exporter to notify either through the channel of the competent authority in the State of export, or by providing a copy to this authority, the State of transit of the first intended transit movement of a specific LMO for a specified use or purpose. In these cases, the State of export shall supply the information included in (Annex III) to the State of transit. The State of transit shall promptly acknowledge the receipt of the notification to the notifier. It may subsequently respond to the notifier in writing, within 30 days:</p> <ul style="list-style-type: none"> <li>a. consenting to the transit movement with or without conditions;</li> <li>b. denying permission for the movement; or</li> <li>c. provide an interim response, that may contain a statement to import with or without specified conditions or prohibiting import during the interim period. This may include a statement that a final decision is under consideration and/or a request for further information and/or extended period of time to respond.</li> </ul> <p>2. The State of transit may declare in writing whether a notification is required for subsequent transit movements of the same LMO or whether this is not the case and it shall inform the Secretariat and previous notifiers of such decisions. The handling and transport requirements for LMOs referred to in (Article 18) shall be followed in all transit movements.</p>		
<p>Acknowledgment/Response</p>		
<p>Option 1</p> <p>Upon receipt of this information, the Party whose territory is to be transited shall inform the exporting Party, within a reasonable period of time, of any provisions that may be required.</p>		
<p>Option 2</p> <p>On receipt of such notification, the Party (shall)(should) advise, within a reasonable period of time, the exporting Party or the exporter, and the Clearing House, of any transport, handling, packaging and labeling provisions for transit of the living modified organisms or other requirements in addition to those contained in (Article 18).</p>		
<p>Option 3</p> <p>The Party of transit shall be able with due substantiation, to object to or to place conditions on the passage of the LMO through its territory.</p>		
<p>Treatment of goods in Transit</p>		
<p>Option 1</p> <p><u>The documentation provided for the transport of LMOs must specify the care needed during their transit.</u></p>		
<p>No specific provisions under this Article</p>		

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<p>Option 1      The Protocol shall neither apply to the transboundary movement of LMOs destined for subsequent contained use, nor to the transit of LMOs, except as regards (Articles 4) (on general provisions) and (11) (on unintentional transboundary movement).</p>		
<p><b><u>ARTICLE 9 - SIMPLIFIED PROCEDURE</u></b></p> <p>Option 1:      No provisions for simplified procedure.</p> <p>Option 2:      The State of export may, subject to the written agreement of the States concerned, use or allow the exporter to use a general notification where living modified organisms or the products thereof having the same characteristics as transferred regularly to the same user via the same customs office of the exit of the State of export, via the same customs office of entry of the State of import.</p> <p>Option 3:      I. Without prejudice to (Article on Procedures), a party of import can with justification specify, in advance, to other Parties cases:                           A.      for which the intentional transboundary movement of LMOs to that Party may proceed according to its regulatory framework implementing Article 8(g) of the CBD, provided the framework includes a control mechanism for transboundary movement consistent with the protocol;                           B.      for which the intentional transboundary movement can take place at the same time that movement is notified to the relevant instance in the Party of import. Such notifications may apply to subsequent similar movement to the same Party.</p> <p>                 II. Information to be provided in the notification is specified in (Annex I).</p> <p>Option 4:      The State of export may, subject to the written agreement of the States concerned, use or allow the exporter to use a general notification where living modified organism or the products thereof having the same characteristics as transferred regularly to the same user.</p> <p>Option 5:      Notification of intent to export LMO's in terms of (para. 2), will contain the following information;                           (a) name and address of exporting company/institution                           (b) name and address of receiving company/institution                           (c) origin, name and taxonomic status of donor and recipient organisms                           (d) information on previous exports of same LMO to recipient State                           date of intended transfer, which will not be less than 30 days from the date of notification</p>		

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<p>Option 6: 1. If it is established that there does not exist any risk by the use and release of certain LMOs on the basis of the best available scientific knowledge and experience, as well as relevant information, a recipient Contracting party by means of unilateral declaration or bilateral, regional or multilateral agreement or arrangement, may exempt such LMOs from the application of the AIA procedures, by which no explicit agreement by the competent authority of the recipient Contracting party is required.</p> <p>2. Moreover, in the case of repeated transboundary transfers of LMOs, a recipient Contracting Party may decide that the application of the AIA procedures be exempted or replaced by simple notification procedures provided for in 1 above.</p> <p>3. If a recipient Contracting Party decides to exempt certain LMOs from the application of the AIA procedures or to apply simple notification procedures to certain LMOs, it shall inform the Secretariat of the Protocol accordingly. The Secretariat shall forthwith inform all Contracting Parties of such decisions.</p> <p>Option 7: The State of import shall communicate in its response to the State of export whether an AIA procedure with explicit consent or implicit consent is required for subsequent imports of the same LMO or whether a simple notification in accordance with (Article 9) shall be applied.</p> <p>Option 8: 1. If it is established by the State of import, on the basis of the best available scientific knowledge and experience, as well as all relevant information, that there is no significant risk associated with the use and release of certain LMOs, a Contracting Party which is a State of import may substitute the AIA procedure regarding such LMOs with a notification procedure in which case no AIA will be required by the recipient State.</p> <p>2. The Competent Authority of the State of export may, subject to the provisions (general provisions and notification), substitute or allow the exporter to substitute, an AIA with notification of intent to export LMOs to the recipient State of import.</p> <p>Option 9: If the Competent Authority of the State of export is not notified by the Competent Authority of the State of import of any objection or reservations to the intended transfer within 30 days of the date of notification of intent to transfer, subject to the provisions of (Article 3), the State of import will be deemed to have given consent for the intended transfer.</p> <p>Option 10: If, at any time before, during or after the transboundary transfer, the exporter becomes aware of relevant new information on the LMO, which may have significant consequences for the associated risks, the competent authorities of the States concerned and the Secretariat and Clearing House will be informed within 30 days of such information becoming available.</p>		

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<p><b>ARTICLE 10 - SUBSEQUENT IMPORTS</b></p> <p>Notification</p> <p>Option 1</p> <ol style="list-style-type: none"> <li>1. Notification of subsequent imports of the same living modified organism into the same importing party shall not be required unless specifically requested, in writing, by the importing Party, in cases where there may be:               <ol style="list-style-type: none"> <li>a) a change in the intended use of the living modified organism; or</li> <li>b) variation in the receiving environment; or</li> <li>c) other factors likely to affect the risk assessment or risk management.</li> </ol> </li> <li>2. Where notification for subsequent imports is specifically requested by the importing Party, full details regarding the information required (shall) (should) be provided, in writing, to exporting Parties or exporters and to the Clearing House. The information required (shall) (should) be based on that identified in (Annex I) (Information Required for Notification of Import of a Living Modified Organism).</li> <li>3. The importing Party (shall) (should) acknowledge the notification, in writing, within a reasonable period of time. This acknowledgment shall include:               <ol style="list-style-type: none"> <li>a) advice that a risk assessment has been or is to be carried out, in accordance with Article 13 (Risk Assessment); and</li> <li>b) request for any further information which remains to be provided in accordance with this Article.</li> </ol> </li> </ol> <p>Option 2</p> <ol style="list-style-type: none"> <li>1. Notification in writing is required for all subsequent imports of the same living modified organism into the same importing Party.</li> <li>2. The importing Party will acknowledge receipt of notification as quickly as possible and will inform the exporting Party that:               <ol style="list-style-type: none"> <li>(a) importation can proceed; or</li> <li>(b) a new risk assessment procedure will be undertaken.</li> </ol> </li> </ol> <p>Option 3</p> <p>A single notification as well as a consent given in response to a notification may cover several similar, including subsequent, transboundary movements to the same Party of import.</p> <p>Option 4</p> <ol style="list-style-type: none"> <li>1. A State of import may at any time declare that subsequent imports of a specific LMO into its territory for specified uses or purposes, are exempted from the requirement of AIA in (Article 4). Such an exemption may specify a procedure for simple notification indicating that the intentional transboundary movement can take place at the same time that specific movement is notified to the State of import.</li> </ol>	<p>Canadian view submitted to the Secretariat (January, 1997):</p> <p>Subsequent AIA action on a particular LMO (after first intended transboundary movement) would depend on national requirements and on the results of the assessment by the national authority in the importing Party. National authorities may wish to establish subcategories of LMOs after assessment such as no further AIA action required or AIA required for each importation of the LMO. Examples of LMOs that may fall into the category requiring AIA at each importation could include: those that could have adverse effects on a species in its centre of origin or diversity; pathogenic, infective, or invasive organisms; and ones with insufficient information to determine if they can be freely released. Further, Canada sees the need to discuss possible general provisions such as renotification (regardless of previous decisions) for imports on the basis of changes in use, containment and conditions of release; and reassessment of LMOs on the basis of new information to competent authorities regarding risk. Canada proposes that consideration of a requirement to provide new information regarding risk be considered as a general provision.</p> <p>Canadian proposed legal text submitted to the Secretariat (July, 1997):</p> <p>5. Where the competent authority of the Party of import requires as a condition under subparagraph 2(b) of this Article that subsequent imports be notified, it may establish for this purpose:</p> <p>(a) notification procedures;</p>	

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<p>2. The Parties shall inform the Secretariat and previous notifiers of such declarations followed by a verification that a risk assessment has been carried out earlier, and of any requirements concerning movements, handling and use applicable to such LMOs. Such a declaration may be withdrawn at any time by the State of import and the Secretariat and notifiers who have been previously notified movements of such LMOs to it in accordance with this Protocol shall be informed no later than 30 days prior to the withdrawal.</p> <p>3. The Secretariat shall inform all parties of the information it has received pursuant to paragraph 1 and 2. The Secretariat shall be responsible for transmitting this information for inclusion in the database established under (Article 20).</p> <p>Option 5</p> <p>1. 30 days prior to subsequent transboundary movements of a living modified organisms falling into the scope of this Protocol, the exporter shall notify the national focal point of the importing Contracting Party. If no response is received within this 30 day period, the exporter may proceed with the transboundary movement.</p> <p>2. When the conditions described in (Annex X) are fulfilled subsequent transboundary movements may proceed without notifying the national focal point of the importing Contracting Party. In this case, the exporter must ensure that appropriate relevant information is provided to the importer and/or the final user.</p> <p>Option 6:</p> <p>Where the competent authority of the Party of import requires that subsequent imports of an LMO be notified, it shall establish for this purpose:</p> <p>(a) notification procedure;</p> <p>(b) information requirements to be contained in the notification; and</p> <p>(c) procedures for risk assessment and decision making alternatives to those established for first import.</p> <p>Application</p> <p>Option 1</p> <p>1. <u>The exporter must submit a new application for subsequent imports even though the competent authority may have given a positive clearance for the importation of a specific LMO.</u></p>	<p>(b) information requirements to be contained in the notification; and</p> <p>(c) procedures for risk assessment and decision making, alternative to those provided in paragraphs 2(1) and (2).</p>	



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<p>2. The Parties shall inform the Secretariat and previous notifiers of such declarations followed by a verification that a risk assessment has been carried out earlier, and of any requirements concerning movements, handling and use applicable to such LMOs. Such a declaration may be withdrawn at any time by the State of import and the Secretariat and notifiers who have been previously notified movements of such LMOs to it in accordance with this Protocol shall be informed no later than 30 days prior to the withdrawal.</p> <p>3. The Secretariat shall inform all parties of the information it has received pursuant to paragraph 1 and 2. The Secretariat shall be responsible for transmitting this information for inclusion in the database established under (Article 20).</p> <p>Option 5</p> <p>1. 30 days prior to subsequent transboundary movements of a living modified organisms falling into the scope of this Protocol, the exporter shall notify the national focal point of the importing Contracting Party. If no response is received within this 30 day period, the exporter may proceed with the transboundary movement.</p> <p>2. When the conditions described in (Annex X) are fulfilled subsequent transboundary movements may proceed without notifying the national focal point of the importing Contracting Party. In this case, the exporter must ensure that appropriate relevant information is provided to the importer and/or the final user.</p> <p>Option 6:</p> <p>Where the competent authority of the Party of import requires that subsequent imports of an LMO be notified, it shall establish for this purpose:</p> <p>(a) notification procedure;</p> <p>(b) information requirements to be contained in the notification; and</p> <p>(c) procedures for risk assessment and decision making alternatives to those established for first import.</p> <p>Application</p> <p>Option 1</p> <p>1. <u>The exporter must submit a new application for subsequent imports even though the competent authority may have given a positive clearance for the importation of a specific LMO.</u></p>	<p>(b) information requirements to be contained in the notification; and</p> <p>(c) procedures for risk assessment and decision making, alternative to those provided in paragraphs 2(1) and (2).</p>	

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<p>Option 2 1. <u>No application or any corresponding study shall be in any way influenced by the existence of a prior acceptance of the same LMOs or products derived from them in the importing country or any other country Party.</u> (a)<u>The importation of an LMO or any of its products is permitted for a specific use; if the use changes, a fresh application must be made to the competent national authority for a new clearance for the new use.</u></p> <p>Regulation</p> <p>Option 1 <u>The regulations applied to imports shall be identical to those applied to LMOs produced in the country.</u></p>		
<p><u>ARTICLE 11- BILATERAL &amp; REGIONAL AGREEMENTS</u></p> <p>a) No bilateral and regional agreement provision</p> <p>Option 1 No provision for such article.</p> <p>b) Type of agreements or arrangements</p> <ul style="list-style-type: none"> <li>• bilateral, regional and/or multilateral</li> </ul> <p>Option 1 Contracting Parties may enter into bilateral, multilateral, or regional agreements or arrangements regarding transboundary movement of living modified organisms falling within the scope of this Protocol provided that such arrangements do not derogate from the environmentally sound management of living modified organisms as required by this Protocol. These agreements or arrangements shall stipulate provisions which are not less environmentally sound than those provided for by this Protocol in particular taking into account the interests of developing countries.</p> <p>Option 1b These agreements or arrangements shall (stipulate provisions which are not less environmentally sound than those provided for by this) (comply to the minimum requirements of the) Protocol.</p> <ul style="list-style-type: none"> <li>• multilateral</li> </ul> <p>Option 2 Parties may enter into multilateral agreements or arrangements regarding procedures and information exchange relating to transboundary movement of LMOs provided that such agreements or arrangements do not result in a lower level of protection than the one provided</p>		

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<p>for by the Protocol.</p> <ul style="list-style-type: none"> <li>• bilateral or multilateral</li> </ul> <p>Option 3      Parties to this protocol may enter into bilateral or multilateral agreements or arrangements regarding requirements relating to the import and/or export of LMOs between or among them, in lieu of the advance informed agreement requirements.</p> <ul style="list-style-type: none"> <li>• to implement the obligations of the Parties under the Protocol</li> </ul> <p>Option 4      The Parties may enter into bilateral or multi-lateral agreements or other arrangements in order to implement their obligations under this Protocol.</p> <ul style="list-style-type: none"> <li>• Transboundary movement of LMOs with Parties</li> </ul> <p>Option 5      Parties may enter into bilateral, regional or multilateral agreements or arrangements regarding transboundary movements of living modified organisms with Parties or Non-Parties, provided that adequate measures are observed to ensure the safe transboundary movement of living modified organism resulting from modern biotechnology, in accordance with the objectives of this Protocol. The provisions of this Protocol shall not affect transboundary movements that take place pursuant to such agreements and arrangements as between the Parties to that agreement or arrangement.</p> <p>Option 5b      If it is established that there does not exist any risk by the use and release of certain LMOs on the basis of the best available scientific knowledge and experience, as well as relevant information, a recipient Contracting party by means of unilateral declaration or bilateral, regional or multilateral agreement or arrangement, may exempt such LMOs from the application of the AIA procedures, by which no explicit agreement by the competent authority of the recipient Contracting party is required.</p> <p>c) Notification of agreements or arrangements</p> <ul style="list-style-type: none"> <li>• Prior to or after entry into force of the Protocol</li> </ul> <p>Option 1      Parties shall notify the Secretariat of any such bilateral, regional and multilateral agreements or arrangements entered into:</p> <ol style="list-style-type: none"> <li>a. prior to entry into force of this Protocol and which will continue to operate after entry into force of the Protocol; or</li> <li>b. after entry into force of the Protocol.</li> </ol>		

