Toward a Canadian Stewardship Framework for GMOs - A Discussion Paper

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Toward a Canadian Stewardship Framework for GMOs

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Introduction and Executive Summary

This paper is a discussion document regarding possibilities for an explicit, federally-coordinated approach to the stewardship of genetically modified organisms (GMOs). As such, it is not intended to represent the policy or opinion of the federal government, nor is it intended to suggest that there aren't already stewardship mechanisms in place for GMOs and other products of biotechnology. Rather, it seeks to contribute to the ongoing discussion about optimal approaches necessary to provide for a more comprehensive stewardship of present and future GMOs.

Although it addresses issues regarding the federal government as a whole, the paper's focus is on the role of Environment Canada within the federal framework. The paper begins by considering the concept of stewardship. It recommends that an explicit, open discussion of the principles, values and ethics underlying our stewardship regime occur in order for a coherent framework to be put in place. A holistic stewardship framework based on a detailed eighteen-step product lifecycle is proposed. Working from this framework, roles and actions are suggested for the three major players in the development production and regulation of GMO products: universities, industry and government departments and agencies.

In line with current thinking on "smart regulation," the paper includes a variety of means by which stewardship goals can be achieved: codes, guidelines, standards and best practices. Within this context of smart regulation, practical issues such as: implications for Environment Canada, necessary capacity development, and a model for interdepartmental cooperative governance regarding research on ecosystem effects of GMOs are presented. The paper's final section includes a series of twelve conclusions and four recommendations. These conclusions and recommendations all support the view of the author that Canada should develop a more fully collaborative, integrated approach to stewardship of GMOs.

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Toward a Canadian Stewardship Framework for GMOs

1.0 BACKGROUND

This report was commissioned by Environment Canada to help the department better understand its role and capacity requirements, in the context of a wider federal government stewardship framework, in dealing with the environmental effects of genetically modified organisms (GMOs)[1]. The report was prompted by a number of converging issues and ideas:

1. The public wants assurance that responsible federal authorities "have their act together" in dealing with the environmental effects of GMOs (EEGMO) - the safe release of GMOs in the environment. To this end, Environment Canada believes that the department should reinforce its framework for science-based decision-making (for policy, regulations, guidelines, agreements, enforcement, etc.) with respect to GMOs. While this framework is primarily intended to aid the department, it may also have wider value in establishing a broader framework which would apply to all its departments and agencies with GMO responsibilities. Environment Canada has a science-based framework in place under CEPA, but sees merit in strengthening its roles, responsibilities and activities with respect to GMOs.

2. The Canadian Environmental Protection Act (CEPA) acts as umbrella legislation governing the ecosystem effects of new biotechnology products. A number of acts and regulations administered by other departments (see section 8) have demonstrated that their environmental regulations are equivalent to CEPA's. Thus products of biotechnology, including GMOs, are regulated by the CFIA, Health Canada, or Environment Canada according to the Canadian Biotechnology Regulatory Framework.

3. Environment Canada's responsibility with respect to GMOs is derived from The *Canadian Environmental Protection Act, 1999*, (promulgated in 1988 and amended in 1999), which provides the federal government the authority to address pollution issues. CEPA addresses substances ranging from chemicals to animate products of biotechnology (i.e. living organisms). The Act takes a preventative approach by requiring that substances be identified and assessed prior to market introduction, to determine whether they are "toxic" or capable of becoming toxic. Toxic, as defined in CEPA 1999, refers to risk to human health, the environment or its biological diversity. The Act also provides for a comprehensive "cradle-

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[1] A number of different terms are nowadays being used to describe the organisms that result from the application of genetic technologies: "products of biotechnology", "plants with novel traits", "living modified organisms (LMOs), "genetically modified crops (GMCs), "animate products of biotechnology", "genetically-modified organisms (GMOs)", and so forth. This report will use the term GMOs to include all these.

to-grave" management approach for toxic substances. Principal amendments in CEPA 1999 concerning new substances that are living organisms include a new Part to deal specifically with animate products of biotechnology[2]. However, accepted standards for approvals are sometimes not in place, and many departments are still trying to build the capacity they will need to deal comprehensively with the Act.

4. Because a number of federal departments and agencies have responsibilities regarding the environmental effects of GMOs, it will be hard to specify EC's science and policy capacity requirements for GMOs until the department's role - and other stakeholders' roles - are well understood. Once there is agreement on roles, it will be possible to develop an integrated and collaborative research agenda involving the relevant players.

5. A life cycle and ecosystem approach would help authorities to better understand where and how they should exercise stewardship responsibilities.

6. A comprehensive federal GMO stewardship framework needs to be more than the sum of individual stewardship responsibilities and activities. There are principles, roles, tools, and capacities that apply across-the-board, and it would be helpful to identify these. An effective stewardship framework will ensure that the government has a science and policy "safety net" for dealing with GMOs.

7. A comprehensive national approach to GMO stewardship will inevitably require the cooperation of different institutions from different sectors. The challenge will be for EC to be a valued partner in a federal government stewardship effort by respecting the legitimate roles of OGDAs. This implies the need for a multi-lateral mechanism - such as a federal

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[2]Part II of the Regulations was also amended to include Part II.1, which prescribes the process for notification of new substances that are living organisms, including micro-organisms and organisms other than microorganisms. Part II.1 of the NSNRs (New Substances Notification Regulations) came into force on September 1, 1997 and was amended on March 31, 2000 to reflect the legislative changes in CEPA 1999. Information from notifications under Part II.1 of the Regulations is used by Environment Canada and Health Canada to assess living organisms before they are imported into or manufactured in Canada. The assessment is to ensure that human health, the environment and biological diversity are protected. The main regulatory features of the program are the establishment of classes or groups of substances; identification of administrative and information requirements; timing of notification before import, manufacture or use outside the scope of a significant new activity notice; requirements for the departments to assess information within a set time; and specification of conditions, test procedures, and laboratory practices to be followed when developing test data. To meet the need for evaluating different categories of living organisms, information requirements are arranged into schedules for different notification groups of living organisms. Living organisms are first categorized by generic class (i.e., ,micro-organisms, organisms other than micro-organisms), and then factors such as conditions or circumstances
of introduction. This system of notification groups allows the government to match information requirements with anticipated concerns about the characteristics of specific notification group of living organisms and to ensure appropriate assessment of potential environmental and human health risks.

stewardship framework - to provide an umbrella for good science and policy for decision making.

8. Any federal stewardship framework should incorporate the science–policy principles contained in recent policy documents, such as the Framework for S&T Advice, BEST, SAGE, etc.

9. As a field where there is comparatively little international experience in regulation, new approaches may be required to deal with GMOs. Regulatory impact analysis (RIA) is one tool the Canadian government uses for regulatory reform. Requirements for RIA force regulators to think in a structured way before they act and increase the accountability of regulatory departments. Canada's RIA requirements include benefit-cost analysis, but go much further. Each proposed regulation must have a Regulatory Impact Analysis Statement (RIAS). The RIAS must: demonstrate that the proposed regulation is preferred over other policy tools to achieve the objectives; describe the stakeholder consultations that have taken place; and explain the strategy to ensure compliance and enforcement.

The objective of this assignment is to develop a discussion paper on the topic of a federal stewardship framework for GMOs, with an emphasis on the role of Environment Canada. It will address the following issues:

1. What is a stewardship framework, what are the elements of a stewardship framework, and are there generic frameworks that could serve as a model?

2. What would a federal stewardship framework for GMOs look like, and what elements should be included an GMO stewardship framework?

3. What are the implications of a federal GMO stewardship framework for the research and policy roles and capacity requirements of EC and other stakeholders?

2.0 UNDERSTANDING STEWARDSHIP FRAMEWORKS

2.1 The Stewardship Concept

A large number of public policy documents refer to the notion of *stewardship*[3], but far fewer talk about *stewardship frameworks*. In light of the growing popularity of the stewardship concept, there has been surprisingly little research about stewardship frameworks. A majority of citations discuss stewardship frameworks as a passing reference, but there is surprisingly little solid work on the topic - for instance in developing stewardship models.

The storyline that the federal government prepared for BIO 2002 has a good working explanation of the term stewardship. It discusses how stewardship:

> "...draws upon the long-standing traditions of entrusting the management of an estate to a steward who remains knowledgeable about all aspects of the property, and can be counted upon to do the right thing according to the wishes of the estate owner.
>
> "Stewardship entails managing resources entrusted to one's care, with proper regard to the rights of others, present and future ... In this case, the "estate" is Canada's capacity to develop and apply biotechnology and to manage the technology responsibly. The "estate owner" is the people of Canada - both present and future generations. The "steward" is the federal government, although Canadians also share in these stewardship responsibilities ... "Proper stewardship has many facets: helping prevent harm to people, animals or the environment; helping ensure that people and the environment can benefit from innovation; and creating the capacity to respond efficiently and effectively to the advances and new applications of a transformative technology such as biotechnology."[4]

The storyline goes on to say that stewardship means that (GMO) policymakers are concerned with:

1. Understanding the important issues, including those relating to protecting the health of people, animals, and the environment (which includes issues of biological diversity, societal values, and sustainable development);
2. Managing the risks through a strategy which adopts appropriate legislation, regulations, policies, guidelines and other means;
3. Earning public trust in the government's delivery of this strategy on behalf of Canadians, particularly by exercising transparency;
4. Making health and environmental benefits available in a timely manner; and

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[3]For example, a 31 July Google web search un-covered 818,000 references to "stewardship", but only 112 references to "stewardship framework".