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<p>Option 2 Parties shall notify the Secretariat of any multilateral agreements or arrangements referred to in paragraph 1 and those which they have entered prior to the entry into force of the Protocol, for the purpose of controlling transboundary movements of LMOs which take place entirely among the Parties to such agreements. The provisions of the Protocol shall not affect transboundary movements which take place pursuant to such agreements.</p> <p>d) International cooperation</p> <ul style="list-style-type: none"> <li>Parties shall co-operate in exchanging information, developing technical guidelines</li> </ul> <p>Option 1 The Parties shall co-operate among themselves in exchanging information, developing appropriate technical guidelines and/or codes of practice, and monitoring the effects of risks posed by living modified organisms and products thereof on human and animal health, biological diversity, the environment and socio-economic welfare of societies with a view to promoting the safe management of these organisms and products.</p> <ul style="list-style-type: none"> <li>co-operation in the implementation of the Protocol</li> </ul> <p>Option 2 The Parties shall employ appropriate means to co-operate in order to assist developing countries in the implementation of this Protocol. They shall take due account of the needs of developing countries with respect to capacity building in order to promote the development and transfer of safe biotechnology and knowledge.</p> <p>e) Regional economic integration organizations</p> <p>Option 1 A regional economic integration organization, which itself is a contracting Party to the Protocol and has a specific legal framework for biosafety, may declare that the Protocol shall not apply to movements within its territory.</p>		
<p><b>ARTICLE 12- RISK ASSESSMENT</b></p> <p>Aim of risk assessment</p> <p>Option 1 No provision in the Protocol is necessary.</p> <p>Option 2 The objective of a risk assessment is to enable evaluation of the risks of possible adverse</p>	<p>Canadian proposed legal text submitted to the Secretariat (July, 1997):</p> <p>1. Upon providing acknowledgement to the importer in Article 1.5, the competent authority of the Party of import shall conduct a science-based risk assessment to evaluate the potential adverse effects of the living modified organism to the conservation</p>	

<sup>4</sup> Consideration should be given to re-assessment following receipt of new information.

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<p>impacts of LMO's and products thereof in the receiving country party and its environment in particular to the conservation and sustainable use of biodiversity, agriculture, human and animal health, ecological stability and socio-economic imperatives.</p> <p>Option 3: Adequate risk assessment of possible adverse effects of LMOs on the conservation and sustainable use of biological diversity and adverse impacts on human health in the State of Import is the basis for AIA and also is a necessary requirement for decision on handling, use and release of any LMO in that country.</p> <p>Option 4: The (importing party) (receiving country) shall make all decisions on the basis of inter alia risk assessment, socio-economic imperatives, and social and ethical considerations.</p> <p>Option 5: Decisions by importing parties regarding risk assessment in regard to potential adverse effects on the conservation and sustainable use of biological diversity should make use, as appropriate, of existing guidelines relevant to biosafety. Decisions shall be based on scientific principles and should take into account relevant technical experience. Parties are encouraged to assist importing Parties with importing Parties' risk assessment decisions through the sharing of information and expertise. No other provisions are necessary.</p> <p>Option 6: Risk assessment should be undertaken to identify and evaluate possible adverse effects of the living modified organisms to the conservation and sustainable use of biological diversity taking also into account risks to human health.</p> <p>When does risk assessment have to be carried out</p> <p>Option 1: On receipt of a notification for first import of a living modified organism, the importing Party shall undertake, or have undertaken, an assessment of the risk of the living modified organism having an adverse effect on the conservation and sustainable use of biological diversity in the importing Party.</p> <p>Option 2: A risk assessment shall be carried out prior to decisions under the Protocol, in regard to adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health.</p> <p>Option 3: (As a basis for AIA, and national regulations,) Risk Assessment will be undertaken:</p> <ul style="list-style-type: none"> <li>a) prior to the use, (transboundary movement) (transfer) or handling or LMOs, as the case may be to or within the receiving country party;</li> <li>b) prior to undertaking a transfer handling or use of LMOs to or within the receiving Party;</li> <li>c) prior to a first import;</li> </ul>	<p><b>and sustainable use of biological diversity within the territory of the Party of import, within set timeframes.<sup>4</sup></b></p> <p>- the scope of considerations to be included in a "science-based risk assessment" may need further clarification.</p>	

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<p>d) on a case by case approach.</p> <p>Option 4: Each Party shall carry out/shall require any natural or legal person under its jurisdiction who intends to undertake a transfer, handling and use of LMOs to conduct a risk assessment in accordance with Annex II and to submit an application to the competent authority for approval before undertaking a release into the environment.</p> <p>Option 5: The Risk Assessment shall be undertaken by the importing Party whenever it deems it to be appropriate.</p> <p>Basic parameters</p> <p>Option 1: Each country shall determine for itself, in accordance with its own legislation, the institutional arrangements for the conduct of risk assessments and for the preparation of technical findings with regard to requests for transboundary movement</p> <p>Option 2: The State of import shall in its assessment particularly take into account the characteristics of the receiving environment.</p> <p>Option 3: Risk assessment should not only be based solely on scientific data that would take into account the characteristics of the LMO and its possible adverse effect on the environment, but also other data to address its possible impacts on the conservation and sustainable use of biological diversity, socio-economic imperatives and the risks to agriculture and human health. The receiving country Party shall take into account other factors including without limitation, social, socio-economic and ethical considerations, in making decisions regarding such transfer, handling or use.</p> <p>Option 4: Risk assessments shall be carried out at the discretion of the importing party, in a scientifically sound and transparent manner tailored to the environment of the specific receiving country, and should also take into account other issues, including agricultural production, human and animal health, the population balance of the related organisms, social, economic, and ethical considerations, taking into account information submitted by the country of import.</p> <p>Option 5: Risk assessments shall be carried out at the discretion of the importing party, in a scientifically sound and transparent manner.</p> <p>Option 6: Further parameters for risk assessment can be adopted at the discretion of the importing party</p> <p>Option 7: <u>The Competent Authorities of the recipient Contracting Party may request the Exporter to provide additional relevant information if necessary.</u></p>		

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<p>Option 8: Risk assessments should, inter alia, take into account:</p> <ul style="list-style-type: none"> <li>(a) all relevant scientific evidence and experience;</li> <li>(b) the general characteristics of both the living modified organism and the parent organism, the vector used, the genetic modification and the novel trait;</li> <li>(c) the intended use of the living modified organism and the nature of the receiving environment;</li> <li>(d) impact on centres of origin and areas with high genetic diversity relevant to the living modified organism;</li> <li>(e) risk assessment techniques developed by relevant international organisations.</li> <li>f) <u>Take into account information submitted by the country of origin;</u></li> <li>g) <u>Consider the actual and/or potential effects on human health, the environment and agricultural production, including the population balance of the related organisms;</u></li> <li>h) <u>Ensure that the risk assessment and management processes of micro-organisms of all kinds are conducted in contained conditions.</u></li> <li>i) socio-economic imperatives and ethical considerations.</li> </ul> <p>Further specifications concerning parameters for risk assessment</p> <p>Option 1: Evaluation of risk should be conducted, where applicable, at each step of development from the research laboratory to small-scale and large-scale release for production and testing, including commercial use. A multi-disciplinary approach is necessary. Risk assessment should be applied for safety in biotechnology including a step-wise and case-by-case approach.</p> <p>Option 2: Each Party shall ensure that appropriate decisions are taken based on the outcome of the risk assessment and on a case-by-case basis.</p> <p>Option 3: Decisions under the Protocol, in regard to adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health shall be based on scientific grounds and experience and take account of:</p> <ul style="list-style-type: none"> <li>(a) the characteristics of the organisms involved, including any introduced sequences or modified traits;</li> <li>(b) the characteristics of the intended application;</li> <li>(c) the characteristics of the potential receiving environment;</li> <li>(d) and the interaction between these.</li> </ul> <p>Option 4: Special considerations should be incorporated into risk assessment in the transfer, handling or use of LMOs into centres of origin and genetic diversity.</p>		

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<p>Option 5: The Conference of the Parties to the Protocol shall establish a minimum standard of risk assessment of LMOs. The minimum standard shall be reviewed periodically by the Conference of the Parties in the light of the most recent and best available scientific knowledge and experience, as well as other relevant information. The Conference of the Parties to the Protocol may establish a technical advisory body for providing the Contracting Parties with scientific backgrounds for reviewing the standard.</p> <p>Option 6: The risk assessment shall, as appropriate, be based on the information and principles set out in Annex (II).</p> <p>Option 7: Details should be covered in an Annex.</p> <p>Option 8: No further specifications should be included.</p> <p>Option 9: No Annex to be developed.</p> <p>Subsequent risk assessments</p> <p>Option 1: No provisions for subsequent transfers.</p> <p>Option 2: Risk assessment for subsequent imports of the same living modified organisms into the same Party, at the discretion of the receiving Party shall not be required, but should be undertaken in cases where there may be:</p> <ul style="list-style-type: none"> <li>(a) a change in the intended use of the living modified organism;</li> <li>(b) a variation in the receiving environment; or</li> <li>(c) other factors likely to affect the risk assessment or risk management.</li> </ul> <p>Option 3: Risk Assessment for subsequent imports should be carried out at the discretion of the importing party.</p> <p>Option 4: If the assessment shows that risks cannot be avoided or reduced to an acceptable level, the States concerned shall/may refuse authorization to the import or transfer of that particular living modified organism.</p> <p>Option 5: Where the competent Authority of the Party of import' requires that subsequent imports be notified, it shall establish procedures for risk assessment and decision making alternative to those established for the first import.</p>		



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<p>Information to be provided</p> <p>Option 1: No annex provision.</p> <p>Option 2: The State of export shall provide or shall require the exporter to provide, the State of import, information on the risk assessment as required by Annex II, and other relevant information, in order for the State of import to conduct its own risk assessment.</p> <p>Option 3: Item to be dealt with under information requirements for AIA.</p> <p>Option 4: The risk assessment documentation/report to be submitted to the competent authorities of the states concerned shall, as appropriate, be based on the information and principles set out in Annex (II), to be an integral part of the Protocol.</p> <p>Option 5: The information set out in Annex (II) is considered as the comprehensive list. Any country who wants more information than contained in Annex (II), has to prove it is an essential part of Risk Assessment in that specific case.</p> <p>Option 6: The State of export shall provide or shall require the exporter to provide the competent authority/focal point in the State of Import with information related to the risk assessment carried out by it, as required by Annex (II), and other relevant information, in order for the State of import to conduct its own risk assessment on the basis of this information. The exporter is responsible for the reliability of the information provided.</p> <p>Option 7: The exporting party/exporter/importer shall provide information for notification.</p> <p>Option 8: The information requirements contained in the notification for risk assessment should be covered in an annex and/or in the main text.</p> <p>g) Additional information</p> <p>Option 1: The competent authorities of the receiving contracting party may request the exporter to provide additional relevant information if necessary.</p> <p>h) Responsibility for risk assessment</p> <p>Option 1: No provisions necessary.</p> <p>Option 2: The intending country Party shall also be responsible over the risk assessment prepared by the individual person or entity under its jurisdiction.</p>		

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<p>Option 3: Responsibility of risk assessment (after the risk assessment decision) shall lie in the competent authorities of the recipient Contracting Party.</p> <p>Option 4: Each receiving country shall undertake risk assessment to make a decision.</p> <p>Option 5: The concept of responsibility does not apply to risk assessment.</p> <p>Option 6: Risk assessment shall be undertaken by, or on behalf of, the importing party.</p> <p><b>i) Financial responsibility</b></p> <p>Option 1: No provisions necessary.</p> <p>Option 2: The financial responsibility for such risk assessment shall rest with the intending country Party.</p> <p><b>j) Financial and technical assistance</b></p> <p>Option 1: If the receiving country Party lacks the financial and technical capacity to do so, the intending country Party shall technically and financially assist and collaborate with the receiving country Party in the risk assessment evaluation.</p> <p>Option 2: The competent authorities of the recipient Contracting Party may request assistance from the Exporter or the competent authorities of the exporting Contracting Party, who should respond to the request to the extent possible. Especially in cases where the competent authorities of the recipient Contracting Party do not have sufficient experiences with the LMOs in question.</p> <p>Option 3: The Contracting Parties shall, taking into account in particular the needs of the developing countries and the countries with economies in transition, cooperate in order to promote international harmonization in risk assessment and risk management procedures.</p>		
<p><b><u>ARTICLE 13- RISK MANAGEMENT</u></b></p> <p>Option 1: No Article provisions concerning Risk Management.</p> <p>Option 2: In accordance with Article 8(g) of the Convention, Parties intending to undertake any transfer, handling or use of LMOs to or within the receiving country shall establish and maintain appropriate risk management measures and strategies that may be implemented in the receiving</p>	<p>Canadian proposed legal text submitted to the Secretariat (July, 1997):</p> <p><b>1. Each Party shall:</b></p> <p><b>(a) establish at the national level procedures to assess the risks of living modified organisms under Article 2;</b></p>	

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<p>country Party for the management of risks and harm associated with the transfer, handling and use of the LMO and the protection and mitigation of potential harm to the receiving country party, and incorporate such measures and strategies with the risk assessment under Article (13) (Risk Assessment) above.</p>	<p>(b) ensure that it has appropriate domestic laws in place to manage the risks identified under its risk assessment procedures under Article 2; and</p>	
<p>Option 3 Parties to undertake any transfer, handling or use of LMOs to or within the receiving country shall formulate appropriate risk management measures and strategies that may be implemented in the receiving country Party for the management of risks and harm associated with the transfer, handling and use of the LMO and the protection and mitigation of potential harm to the receiving country party, and incorporate such measures and strategies with the risk assessment under Article (13) (Risk Assessment) above.</p>	<p>(c) ensure that it has appropriate domestic laws in place to enforce any conditions or prohibitions decided under Article 2.</p>	
<p>Option 4 Parties shall establish or maintain national means to regulate, manage or control risks associated with the safe use, handling and transboundary movement of living modified organisms, in accordance with Article 8(g) of the Convention. Importing Parties and exporting Parties are encouraged, where appropriate, to cooperate in the development of risk management procedures</p>	<p>4. Import-restrictive measures such as those referred to in Article 2.2 b), c) and d) shall be imposed to the extent necessary to prevent the adverse effects of the living modified organism on the conservation and sustainable use of biological diversity within the territory of the Party of Import, as demonstrated by the risk assessment conducted under Article 2.1.</p>	
<p>Option 5 The type of risk management to be employed shall depend on the LMOs and the activity in question and such risk management strategies and measures shall be commensurate with the risk assessment. In any event, the type of risk management and the practices thereto set out in Annex (III) shall be employed as a minimum.</p>		
<p>Option 6 Where applicable, obligatory risk management measures shall be implemented by the intending country Party or person or entity undertaking such transfer, handling or use.</p>		
<p>Option 7 Risk management strategies shall:</p> <ul style="list-style-type: none"> <li>a) correspond to the results of the assessment referred to in Article (Risk Assessment);</li> <li>b) be established both for confined and contained uses and releases;</li> <li>c) contain a description of the type and class of containment and confinement of the organisms under consideration.</li> </ul>		
<p>Option 8 The risk management strategies and measures shall consist of such measures and strategies applicable at any/all stages of transfer, handling, release and/or use of the LMO to or within the receiving country and shall address the ways and means to manage the risks associated with the transfer, handling, or use of the LMO to or within the receiving country.</p>		
<p>Option 9 The intending Party shall ensure that the risk management strategies and measures proposed to be implemented by the receiving country Party under Article 7 shall incorporate strategies and measures that will minimise, prevent or mitigate the potential socio-economic effects and</p>		