[4]Source: Canadian Biotechnology Secretariat. Stewardship Storyline. BIO 2002. Don Cummer & Associates. 10 May 2002.

5. Being a responsible world leader by seeking global solutions to distributing the public benefits of biotechnology and protecting the environment.

In some respects industry - rather certain industries - is far ahead of the public sector in developing and applying stewardship frameworks. Although they may not refer to them as "stewardship frameworks", some industry sectors have incorporated the stewardship concept into their own programs. For example, the chemical industry has developed a *Responsible Care®* approach for chemical products, and CropLife Canada[5], has its *stewardshipFirst™* program[6] for genetically-modified crops. Each of these is, in effect, a stewardship framework. As we shall discuss later, these approaches have much to recommend them.

2.2 Elements of a Stewardship Framework

A stewardship framework is best thought of as a social system. The stewardship system includes: Principles, Values and Ethics; Roles and Responsibilities, Tools and Activities; and Capacities, which are applied to the sound management of a (public policy) issue (Fig. 1).

Fig. 1 Elements of a Stewardship Framework

Principles, values and ethics express the social priorities which are used to frame government's approach to an issue. For example, most people would agree that protecting native species genetic diversity in the environment is an important principle governing society's use of GMOs. Another example of an important principle comes from the federal government's *Framework for S&T Advice*, which advocates that *"Advice should be drawn from a variety of scientific sources and from experts in relevant disciplines, in order to capture the full diversity of scientific schools of thought and opinion"*. A great deal of the uncertainty surrounding GMOs today is really about uncertainty over the principles, values and ethics that people hold about nature and humankind's role in altering it. That is why no stewardship framework can ignore the explicit and implicit core principles and values that concern it.

[5]Formerly the Crop Protection Institute.

[6]*stewardshipFirst* adapts CCPA's Responsible Care approach to GM crops.

Roles and responsibilities refer to the governance and management mechanisms, authorities, and accountability of different GMO stakeholders. In the public policy context, these refer primarily to the roles conferred by an organization's charter, mission or legislation/regulations, but also to roles designated by policy and practice.

Tools and activities includes the various mechanisms (e.g. the CEPA Guideline for the Notification and Testing of New Substances: Organisms) and activities (e.g. self-assessment verification audits, annual reports) that stakeholders engage in to put the framework into action.

Finally, **capacities** refers to the knowledge, expertise, resources, infrastructure, and so forth that organizations need to have in order to be good stewards. (A large concern in many federal SBDAs with responsibility for GMOs is whether they have the capacity needed to effectively deal with the issues for which they are responsible.)

All these ingredients must work together to create an effective stewardship system. If the right principles, values and ethics are not in place, the stewardship system will be rudderless - it won't know what to value, and therefore how to act in any situation. If roles and responsibilities are not clear, then organizations and individuals won't know who is ultimately to be held accountable for the proper functioning of the system. Organizations need a panoply of tools and activities they can use to implement or act on their stewardship responsibilities. And, organizations need a certain degree of capacity - which may encompass research, policy development, legal understanding, and so on - in order to deal effectively with their stewardship responsibilities.

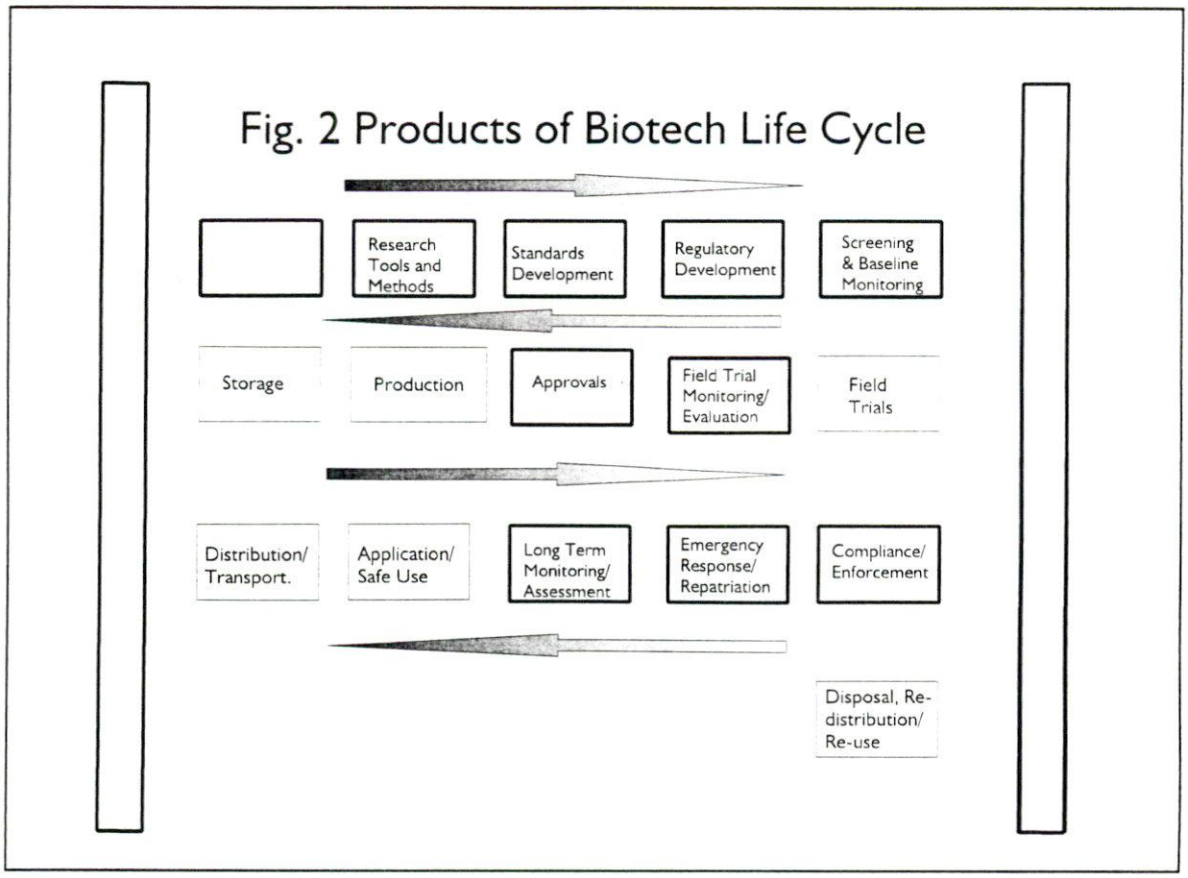
Finally, a true stewardship framework must result in a **formal system with appropriate documentation**. Unless organizations formalize and document their stewardship values, responsibilities, actions and capacities they cannot make the claim to have real stewardship systems.

2.3 A Life Cycle Approach to GMO Stewardship

Life cycle, cradle-to-grave, "lab-to-label", and like terms describe comprehensive approaches to the dealing with new substances. We can use a similar approach to think about GMOs (Figure 2). The GMO "life cycle" describes the major aspects of GMOs - from their creation in a laboratory, through to how they are disposed-of. Stewardship considerations come into play at each step in the life cycle, and so we will devote some space here to discussing the life cycle approach to GMOs. Although to simplify the discussion we have represented the life cycle as a linear process, readers will recognize that the process is often non-linear, with multiple connections, directions and feedback loops.

The GMO life cycle process includes 18 distinct steps in which industry, government and universities may each be involved. As we will discuss later in this report, the challenge for each

stakeholder is to understand what are its stewardship responsibilities at each stage of the life cycle, what tools and activities it has, or needs to develop, to carry out those responsibilities, and what capacities it will require to effectively fulfill them.



Almost by definition, the first phase of the GMO life cycle begins in a **laboratory**, where researchers and technicians use genetic techniques to create an organism with novel traits. These traits are conferred by a sequence of DNA which is taken from a related member of the species (e.g. another variety of Canola or poplar tree) or from another species entirely (e.g. injecting spider silk-producing genes in goats) and introduced into the target organism. A stewardship framework needs to take into account the activities which go on in laboratories, the places where GMOs originate, and where any environmental effects have the possibility of starting (e.g. through uncontrolled release of an experimental substance).

Advances in the **research tools and methods**, the technology that scientists use to make, analyze and test their discoveries, are a central part of the genomic revolution. Developing new equipment, techniques and testing procedures, and certifying their use, is an integral part of the GMO life cycle, and may have stewardship implications for government and others. For

example, governments often play a role in certifying the use of new equipment and methods as part of developing standards and regulations or of licensing new products of biotechnology.

Standards development is an integral part of the stewardship process. Standards development takes place in national and international scientific fora, government laboratories, and other places. Governments contribute to standards development in a number of ways; for example, by participating in international scientific fora, and commissioning standards-related R&D. A large part of the GMO debate revolves around the standards that will apply to different GMO activities; for example, field trials[7], manufacturing, storage, transportation, etc. Without accepted standards it is difficult to develop regulations.

Developing **regulations** lies at the core of public sector stewardship activities. Regulations are the principal tool that governments use to exercise stewardship over social activities. Regulations need to be science-based, and to adhere to society's values and ethics. Regulations should be based on accepted standards. In Canada, we expect biotechnology regulation to strike a balance between the potential benefits of GMOs and the potential risks.