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<p>impacts within the receiving country Party, in particular where the introduction of LMOs in the environment of the receiving country Party may entail a displacement of a particular agricultural or resource use system or the culture and livelihood of the local people.</p> <p>Option 10 Parties shall require the producers to phase out all antibiotic resistance marker genes in LMOs by the year 2002.</p> <p>Option 11 If management can not minimise risks to an acceptable level, the Competant Authority of the importing state shall not allow the transfer, use and release of that LMO.</p> <p>Option 12 The type of risk management and the practices thereto set out in Annex (X) shall be employed as a minimum.</p> <p>Option 13 Import-restrictive measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the LMO on the conservation and sustainable use of biological diversity within the territory of the importing party.</p> <p>Option 14 Each Party shall ensure that it has appropriate domestic laws in place to manage the risks identified under the risk assessment provisions of the Protocol.</p> <p>Option 15 If the receiving country Party lacks the financial and technical capacity to do so, the intending country Party shall technically and financially assist and collaborate with the receiving country Party in the risk management.</p>		
<p><u>ARTICLE 14- MINIMUM NATIONAL STANDARDS</u></p> <p>Option 1 No provisions necessary.</p> <p>Option 2</p> <p>[1. Each Party shall ensure that appropriate legal, institutional and administrative frameworks with regard to the safe [research, manufacture, development]transfer, handling and use of LMOs are in place upon the date of the entry into force of this Protocol for it. Such regulations shall contain adequate measures for both contained and deliberate release. With regard to contained use each Party shall apply measures referred to in Annex [ ] (to be developed).</p> <p>2. The national regulations shall as a minimum fulfil the requirements set out in this Protocol with regard to the safe transfer, handling and use of LMOs, including risk assessment procedures under Article 13 and enforcement of conditions or prohibitions under Article 14.]</p>		

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<p>Option 3</p> <p>[1. Each Party shall:</p> <ul style="list-style-type: none"> <li>(a) establish at the national level, or co-operate in establishing at the multi-national regional level, procedures to assess the risks of living modified organisms under Article 13;</li> <li>(b) ensure that it has appropriate domestic laws in place to manage the risks identified under its risk assessment procedures under Article 13; and</li> <li>(c) ensure that it has appropriate domestic laws in place to enforce any conditions or prohibitions decided under Article 14.]</li> </ul> <p>[2. Parties may impose more stringent or comprehensive requirements, based on scientific consideration.]</p>		
<p><u>ARTICLE 15 - UNINTENTIONAL TRANSBOUNDARY MOVEMENTS</u></p> <p>Option 1 No provisions necessary.</p> <p>Option 2</p> <p>[1. The Parties shall take all possible precautions to prevent accidental and unintentional release and to reduce natural movements of intentionally released living modified organisms which may result in unintentional transboundary movements.]</p> <p>[2. The Parties shall, whenever it comes to their knowledge, ensure that, in the case of an accident which may have transboundary effects on human health and/or the environment in other states, these states are immediately informed, and inform affected states about any planned activities associated with LMOs within their territories that are likely to have transboundary effects. The affected state(s) may ask for consultations between the concerned states.]</p> <p>[3. The information supplied shall include, inter alia, the identity, relevant characteristics and numbers/volumes of the LMOs involved and any available information necessary to assess the effects of the accident and emergency measures taken or needed to be taken, including measures identified under Article 14 (1) of the Convention.]</p> <p>[4. Parties shall immediately notify affected Parties, potentially affected Parties and the Clearing House, in case of known unintentional transboundary movements of living modified organisms, or of known domestic releases of living modified organisms which may result in unintentional transboundary movements. Such notification shall include, inter alia:</p> <ul style="list-style-type: none"> <li>a) circumstances of the unintentional movement;</li> </ul>		

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<p>b) the identity and quantities released; c) an assessment of the risks to the conservation and sustainable use of biological diversity and/or human health; d) emergency measures taken or needed to be taken; e) any available information regarding the handling of the organisms and related risk management measures to be applied; f) information specified in Annex I.]</p> <p>[5. The Party which is the origin of the unintentional transboundary movement [which is likely to present a threat] shall take immediate action, in consultation with the affected Party, [to minimise negative impact on the environment and] to prevent further release or transboundary movement of the living modified organism.]</p> <p>[6. A Party which suspects that an unintentional transboundary movement has occurred into its territory shall inform the Party from which the unintentional movement is suspected to have originated. The Party from which the unintentional movement is suspected to have originated, shall immediately investigate this possibility and, if confirmed, trigger the mechanisms described paragraphs 2 and 3 of this Article.]</p> <p>[7. Each Party shall avoid any activity that may lead to accidental or unintended releases of aquatic living modified organisms to freshwater and marine ecosystems.]</p> <p>[8. If necessary, the affected Party(ies) may request the Party from which the unintentional transboundary movement originates, to assist in emergency measures with the aim of minimising adverse effects on conservation and sustainable use of biological diversity and human health.]</p> <p>[9. In the event of an unintentional release occurring during the international transport of a living modified organism subject to the article on Advance Informed Agreement [where such unintentional release is likely to present risks to the conservation and sustainable use of biodiversity], each Party shall, whenever it comes to its knowledge, ensure that the national focal point of each suspected affected Party is immediately informed and provided with all available relevant information [, subject to the domestic legal requirements for the protection of confidential information and intellectual property rights in the Party providing such information]. For purposes of this Article, international transport refers to that portion of movement that occurs after the LMO has left the area under the national jurisdiction of the exporting Party and before it has entered the area under the national jurisdiction of the importing Party.]</p> <p>Option 3</p> <p>[1. In the case that an unintentional transboundary movement of LMOs is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, the Party from which the unintentional movement originates shall ensure that any affected Party(ies) and non-Party(ies) receives, as soon as possible, all relevant information concerning the unintentional transboundary movement and risks to the conservation and sustainable use of biological diversity, taking also into account risks to human health, and their management.</p>		

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2. Information to be provided is specified in Annex I.]		
<p><u>ARTICLE 16- EMERGENCY MEASURES</u></p> <p>Option 1 No provisions necessary.</p> <p>Option 2</p> <p>[1. Each Party shall endeavour to establish appropriate national measures and procedures, including national contingency plans, related to accidental transfers of LMOs which may have potential risks to its environment, in particular, the conservation and sustainable use of biological diversity, and the risks to human health and the emergency measures that need to be taken in regard therewith.</p> <p>2. Parties shall take the necessary measures to ensure that, in the event of an accident, the user shall be required to inform immediately the competent authorities of the State(s) concerned. The information shall include, inter alia,</p> <ul style="list-style-type: none"> <li>a) the circumstances of the accident;</li> <li>b) other facts necessary to assess the effects of the accident on human and animal health, the environment, and the biological diversity;</li> <li>c) the emergency measures taken or needed to be taken together with any available information regarding the handling of the organisms; and</li> <li>d) any other information considered relevant.</li> </ul> <p>3. The States concerned shall, where information is provided under paragraph 2 above, ensure that in any emergency, the medium and long-term measures necessary are taken, including the immediate alerting of any other State which could be affected by the accident.</p> <p>4. The Parties shall ensure that appropriate risk management strategies and measures, including emergency plans, are incorporated in the risk management strategies and measures under Article 14 above to prevent, mitigate or rectify any potential risks to the relevant Parties in case of any accidental or emergency release of LMO's.]</p>		
<u>ARTICLE 17- HANDLING TRANSPORT PACKAGING AND LABELLING</u>		

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<p>Option 15</p> <p>[1. In order to maintain adequate safety levels during transport each exporting Contracting Party shall [establish appropriate,] [promote, as appropriate,] measures for handling, transportation [,] [and] packaging [and transit] of LMOs [subject to the article on AIA] for transboundary transfer.</p> <p>2. The receiving Party shall have the right to impose such terms and conditions on the packaging, labelling and transportation of the LMO to or within the receiving country, for the protection of its environment [, in particular the conservation and sustainable use of biological diversity, socio-economic imperatives and the risks to agriculture and human health and taking into account also such social and ethical matters it deems fit for national interest purposes].</p> <p>3. The Parties shall take into account international conventions, agreements and recommendations on classification , bottling , labeling and documentation established by appropriate international organizations related to transport, particularly , the International Civil Aviation Organization (ICAO), the International Maritime Organization (IMO), International Rules of Transport and Dangerous Goods by Road (RID) and the International Airway Transport Association (IATA).</p> <p>4. Exporting Parties shall ensure that shipments containing living modified organism:</p> <ul style="list-style-type: none"> <li>(a) are clearly identified as containing living modified organism;</li> <li>(b) are handled and packaged in such a way as to prevent accidental release into the environment;</li> <li>(c) include names and contact details of Focal Points for exporting, importing and transit Parties, for use in the case of accidental release living modified organisms, consistent with Article 16 {Unintentional Transboundary Movements};</li> <li>(d) [ that LMOs exported from their territories are subject to no less stringent requirements of classification, packaging and labelling than comparable products destined for use in the State of export;]</li> <li>(e) require that living modified organisms be accompanied by a movement document from the point at which the transfer commences to the point of use.</li> </ul> <p>5. The Parties shall ensure that LMOs which have not been approved for use shall be handled and packaged in such a way as to ensure their complete isolation.</p> <p>6. The Parties shall aim at developing standards with regard to packaging and transport practices under the Protocol.]</p> <p>Option 2</p> <p>[1. Transport of living modified organisms shall be carried out under safe conditions in order to avoid</p>		

<sup>5</sup> [Variations within Option 1 are: i) paragraphs 1 to 6 in their entirety; ii) only paragraph 1; and iii) only paragraph 4, with sub-paragraph (d) deleted.]



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<p>adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.]</p> <p>Option 3</p> <p>[1. Each Party shall require that living modified organisms that are to be subject to a transboundary movement and are subject to AIA be packaged, labelled, and transported in conformity with generally accepted and recognized international rules and standards in the field of packaging, labelling and transport, and that due account is taken of relevant internationally recognized practices.]</p> <p>Option 4</p> <p>[1. Each exporting Contracting Party shall establish appropriate measures for handling, transportation, packaging and transit of LMOs for transboundary transfer according to the standards to be elaborated by the Conference of the Parties to the Protocol.]</p> <p>Option 5</p> <p>[1. Each Party shall:</p> <ul style="list-style-type: none"> <li>(a) ensure that LMOs exported from their territories are subject to no less stringent requirements of classification, packaging and labelling than comparable products destined for use in the State of export;</li> <li>(b) require that living modified organisms be accompanied by a movement document from the point at which the transfer commences to the point of use;</li> <li>(c) ensure that all LMOs to be exported are clearly labelled as such. The labelling shall inform that the movement contains a living modified organism. The labelling shall also inform about the type of living modified organism and the names and addresses of the exporter and importer.</li> </ul> <p>2. Ensure that LMOs to be exported are packaged and transported in accordance with international rules and standards in the field of packaging and transport, particularly in accordance with the UN Recommendations on Transport of Dangerous Goods. The Parties shall aim at developing standards with regard to packaging and transport practices under the Protocol.]</p>		
<p><u>ARTICLE 18- COMPETENT AUTHORITY/FOCAL POINT</u></p> <p>Option 1</p> <p>[1. To facilitate the implementation of this Protocol, each Party shall designate or establish a national focal point and one or more competent authority(s) which shall receive applications and notifications and communicate decisions on living modified organisms in accordance with the Advance Informed Agreement</p>		

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<p>procedure set out in Article 3, 4 and 5 and Annex I and II. Where a Party designates more than one competent authority, it shall specify the areas of responsibility for each</p> <p>2. Each Party shall inform the Secretariat no later than the date of entry into force of the Protocol for that Party in question, which agencies have been designated as its focal point/competent authority(ies).</p> <p>3. The Secretariat shall forthwith inform the Parties of notifications received under paragraph 2. The Secretariat shall also transmit the information from Parties in accordance with paragraphs 1, and 2 above for inclusion in the Database provided for in Article 20 on information exchange.</p> <p>4. Parties shall inform the Secretariat and the Biosafety Clearing House within [ ] days of the date of decision, of any changes regarding the designation made by it under paragraphs 1 and 2 above.</p> <p>5. The Competent Authority of each Party shall be the authoritative/decision-making body regarding any intended transfer, handling or use LMOs to or within the receiving country. The Competent Authority shall be provided with adequate [and timely] financial and technical assistance to establish and develop its infrastructure and human resources to carry out the responsibility assigned to it including as a minimum the responsibilities listed in Annex IV.</p> <p>6. The Competent Authority of the receiving country Party may impose [au pays exporteur] such conditions and/or national procedures it deems fit regarding the transfer, handling or use of the LMO by the intending Party in order to protect its environment, in particular the conservation and sustainable use of biological diversity, and the [prévention des] risks to human health.]</p> <p>Option 2</p> <p>[1. Parties shall:</p> <ul style="list-style-type: none"> <li>(a) designate a Focal Point<sup>1</sup>;</li> <li>(b) designate one or more Competent Authorities<sup>1</sup>;</li> <li>(c) inform the Clearing House, within three months of the date of entry into force of the Protocol for them, which agencies have been designated as the Focal Point and the Competent Authority; and</li> <li>(d) inform the clearing house, within one month of the date of decision, of any changes regarding the above designations.] <p>[Footnote 1/: These terms will be defined in Article [ ] of the Protocol 'Definition of Terms']</p> <p>Option 3</p> <p>[1. Each Party shall designate or establish competent authority/ies and/or focal points/s that shall be</p> </li></ul>		