Screening and baseline monitoring is considered to be a key element of GMO research. Knowing the current state of ecosystems - at least ecosystems deemed to be at risk of genetic change - is deemed critical to measuring any changes that may result from the introduction of GMOs into the environment. However, indiscriminate screening and baseline monitoring is potentially a limitless, resource-consuming activity. The public sector generally, and Environment Canada in particular, needs to find a strategy that will help it to set priorities for screening and baseline monitoring, and to target resources accordingly. Practically speaking, we can't measure everything, just in case the baseline knowledge might come in handy at some future time.

Field trials are an essential step in the development of many GMOs, in particular crops[8]. GMO developers use field trials not only to test the impact of genetic changes on (plant) productivity, disease resistance, etc., but also to test for environmental impacts (e.g. genetic diversity of wild relatives) and un-intended consequences (e.g. growth of pest resistance) in related and unrelated species. Field trials also help firms decide on the commercial viability of new substances.

Monitoring and evaluating field trials is a complementary GMO life cycle process. This step refers to independent, often third-party review of field trial results by regulators. (In fact, such reviews are often contracted-out to experts.) Much as pharmaceutical companies submit the results of clinical trials research to government regulators prior as evidence for the approval of a

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[7]In a health sciences context we would also include clinical trials.

[8]Field trials are also important in testing such GMOs as insects or microorganisms with novel traits.

new drug, GMO developers submit the results of field trials as evidence for approval of new products.

All GMOs are required to gain regulatory **approval** from relevant authorities. Regulating acts contain explicit guidelines and requirements for developers seeking approval for novel organisms. The approvals process is central to stewardship. A key stewardship issue is on what basis to grant approvals. For example, whether new product proponents need to demonstrate beyond a reasonable doubt that their GMO will not pose a significant risk for the native environment, or only that on the balance of probabilities the substance will have acceptable risks. In either event, what will constitute sufficient evidence of safety?

Once the relevant approvals have been granted, **production** of the GMO can begin. There are a host of stewardship issues related to production, ranging from occupational health & safety concerns for workers, to the disposal of waste materials used in production.

Many GMOs - not least those which are produced in bulk - will need to be held in **storage** for a period of time. Market or export considerations may require that certain guidelines, standards and regulations be put in place to ensure safe storage of GMO materials, for instance, to ensure their segregation from non-GMO products.

Although portrayed in the life cycle figure as a single event, **community awareness** is in fact an ongoing activity that takes place at all phases of the GMO life cycle. All stakeholders have responsibilities in connection with citizen engagement, community awareness and public participation in connection with the development of new products of biotechnology.

Distribution and transportation of GMOs can also require stewardship oversight. Codes, guidelines, standards and regulations - voluntary or mandatory - may be required to ensure safe transportation and distribution. As with some other GMO life cycle steps, jurisdictional issues - federal, provincial and even municipal - can come into play here.

When GMOs are distributed to end-users they enter the **application/safe use** phase of the life cycle[9]. Safe use of GMOs is a major issue of concern both to industry and government. Codes, guidelines and training come into play during this phase. So does certification of end-users.

Although field trials (and clinical trials) try to capture as much information as possible on environmental and un-intended effects of GMOs, they are necessarily limited in time. **Long term monitoring and assessment** is often needed to track changes that take place over time. This is especially true for new GMOs, where practical and theoretical experience of long term effects are both limited.

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[9]Some agencies, such as CFIA, argue that safe use is a tenet of the regulatory system and that safe use guidelines must be addressed before marketplace introduction can take place.

Throughout the life cycle there may be violations of codes, guidelines or regulations, and an **enforcement** function may be needed to ensure compliance. Enforcement is currently dealt with in a number of Acts, coordinated under the biotechnology regulatory framework. Enforcement is often thought of as primarily a government responsibility, but a number of industries have taken it upon themselves (for example through third-party audits) to ensure that their members comply with industry standards.

For a variety of reasons, during the life cycle of a GMO there may be a need to **dispose of** GMO materials. There may also be a requirement to limit distribution to un-authorized users (e.g. farmers not trained in their use). Thus, a GMO stewardship framework need to take into account the disposal/re-distribution/re-use issue[10].

Reporting on GMO activities is central to the principle of transparency. All stakeholders will want to engage in some form of reporting, and thus reporting is included as an item in the GMO life cycle approach.

2.4 Environmental GMO Stewardship

The federal government's biotechnology regulatory framework is the regime under which the ecosystem effects of GMOs are regulated. At the present time most GMOs which have had to be assessed are crop plants, which fall under the auspices of the CFIA.

In deciding how to approach the public policy issues presented by GMOs, the Government of Canada opted to adapt existing legislation rather than create an entirely new legislative framework. The *Canadian Environmental Protection Act, 1999* (CEPA 1999), provides the federal government the authority to address pollution issues, and gives Environment Canada a major role to play. It addresses substances ranging from chemicals to animate products of biotechnology (i.e. living organisms). Biotechnology substances not covered under other federal legislation (e.g. Food and Drugs Act, Fertilizers Act, Pest Control Products Act) come under the purview of CEPA. The Act takes a preventative approach by requiring that substances be identified and assessed, prior to market introduction, to determine whether they are "toxic" or capable of becoming toxic. Toxic, as defined in CEPA 1999, refers to risk to human health, the environment or its biological diversity. The Act also provides for a comprehensive "cradle-to-grave" management approach for toxic substances.

Living organism is defined in section 104 of CEPA 1999 as *a substance that is an animate product of biotechnology*. *Biotechnology* is defined in section 3 of CEPA 1999 as *the application of science and engineering in the direct or indirect use of living organisms or parts or products of living organisms in their natural or modified forms*. As defined in CEPA 1999, biotechnology is not limited to activities

[10]CFIA points out that it takes these conditions into account prior to approval of unconfined release.

involving genetic engineering. Living organisms subject to Part 6 of CEPA 1999 must be animate products of biotechnology and can be either naturally occurring or genetically modified.

CEPA established Guidelines for the Notification and Testing of New Substances, and these are applied to the Animate Products of Biotechnology. These guidelines explain how notifiers determine whether a living organism is subject to notification under the NSNRs and identify the applicable information requirements. In addition, the guidelines elaborate the technical information requirements, provide step-by-step instructions for the completion of a New Substances Notification (NSN) Form, and outline how confidential information should be treated.

The Domestic Substances List (DSL) is the sole basis for determining whether a substance is "new" for the purposes of CEPA 1999. A substance included on the DSL is considered to exist in Canadian commerce and is not required to be notified unless it is proposed for a significant new activity as indicated on the DSL. Substances not on the DSL are considered to be new to Canada and are subject to notification.

The main regulatory features of the program are the establishment of classes or groups of substances; identification of administrative and information requirements; timing of notification before import, manufacture or use outside the scope of a significant new activity notice; requirements for the departments to assess information within a set time; and specification of conditions, test procedures, and laboratory practices to be followed when developing test data.

To meet the need for evaluating different categories of living organisms, information requirements are arranged into schedules for different notification groups of living organisms. Living organisms are first categorized by generic class (i.e., micro-organisms, organisms other than micro-organisms), and then factors such as conditions or circumstances of introduction This system of notification groups allows the government to match information requirements with anticipated concerns about the characteristics of specific notification group of living organisms and to ensure appropriate assessment of potential environmental and human health risks.

Substances determined to be or suspected of being toxic or capable of becoming toxic may be controlled as necessary, including by prohibiting their import or manufacture. The assessment process begins when Environment Canada receives a notification under the New Substances Notification Regulations prepared by the company or individual that proposes to import or manufacture a new substance. New Substances Notifications must contain all required administrative and technical data and must be provided to Environment Canada by a prescribed date before manufacture, or import. Notification information is jointly assessed by the departments of Environment and Health to determine whether there is a potential for adverse effects of the substance on human health, the environment or its biological diversity. This assessment, which must be completed within a specified time, will result in:

1. a determination that the substance is not suspected of being toxic or capable of becoming toxic; or

2. a suspicion that the substance is toxic or capable of becoming toxic, which may require (I) controls on, or prohibition of, import and manufacture, or (ii) prohibition pending submission and assessment of additional information determined to be required by the departments; or

3. limiting the purpose for which a substance may be used to permit the waiver of information requirements defined under paragraph 106(8)(b) of CEPA 1999; or

4. a suspicion that a significant new activity in relation to the substance may result in the substance becoming toxic. In these cases, a significant new activity notice would be issued.

Under the Act, Environment Canada enforcement officers may carry out inspections in order to ensure that the activities governed by the Act are in compliance with all regulatory and legislative provisions. These inspections are part of the National Inspection Plan of the Enforcement and Compliance Policy of CEPA 1999, which was established to ensure that the Act is applied throughout Canada in a manner that is fair, predictable and consistent. Where there is sufficient evidence of a violation, enforcement officers must take the necessary and appropriate measures in accordance with the criteria set out in the Policy.

Anyone convicted of an indictment under CEPA 1999 is liable to a fine not exceeding one million dollars and/or imprisonment for a term not exceeding three years. Upon summary conviction, anyone who commits an offense is liable to pay a fine of up to $200,000 and/or serve up to six months in prison. Environment Canada acts upon violations of the regulations consistent with the Enforcement and Compliance Policy implemented under CEPA.