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<p>responsible for the administrative functions required by this Protocol and shall notify this to the Secretariat no later than the date of entry into force of this Protocol for it.</p> <p>2. Each Party shall also notify relevant data concerning its designated competent authority/ies and/or focal point/s to the Secretariat for inclusion in the Database provided for in Article 20 [on information sharing]. Each party shall also immediately notify the Secretariat of any subsequent changes.</p> <p>3. Each Party shall ensure that its national focal point has sufficient resources to perform its task efficiently.]</p> <p>Option 4</p> <p>[1. Contracting parties shall designate or establish one national focal point and one or more competent authorities for the implementation of the Protocol.</p> <p>2. The national focal point shall perform the following tasks:</p> <ul style="list-style-type: none"> <li>(a) to provide other Contracting Parties, through the Secretariat of the Protocol, with general information on the implementation of the Protocol at the national level including, in particular, information on competent authorities responsible for the AIA procedures and/or for LMOs;</li> <li>(b) to collect information on the implementation of the protocol at its national level; and</li> <li>(c) to assist communication between foreign, regional or international institutions established for the implementation of the Protocol on the one hand and the national competent authorities on the other.</li> </ul> <p>3. The competent authorities shall perform the following tasks:</p> <ul style="list-style-type: none"> <li>(a) to establish national guidelines and/or regulations for the implementation of the AIA procedures including detailed criteria for risk assessment within their competence;</li> <li>(b) to receive from exporters applications for the AIA procedures;</li> <li>(c) to conduct risk assessment;</li> <li>(d) to take a decision on result of the risk assessment;</li> <li>(e) to inform the exporter with the result of the risk assessment; and</li> <li>(f) to conduct, if necessary, additional trials, including field trials.] <p>Option 5</p> <p>[1. Each Party shall designate one or more national authorities that shall serve as its focal point(s) and be authorized to act on its behalf with respect to the functions required by this protocol.</p> </li></ul>		

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<p>2. Each Party shall, concurrently with the deposit of its instruments of ratification, provide the name and address of its designated national focal point(s) to the Convention on Biological Diversity (CBD) Secretariat. Each Party shall also immediately notify the Secretariat of any subsequent changes. Where a Party designates more than one national authority, it shall specify the areas of responsibility for each.</p> <p>3. The Secretariat shall forthwith inform the Parties of the notifications it receives under paragraph 2.]</p>		
<p><b><u>ARTICLE 19 - INFORMATION SHARING / BIOSAFETY CLEARING HOUSE</u></b></p> <p>Option 1</p> <p>[1. Subject to the national laws, regulations and procedures of each Party, and without prejudice to the obligation to provide information under the AIA procedure under Article 4 the Parties shall facilitate through a clearing-house mechanism and/or national focal points of each Party, the exchange of information, relevant to [safety in biotechnology and the transfer, handling or use of LMOs and its impacts thereof, taking into account the special needs of developing countries] [the implementation of the Protocol]. Such information shall be transmitted to the Secretariat [, the Biosafety Clearing House] and other relevant bodies and Parties as the case may be.</p> <p>2. Parties shall endeavour to co-operate with existing international agencies, organizations, mechanisms and regional networks for the dissemination of biosafety-related information[ and standards applicable in other countries].</p> <p>3. A Database for international information exchange shall be established and administered by the Secretariat. [The Biosafety Clearing House should be established no later than the date of entry into force of this Protocol on the basis of existing international Biosafety Exchange Mechanisms.]</p> <p>[4. The Biosafety Clearing House shall serve as a body for information exchange, monitoring of implementation, and scientific and technical co-operation among Parties.. It shall report regularly to the meeting of the parties on all aspects of its work and to the Secretariat regarding the implementation of procedures on notification and Advance Informed Agreement. The modalities of establishment of the Biosafety Clearing House shall be considered and decided upon by the Parties at their first meeting.]</p> <p>[5. Each Party shall inform its public about the contents of, and mode of public accessibility to, the clearing-house mechanism.]</p>	<p><b>Canadian proposed legal text submitted to the Secretariat (July, 1997):</b></p> <p><b>1. The Party of import shall provide to the clearing-house mechanism in a timely fashion each allowance or prohibition made under Article 2, including any conditions forming part of the decision, and the reasons provided under Article 2.3.</b></p> <p><b>1. Each Party of Import shall provide to the clearing-house mechanism<sup>6</sup> established under Article 18.3 of the Convention subject to appropriate protection of confidential business information:</b></p> <p><b>(a) information to assist other Parties in decision-making under the Protocol with respect to its national laws, regulations, guidelines, codes of practice and administrative procedures for the safe transfer, handling and use of living modified organisms;</b></p> <p><b>(b) any other information regarding living modified organisms that the</b></p>	

<sup>6</sup> Canada envisages a two part clearing house. One that would be used primarily for input data on decisions made after notification and assessment. Another that would be for more general use where information in general on LMOs, regulatory requirements, etc., could be housed and more open for people to put on or link information.

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<p>6. The Secretariat shall keep this Database up-to-date and accurate; submit as soon as possible to the Conference of the Parties a proposal for the format to be used for the inclusion of information in the Database.</p> <p>7. Without prejudice to Article 11 the Database shall contain and provide public access to information relevant to the implementation of the Protocol as follows;</p> <ul style="list-style-type: none"> <li>(a) [the information identified in Annex V;]</li> <li>(b) information on risk assessments or environmental reviews generated by the regulatory process;</li> <li>(c) [information on decisions regarding the importation, field testing, or commercial use of any LMO;]</li> <li>(d) information concerning the development, use and transfer of LMOs;</li> <li>(e) available results relating to risk assessment and management;</li> <li>(f) national procedures for regulation, assessment and risk management;</li> <li>(g) [scientific references necessary to risk assessment and risk management;]</li> <li>(h) information on transboundary movement [of LMOs resulting from modern biotechnology which may have an adverse effect on the conservation and sustainable use of biological diversity, taking also into account risks to human health];</li> <li>(i) information on unintentional movements according to Article 16.]</li> <li>(j) [general description of products consisting of or containing LMOs having received consent by a Party or Parties for placing on the market;</li> <li>(k) [a summary of any methods and plans for monitoring LMOs;</li> <li>(l) point a) of Annex V;</li> <li>(m) the text of any decision on a notification of an intentional transboundary movement and the summary of the risk assessment;</li> <li>(n) information concerning its biosafety regulatory framework on LMOs;</li> <li>(o) a summary of any notified unintentional transboundary movements which are likely to have significant adverse effects in another Party or non-Party on the conservation and sustainable use of biological diversity, taking also into account risks to human health;</li> <li>(p) the text of decisions taken pursuant to Article 10 [safeguard clause as referred to in BSWG 3/3/Add 1.]</li> </ul> <p>Option 2</p> <p>[1. The Parties shall facilitate the exchange of publicly available information on, and experience with, living modified organisms (LMOs) to enable Parties to make informed decisions related to Biosafety.</p> <p>2. Each Party shall make available to a [centralized database/]clearing-house its domestic laws, regulations, and guidelines applicable to the production, use, and handling of LMOs.</p>	<p>Party considers would be of benefit to other Parties and to the public, including with respect to risk assessment and management, and other scientific information; and,</p> <p>(c) a list of living modified organisms subject to advance informed agreement which have been assessed for import into or use in its territory at the time of coming into force of this Protocol for that Party and a description of any conditions attached to imports of such living modified organisms.</p> <p>2. Each Party shall inform its public about the contents of, and mode of public accessibility to, the clearing-house mechanism established under Article 18.3 of the Convention.</p> <p>- Canada envisages a two part clearing house. One that would be used primarily for information on decisions made after notification and assessment. Another that would be for more general use where information in general on LMOs, regulatory requirements, etc., could be housed and more open for people to put on or link information.</p>	

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<p>3. Each Party shall make available to a [centralized database/]clearing-house publicly available information on risk assessments or environmental reviews generated by the regulatory process.</p> <p>4. Each Party shall make available publicly available information on its decisions regarding the importation, field testing, or commercial use of any LMO.]</p> <p>[5. Each Party shall provide transparent procedures for validation and verification of data which it makes available to the public and to the clearing-house.]</p> <p>Option 3</p> <p>[1. <u>The mechanism for the exchange of information and cooperation under the Protocol shall be that established by the Convention on Biological Diversity in its Article 18, paragraph 3.</u></p> <p>2. <u>This mechanism shall include, inter alia, the following information:</u></p> <ul style="list-style-type: none"> <li>(a) <u>Information on measures adopted by the national legislation of the countries;</u></li> <li>(b) <u>Information on decisions adopted by the countries with regard to transboundary movement of LMOs;</u></li> <li>(c) <u>Information on accidental or unintended movements of LMOs, including contingency or mitigation plans to be used in such event;</u></li> <li>(d) <u>Information relating to the appropriate assessment and management of risks;</u></li> <li>(e) <u>Information on the implementation of the PIC procedure, including simplified procedures and bilateral, multilateral and regional agreements;</u></li> <li>(f) <u>Updated information on the designated national authorities for the purposes of this Protocol.]</u></li> </ul> <p>Option 4</p> <p>[1. Each Contracting Party shall facilitate the collection and exchange of all publicly available scientific, technical, environmental and legal information relevant to the implementation of this Protocol taking into account the special needs of developing country and the countries with economies in transition through a [Biosafety Clearing House] [International Safety Database] [Database for international information exchange].</p>		

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<p>(Note: Biosafety Clearing House: refer to African Group submission)</p> <p>2. Without prejudice to Article 11 [which address Confidentiality], each Contracting Party shall ensure that the following information is provided to the Secretariat for inclusion in the [Biosafety Clearing House] [International safety Database] [Database for international information exchange]:</p> <ul style="list-style-type: none"> <li>(a) information on intentional movement having been subject to Advance Informed Agreement according to Art. 4 and related decision(s);</li> <li>(b) information on unintentional movements according to Art.16 .</li> </ul> <p>3. A [Biosafety Clearing House] [International Safety Database] [Database for international information exchange] should be established no later than the date of entry into force of this Protocol on the basis of existing international Biosafety Exchange Mechanisms.]</p> <p>Option 5</p> <p>[1. <u>Information to be submitted to the Secretariat of the Protocol</u></p> <p>(a) The Contracting Parties shall provide the Secretariat of the Protocol with the following information:</p> <ul style="list-style-type: none"> <li>(i) National regulatory framework for the implementation of the Protocol, including: <ul style="list-style-type: none"> <li>(a) names, addresses and telecommunication numbers of the national focal point and the competent authorities;</li> <li>(b) national guidelines and/or regulations for the implementation of the Protocol, including information required for the AIA procedures and for risk assessment;</li> <li>(c) if any bilateral, regional and multinational agreements or arrangements as well as unilateral declarations on the exemption and/or the simplification of the AIA procedures.</li> </ul> </li> <li>(ii) Periodical report on the implementation of the AIA procedures, including statistics.</li> </ul> <p>(b) The Secretariat of the Protocol shall circulate the information received pursuant to (1) above to all Contracting Parties.</p> <p>2. <u>Information to be made available</u></p> <p>The Contracting are encouraged to make available to all interested parties, including other Contracting Parties, regional and international institutions as well as individuals information on the implementation of the Protocol, not included in (1) above.]</p> <p>Option 6</p>		

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<p>[1. Each Party of Import shall make available to the clearing-house mechanism<sup>1</sup> established under Article 18.3 of the Convention subject to appropriate protection of confidential business information identified:</p> <ul style="list-style-type: none"> <li>(a) information to assist other Parties in decision-making under the Protocol with respect to national laws, regulations, guidelines, codes of practice and administrative procedures for the safe transfer, handling and use of living modified organisms;</li> <li>(b) any other information regarding living modified organisms that the Party considers would be of benefit to other Parties and to the public, including information with respect to risk assessment and management, and other scientific information; and</li> <li>(c) a list of living modified organisms subject to advance informed agreement which have been assessed or import into or use in its territory at the time of coming into force of this Protocol for that party and a description of any conditions attached to imports of such living modified organisms.</li> </ul> <p>Footnote 1/: A two-part clearing-house is envisaged: one used primarily for information on decisions made after notification and assessment; another would provide for more general information on LMOs, regulatory requirements, etc.]</p> <p>Option 7</p> <p>[1. The Clearing House mechanism under the CBD shall function as the Clearing house mechanism to provide the Parties and, as appropriate the Secretariat, with timely advice and information relating to the implementation of this Protocol.</p> <p>2. Each Party shall ensure that timely information pertaining to Biosafety is provided to the Clearing House.</p> <p>3. The Parties shall facilitate and encourage the collection and exchange of scientific, technical, environmental, socio-economic, commercial and legal information relevant to the implementation of this Protocol. Such information shall be transmitted to the Secretariat, the Clearing House and other relevant bodies and Parties as the case may be.]</p>		
<p><u>ARTICLE 20 - CONFIDENTIAL INFORMATION</u></p> <p>Option 1</p> <p>[1. [Parties receiving notifications<sup>1</sup> ] shall respect the need to protect intellectual proprietary rights and confidential information relevant to living modified organisms. [The information specified in Annex I shall not</p>	<p>- Canadian legislation may vary somewhat in how it addresses CBI. While some Acts permit only specific parts of notifications to be claimed CBI, other Acts may permit an entire notification to be claimed CBI.</p> <p>- while developed countries generally provide protection for CBI, the exact definition of CBI may vary somewhat between countries. The ability to protect CBI in developing countries may vary even</p>	



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<p>be regarded as confidential information, with respect to the Protocol.]]</p> <p>2. The notifier should indicate any information submitted under the procedures of this protocol that it considers to be confidential and/or subject to intellectual property protection. [Confidentiality and proprietary provisions shall not be excessive or broad so as to hinder information-sharing among parties which would undermine the ability of the national competent authority to take informed decisions.] Any Party receiving such information shall establish appropriate internal procedures for the protection of information so received.</p> <p>3. The competent authority shall decide, after consultation with the notifier, which information is confidential and shall inform the notifier of its decisions. If, for whatever reasons, including in case[s where] the competent authority and notifier disagree, a notifier withdraws a notification, the confidentiality of all the information supplied [and indicated as confidential and/or subject to intellectual property protection] must be respected by the competent authorities and focal points, [subject to national legislation].</p> <p>4. [Competent authorities, focal points] [Parties [including their competent authorities and focal points]] [and the Secretariat] shall not divulge any confidential information received under the Protocol and [have the obligation to] [shall] protect intellectual property and proprietary rights relating to the data received.]</p> <p>[5. Cependant la confidentialité ne pourra être retenu si l'information sur le retrait de la notification concerne des aspects de risques pour un éventuel demandeur ultérieur.]</p> <p>[Footnote 1/ This provision should be re-examined in the context of what is agreed regarding contents of the notice in the AIA provisions.]</p> <p>Option 2</p> <p>[1. [Competent authorities, focal points] [Parties] and the Secretariat shall not divulge any confidential information received under the Protocol [without the prior written consent of the notifier and shall comply with such conditions regarding release that the notifier may prescribe] and [have the obligation to] [shall] protect intellectual property [and proprietary] rights relating to the [data] [information] received. [Any Party receiving such information shall establish appropriate internal procedures for the protection of information so received, and the confidentiality of information about imported LMOs should be treated in a way no less favourable than for domestic LMOs.]</p> <p>[2. However, all information requested by the importing Party for the purpose of decision making must be provided by the exporting Party.]</p> <p>3. The notifier may indicate [the] [any] information submitted under the procedures of this Protocol that should be treated as confidential [and/or subject to intellectual property protection]. [Verifiable] justification must be given in such cases [upon request].</p>	<p>more widely.</p>	

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<p>4. [The competent authority or focal points shall decide, after consultation with the notifier, which information will be kept confidential and shall inform the notifier of its decisions.] or [Should the Party decide, after consultation with the notifier, not to treat information as confidential that the notifier has indicated is confidential, the Party shall inform the notifier of its decisions.]</p> <p>[5. Without prejudice to Article 11(6) [in no case may the following information be kept confidential] [the following information should not generally be considered confidential:</p> <ul style="list-style-type: none"> <li>a) the general description of the LMO or LMOs, name and address of the notifier, [purpose of the movement];</li> <li>b) a summary of the risk assessment of effects on the conservation and sustainable use of biological diversity, taking also into account human health;</li> <li>c) any methods and plans for emergency response.]</li> </ul> <p>[6. If, for whatever reasons including in case the [competent authority] [Party] and notifier disagree, a notifier withdraws a notification, the confidentiality of all the information supplied [and indicated as confidential] must be respected by the competent authorities and focal points.]</p>		
<p><u>ARTICLE 21 - CAPACITY BUILDING</u></p> <p>Option 1 No provisions necessary.</p> <p>Option 27</p> <p>[1. The Parties shall design appropriate policies and take effective measures in order to develop and strengthen human resources and institutional capacities in biotechnology and biosafety including where necessary, through the appropriate international and national institutions. They shall take due account of the needs of developing countries with respect to capacity building in order to promote the development and transfer of safe biotechnology and knowledge.</p> <p>2. The Secretariat, in collaboration with the Biosafety Clearing House, shall develop and implement regional and global capacity building programmes based on the identified needs of the concerned Parties. The Secretariat and the Biosafety Clearing House shall, in particular, assist developing countries in their efforts to identify and plan their capacity building requirements and secure funds for the implementation of their capacity</p>	<p><b>Canadian proposed legal text submitted to the Secretariat (July, 1997):</b></p> <p><b>1. Each Party shall promote technical and scientific cooperation with other Parties, in particular developing countries, in implementing this Protocol, inter alia, through the development and implementation of national policies. In promoting such cooperation, special attention should be given to the development and strengthening of national and regional capabilities, by means of human resources development and institution building.</b></p> <p><b>2. The financial mechanism established under the Convention<sup>8</sup> will be a source of financial resources for capacity-building to help achieve</b></p>	

<sup>7</sup> [Variations on Option 2 are: i) paragraphs 1 to 9 in their entirety; ii) only paragraphs 4 and 5 (with amendments shown); and iii) only paragraphs 4, 5 and 6]

<sup>8</sup> "Convention" will be defined to mean the Convention on Biological Diversity.