3.0 GMO STEWARDSHIP PRINCIPLES

At the core of any stewardship system lies a set of principles, values and ethics. Sometimes these are explicit, and sometimes implicit. For example, our earlier definition of stewardship[11] (see p. 4) explicitly states that *"Stewardship entails managing resources entrusted to one's care, with proper regard to the rights of others, present and future ..."*. Implicit here are two different principles; namely that others[12] have rights and that the rights of future generations need to be taken into account in deciding stewardship questions. How the principles are interpreted in practice - for instance, what practical meaning should society attach to "proper regard" of the "rights of others" and "future generations" - is where social divisions (and often legal divisions) come to the surface.

Many of the social divisions that arise in the debate about GMOs and their effects, are in fact arguments about the principles, values and ethics that society will apply to genetic technologies and the products of biotechnology. No stewardship framework can hope to resolve all of the potential conflicts over principles, values and ethics. However, so far as possible, stewardship frameworks need to make explicit the principles, values and ethics upon which they are based. Ideally, they will also resolve inherent conflicts among principles where they exist.

Following are a number of principles which might be considered in developing a stewardship framework for the environmental effects of GMOs (EEGMOs). This meant to be neither an exhaustive nor a definitive list. Rather, it is meant to provide a starting point for discussion on what principles should underlie an GMO framework.

3.1 Generic EEGMO Principles

Appendix 1A includes a proposed list of generic EEGMO principles; that is, principles which might apply broadly to all EEGMO stakeholders and stewardship activities. A second set of principles (see Appendix 1B and section 3.2 following) may relate to different aspects of the GMO life cycle.

3.1.1 Protection of people and the environment is paramount

A GMO stewardship framework needs to affirm the obvious. The purpose of GMO stewardship is to protect people and the environment. The challenge of this principle lies in sorting out the competing interests.

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[11]Borrowed from the BIO 2002 Stewardship storyline.

[12]Presumably, non-GMO proponents.

3.1.2 All sectors and stakeholders need to be involved

An effective national stewardship program will require more than simply a governmental response. This view is echoed in a recent report *Linking In, Linking Out, Linking Up*[13], which states:

> *The overarching conclusion of the paper is that government, industry and civil society must link together to ensure that each has sufficient voice, representation, and accountability in policy and decision-making processes on biotechnology. This is essential if the four issue areas flagged - science capacity, stewardship and credibility, leadership and public engagement - are to be addressed.*

Stewardship is not only the responsibility of government, it necessitates the proactive involvement of all stakeholders - in particular industry, but also the higher education sector. Governmental responses - for instance enforcement - tend to be after-the-fact. The key is to avoid potential problems before they arise, and not to have to deal with them after it is too late, which is why the active involvement of GMO developers and manufacturers is required. There are excellent examples of policy issues where industry has taken a proactive stance - for instance the *stewardshipFirst* program of CropLife Canada and the *Responsible Care* program of the Canadian Chemical Producers Association - and the ideal situation is to involve all stakeholders in the stewardship program.

3.1.3 Voluntary and mandatory measures are both needed

An effective stewardship system will inevitably include voluntary and mandatory measures. Voluntary measures include such items as company/university codes of conduct, and are meant to provide ethical guidance to stakeholders. Mandatory measures obviously include laws and regulations, but can also include, for example, self-imposed (and independently audited) industry association standards and guidelines.

3.1.4 Stewardship should apply at all stages of the GMO life cycle

To be effective, stewardship principles need to be applied at all stages of the GMO life cycle. Probably no single government department or agency will be primarily responsible for stewardship of every element of the GMO life cycle. Each will need to decide where to concentrate its efforts. A comprehensive government-wide stewardship framework will ensure that there is oversight at all stages, by combining the efforts and resources of multiple departments and agencies.

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[13]Source: Institute on Governance. February 2002.

3.1.5 Emphasis needs to be put on prevention

GMO stewardship needs to emphasize prevention over remediation. Given the potentially ubiquitous nature of GMOs in the environment, emphasis needs to be on preventing possible problems. In an ideal world, there would be no need for enforcement because sound stewardship would prevent undesirable situations from developing.

3.1.6 The precautionary principle should guide risk management

The Royal Society report on food biotechnology regulation[14] argues for "... the precautionary regulatory assumption (precautionary principle) - which states that, in general, new technologies should not be presumed safe unless there is a reliable scientific basis for considering them safe. The Panel rejects the use of "substantial equivalence" as a decision threshold to exempt new GM products from rigour safety assessments ...". The report goes on to recommend that "... the primary burden of proof be upon those who would deploy food biotechnology products to carry out the full range of tests necessary to demonstrate reliably that they do not pose unacceptable risks." Presumably, on this basis the precautionary principle should apply to all products of biotechnology[15].

3.1.7 Ethics should apply both to organizations and to individuals

A comprehensive stewardship approach involves an ethical component. The usual tendency is to apply stewardship ethics to organizations - companies, universities, government departments, etc. But to be truly effective, ethics need to apply to individuals as well. Much as doctors practice the Hippocratic oath, and engineers have legislated codes of conduct, individuals working in organizations that develop GMOs should also have a clear ethical framework to which they should adhere.

3.1.8 Stewardship includes an obligation for assessment

Independent, third-party assessment of adherence to codes, guidelines, practices, etc. is an important component of stewardship frameworks. Both the *Responsible Care* and *stewardshipFirst* programs incorporate this element.

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[14]Royal Society of Canada. Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada. Ottawa. January 2001. ISBN 0-920064-71-x.

[15]The CFIA points out that it currently adheres to these principles.

3.1.9 Ongoing review of past decisions based on new information

One mark of a mature stewardship system is that it incorporates the principle of "review". There is an ongoing need to review past decisions in light of new (scientific) information. Stewardship frameworks need to be open to modifying past decisions when new information becomes available[16].

3.1.10 Science-policy best practice principles should apply

The Council of Science and Technology Advisors and the Government of Canada have published a series of reports for the proper conduct of federal S&T[17]. The principles and guidelines contained in these studies should be incorporated into a GMO stewardship framework.

The principles listed above are examples of generic principles that might be adopted as part of a GMO stewardship framework. Part of the work of developing a departmental or government-wide stewardship framework is to elucidate the principles that will be adopted.

3.2 Other EEGMO Principles

The preceding principles (Appendix 1A) are generic examples that might apply to all aspects of GMO stewardship. Federal authorities will need to discuss them and determine which to adopt in a federal stewardship framework. In addition to the generic principles, Appendix 1B contains a suggested list of principles that might apply with respect to aspects of the GMO life cycle.

3.2.1 Industry Stewardship Principles

The list of sample biotech industry stewardship principles is adapted from the stewardship frameworks that have been adopted by the chemical and crop industries. As indicated in the first principle, these industries have attempted to get out in front of government regulation by adopting practices that are at least as stringent, or more so, than might be set by government.

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[16]The CFIA points out that with respect to Plants with Novel Traits, this already occurs. For example, new data arose on Roundup Ready Soybean and it was re-evaluated with this in mind. Please see the following link, specifically question 8. http://www.inspection.gc.ca/english/ppc/biotech/tech/greenrounde.shtml

[17]For example, CSTA's SAGE and BEST reports and the Framework for S&T Advice.

Biotech Industry Stewardship Principles

- Meet or exceed the spirit of current government regulations
- Be seen to do the right (and wrong) thing
- Operate with public consent
- Manage risks to level acceptable to those affected
- Include well-being in risk definitions
- Consult with the public before deciding
- Inform public of hazards, benefits, risks
- Seek informed consent
- Seek out, understand and address public concerns
- Be our own whistle-blowers
- Encourage mutual aid among companies and foster peer pressure to continuously improve
- Inform employees of link between company programs and industry stewardship programs
- Life cycle stewardship
- Contribute positively to public policy
- Seek advocates' input
- Pursue continuous improvement to meet public expectations
- Apply holistic decision making
- Apply industry standards to suppliers

3.2.2 Government Stewardship Principles

The list of government stewardship principles contained in Appendix 1B is based, in part, on the Federal Regulatory Framework for Biotechnology (1993). Added are a number of additional principles that might be considered to complete a federal stewardship framework.

Government Stewardship Principles

- Federal Regulatory Framework for Biotechnology (1993):
  (1) Maintain high standards for the protection of the health of workers, the general public and the environment; (2) Use existing legislation and regulatory institutions to clarify responsibilities and avoid duplication; (3) Develop clear guidelines for evaluating products of biotechnology, which are in harmony with national priorities and international standards; (4) Provide a sound scientific database on which to assess risk and evaluate products; (5) Assure the development and enforcement of biotechnology regulations are open and include consultation; (6) Contribute to the prosperity and well being of Canadians by fostering a favourable climate for investment, development, innovation and adoption of sustainable biotechnology products and processes
- The public interest is paramount
- Separate GM promotion from regulation roles
- Adopt burden of proof principle
- Maintenance of genetic diversity
- Meet or exceed sprit of current regulations in own GM activities
- Operate with public consent
- Inform public of hazards, benefits, risks

A government stewardship framework needs to take into account the dual role which the federal government now plays in biotechnology. Government is both a proponent and developer of biotechnology and a regulator. Some government departments and agencies (e.g. AAFC, NRCan/CFS) are actively involved in developing new products of biotechnology. Those organizations may simultaneously be involved in advising on biotechnology regulation. This implies that the principles that apply to GMOs developed in industry (or universities) should also apply to GMOs developed in government.

3.2.3 Higher Education Stewardship Principles

The higher education sector is the locale for a great deal of biotechnology research. Universities adhere to national guidelines on biotechnology-related research that have been put in place by research funders[18]. Similarly, most institutions have ethics committees, which must vet certain research proposals. What is missing from the university scene - as it is in government research - is a system of personal accountability.

Higher Education Stewardship Principles

- Adherence to national guidelines on biotechnology research
- Adherence to university guidelines on human, animal research
- Publication in peer reviewed journals
- Provide GELS training for all young researchers

4.0 APPLYING THE LIFE CYCLE MODEL TO GMO STEWARDSHIP

Figure 2 detailed the major stages of the life cycle of GMOs. Most - if not all - of the stages have public policy stewardship implications and may require some level of response by (federal) government authorities[19]. The Institute on Governance report[20] concluded that the Canadian Biotechnology Strategy:

> *... sets out key themes and possible actions to be considered for implementation. It does not, however, outline a government-wide strategic action plan with well-defined cross-departmental objectives.*

One value of the life cycle model is that it can help individual organizations with GMO responsibilities to:

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[18]e.g. Human reproductive research guidelines and animal care guidelines.

[19]Some roles may fall to provincial or municipal governments.

[20]February 2002. Ibid.

1. Delineate their roles and authorities at each stage of the life cycle: in other words, decide whether and where they have a stewardship obligations;

2. Identify the science and policy "tools" they will need to exercise their responsibilities; and,

3. Determine the capacity - personnel, infrastructure, research, networks, etc. - they will require to carry out their responsibilities.

In addition to helping individual organizations to determine their stewardship roles, the life cycle approach can help authorities to identify the strengths and weaknesses of government-wide stewardship activities.

4.1 Stewardship Roles and Responsibilities

Included in Appendix 2 is a sample list of stewardship roles and responsibilities that apply to the major GMO stakeholders, industry, government and the higher education sector[21], presenting according to each element of the biotech/GMO life cycle. The table assumes that the biotechnology industry will adopt a GMO stewardship program similar in nature to the *stewardshipFirst* and *Responsible Care* approaches now being used in the crop and chemical industries[22]. As before, the list of roles and responsibilities is not meant to be authoritative; each organization will want to adapt/amend the list according to its own situation.

4.1.1 Laboratory Research

Industry, government and the higher education sector all have important stewardship roles to play during the laboratory research phase of GMO development (Appendix 2). The **biotech industry** will want to train and certify laboratory personnel working on GMOs; for example, to ensure that health and safety standards are applied to the work, and that adequate precautions are taken to eliminate the risk of environmental release. Industry will also want to adopt or establish laboratory best practices. Industry will also want to be consulted as and when government departments and agencies establish research guidelines.

The first responsibility of government organizations is to apply the same (high) laboratory standards as industry is adopting, to their own laboratory work. This would include certifying their own lab personnel working with GMOs and otherwise adopting laboratory best practices in their own research. In addition, government funding

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[21]A similar approach might be taken with non-governmental organizations.

[22]As of August 2002 there are strong indications, based on discussions with BIOTECanada, that such an approach will be adopted by the industry.

organizations (e.g. CIHR, NSERC, Health Canada, etc.) will likely have a hand in establishing GMO research guidelines. These organizations will also be funding public good and commercial biotechnology research, and will need to apply good stewardship practices in their funding activities.

A majority of the GMO research will inevitably be conducted in the **higher education** sector. The higher education sector is also training researchers, technicians and technologists. This sector needs to develop curriculum - which should include, for example, GELS[23] orientation. Ideally, universities and colleges should be certifying their own instructors in a program similar to that adopted by industry and government. The higher education sector can also offer personnel certification to third-parties; i.e. industry and government researchers.

4.1.2 Research Tool Development

The development or research tools - equipment, software, reagents, tests, models, etc. - proceeds in tandem with GMO research. **Industry** is both a developer and user of biotechnology research tools. For the most part, companies use "industry-standard" research tools which have been developed or certified by other companies or by governments.

Governments are often involved in certifying or validating the use of research tools. For example, a government department might specify that a test result (e.g. of the concentration of a toxic substance in potable water) must be measured using a specific test. Some government departments offer third-party certification of laboratory standards and procedures. Governments often fund the development of new (biotech) research tools, for instance through Granting Council funding or different forms of industry support[24]. Government researchers are also users of "industry-standard" research tools, as are researchers in the **higher education** sector.

Thus, some level of government involvement is almost inevitable in the area of research tool development, and those departments so-involved will need to sort out their roles and responsibilities in this area.

4.1.3 Standards Development

Developing standards that apply to different stages of the GMO life cycle - research, trials, application, manufacturing, storage, transportation, environmental effects etc. - is a

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[23]GELS = Genomics Ethical Legal and Social

[24]e.g. Technology Partnerships Canada

central challenge of this rapidly-evolving field. For example, the recent report of the Canadian Biotechnology Advisory Committee (CBAC) stated:

> *"We emphasize that before any labelling system, whether voluntary or mandatory, can be introduced, an effective, agreed-upon standard is essential".*[25]

CEPA *"takes a preventative approach by requiring that substances be identified and assessed, prior to market introduction, to determine whether they are "toxic" or capable of becoming toxic. Toxic, as defined in CEPA 1999, refers to risk to human health, the environment or its biological diversity. The Act also provides for a comprehensive "cradle-to-grave" management approach for toxic substances."*

Biotechnology presents a seemingly un-ending list of standards-oriented challenges, as new techniques are developed and new organisms created. To a large extent, the standards issue revolves around assessing the risk profile of different substances: What amount of substance X (in the environment), if any, is deemed safe? How is safety to be judged; are any environmental effects acceptable, or must new substances have zero environmental effects? How will environmental effects be measured? How can non-effects be proven? Under what circumstances can new substances be used? These are all standards-development issues, and without standards, it is difficult to establish regulations.

Industry has an important role to play in advising government on proposed standards, and in many instances in providing scientific or technical information upon which the standards will be based. Consistent with the principles of industry stewardship programs, companies are responsible for self-auditing their adherence to established standards, and in some instances, for undergoing third-party audits.

Government organizations are trying to develop the capacity for standards development across a wide range of GMO life cycle activity. Some of the scientific input to standards comes from government labs with expertise in the area. Some will come from adopting/adapting emerging international standards. Some will come from research conducted by the **higher education** sector; for example, safety, efficacy or validation studies.

4.1.4 Regulatory Development

Once standards are in place it is possible to develop a more comprehensive regulatory regime for GMOs. **Industry** will advise government on draft regulations, and adhere to

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[25]Canadian Biotechnology Advisory Committee. Improving the Regulation of Genetically Modified Foods and Other Novel Foods in Canada. Report to the Government of Canada. Ottawa. August 2002

the regulations once they are promulgated. **Government** will conduct or sponsor regulatory research in support of developing science-based regulations. Government will adopt regulations that apply to new substances in general and to GMOs in particular. Government will also align domestic and international regulations. The **higher education** sector will provide scientific input into regulatory development.

The federal government will need to recognize that roughly 95% of the knowledge required for GMO standards and regulatory development will come from sources outside of Canada[26]. This implies that government organizations will need to engage in a considerable amount of assessment activity. Resources for original research will need to be concentrated in areas of special importance to Canada; for example, ecological niches which are unique to this country.

4.1.5 Screening & Baseline Monitoring

Understanding the current state of the environment is often a prerequisite for measuring whether a new substance (GMO) will have environmental consequences. Two cases in point arise in a 17 August 2002 report in *New Scientist*. Although these relate to farmed crops and their effect on similar plants, one can easily imagine a situation in which genetic effects are felt further afield.

> *Weeds have been shown for the first time to become stronger and fitter by cross-breeding with genetically engineered crops, in this case sunflowers ... Allison Snow's team at Ohio State University has shown in controlled tests that wild sunflowers, considered a weed by many farmers in the US, become hardier and produce 50 per cent more seeds if they are crossed with a GM sunflower resistant to seed-nibbling moth larvae. 'We were shocked', says Snow ... 'I just think we need to be careful because genes can be very valuable for a weed and persist for ever once they're out there'" (p. 11).*

Another item in the same report said:

> *"Studies of normal beet fields by Henk van Dijk and his colleagues at the University of Lille in France suggest that they have underestimated the likelihood of GM beets swapping genes with the beet weeds that grow among them. 'We found gene flow to be possible between all forms' ... the situation with beet is particularly complicated because there is a two-way flow, with weed genes often polluting farm strains and reducing yields. The beet weeds could become even more of a nuisance to farmers if they pick up herbicide-resistance genes ... while (technical measures) could reduce the chance of gene spread, they would not eliminate it. 'It's almost inevitable' (van Dijk) says." (p. 11)*

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[26]Canada produces on average roughly 3-4% of the world's scientific knowledge, and perhaps slightly more in the field of biotechnology, where Canadian researchers are particularly adept.

Industry will frequently conduct baseline monitoring as part of a field trial of a new substance. In fact, such studies may be necessary for approval under various pieces of federal legislation. However, this type of baseline monitoring tends to be local in nature (e.g. environmental impacts of substance X on surrounding crops, wildlife, insects, micro-organisms, etc.), rather than regional (e.g. long-distance transport of substance X).