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<p>building programmes.</p> <p>3. The Parties agree that, according to the specific needs of different regions and sub-regions, regional or sub-regional activities/centres for training and capacity building regarding the safe management of living modified organisms shall be established, with financial assistance provided through the financial mechanisms under the Convention on Biological Diversity (CBD).</p> <p>4. The Parties shall promote [technical and scientific cooperation][capacity building], including the promotion of cooperation in the training of personnel and the exchange of experts, informational exchange and institutional capacity building in order to strengthen the ability of importing states to perform risk assessments and to develop and implement [decision making and] risk management procedures.</p> <p>5. Capacity building programs should maximize the use of existing multilateral, regional and bilateral mechanisms [where possible, including those addressed under the Convention]. Technical assistance from the private sector should also be facilitated and encouraged.]</p> <p>6. Such capacity-building shall aim to ensure:</p> <ul style="list-style-type: none"> <li>(a) that Parties develop and strengthen their capacities to implement this Protocol;</li> <li>(b) that national legislation, frameworks and guidelines related to biosafety are developed;</li> <li>(c) that states involved in the transfer, handling and use of LMOs and or products thereof are aware of any associated risks and have the means to assess and manage the risks;</li> <li>(d) that states are able to achieve safety through proper risk assessment and management when certain LMOs and or products thereof are transferred into and/or to be used in their territories and act adequately in cases of accidental release of LMOs;</li> <li>(e) the development of procedures for risk assessment and risk management of LMOs.</li> </ul> <p>7. Any Party to this Protocol or any of its signatories will be able to make scientific-technical cooperation requests to the Secretariat for the purpose of applying the Protocol or participating in it, in particular:</p> <ul style="list-style-type: none"> <li>(a) preparing or evaluating risk assessment reports or impact statements;</li> <li>(b) developing or evaluating risk management schemes and appropriate monitoring programmes, procedures and standards;</li> <li>(c) preparing emergency plans and other safety measures;</li> <li>(d) transmitting requests for assistance and relevant information in the event of accidents;</li> <li>(e) providing information that may be relevant to the settlement of disputes.</li> </ul> <p>8. The developed country Parties shall establish effective measures for strengthening and/or development of human resources and institutional capacities in biotechnology and biosafety in developing country Parties, encompassing technical, financial and institutional provisions.</p>	<p>the purposes of this Protocol, in particular for risk assessment and management.</p>	

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<p>9. The developed country Parties shall establish such measures to enhance the capacity of developing country Parties to acquire and/or develop relevant biotechnology, and its proper and safe management, and the building up of their local, technological and institutional competence, thereby contributing to the distribution of benefits from the potentials of biotechnology. through training in science related to safety in biotechnology and in the use of risk assessment and risk management techniques and the transfer of relevant knowledge, in biotechnology and biosafety on fair and most favourable terms including on concessional and preferential terms.]</p> <p>Option 3</p> <p>[1. The Parties agree that measures for capacity building in the form of information exchange, training, education and institutional capacities, are essential for the effective functioning of the Protocol.</p> <p>2. The Parties shall design appropriate policies and take effective measures in order to develop and strengthen human resources and institutional capacities in biotechnology and Biosafety including where necessary, through the appropriate international and national institutions. They shall take due account of the needs of developing countries with respect to capacity building in order to promote the development and transfer of safe biotechnology and knowledge. (NB: same as Option 2, para 1)</p> <p>3. Such capacity-building shall aim to ensure:</p> <ul style="list-style-type: none"> <li>(a) that Parties develop and strengthen their capacities to implement this Protocol;</li> <li>(b) that national legislation, frameworks and guidelines related to Biosafety are developed;</li> <li>(c) that states involved in the transfer, handling and use of LMOs and or products thereof are aware of any associated risks and have the means to assess and manage the risks;</li> <li>(d) that states are able to achieve safety through properrisk assessment and management when certain LMOs and or products thereof are transferred into and/or to be used in their territories and act adequately in cases of accidental release of LMOs;</li> <li>(e) the development of procedures for risk assessment and risk management of LMOs.] (NB: same as Option 2, para 6, above)</li> </ul> <p>Option 4</p> <p>[1. Each Party shall strengthen and/or develop human resources and institutional capacities in order to facilitate effective implementation of the Protocol. Such capacity building shall aim to ensure:</p> <ul style="list-style-type: none"> <li>(a) that national legislation related to Biosafety is developed;</li> <li>(b) that Parties involved in the transfer, handling and use of living modified organisms and/or products thereof, are aware of associated risks and have the means to assess and manage such risks; and</li> </ul>		

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<p>(c) that Parties are able to conduct proper risk assessment and management when living modified organisms and/or products thereof are transferred into and/or used in their national territories.</p> <p>2. Parties shall co-operate to build capacity for risk assessment, decision making and risk management. Capacity building may include technical assistance, information exchange, training, education and institutional strengthening.</p> <p>3. Capacity building programmes should maximise use of existing mechanisms where possible, including those addressed under the Convention, and should be particularly aimed at developing countries.</p> <p>4. Technical assistance from the private sector should be facilitated and encouraged.]</p> <p>Option 5</p> <p>[1. The Parties shall design appropriate policies and take effective measures in order to develop and strengthen human resources and institutional capacities in biotechnology and Biosafety including where necessary, through the appropriate international and national institutions. They shall take due account of the needs of developing countries with respect to capacity building in order to promote the development and transfer of safe biotechnology and knowledge. (NB: same as Option 2, para 1, above)</p> <p>2. The Parties agree that, according to the specific needs of different regions and sub-regions, regional or sub-regional activities/centres for training and capacity building regarding the safe management of living modified organisms shall be established. with financial assistance provided through the financial mechanisms under the Convention on Biological Diversity (CBD). (NB: same as Option 2, para. 3, above)</p> <p>3. Implementation of [these measures] is properly addressed in the general framework of the Convention and through programmes and activities under international organizations such as UNEP and UNIDO.]</p>		
<p><u>ARTICLE 22 - PUBLIC AWARENESS / PUBLIC PARTICIPATION</u></p> <p>Option 1 No provisions necessary.</p> <p>Option 2 [Include these matters in the Preamble]</p> <p>Option 3 9</p> <p>[1. The Parties shall ensure that adequate information on the safe transfer, handling and use of LMOs is</p>	<p>Canadian proposed legal text submitted to the Secretariat (July, 1997):</p> <p>With respect to the safe transfer, handling and use of living modified organisms, specifically focusing on transboundary movement, each Party shall:</p> <p>(a) promote and encourage understanding of the importance of, and the measures required for,</p>	

<sup>9</sup> [Variations to Option 3 are: i) paragraphs 1 to 7 in their entirety; ii) only paragraphs 4 and 6, with amendments; iii) only paragraphs 3, 4 and 6; and iv) paragraphs 1 to 7 in their entirety, with the amendments to paragraphs 1 and 2 proposed by Mali. (awaiting text).]

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<p>provided to the public in accordance with Article 13 and Article 14(1) of the Convention with regard to public participation Parties are encouraged to facilitate public participation in risk assessment decisions.</p> <p>2. The Parties shall promote and facilitate, at the national, sub-regional and regional levels, as appropriate, and in accordance with national laws and regulations, and within their respective capacities, the development and implementation of educational, both formal and informal, and public awareness programmes on safety in biotechnology.</p> <p>3. Each Party shall, in accordance with its national laws and regulations, provide the public which is likely to be affected by any activity or product involving living modified organisms, an opportunity for public hearings in the process of approving the release, transfer or use, contained or otherwise, of such living modified organisms.</p> <p>4. While respecting the need to protect commercial-in-confidence information, Parties shall:</p> <ul style="list-style-type: none"> <li>a) promote and encourage understanding of the safe use, handling and management of living modified organisms in relation to the transboundary movements and the conservation and sustainable use of biological diversity, including human health;</li> <li>b) make available to the public risk assessment results and decisions concerning the transboundary movement of living modified organisms;</li> </ul> <p>5. The Parties shall stipulate public participation by allowing access to information on which decisions are based and shall cooperate to favor public awareness on any possible effects for the environment and health in general that Living Modified Organisms release may produce.</p> <p>6. The Parties shall cooperate as appropriate, with other States and international organizations in developing educational and public awareness programmes [with respect to any risks and benefits associated to] [on safety in] modern biotechnology.</p> <p>7. Subject to relevant national legislation, Parties shall endeavour to disclose or make available information on biotechnology, safety in biotechnology and the results and impacts of any releases or use of any LMO thereof to the public.]</p> <p>Option 4</p> <p>[1. The Contracting Parties shall take appropriate measures to enhance public awareness of and/or public participation in the implementation of the Protocol.]</p> <p>Option 5</p>	<p>such safe transfer, handling and use; and</p> <p>(b) cooperate, as appropriate, with other States and international organizations in developing public awareness material on these topics.</p>	

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<p>[1. Each Contracting Party shall take appropriate measures to ensure to the extent practicable, that the public has appropriate access to information related to the implementation of this Protocol, whilst respecting confidential commercial information.</p> <p>2. Each Contracting Party shall promote and facilitate, as appropriate and in accordance with national laws and regulations, and within their respective capacities, the development of educational public awareness program on safety in biotechnology.]</p>		
<p><u>ARTICLE 23 - NON PARTIES</u></p> <p style="text-align: center;">Element Paper</p> <p>Element I. Non-Parties</p> <ol style="list-style-type: none"> <li>1. This item of non-Parties should not be addressed in the Protocol at this stage.</li> <li>2. This issue of non-Parties should be addressed in the Protocol. <ol style="list-style-type: none"> <li>a) they may have an important role/influence (in accordance or against) the provisions of the Protocol and in the transfer of LMOs.</li> <li>b) due to increasing globalization and transboundary movement, commercialization by non-Parties will become an increasingly important issue.</li> <li>c) However it is not just a trade issue, but should be dealt with in the context of whether the transfer, handling or use of LMOs with non-Parties should be allowed</li> </ol> </li> <li>3. The Biosafety Protocol once established should be ratified by as many countries as possible in order that it will provide a real international standardized procedure for the transboundary transfer of LMOs.</li> <li>4. Parties and non-Parties may enter into bilateral or regional agreements provided that such agreements are compatible with the Biosafety Protocol. Such agreements should be made available to Parties through the CHM and through the Secretariat of the Protocol.</li> <li>5. The Protocol should contain a provision related to the traffic of Parties and non-Parties considering the movement and transit of LMOs: (a) from Parties to the CBD to non-Parties; (b) from non-Parties to Parties to the CBD. The provision should address export and imports of LMOs from non-Parties only under certain conditions.</li> <li>6. The provisions on non-parties in the Basel Convention is not relevant to the Protocol as the objectives and the nature of that Convention are different from those of the Biosafety Protocol.</li> </ol>		

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<p>Element II. Trade with Non-Parties</p> <p>7. Trade with non-Parties should be permitted if adequate measures are taken to ensure safe movement. This could be included in the article on bilateral agreements.</p> <p>8. The Protocol should not impose restrictions more stringent than those of WTO in regard to LMOs and trade with non-Parties.</p> <p>9. The question of whether trade with non-Parties should be allowed should not be relevant if no LMOs are involved.</p> <p>10. Non-Parties should be permitted to transfer LMOs to Parties, because non-Parties to the Convention may possess technology and LMOs which Parties may wish to access. Importers may need to access technology and LMOs on a bilateral basis.</p> <p>11. Trade with non-Parties who are in compliance with the Protocol should be permitted and non-Parties should fulfill safety provisions in regard to trade of LMOs.</p> <p>12. In the event that the Protocol contains non-Parties provisions, trade could be permitted but must be flexible and not overly restrictive.</p> <p>13. The provisions are needed so as to assure the compliance with the terms established within this Protocol, either on a bilateral or regional basis.</p> <p>14. Non-Parties should commit themselves to being subjected to the arbitration mechanism provided for in the protocol (by becoming a party to such protocol).</p> <p>15. Measures taken to implement the Protocol should not create unnecessary obstacles to and do not constitute a means of arbitrary or unjustifiable discrimination or disguised restrictions on international trade.</p> <p>GOVERNMENT SUBMISSIONS</p> <p>Option 1 No Party shall export or import living modified organisms or products thereof to or from non-Parties.</p> <p>Option 2 Parties may enter into bilateral, regional or multilateral agreements or arrangements regarding transboundary movements of living modified organisms with Parties or Non-Parties, provided that adequate measures are observed to ensure the safe transboundary movement of living modified organisms resulting from modern biotechnology, in accordance with the objectives of this Protocol. The provisions of this Protocol shall not affect transboundary movements that take place pursuant to such agreements and arrangements as between the Parties to that agreement or arrangement.</p>		



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<p>Option 3 Parties shall not be restricted from trade in living modified organisms with Non-Parties, provided that adequate measures are observed to ensure the safe transboundary movement of living modified organisms resulting from modern biotechnology, in accordance with the objectives of this Protocol.</p> <p>Option 4 Any transboundary movement of LMOs, their parts, products, subproducts and derivatives resulting from biotechnology, originating from the jurisdiction of non-party States, shall be regulated in accordance with the national law of each Contracting Party.</p>		
<p><u>ARTICLE 24 - NON DISCRIMINATION</u></p> <p>Option 1 No provisions necessary.</p> <p>Option 2 the Protocol should contain such an Article, which may take into account the following elements, as appropriate:</p> <ol style="list-style-type: none"> <li>1. The concept of national treatment should be applied in the course of the AIA procedure in the sense that any LMO of foreign origin should be treated in the same way as LMOs of domestic origin.</li> <li>2. The decision of risk assessment should not be biased by the mere fact that the LMO in question is of foreign origin.</li> <li>3. The parameters and information used for risk assessment should not be interpreted in a manner that LMOs of foreign origin are unnecessarily discriminated.</li> <li>4. The Protocol should be consistent with trade related international treaties, especially those under the WTO.</li> <li>5. Further work is required to determine what non-discrimination would mean in the context of the Biosafety Protocol.</li> <li>6. Parties may [not] restrict trade of certain LMOs while permitting others.</li> <li>7. LMOs should be equally evaluated and equally considered.</li> <li>8. Parties are best placed to judge their environment and as such should be allowed to discriminate as to what to allow into their country/environment.</li> <li>9. Parties may discriminate only on the basis/context of AIA.</li> </ol>		