The challenge for **government** is that it faces a potentially limitless requirement for baseline monitoring - sunflowers, canola, corn, salmon, etc. Will government undertake baseline (environmental) monitoring for every new substance? How will it determine when to conduct baseline monitoring? A related dilemma is whether it will require GMO developers - the direct beneficiaries of the research - to pay for the cost of long term monitoring. Also, there may be a need to determine the standards that proponents must meet in conducting baseline monitoring.

As indicated in the foregoing sunflower example the **higher education** sector has an important role to play in undertaking baseline research studies. Some of these studies will be investigator-driven, using funds from NSERC, CIHR, etc. Others will need to be paid for directly by government departments and agencies.

4.1.6 Field Trial Monitoring

Monitoring of field trials in progress is of joint interest to industry and government. **Industry** will want to monitor field trials to ensure that trials are being carried out according to design protocols. **Government** may want to monitor field trials to ensure that they conform to the research protocols upon which they were approved[27].

4.1.7 Approvals

Approving new GM substances under CEPA (and other federal legislation) requires that **government** agencies review the information submitted by proponents and determine whether the substance in question will have negative environmental (human, animal, etc.) impacts. There may be time limits placed upon government review (as in CEPA), which adds urgency to the approvals function. Because there is a potentially enormous range of new (GM) substances with largely uncharted environmental effects, departments and agencies involved in the review process need access to a considerable amount of expert scientific advice. Establishing a scientific-administrative system to review new substances is a considerable challenge, which is likely to grow in the future.

4.1.8 Production/Manufacturing

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[27]This is already included in CFIA's Regulatory directive 2000-07: Guidelines for the environmental release of plants with novel traits within confined field trials - Section 3.3 as well as their amendments.)

Once new substances gain regulatory approval, developers are free to undertake production. As with any new substance (pharmaceutical, pesticide, etc.) there is a need to establish manufacturing standards covering such issues as worker health and safety, safe storage, quality control, product labelling, etc. Many of these standards will be developed in **industry**, but there may well be a **government** oversight role.

4.1.9 Community Awareness/ Public Participation

Although the life cycle model portrays community awareness/public participation as a discrete activity, we well recognize that it applies at all stages of the GMO life cycle. Individual GMO developers need to engage in a dialogue with stakeholders about the impacts and benefits of the substances they produce. **Industry** associations need to engage in dialogue about the impacts and benefits of the biotechnology enterprise writ large. The challenge for **government** is to inform the public of the safeguards - the "stewardship safety net" - they have created.

4.1.10 Storage

Storage of GMOs is another stage in the life cycle where stewardship considerations come into play. **Industry** will want to establish storage standards as part of any stewardship program it may develop. **Government** will want to validate any standards developed by industry. Government may also have a role to play in monitoring (safe) storage of GMOs.

4.1.11 Distribution/Transportation

Safe transportation of GM substances can be an important public policy issue. For example, in a worst-case scenario, a GM substance that might ordinarily require level-4 facilities[28] will from time to time need to be transported. **Industry** will want to ensure that it has best-practice transportation techniques and that it complies with existing guidelines or regulations. **Government** will need to review existing transportation guidelines and regulations to ensure that they adequately cover such materials. Government may also have an oversight role to ensure safe transportation of materials.

4.1.12 Application/Use

For the most part the preceding (10) stages of the GMO life cycle come before their application or end-use (by farmers, doctors, consumers, other researchers, etc.). Sound stewardship of GMOs will also likely require that **industry** put in place training programs

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[28]For example, a highly infectious virus.

for sales personnel or end-users[29]. In some instances there might also be a requirement that these individuals also take a safe-use certification program. **Government** may want to develop safe use guidelines (or validate guidelines developed by industry).

4.1.13 Long Term Monitoring/Assessment

Unlike field trial monitoring, which tends to be shorter term in duration (e.g. 1-3 crop years), in some instances there will be a need for long term monitoring of environmental effects. This may be particularly relevant when new classes of substances are introduced for which there is little existing information. **Industry** may well undertake long term monitoring of local environments where field trials have/are taking place, but this is by no means assured. Oftentimes, responsibility for long term monitoring will fall to **Government** organizations. (For example, in a situation analogous to abandoned mines, responsibility for "abandoned GMOs" may well fall to government.)

4.1.14 Emergency Response/Repatriation

On occasion monitoring and assessment activities or international trade may reveal an environmental problem with a GMO previously approved for release or use. In these situations, there may be a need for an emergency response, or even repatriation of a GMO from abroad. For its own commercial reasons (e.g. to secure insurance coverage) **industry** will want to have in place a contingency plan to deal with emergency response to GMO problems. That will involve establishing "cleanup" practices and training emergency response personnel. **Government** will want to participate in international (cleanup) standard development, and to adopt cleanup standards, guidelines and regulations. In some particular emergency situations government will need to monitor industry's emergency response actions, and in others it will need to undertake the cleanup itself.

4.1.15 Enforcement

Federal regulations mandate an enforcement function, with significant penalties for major violators. **Industry's** role is to avoid enforcement by implementing good stewardship practices in the development and use of GMOs. **Government**, on the other hand, needs to establish enforcement standards, monitor company compliance with regulations, and enforce standards when required.

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[29]This has already happened in the chemical and crop industries.

4.1.16 Disposal

Toward the end of the GMO life cycle, disposal issues will come into play. Disposal issues surround the GMOs themselves, but also the containers in which they are shipped and stored. **Industry** will want to establish product disposal and container disposal guidelines. **Government** will want to establish standards for safe disposal and monitor disposal practices.

4.1.17 Reporting

Like community awareness/community participation, reporting is a theme that runs throughout the GMO life cycle. **Industry** and **government** each need to establish reporting guidelines to shareholders, employees, customers, stakeholders and the public.

4.2 Conclusion

The framework model proposed in this report implies that governments and other stakeholders should take a more comprehensive approach to assessing the safety of GM substances than the limited new substance assessment approach which is required under current legislation. For the most part, current legislation only requires the federal government to assess the apparent safety (for people, animals and the environment) of new GM substances. Yet, from a stewardship perspective, legislation overlooks other aspects of the potential impacts of new substances.

The current regime operates as, for example, Transport Canada were to certify the safety of a new aircraft (cf. GMO) without also having in place an air traffic control system (cf. GMO stewardship system) which would ensure that the aircraft could safely fly from one place to another: in this instance the aircraft would be safe, but the air transportation system would not be. Another example would be if Justice required the registration and testing of firearms, but there was no legislation on the use of firearms. Federal legislation requires SBDAs to certify the safety of new substances themselves, but it does not require them to certify other important aspects of safe use[30].

A central requirement of a working GMO stewardship system is that major interests - industry, government, and the higher education sector - must first explicitly delineate their respective stewardship roles at each stage of the GMO life cycle, and then adopt the measures needed to fulfill their roles in a socially and scientifically responsible way. Practically speaking, in an open society such as Canada, this will take place through the application of voluntary and mandatory stewardship measures within a social system that allows for checks-and-balances among competing interests.

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[30]For instance, safe transportation, storage, operator training, and so forth.

The preceding discussion of GMO stewardship roles and responsibilities is not meant to be either comprehensive or prescriptive; rather, it is intended to provide concrete examples that GMO stakeholders can use to understand and develop their own roles and responsibilities in ensuring the safe and beneficial use of the products of biotechnology. In our opinion, for a country, industry association, company, government, government department/agency, university or college to claim that it is indeed exercising sound stewardship, each interest will need to document its own GMO stewardship roles and responsibilities. A true stewardship system needs to be formal, in the sense that those responsible for stewardship need to be able to provide an "accountability trail" for their stewardship responsibilities.

5.0 STEWARDSHIP TOOLS AND ACTIVITIES

Appendix 3 illustrates a variety of mechanisms, tools and activities - codes, guidelines, standards, best practices, etc. - that different GMO stakeholders can use or are using to carry out with their stewardship responsibilities at each stage of the GMO life cycle. Many of the tools and activities listed are already in use, in such industry programs as *Responsible Care* and *stewardshipFirst*, or in such government stewardship initiatives as CEPA. Others listed have been proposed in such studies as the Royal Society report on biotechnology food safety[31], and may not yet be in place. The list of tools and activities is not meant to be authoritative or comprehensive; each organization will need to select or develop the stewardship tools that are most appropriate to its role and capacities.

In adopting stewardship tools and activities, Government will need to consider its split role with respect to GMOs and adopt the appropriate set of tools depending on whether its role is that of GMO developer or regulator. In general, government departments and agencies that are in a GMO development role should apply industry best practices to their development activities. When acting in a regulatory role, organizations need to adopt a different set of stewardship measures; those which support public good stewardship.

Discussion with two biotech industry associations[32] indicate that the industry is moving in a proactive way to voluntarily develop and adopt a comprehensive set of stewardship programs, tools and activities. With large sums of money invested in the future of the industry, biotech companies are concerned that an untoward incident could delay or even negate the industry's ambitious product development plans. For that reason, the biotech industry as a whole, along with sub-industry groupings (e.g. plant science, animal science, etc.), are keen to implement an effective voluntary stewardship program. They are drawing their inspiration from the chemical industry's *Responsible Care* model. As such, the industry will rely on a system of voluntary codes, guidelines, standards, and best practices for biotech stewardship. (In addition, industry will

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[31] Op. cit.