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<p>10. Parties shall ensure that advance informed agreement measures for the import of a living modified organism are not more restrictive than measures applied to the same living modified organism produced domestically or imported from other Parties.</p> <p>11. Parties shall ensure that advance informed agreement measures for the import of a living modified organism are applied in a manner which does not constitute a disguised restriction on international trade.</p> <p>12. Non-discrimination issue is subject to sovereign right and prerogative of national authority in receiving country</p> <p>Non discrimination could cover a number of issues such as non-discrimination between Parties, between Parties and non-Parties, between LMOs, between uses of LMOs or any number of issues including in a trade context.</p>		
<p><u>ARTICLE 25 - ILLEGAL TRAFFIC</u></p> <p>Option 1        No provisions necessary.</p> <p>Option 2        the Protocol should contain such an Article, which may take into account the following elements, as appropriate:</p> <ol style="list-style-type: none"> <li>1. Illegal traffic must be understood to mean movement of LMOs not in accordance with national legislation implementing the Protocol;</li> <li>2. Parties should introduce appropriate measures/national legislation to prevent illegal traffic;</li> <li>3. In case of a transboundary movement of LMOs or living products thereof deemed to be illegal traffic, the State of import/receiving country shall exercise the right of sovereignty to destroy or dispose the organisms or products in question. Each Party shall adopt appropriate domestic legislation that prevents and punishes illegal traffic. The Parties shall cooperate in this respect with a view to achieving the objective of this Protocol;</li> <li>4. The Protocol should contain a provision related to the traffic of Parties and non-Parties;</li> <li>5. Data concerning known cases of illegal traffic could be included in the information exchange mechanism;</li> <li>6. Illegal traffic could be addressed in the Protocol by a general provision referring to the relevant World Trade Organization provisions;</li> <li>7. Parties should transmit to all affected Parties, as quickly and as effectively as possible, all the relevant available information concerning the illegal traffic movement and any related risks.</li> </ol>		

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<p>GOVERNMENT SUBMISSIONS</p> <p>Option 3.</p> <ol style="list-style-type: none"> <li>1. Any transboundary transfer of living modified organisms or products thereof without notification to, or advance informed agreement of, all States concerned, pursuant to the provisions of this Protocol; or with advance informed agreement obtained from States concerned through falsification, misrepresentation or fraud; or with advance informed agreement which does not conform in a material way with the documents submitted or which results in the deliberate release of living modified organisms in contravention of this Protocol and of general principles of international law, shall be deemed to be illegal traffic.</li> <li>2. In case of a transboundary transfer of living modified organisms or products thereof deemed to be illegal traffic, the State of import shall have the right to destroy or dispose of the organisms or products in question.</li> <li>3. Each Party shall adopt appropriate domestic legislation that prevents and punishes illegal traffic. The Parties shall cooperate in this respect with a view to achieving the objective of this Protocol.</li> </ol> <p>Option 4.</p> <ol style="list-style-type: none"> <li>1. For the purpose of this Protocol, any transboundary movement of living modified organisms shall be deemed to be illegal traffic if it: <ol style="list-style-type: none"> <li>a) occurs without compliance with the advance informed agreement provisions outlined in this Protocol, including notification and approval, except as provided under Article 15 for Bilateral, Regional and Multilateral Agreements, or;</li> <li>b) occurs with approval obtained through falsification, misrepresentation or fraud, or;</li> <li>c) does not conform in a material way with the documentation provided pursuant to this Protocol.</li> </ol> </li> <li>2. Parties shall introduce appropriate national legislation to prevent and punish illegal traffic. In cases where illegal traffic has occurred, the importing Party may: <ol style="list-style-type: none"> <li>a) impound the living modified organisms, or;</li> <li>b) require and direct the disposal or re-export of the living modified organisms.</li> </ol> </li> <li>3. Parties may impose additional penalties for illegal traffic, as appropriate.</li> </ol> <p>Option 5.</p> <ol style="list-style-type: none"> <li>1. For the purposes of this Protocol, any transfer, handling or use of any LMO to or within the receiving country Party by the intending Party or person or entity under the jurisdiction of the intending Party :</li> </ol>		

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<p>a) without notification pursuant to the provisions of this protocol to Parties under this protocol; or</p> <p>b) without the advance informed agreement pursuant to the provisions of this protocol of any Party concerned; or</p> <p>c) with advance informed agreement obtained from Parties concerned through falsification, misrepresentation or fraud ; or</p> <p>d) that does not conform in any material way with the information given under the AIA procedure; or</p> <p>e) that results in deliberate transfer, release, handling or use of LMOs in contravention of this protocol and of general principles of international law, shall be deemed to be illegal traffic/unauthorized transfers.</p> <p>2. In the case of a transfer, handling or use of LMOs deemed to be illegal traffic/unauthorized transfers, the receiving country Party has the right to destroy or dispose the LMO in question or where possible require the person responsible for the illegal traffic to remove the LMO from the environment of the receiving country party at his own expense.</p> <p>3. Each Party shall develop appropriate national/domestic legislation to prevent or punish illegal traffic.</p> <p>Option 6.</p> <p>1. Any transboundary transfer of LMOs without appropriate notification to, or advance informed agreement of, all States concerned, pursuant to and in accordance with the provisions of this Protocol, shall be deemed to be illegal traffic.</p> <p>2. [In the case of a transboundary transfer of LMOs thereof deemed to be illegal traffic, the State of import shall have the right to destroy or dispose of the organisms or products in question.]</p> <p>Each Party shall adopt appropriate legislative measures to prevent illegal traffic. Parties shall co-operate in this respect , with a view to achieving the objective of this Protocol.</p>		
<p><u>ARTICLE 26 - SOCIO-ECONOMIC CONSIDERATIONS</u></p> <p>Option 1</p>		

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<p>1. Socio-Economic considerations should not be dealt with in the Protocol.</p> <p>Option 2</p> <p>1. Parties shall ensure that the socio-economic impacts of the introduction of living modified organisms and products thereof are appropriately considered during the assessment and management of risks. In particular, the user shall take due account of the long observation period that these socio-economic impacts may require to manifest such adverse consequences as genetic erosion and associated loss of income and dislocation of traditional farmers and farm products.</p> <p>2. A Party that intends to produce, using a living modified organism, a hitherto imported commodity, shall notify the other Party or Parties whose export is to be affected long enough, and in no case less than seven years in advance so as to enable them to diversify their production and to implement measures concerning the biodiversity that would be reduced following the disruption of production of the commodity in question. The Party substituting its import in such unnatural way shall, when the affected Party is a developing country, provide financial and technical assistance to the affected Party.</p> <p>Option 3</p> <p>1. The Parties hereby agree that socio-economic imperatives must be taken into account at all levels, during the transfer, handling or use of LMOs. To this end, the intending country Party shall ensure that the risk assessment prepared by it or person or entity under its jurisdiction under Article 6 shall incorporate specific assessments on the socio-economic effects and impacts of the transfer, handling or use of the LMO to or within the receiving country and its environment, in particular to the conservation and sustainable use of biological diversity, taking into account its human health, agriculture and welfare.</p> <p>2. The risk assessment shall in particular include an assessment of whether introduction of LMOs in the environment of the receiving country may entail a displacement of a particular agricultural and resource use system or the culture and livelihood of the local people.</p> <p>3. The intending Party shall ensure that the risk management strategies and measures proposed to be implemented by the receiving country Party under Article 7 shall incorporate strategies and measures that will minimise, prevent or mitigate the potential socio-economic effects and impacts within the receiving country Party, in particular where the introduction of LMOs in the environment of the receiving country Party may entail a displacement of a particular agricultural or resource use system or the culture and livelihood of the local people.</p> <p>Option 4</p> <p>1. The Parties shall ensure that the socio-economic impacts specific and unique to the use of living modified organisms that may manifest adverse consequences are appropriately considered during the assessment and</p>		

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<p>management of risks taking into account the fact that socio-economic considerations will vary considerable from Party to Party.</p> <p>Parties shall encourage research on socio-economic considerations relating to the use, handling and transfer of living modified organisms and the exchange of the results of such research.</p>		
<p><u>ARTICLE 27 - LIABILITY AND COMPENSATION</u></p> <p>Option 1</p> <p>1. Liability and Compensation should not be dealt with in the Protocol</p> <p>Option 2</p> <p>1. Liability and Compensation should only be dealt with by reference to Paragraph 2 of the Article 14 of the Convention.</p> <p>Option 3</p> <p>1. If harm, including transboundary harm, arises as a consequence of living modified organisms or activities or products involving such organisms, the State or States of origin shall be bound to negotiate with the affected State or States to determine the legal consequences of the harm, and the State or States of origin shall be strictly liable and the harm must be fully compensated.</p> <p>2. If the harm, including the transboundary harm, proves detrimental to human or animal health, biological diversity, the environment or the socio-economic welfare of the affected State:</p> <p>(a) The State of origin shall bear the costs of any operation to restore, as far as possible, the conditions that existed prior to the occurrence of the harm. If it is impossible to restore these conditions fully, agreement may be reached on compensation, monetary or otherwise, between the State of origin and the affected State for the deterioration suffered.</p> <p>(b) If, as a consequence of the harm referred to in the preceding subparagraph, there is also harm to persons or damage to property in the affected States, payments by the State of origin shall also include compensation for such harm.</p> <p>3. In the cases referred to in subparagraph 2, if there is more than one State of origin, they shall be jointly and severally liable for the resulting harm, without prejudice to any claims which they may bring among themselves for their proportionate share of liability.</p> <p>4. There shall be no liability on the part of the State of origin if the harm was directly due to a natural catastrophe</p>		

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<p>of an exceptional, inevitable and irresistible character.</p> <p>5. Proceedings in respect of liability under this Article shall lapse after a period of five years from the date on which the affected Party learned, or could reasonably be expected to have learned, of the harm and of the identity of the state of origin or the user, as the case may be. In no event shall proceedings be instituted once 150 years have elapsed in the case of trees, and 30 years in all other cases since the date of the occurrence of events or the accident that caused the harm. If the cause of the harm consisted of a series of occurrences, the 150 or the 30 years duration shall start from the date of the last occurrence.</p> <p>6. The preceding subparagraphs shall not prevent:</p> <p>(a) The Parties from adopting and elaborating further the rules of liability and enforcement of judgements.</p> <p>(b) Any Party from submitting its claim to the World Biosafety Court, or to arbitration, or to the international Court of Justice, or to conciliation.</p> <p>(c) A Party, or any individual or legal entity represented by a Party, that considers it has been injured as a consequence of an activity or product involving living modified organisms, from submitting a claim to the courts of the State of origin or, where access to courts is permitted by domestic law, to the courts of the affected State. In that case, however, the affected State may not use the diplomatic channel to claim for the same harm for which such claim has been made.</p> <p>Option 4</p> <p>1. While importing Parties remain responsible for the use of living modified organisms, and products thereof, within their national territories, exporting Parties shall be liable for any negative or harmful effects of living modified organisms, or products thereof, which could not have reasonably been foreseen on the basis of the information provided at the time of the first import.</p> <p>2. Exporting Parties shall also be liable for any negative or harmful effects produced as a result of any breach of the obligations under this Protocol.</p> <p>3. Exporting Parties shall also be liable for all forms of unauthorised, uninformed or otherwise illegal transboundary movements of living modified organisms and products thereof, including, inter alia:</p> <p>a) unsafe packaging;</p> <p>b) fraud, falsification of approval; or</p> <p>c) material exported that does not conform with information provided by exporting Party.</p> <p>4. The Parties from which unintentional transboundary movements of living modified organisms originate shall pay any costs incurred as a result of the unintentional movements and shall be liable for any resulting negative or harmful effects.</p> <p>5. All cases of proven liability shall result in the payment of fair and adequate compensation by the exporting</p>		

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<p>Parties to Parties affected.</p> <p>6. If necessary, the importing Parties may impound, destroy or re-export unauthorised living modified organisms, or products thereof, at the cost of the exporting Party.</p> <p>Option 5</p> <p>1. The exporter shall be liable for and shall fully compensate any damage deriving from the transboundary movement of LMOs, in accordance with the provisions of the present Protocol.</p> <p>Option 6</p> <p>1. The Parties shall cooperate with a view to adopting in accordance with art. 14(2) of the Convention, appropriate rules and procedures in the field of liability and redress, including restoration and compensation for damage to the conservation and sustainable use of biological diversity.</p> <p>Option 7</p> <p>1. Parties are responsible for the fulfillment of their international obligations concerning the conservation and sustainable use of biological diversity and preservation of the environment. They shall be liable in accordance with international law.</p> <p>2. Parties shall ensure that recourse is available in accordance with their legal systems for prompt and adequate compensation or other relief in respect of damage caused by the use, handling and transfer of living modified organisms by natural or juridical persons under their jurisdiction.</p> <p>With the objective of assuring prompt and adequate compensation in respect of all damage cause by the use, handling and transfer of living modified organisms, Parties shall cooperate in the implementation of existing international law and the further development of international law relating to responsibility and liability for the assessment and compensation of damage and the settlement of related disputes, as well as, where appropriate, development of criteria and procedures for payment of adequate compensation, such as compulsory insurance and compensation funds.</p>		
<p><u>ARTICLE 28 FINANCIAL MECHANISM AND RESOURCES</u></p> <p>Option 1</p> <p>(1) The financial mechanism defined in Article 21 of the Convention, as well as the institutional structure</p>		



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<p>carrying out its operation, shall serve as the financial mechanism and institutional structure for the purposes of this Protocol.</p> <p>(2) Additional funding for the purposes of implementing the provisions of this Protocol shall be provided to the financial mechanism by developed country Parties in a predictable and timely manner.</p> <p>(3) On matters related to activities under the provisions of this Protocol, the financial mechanism, as well as the institutional structure carrying out its operation, shall function under the authority and guidance of, and be accountable to, the Conference of the Parties.</p> <p>(4) The developed country Parties may also provide, and developing country Parties avail themselves of, financial and technological resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.</p> <p>Option 2</p> <p>The developed country Parties may provide, and developing country Parties avail themselves of, financial and technological resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.</p>		
<p><u>ARTICLE 29 - CONFERENCE OF THE PARTIES</u></p> <p>(1) The Conference of the Parties to the Convention shall serve as the supreme body of this Protocol and shall be able to exercise all of its functions in this capacity.</p> <p>(2) In accordance with Article 32(2) of the Convention, when the Conference of the Parties exercises its functions in relation to this Protocol, decisions shall be taken only by those of its members that are, at the same time, Parties to this Protocol.</p> <p>(3) When the Conference of the Parties exercises its functions in relation to this Protocol, any member of the Bureau of the Conference of the Parties representing a Party to the Convention but, at the same time, not a Party to this Protocol, shall be substituted by an additional member to be elected by and from the Parties to this Protocol.</p> <p>Option 1</p> <p>The Conference of the Parties, acting in relation to this Protocol, shall, at its first meeting after the entry into force of this Protocol, decide upon modalities for the conduct of business on matters relating to this Protocol.</p> <p>Option 2</p> <p>The members of the Conference of the Parties whose members are, at the same time, Parties to the Protocol, shall, at the first meeting of the Conference of the Parties after the entry into force of this Protocol,</p>		

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<p>decide upon modalities for the conduct of business on matters relating to this Protocol.</p> <p>(5) Without prejudice to paragraphs (1) to (4) above, the Parties to this Protocol may also meet at any such times as may be deemed necessary by the Parties to this Protocol.</p>		
<p><u>ARTICLE 30 - SUBSIDIARY BODIES AND MECHANISMS</u></p> <p>(1) Subject to Article [financial mechanism and resources], the subsidiary bodies and mechanisms of the Convention shall, where appropriate, serve as subsidiary bodies and mechanisms for this Protocol.</p> <p>Option 1 When a subsidiary body exercises its functions with regard to matters concerning this Protocol, decisions shall be taken only by the Parties to the Protocol.</p> <p>Option 2 Delete Article 30(2)</p>		
<p><u>ARTICLE 31 - SECRETARIAT</u></p> <p>(1) The Secretariat established by Article 24(1) of the Convention shall serve as the Secretariat to this Protocol.</p> <p>Option 1 To the extent that these are distinct, the costs of Secretariat services for this Protocol shall be met by the Parties hereto. A Trust Fund is hereby established for this purpose.</p> <p>Option 2 To the extent that these are distinct, the costs of Secretariat services for this Protocol shall be met by the Parties hereto on a voluntary basis. A Trust Fund is hereby established for this purpose.</p>		
<p><u>ARTICLE 32 - JURISDICTIONAL SCOPE</u></p> <p>Article 4 of the Convention shall apply to this Protocol.</p>		

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<p><u>ARTICLE 33 - RELATIONSHIP WITH THE CONVENTION</u></p> <p>Except as otherwise provided in this Protocol, the provisions of the Convention relating to its protocols shall apply to this Protocol.<sup>10</sup></p>		
<p><u>ARTICLE 34 - RELATIONSHIP WITH OTHER INTERNATIONAL CONVENTIONS</u></p> <p>Option 1</p> <p>The provisions of this Protocol shall not affect the rights and obligations of any Party to this Protocol deriving from any existing international agreement to which it is also a Party at the time that this Protocol enters into force for that Party.</p> <p>Option 2</p> <p>The provisions of this Protocol shall not affect the rights and obligations of any Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause serious damage or threat to biological diversity.</p>		
<p><u>ARTICLE 35 - MONITORING AND COMPLIANCE</u></p> <p>Option 1</p> <p>The Parties to this Protocol shall, at their first meeting, determine how to establish procedures and institutional mechanisms for determining non-compliance with the provisions of this Protocol and for the treatment of Parties found in non-compliance.</p> <p>Option 2</p> <p>The Parties to this Protocol shall determine whether to establish procedures and institutional mechanisms for determining non-compliance with the provisions of this Protocol and for the treatment of Parties found in non-compliance.</p> <p>Option 3</p>		

<sup>10</sup> This provision potentially allows for the provisions of the Convention on, for example, settlement of disputes; amendment; adoption and amendment of annexes; and right to vote to apply to the Protocol.

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<p>(1) Parties shall introduce, as necessary, implement and enforce national compliance and monitoring systems, taking into account, as appropriate, recognized international standards and guidelines.</p> <p>(2) Parties shall provide information on national monitoring and compliance systems to the Clearing House.</p> <p>(3) Parties should provide information on any significant incidents of illegal traffic to the Clearing House.</p> <p>Option 4</p> <p>(1) Each Party shall report annually to the Secretariat and the Clearing House on the steps taken to implement this Protocol. Reports shall, in particular, include information on the status of living modified organisms released deliberately or accidentally, and on the operation of the advance informed agreement system.</p> <p>(2) Each Party shall ensure that monitoring of activities and products involving living modified organisms is undertaken at regular intervals by the user and the same is reported to the competent authority.</p>		
<p><u>ARTICLE 36 - ASSESSMENT AND REVIEW OF PROCEDURES/ANNEXES</u></p> <p>Beginning in [ ], and at least every five years thereafter, the Parties shall assess the procedures and annexes provided in this Protocol on the basis of available scientific, environmental and technical information. At least one year before each assessment, the Parties shall convene appropriate panel of experts and determine its composition and terms of reference. Within one year of being convened, the panels will report their conclusions, through the Secretariat, to the Parties.</p>		
<p><u>ARTICLE 37 - SIGNATURE</u></p> <p>This Protocol shall be open for signature at [ ] by all States and any regional economic integration organization from [ ] until [ ], and at the United Nations Headquarters in New York from [ ] to [ ].</p>		
<p><u>ARTICLE 38 - RATIFICATION, ACCEPTANCE, OR APPROVAL</u></p> <p>(1) In accordance with Article 34 of the Convention, this Protocol shall be subject to ratification, acceptance or approval by States and by regional economic integration organizations. Instruments of ratification, acceptance or approval shall be deposited with the Depositary.</p> <p>(2) Any organization referred to in paragraph (1) above which becomes a Party to this Protocol without any of its member States being a Party hereto shall be bound by all the obligations under the Protocol. In the case of</p>		

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<p>such organizations, one or more of whose member States is a Party to this Protocol, the organization and its member States shall decide on their respective responsibilities for the performance of their obligations under the Protocol. In such cases, the organization and the member States shall not be entitled to exercise rights under the Protocol concurrently.</p> <p>(3) In their instruments of ratification, acceptance or approval, the organizations referred to in paragraph (1) above shall declare the extent of their competence with respect to the matters governed by the Protocol. These organizations shall also inform the Depositary of any relevant modification in the extent of their competence.</p>		
<p><u>ARTICLE 39 - ACCESSION</u></p> <p>(1) In accordance with Article 35 of the Convention, this Protocol shall be open for accession by States and by regional economic integration organizations from the date on which the Protocol is closed for signature. The instruments of accession shall be deposited with the Depositary.</p> <p>(2) In their instruments of accession, the organizations referred to in paragraph (1) above shall declare the extent of their competence with respect to the matters governed by the Protocol. These organizations shall also inform the Depositary of any relevant modification in the extent of their competence.</p> <p>(3) The provisions of Article [Ratification,] paragraph (2), shall apply to regional economic integration organizations which accede to this Protocol.</p>		
<p><u>ARTICLE 40 - ENTRY INTO FORCE</u></p> <p>(1) In accordance with Article 36(2) of the Convention, this Protocol shall enter into force on the ninetieth day after the date of deposit of the [ ] instrument of ratification, acceptance, approval or accession.</p> <p>(2) This Protocol shall enter into force for a Party that ratifies, accepts or approves this Protocol or accedes thereto after its entry into force pursuant to paragraph (1) above, on the ninetieth day after the date on which that Party deposits its instrument of ratification, acceptance, approval or accession, or on the date on which this Protocol enters into force for that Party, whichever shall be the later.</p> <p>(3) For the purposes of paragraphs (1) and (2) above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.</p>		
<p><u>ARTICLE 41 - RESERVATIONS</u></p>		

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<p><u>Option 1</u> No reservations may be made to this Protocol.</p> <p><u>Option 2</u> Delete Article 41.</p>		
<p><u>ARTICLE 42 - WITHDRAWALS</u></p> <p>(1) At any time after two years from the date on which this Protocol has entered into force for a Party, that Party may withdraw from the Protocol by giving written notifications to the Depositary.</p> <p>(2) Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.</p> <p>(3) Any Party which withdraws from the Convention shall be considered as also having withdrawn from this Protocol.</p>		
<p><u>ARTICLE 43 - AUTHENTIC TEXTS</u></p> <p>The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.</p>		
<p><u>ANNEXES</u></p>		
<p style="text-align: center;"><u>ANNEX I to the Protocol</u></p> <p style="text-align: center;">INFORMATION REQUIRED IN ORDER TO OBTAIN ADVANCE INFORMED AGREEMENT</p> <p>a) name and address of exporting company/institution;  b) name and address of receiving company/institution;  c) origin, common name and taxonomic status of recipient organism;  d) description of all traits introduced or modified and characteristics of the organism;  e) purpose and methodology of the genetic modification (and stability of introduced genetic material;  f) A complete risk assessment report on the living modified organism in accordance with the risk assessment parameters stated in Annex II of the protocol including as far as possible the conditions in the State of import. Taking particularly into account releases in centers of origin for the LMO, the State of export shall also</p>	<p>Information requirements should be consistent with those under Canadian legislation.</p>	

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<p>evaluate whether the LMOs in question may establish viable populations or may hybridize with local species in the receiving environment;</p> <p>g) quantity of organisms to be transferred or volume or culture and physical state;</p> <p>h) any relevant requirements to ensure safe handling, storage, subsequent transport and use</p> <p>i) intended dates of transfer/movement/release/activity;</p> <p>j) intended means of transport;</p> <p>k) intended use of the organism;</p> <p>l) methods for safe disposal and contingency plans in case of accidents/unintended movements;</p> <p>m) information on experiences with previous releases and the impacts on conservation and sustainable use of biological diversity human health of such releases;</p> <p>n) intended labeling of the LMO;</p> <p>o) any differences between the environment of the exporting country and the environment into which the organism is to be released;</p> <p>p) Center of origin of the organism that has been modified and areas with high genetic diversity relevant to the living modified organism);</p> <p>q) The applicable laws, procedures and guidelines of the State of export and the stage reached in the testing and observation of the living modified organism or the product thereof according to the legal and administrative requirements of the State of export;</p> <p>r) Any requirements to manage risks and to ensure safe handling (storage, transport) and use, and methods for safe disposal and appropriate emergency procedures in case of accidents;</p> <p>s) Information relating to insurance (liability and compensation);</p> <p>t) Declaration by the exporter (Competent Authority or the accredited agency of the Party of export) that the information is correct;</p> <p>u) Specific introductions or recommendations for storage and handling;</p> <p>v) Name of person(s) responsible for planning and carrying out the release including those responsible for supervision, monitoring and safety, in particular, name and qualifications of the responsible scientist;</p> <p>w) Information on training and qualifications of personnel involved in carrying out the release.</p>		
<p style="text-align: center;"><u>ANNEX II to the Protocol</u></p> <p style="text-align: center;"><b>RISK ASSESSMENT PARAMETERS</b></p> <p>1. Prior to the use and release of living modified organisms an assessment as regards the risks to human and animal health, biological diversity, the environment and the socio-economic welfare of societies shall be performed. This assessment shall take the following parameters into consideration, including any other parameter deemed to be relevant:</p> <p>A. General Principles:</p> <p>Risk assessment should, inter alia, take into account:</p>	<p>Risk assessment parameters should be consistent with those considered under Canadian legislation.</p>	



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<p>a) all relevant scientific evidence and experience;</p> <p>b) the general characteristics of both the living modified organism and the parent organism, the vector used, the genetic modification and the novel trait;</p> <p>c) the intended use of the living modified organism and the nature of the receiving environment;</p> <p>d) potential impact of the living modified organism on the environment , particularly on centers of origin and areas with high genetic diversity relevant to the living modified organism;</p> <p>e) possible effects of the living modified organism on human health;</p> <p>f) risk assessment techniques developed by relevant international organizations; and details of risk assessments completed elsewhere, as appropriate.</p> <p><b>B. Specific information requirements:</b></p> <p><b>1. Characteristics of donor and recipient organisms or parental organisms:</b></p> <p>a) Strain, cultivar or other name;</p> <p>b) Species it is related to and degree of relatedness;</p> <p>c) The degree of relatedness between the donor and recipient organisms, or between parental organisms; pathogenicity, toxicity and allergenicity (in the case of micro-organisms, it should be noted that there are internationally accepted classification lists for human pathogens. Similar lists exist at national level for plant and animal pathogens in some countries);</p> <p>d) The natural habitat and the geographic origin of the organism, its distribution and its role in the environment;</p> <p>c) All sites from where the donor and recipient organisms or parental organisms were collected, if known;</p> <p>d) Information on the type of reproduction (sexual/asexual) and the length of reproductive cycle or generation time, as appropriate, as well as the formation of resting and survival stages;</p> <p>e) History of prior genetic manipulation, whether the donor or recipient organisms are already genetically modified;</p> <p>f) Phenotypic and genetic markers of interest;</p> <p>g) Ability of the organisms to survive and colonize the environment to which release, is intended or otherwise;</p> <p>h) Genetic stability of the organisms, and factors affecting the stability;</p> <p>i) The presence of endogenous mobile genetic elements of viruses likely to affect the genetic stability;</p> <p>j) The potential of the organisms to transfer or exchange genes with other organisms, either vertically or horizontally;</p> <p>k) Pathogenicity to humans or animals, if any;</p> <p>l) If pathogenic, their virulence, infectivity, toxicity and modes of transmission;</p> <p>m) Known allogenicity and/or toxicity of biochemical and metabolic products;</p> <p>n) Availability of appropriate therapies for pathogenicity, allergenicity and toxicity.</p> <p><b>2. Characteristic of the vector(s):</b></p>		

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<p>o) Nature and source of the vector(s);</p> <p>p) Genetic map of the vector(s), position of the gene(s) inserted for the transfer, other coding and non-coding sequences affecting the expression of introduced gene(s), and maker gene(s);</p> <p>q) Ability of the vector(s) to mobilize and transfer genes by integration and methods for determining the presence of the vector(s);</p> <p>r) History of prior genetic manipulation, whether the donor or recipient organisms are already genetically modified;</p> <p>s) Potential for pathogenicity and virulence;</p> <p>t) Natural and host range of vectors;</p> <p>u) Natural habitat and geographic distribution of natural and potential hosts;</p> <p>v) Potential impacts on human and animal health and the environment;</p> <p>w) Measures for counteracting adverse impacts;</p> <p>x) Potential to survive and multiply in the environment, or to form genetic recombinants;</p> <p>y) Genetic stability of vector(s), such as hypermutability.</p> <p>3. Characteristics of living modified organisms The LMO should be compared with the organism from which it is derived, examining, where relevant the following points:</p> <p>z) The description of the modifications made using gene technology;</p> <p>aa) The function of the genetic modifications and/or the new insert, including any marker gene(s);</p> <p>bb) Purpose of the modification and intended use in relation to need or benefit;</p> <p>cc) Method of modification, and in case of transgenic organisms, the methods for constructing inserts and to introduce them into the recipient organism;</p> <p>dd) Whether introduced gene(s) integrated or extra-chromosomal;</p> <p>ee) Number of insert(s) and its/their structure(s), for example, the copy number whether in tandem or other types of repeats;</p> <p>ff) Products of the transferred gene(s), levels of expression and methods for measuring expression;</p> <p>gg) Stability of the introduced gene(s) in terms of expression and integration;</p> <p>hh) Biochemical and metabolic differences of living modified organism compared with the unmodified organism;</p> <p>ii) Probability of vertical or horizontal gene transfer to other species;</p> <p>jj) Activity of the expressed protein(s);</p> <p>kk) Description of identification and detection techniques including techniques for the identification and detection of the inserted sequence and vector;</p> <p>ll) Sensitivity, reliability (in quantitative terms) and specificity of detection and identification techniques;</p> <p>mm) Health considerations:</p> <p>nn) Probability of inserts or transferred gene(s) to generate pathogenic recombinants with endogenous viruses, plasmids and bacteria;</p> <p>oo) Allogenicities, toxicities, pathogenicities and unintended effects;</p> <p>pp) Autoecology of the living modified organism compared with that of the unmodified organism;</p> <p>qq) Susceptibility of the living modified organism to diseases and pests compared with the unmodified organism;</p>		