[32] BIOTECanada and CropLife Canada

comply with codes, guidelines, standards, and regulations that are put in place by government.) Following is a discussion of how codes, guidelines, standards and best practices can contribute to sound GMO stewardship.

5.1 Codes

GMO stewardship codes are sets of conventions governing the behaviour of associations, companies and individuals operating in the field of biotechnology. Codes may or may not have a third-party compliance or enforcement component. For example, the Canadian Chemical Producers Association's *Responsible Care* program requires third-party audits of company compliance. Presumably, companies found not to be in compliance will be given an opportunity to improve their practices, and in the worst case could face expulsion from the industry association. Other codes - such as labour standards codes - could be enforced by government authorities.

A good example of a voluntary code is CropLife Canada's[33] Marketing Code of Standards that is meant to govern members' marketing activities. The marketing code includes a Code of Ethics, which commits companies to abiding by such values as:

> *Members will comply with all laws and regulations governing the research, development, production, distribution, storage, advertising, promotion, sale and use of crop protection products;*
>
> *Members will constantly seek ways to protect the environment through innovative packaging, management of waste and storage of products; and,*
>
> *Members will develop programs and professional standards of self-regulation to demonstrate responsible conduct and industry leadership.*

The CropLife marketing code also contains items related to: standards for industry personnel, guidelines for maintaining health, safety and protection of the environment, guidelines on handling product performance inquiries, guidelines for advertising and promotion, guidelines for the management of pest resistance, a position statement on television advertising, a compliance policy, and so forth. As indicated in Appendix 3, we envisage that an effective industry stewardship system would include such codes as:

- Professional code of conduct
- R&D code of practice
- Environmental code of conduct
- Manufacturing code of practice
- Marketing standards code of standards
- Code commitment/compliance verification
- Etc.

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[33]Formerly the Crop Protection Institute

It appears in the biotechnology sector that codes tend to be developed and adopted voluntarily, typically by industry associations. However, there is no reason that such codes should not apply equally to government biotechnology development activities.

5.2 Guidelines

A GMO stewardship guideline is a general rule, principle, or piece of advice. Guidelines are typically less prescriptive than codes or standards, and are not normally monitored by outside parties or have formal sanctions attached to them. Nevertheless, guidelines are an important component of stewardship frameworks. We envisage that a comprehensive industry stewardship program would include the following types of guidelines:

- Health and safety guidelines
- Laboratory biosafety guidelines
- Research guidelines
- Field trial guidelines
- Safe use guidelines
- Cleanup guidelines
- Disposal guidelines
- Etc.

Some guidelines (e.g. health and safety) might also be reflected or embodied in formal codes and (government) regulations, in which case they could be subject to external review and possibly to enforcement.

5.3 Standards and Best Practices

A (GMO) standard is a required or agreed level of quality or attainment that applies to the processes and products of biotechnology. A best practice is a commendable example of how a standard is developed or implemented. Standards may be set by governments (e.g. field trial standards, Xenotransplantation standards), by international organizations (e.g. laboratory standards), by professional societies (e.g. professional standards), and so forth. One of the key responsibilities of government is to work with industry and the higher education sector to determine what parts of the GMO life cycle require associated standards, and then to determine how and by whom the standards should be set. As discussed above (see Roles and Responsibilities), because biotechnology is moving so rapidly, standards development is inevitably lagging behind. Following are some examples of where GMO standards might be required:

- Laboratory standards
- Warehousing and storage standards
- Field trial standards
- Greenhouse standards
- Labelling

- Allergenicity standards
- Transportation standards
- Long term monitoring standards
- Transgenic animal standards
- Assisted human reproduction standards
- Xenotransplantation standards
- Product quality standards
- Audit standards
- Safe disposal standards
- Etc.

In many instances, responsibility for standards development can be shared between government and industry. Industry often has the technical expertise needed to frame standards, and at a minimum needs to be consulted on new standards, in order to balance the social and economic imperatives of biotechnology. Along with standards development, it is often useful to illuminate best practices - essentially, case studies that demonstrate how codes, guidelines and standards are being implemented in a sound way, in the real world. A catalogue of exemplary practices - for example in the form of case studies - can be a useful practical guide for organizations and individuals.

5.4 Other Stewardship Tools and Activities

Apart from codes, guidelines, standards and best practices, there are a number of additional tools that can and should be used for GMO stewardship. **Scientific research** is chief among them. The state of knowledge of the environmental effects of GMOs is still under-developed; worldwide, large scale longitudinal studies of environmental effects are in their infancy. Inevitably, most of the world's scientific knowledge in these areas will be created outside of Canada[34]. This implies that Canada should devote its limited GMO (environmental effects) research funds to studying the effects of GMO products and processes on environmental niches/ecosystems which are critical or unique to this country. For example, given the economic importance of GM canola to Canada, and given that most canola is produced in Western Canada, it would make sense that there be a research program which examines the environmental effects of GM canola in that region.

There might be merit in launching an environmental effects research program to accompany the field trial stage of each significant new GM product judged to have potential environmental effects[35].

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[34]Canada produces roughly 3-4% of the world's scientific knowledge, and perhaps slightly higher in the case of biotechnology.

[35]It might not be necessary to have an environmental effects research program for every GM product; some of these will not find their way into the environment.

Scientific research is also needed to establish many standards; for example, allergenicity standards, transgenic animal standards, GM food testing protocols, plant nutrient profiles, and so forth. Once again, as resources will be limited, choices will need to be made in terms of when Canada should lead standards research projects, when it should participate in other countries' studies, and when it should simply monitor world research to glean the needed information.

Public consultation is another important stewardship tool. While industry will be mostly concerned with product-specific consultations, government needs to take a more holistic approach to consultation. Government's chief concerns are public consultation surrounding its own stewardship roles, activities and capacities, as well as new product-specific consultation.

Third-party verification is a practice that is well-established in industry and government stewardship programs. Audits, independent scientific advisory committees, expert review committees and the like are important tools. Appendix 3 refers to their use at different stages of the GMO life cycle.

Expert/peer review committees, advisory committees, and similar bodies are also important tools for GMO stewardship.

6.0 STEWARDSHIP CAPACITIES

Organizations that have stewardship responsibilities also require the capacity to fulfill those responsibilities. Because GMOs are just now finding their way into the economy and the environment in significant numbers, GMO stewardship is a comparatively new responsibility for most government departments and agencies. Although the volume of requests for new GMO substance approval under CEPA[36] is still relatively small, most observers agree that we are only seeing the beginning of a growth trend. The issue facing many federal SBDAs is how to develop the capacity they will need for sound stewardship of GMOs in the future.

As this report argues, a sound stewardship regime for GMOs requires that responsible authorities exercise oversight of aspects of GMO development, trials, end-use applications and long term effects, at each stage of the life cycle. In our view, industry - and to some extent the higher education sector - will concentrate its GMO stewardship activities at the development and trials end of the spectrum. A large part of the stewardship burden for monitoring long term effects (and unintended consequences) will accrue to the public sector. That said, many stewardship functions will - and as argued above should be - a joint responsibility of industry and government.

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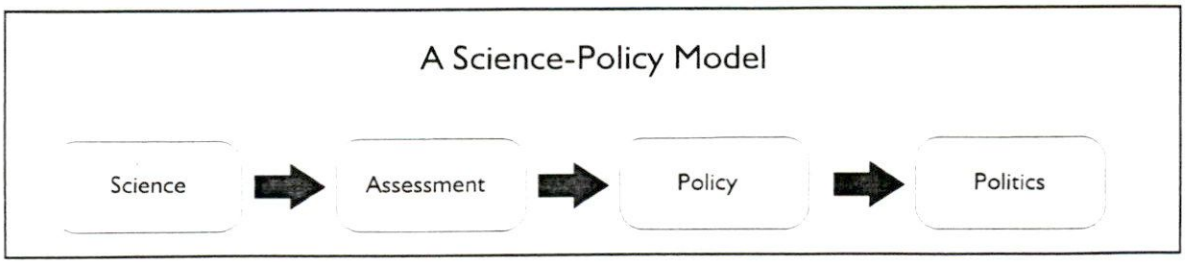
[36]And other federal legislation dealing with GMOs.

From one perspective, GMO stewardship poses the same sorts of challenges as any other public sector stewardship responsibility. Government's GMO capacity requirements follow from a simple science-policy model. In order to create stewardship policy and exercise its public good responsibilities, government requires a capacity both for **science** and for **assessment**.



In the situation of Environment Canada, legislation such as CEPA places primary GMO onus on government to assess other people's science; i.e. the science that forms part of new substance applications Given that most of the scientific knowledge relevant to GMO stewardship will be produced outside of Canada, a robust capacity to access, assess and apply scientific knowledge produced by other countries is a primary requirement for SBDAs[37]. Some in-house science capacity to sustain or develop a knowledge base for assessment may also be required. However, in our view, investing in in-house infrastructure at this time should be considered on a case-by-case basis.

Whether considering government's GMO science, assessment or policy capacity requirements, stewardship needs will inevitably fall into three broad categories: **personnel**, **infrastructure (facilities and equipment)**, and **institutional arrangements**.

The dilemma for government is to know at an operational level what stewardship capacity is required, and how to build it. A key issue will be whether all the capacity required for government stewardship of GMOs needs to be established in-house, or whether it can reside elsewhere (higher education, industry, international sources) and be accessed by government as-needed.