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<p>rr) Detailed information on past uses including results on all experiments leading to previous releases.</p> <p>ss) History of previous genetic modifications</p> <p>tt) natural and potential range of geographical distribution of the LMO and its parental organisms including information on their natural habitats, predators, prey, parasites, competitors, symbionts, commensals and hosts;</p> <p>uu) biochemical and metabolic differences of the LMO compared with those of the unmodified organisms;</p> <p>vv) probability of inserts or transferred genes to generate pathogenic recombinants with endogenous viruses, plasmids and bacteria;</p> <p>ww) Description of genetic traits which may prevent or minimize dispersal of genetic material</p> <p>4. Safety considerations for human and animal health: Information on the living modified organism and when it is genetically engineered, information on the donor and recipient organisms as well as the vector before it was disarmed or disabled in cases where it has been disarmed or disabled, regarding:</p> <p>a) Capacity for colonization;</p> <p>b) If the living modified organism is pathogenic to humans or animals the following information is required:</p> <p>i) Diseases caused and mechanism of pathogenicity, including invasiveness and virulence, and property of virulence;</p> <p>ii) Communicability;</p> <p>iii) Infective dose;</p> <p>iv) Host range and possibilities of alteration;</p> <p>v) Ability to survive outside of the human or animal host;</p> <p>vi) The existence of vectors or other means of transmission;</p> <p>vii) Biological stability;</p> <p>viii) Allergenicity;</p> <p>ix) Availability of appropriate therapies;</p> <p>x) Comparison of the modified organism to the donor, recipient or (where appropriate) parental organism regarding pathogenicity;</p> <p>xi) Antibiotic-resistance patterns;</p> <p>xii) Generation time in natural ecosystems, sexual and asexual reproductive cycle;</p> <p>xiii) Information on ability to form survival structure e.g.: seeds, spores or sclerotia;</p> <p>xiv) Possible activation of latent viruses (parvoviruses).</p> <p>xv) Ability to colonize other organisms;</p> <p>xvi) Involvement in environmental processes: primary production, nutrient turnover, decomposition of organic matter, respiration, etc</p> <p>xvii) classification of hazard according to existing rules concerning the protection of human health and/or the environment;</p> <p>5. Environmental considerations: Information on the living modified organism and when it is genetically engineered, information on the donor and recipient organisms as well as the vector before it was disarmed or</p>		

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<p>disabled in cases where it has been disarmed or disabled, regarding:</p> <ul style="list-style-type: none"> <li>a) Factors affecting the survival, reproduction and spread of the living modified organism in the environment;</li> <li>b) Available techniques for detection, identification and monitoring of the living modified organism;</li> <li>c) Available techniques for detecting transmission of genes from the living modified organism to other organisms;</li> <li>d) Known and predicted habitats of the living modified organism;</li> <li>e) Description of the ecosystems which could be affected by accidental release of the living modified organism;</li> <li>f) Possible interactions between the living modified organism and other organisms in the ecosystem which might be affected by accidental release;</li> <li>g) Known or predicted effects on plants and animals such as pathogenicity, infectivity, toxicity, virulence, being a vector of pathogens, allergenicity, and colonization;</li> <li>h) Possible involvement in biogeochemical processes;</li> <li>i) Availability of methods for decontamination of the area in case of accidental releases;</li> <li>j) Effects on agricultural practices with possible undesirable impacts on the environment.</li> <li>k) purpose and scale of the release;</li> <li>l) geographical description and location of the release;</li> <li>m) proximity to residences and human activities;</li> <li>n) method and frequency of release;</li> <li>o) training and supervision of personnel carrying out the work;</li> <li>p) expected environmental conditions during the release</li> <li>q) subsequent treatment of the site and plans for waste management;</li> </ul> <p>6. Release of GMOs for biological control: Apart from compliance with the general principles, other specific factors that should be taken into consideration can include:</p> <ul style="list-style-type: none"> <li>a) effect on species targeted for biological control, parent organism and probable effect on ecosystem;</li> <li>b) host range specificities as to whether there will be possibilities of GMOs affecting non-target species;</li> <li>c) secondary effect on predators and parasite of the target species;</li> <li>d) effect of secondary metabolites produced by GMOs on other organisms in the food chain.</li> </ul> <p>7. Release experiment of GMO for bioremediation: Apart from compliance with the general principles, other specific factors that should be taken into consideration can include:</p> <ul style="list-style-type: none"> <li>a) effect of the parent organism on its target substrate;</li> <li>b) effect of GMOs on target substrate;</li> <li>c) effect of secondary metabolites produced by a GMO on other organisms in the community/site of release;</li> <li>d) effect of GMO on water, air or soil quality;</li> </ul>		

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<p>e) possible toxicity effect to other organisms that ingest the GMO;  f) possible dispersal of GMO from site of application and its consequences.  g) the geographical location of the site, the identity and any special features of the receiving environments that expose them to damage;  h) the proximity of the site to humans and to significant biota;  i) any flora, fauna and ecosystems that could be affected by the release, including keystone, rare endangered or endemic species, potential competitive species and non-target organisms;  j) the potential of any organism in the potential receiving environment to receive gene</p> <p>8. Socio-economic considerations:</p> <p>a) Anticipated changes in the existing social and economic patterns resulting from the introduction of the living modified organism or product thereof;  b) Possible threats to biological diversity, traditional crops or other products and, in particular, farmers' varieties and sustainable agriculture;  c) Impacts likely to be posed by the possibility of substituting traditional crops, products and indigenous technologies through modern biotechnology outside of their agro-climatic zones;  d) Anticipated social and economic costs due to loss of genetic diversity, employment, market opportunities and, in general, means of livelihood of the communities likely to be affected by the introduction of the living modified organisms;  e) Possible countries and/or communities to be affected in terms of disruptions to their social and economic welfare;  f) Possible effects which are contrary to the social, cultural, ethical and religious values of communities arising from the use or release of the living modified organism or product thereof.</p>		
<p style="text-align: center;"><u>ANNEX III to the Protocol</u></p> <p style="text-align: center;">RISK MANAGEMENT SCHEMES</p> <p>1. The user shall employ the following risk management schemes and procedures from the development, through all stages of testing of the living modified organism or the product thereof, to its intended use or commercialization.</p> <p>A. General Precautions</p> <p>a) Appropriate information and training is provided for those involved in handling the organisms;  b) Monitoring procedures are applied in such a way that appropriate measures can be taken in case of unexpected effects during or after the release;  c) The dissemination of the released organisms and/or gene flow from the released organisms are controlled;  d) Controlling access to the release site.  e) All trials, experiments or observations shall be subjected to the procedures of approval by the institutional</p>		

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<p>and national level bodies.</p> <p>f) All experiments outside of strict laboratory isolation and initial experiments involving imported living modified organism shall be subject to approval.</p> <p>g) Once approval from the appropriate national authority is obtained at the completion of the final stage of the trials, experiments or observations, the living modified organisms in question can be employed for its intended use. The appropriate national authority shall notify its decision in writing to the competent authority</p> <p>h) Whenever there is a need to dispose of the living modified organism upon the completion of every trial or experiment, it shall be made through complete incineration or other approved means of complete destruction.</p> <p>i) The release of living modified organism shall be monitored appropriately and emergency plans to prevent escape and accident shall always be in place.</p> <p><b>B. For Plants</b></p> <p>Applying reproductive isolation, by:</p> <ul style="list-style-type: none"> <li>a) spatial separation;</li> <li>b) temporal separation: use of plants that will flower either earlier or later than plants of nearby reproductively compatible species;</li> <li>c) biological prevention of flowering (e.g. by omitting vernalisation);</li> <li>d) removal of the male or female reproductive structures;</li> <li>e) bagging of flowers;</li> <li>f) making use of sterility;</li> <li>g) controlling the persistence or reproductive structures such as propagates or seeds.</li> <li>h) Destroying volunteer plants after harvest; control of volunteers may be necessary during longer periods, depending on the species. The reports from releases in areas other than the State of import shall be thoroughly evaluated by the designated authority. Particular emphasis shall be given to whether the applicable regulations in the previous release have been adequate to ensure safety;</li> <li>i) If it is decided that the previous release mechanisms have been rigorous enough, observations shall be made in experimental conditions completely contained from the outside environment, but otherwise kept at the same soil community, moisture, air temperature and plant and animal community conditions as the intended area of release;</li> <li>j) The observations will include the health of the living modified organism, the health of the organism within the area of limited release, the biological diversity and the ecology of the area;</li> <li>k) Nationally approved limited filed releases will be carried out with appropriate emergency procedures in place to deal with possible cases of escape.</li> </ul> <p><b>C. For Animals</b></p> <ul style="list-style-type: none"> <li>a) Confining by appropriate means such as fences, filters, islands, ponds;</li> <li>b) Applying reproductive isolation by using sterile animals;</li> </ul>		

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<ul style="list-style-type: none"> <li>c) Isolation from feral animals of the same species.</li> <li>d) Controlling the persistence or dispersal of reproductive structures such as larvae or eggs. The reports from releases in areas other than the State of import shall be thoroughly evaluated by the designated authority. Particular emphasis shall be given to whether the applicable controls in the previous release have been adequate to ensure safety;</li> <li>e) If the controls used in the previous release have been rigorous enough, then observations will be made in complete containment in the expected ambient climatic, nutritional and other environmental conditions to monitor physiological functions, adaptations and gene transfers;</li> <li>f) When the results have met the stated requirements, then a trial release may be authorized with adequate emergency plans put in place to deal with cases of escape.</li> </ul> <p>D. For micro-organisms</p> <ul style="list-style-type: none"> <li>a) Using organisms with impaired ability to grow or persist in the environment;</li> <li>b) Minimizing gene transfer by: <ul style="list-style-type: none"> <li>i) Using organisms that do not contain known self-transmissible mobilizable or transposable genetic elements;</li> <li>ii) Ensuring that introduced traits are stably located on the chromosome.</li> </ul> </li> </ul> <p>These measures will often not be applicable once an LMO, such as a modified crop plant, as a result of testing during research and development, it has been shown that the risks are acceptable low.</p>		
<p style="text-align: center;"><u>ANNEX IV to the Protocol</u></p> <p style="text-align: center;">FUNCTION OF FOCAL POINTS/COMPETENT AUTHORITIES</p> <ol style="list-style-type: none"> <li>1. The competent authority/ies shall be responsible for procedures related to Advance Informed Agreement (AIA), notification and information exchange.</li> <li>2. The competent authority in the State of import shall also be responsible for procedures related to risk assessment and risk management.</li> <li>3. The Competent Authority shall fulfill the following responsibilities: <ul style="list-style-type: none"> <li>a) to establish national guidelines and/or regulations for the implementation of the AIA procedures including detailed criteria for risk assessment within their competence;</li> <li>b) to receive from exporters applications for the AIA procedures;</li> <li>c) to conduct/evaluate risk assessment;</li> <li>d) to take a decision on result of the risk assessment;</li> <li>e) to transmit decisions on AIA to the notifier and other relevant agencies;</li> <li>f) making decisions on the transfer, handling or use of the LMO to or within the receiving country.</li> <li>g) to establish and impose such conditions as it deems appropriate regarding the movement of LMOs in order to protect its environment and human health;</li> <li>h) to establish appropriate procedures of control or mitigation, to finish release and eliminate wastes.</li> </ul> </li> </ol>		

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<ul style="list-style-type: none"> <li>i) to establish mechanisms for information exchange between countries and to develop national data bases.</li> <li>j) to keep a Registry of all activities related to Living Modified Organisms</li> <li>k) the rest as established by this Protocol</li> <li>l) any other assigned by their corresponding governments</li> </ul> <p>4. The focal point, which preferably shall be identical to the competent authority/ies, shall function as the contact point for the Protocol and shall be responsible for receiving and submitting information provided for in Articles 4, 5 &amp; 6.</p> <p>5. The focal point shall have the following responsibilities:</p> <ul style="list-style-type: none"> <li>a) to provide other Contracting Parties, through the Secretariat of the Protocol, with general information on the implementation of the Protocol at the national level including, in particular, information on competent authorities responsible for the AIA procedures and/or for LMOs;</li> <li>b) to collect information on the implementation of the protocol at its national level;</li> <li>c) to assist communication between foreign, regional or international institutions established for the implementation of the Protocol on the one hand and the national competent authorities on the other.</li> <li>d) to serve as the focal point for handling inquiries and proposals regarding any intended transfer/transboundary movement/release which affects its country or any activity undertaken on LMOs within its national boundaries;</li> <li>e) to be informed immediately in the event of an adverse effect of the transfer of the LMOs which could affect it.</li> </ul>		
<p style="text-align: center;"><u>ANNEX V to the Protocol</u></p> <p style="text-align: center;">INFORMATION TO BE PROVIDED TO THE SECRETARIAT UNDER INFORMATION SHARING/CLEARING HOUSE</p> <p>1. The Parties shall facilitate and encourage the collection and exchange of information relevant to the implementation of this Protocol. The Parties shall provide the Secretariat with the following information inter alia:</p> <ul style="list-style-type: none"> <li>a) designations of competent authorities/focal points and changes in such designations;;</li> <li>b) the text of any national decisions/reviews about LMOs contained uses, releases, marketing and transboundary transfers under AIA;</li> <li>c) general matters relevant to risk assessment/management associated with LMOs;</li> <li>d) information on accidental/unintentional movements of LMOs</li> <li>e) other relevant information ;</li> <li>f) national risk management procedures for use and handling of living modified organisms;</li> <li>g) national institutional framework for monitoring and compliance within their territories;</li> <li>h) all living modified organisms which have been subject to bans or restrictions by that Party;</li> <li>i) any unintentional/accidental transboundary movements of living modified organisms and biosafety measures implemented in that cases;</li> </ul>		



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<ul style="list-style-type: none"> <li>j) any releases of living modified organisms which could result in unintentional transboundary movements of living modified organisms; and biosafety measures implemented in that cases;</li> <li>k) any incidents of unauthorized or otherwise illicit transboundary movements of living modified organisms</li> <li>l) a list of living modified organisms subject to advance informed agreement which have been assessed for import into or use in its territory at the time of coming into force of this Protocol for that Party and a description of any conditions attached to imports of such living modified organisms.</li> <li>m) general description of products consisting of or containing LMOs having received consent by a Party or Parties for placing on the market;</li> <li>n) a summary of any methods and plans for monitoring of LMOs</li> <li>o) national guidelines and/or regulations for the implementation of the Protocol, including information required for the AIA procedures and for risk assessment</li> <li>p) any bilateral, regional and multinational agreements or arrangements as well as unilateral declarations on the exemption and/or the simplification of the AIA procedures.</li> <li>t) periodical report on the implementation of the AIA procedures, including statistics.</li> <li>w) information on LMOs released on the market;</li> <li>x) information on prohibited, approved and newly developed LMOs;</li> <li>y) information on monitoring post-commercial release of LMOs;</li> <li>z) lists of experts, advisory bodies and training workshops/programmes.</li> </ul>		