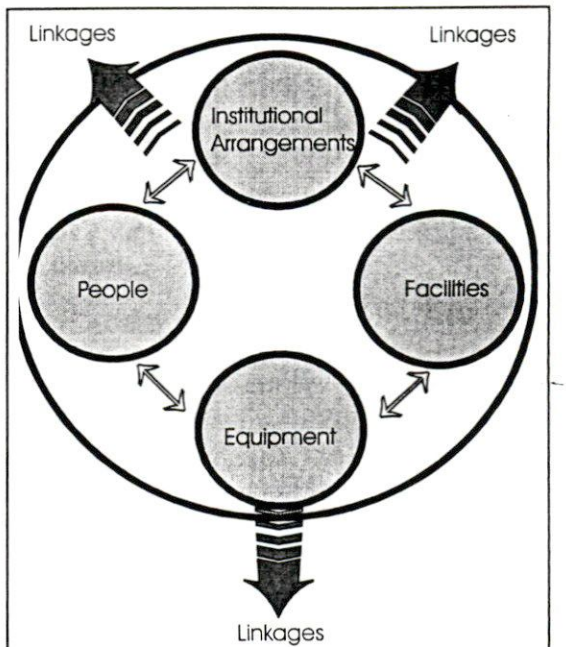


Fig. 2. A Science Capacity Model

[37]SBDAs with a large GMO development capacity will obviously need to invest correspondingly in their own science capacity.

It is beyond the scope of this report to advise on the specifics of each SBDA's stewardship capacity needs and solutions. Each SBDA with GMO stewardship responsibilities will need to determine its own capacity requirements, in light of whether it is primarily a GMO developer or regulator, and how to address those requirements in the short and long term.

Such exercises should include an evaluation of national GMO stewardship capacities in a particular policy field (agriculture, fisheries, health, etc.); that is, the state of Canada's overall GMO personnel and infrastructure capacity. The reason is to help government organizations understand their make-or-buy options. In general, government should avoid building capacity "in case" it is required. If the capacity exists in other institutions and sectors, the government has the option of purchasing capacity when it is required.

Appendix 4 describes some of the types of stewardship capacity that government will require for dealing with GMOs and their environmental effects. Again, it is not meant to be a comprehensive list of capacities - that is for each SBDA to determine on its own - but rather to indicate the various kinds of capacity needs that may come into play.

In our view, the strongest argument to be made for original Canadian government investment for GMO science and assessment stewardship lies in creating knowledge in those ecological or environmental niches which are unique to Canada. Other relevant knowledge can be drawn from world science.

6.1 Personnel Requirements

Sound GMO stewardship begins with people who have the expertise needed to understand and assess the science and policy issues concerning GMOs. In principle, 3 kinds of personnel are required.

6.1.1 Science

Depending on the department or agency involved, and its main GMO role (developer or regulator), it may have a need to recruit practising bench scientists with hands-on GMO expertise (e.g. for gene manipulation). Organizations primarily developing GMOs will need different science expertise than those with a primary assessment function.

6.1.2 Assessment

All organizations that have a mandate for GMO assessment - and this largely describes Environment Canada's role - will require people with the ability to access, understand and apply current scientific knowledge to the process of assessing new substances. These individuals will require a substantive hands-on science background in different fields of genetics research (microbiology, genetics, crop science, veterinary medicine,

etc), and the ability to keep up-to-date with new developments in the field. This may require some hands-on in-house research activity.

6.1.3 Policy

To fulfill their GMO policy requirements, government organizations need individuals with a mix of skills which are social-science oriented in nature: legal, economic, enforcement, communications, policy, etc. In principle, the GMO policy stewardship requirement is no different than that posed by other government science-policy stewardship files. The challenge is to build up and sustain policy groups with GMO-oriented expertise.

Overall, we have strong reservations that government can afford to develop all the in-house expertise it will conceivably require to deal with GMOs when they are more prevalent than they are today, simply "in case" the expertise is required in the future. A strategy that balances investment in in-house resources with total requirements is therefore called for.

6.2 Infrastructure Requirements

Certainly, organizations that have a significant GMO developer mandate will require infrastructure - buildings and equipment - with which to carry out their mandates. Each organization will develop a business case for its requirements, and the normal government allocation processes will consider the different cases.

However, it is far less apparent that organizations whose primary role is assessment will need to build up their own research infrastructure. Far better, in our view, to utilize the external investments that government is making in national genetics expertise and infrastructure; for example, through such programs as Genome Canada, the Canada Foundation for Innovation, Canada Research Chairs, the Granting Councils, and so forth. How to accomplish that requires development and exploitation of institutional arrangements between and among government organizations and the outside world.

6.3 Institutional Arrangements

Around the world and in Canada, governments are investing large sums in their national GMO science capacity and infrastructure. They key for many Canadian government organizations will be to address their expanding GMO science, assessment and policy needs by leveraging their limited resources through enhanced arrangements with other international and national institutions and organizations.

Many of these arrangements can be accommodated through investments and participation in what we would generically term "research networks". For example, Environment Canada might sponsor and participate in "environmental effects research networks", Health Canada in "human effects research networks", Agriculture Canada in "plant effects research networks", and so forth. Active participation in international science and policy networks is another way of gaining access to the knowledge needed for domestic GMO stewardship.

The strength of this approach is that it allows governments to tap into the latest and best science for their own policy needs, at a lesser cost than doing everything themselves. The weakness of the research network approach to gaining knowledge for GMO stewardship is that research networks can be unwieldy, and it can be difficult to directly influence their research agenda unless the government sponsor is paying a majority of the associated costs and assuming a leadership role. Research networks also tend to produce results in the medium and long term, and situations will undoubtedly arise in the future that call for a short term science response. In these situations, contractual arrangements with different sources of expertise are required, combined with some in-house capacity.

Nevertheless, government will necessarily rely on arrangements with outside organizations, institutions, individual experts, and expert groupings[38] to supply a large part - perhaps the majority - of the GMO stewardship knowledge they will require.

7.0 GMO STEWARDSHIP - IMPLICATIONS FOR ENVIRONMENT CANADA

At the present time Environment Canada's GMO stewardship role is primarily that of regulator: assessing the environmental risk of GMOs which do not fall under the purview of other government departments. A case in point is transgenic animals[39], which are not presently covered under other departments' legislation and therefore fall under CEPA. In fiscal 2001-02 Environment Canada staff dealt with no more than 5 GMO new substance notifications. EC staff estimate there are currently no more than 30 notifications in the pipeline, which could reach them in the next year or more.

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[38]For instance, Expert Advisory Committees.

[39]Organisms that contain genes from other non-related species.

The department's present EEGMO challenge is determining what capacity it will require in the future to deal with its assessment and enforcement responsibilities, in the face of an expected increase in the number and variety of GMO applications under CEPA. A related concern is how to acquire the needed capacity to fulfil these tasks. The department's dilemma is that it is simply not possible to build a broad-enough in-house science and assessment capacity to cover every future contingency. Similarly, knowing how to go about enforcing GMO legislation and regulations is largely uncharted territory. The dilemma is compounded by the fact that environmental effects may only become apparent in the medium or long term, by which time new substances may have already gained approval.

Federal Risk Management Model

Impact	Risk Management Actions		
Significant	Considerable management required	Must manage and monitor risks	Extensive management essential
Moderate	Risks may be worth accepting with monitoring	Management effort worthwhile	Management effort required
Minor	Accept risks	Accept, but monitor risks	Manage and monitor risks
	Low	Medium	High
	Likelihood		

Under existing legislation Environment Canada's principal role is to assess the safety of new substances. Currently, assessments are largely based on two sources of information: information on environmental effects which is supplied by applicants (often in the form of field trial or equivalency data), and information from the scientific literature. Once a preliminary risk assessment has been made, it is presumably put through the "filter" of the federal government's Integrated Risk Management Framework[40]. The purpose of the Integrated Risk Management Framework is to:

- *provide guidance to advance the use of a more corporate and systematic approach to risk management;*
- *contribute to building a risk-smart workforce and environment that allows for innovation and responsible risk-taking while ensuring legitimate precautions are taken to protect the public interest, maintain public trust, and ensure due diligence; and*
- *propose a set of risk management practices that departments can adopt, or adapt, to their specific circumstances and mandate.*

The Risk Management Framework contains a model that can be used to balance risks against government management actions (see chart at right). However, the Risk Management

[40]Treasury Board of Canada. Results for Canadians. Ottawa. March 2000.

Framework provides little concrete guidance on what constitutes "significant", "moderate" or "minor" impacts, leaving that judgement to managers.

A potential weakness of the current assessment process at EC is that it does not permit sufficient time for managers to routinely seek outside expert advice (on potential environmental effects). As such, the current assessment process risks running counter to the federal government's Framework for Science and Technology Advice, which states that "*Advice should be drawn from a variety of scientific sources and from experts in relevant disciplines, in order to capture the full diversity of scientific schools of thought and opinion*". A complicating factor is that the CEPA guidelines require that reviews normally be completed within 90 days of submission of a complete application[41], and this may not be sufficient to organize an external scientific review. By definition, CEPA puts Environment Canada (and other SBDAs) in a reactive position, in which it must respond in a comparatively short time frame (90 days) to specific requests for new substance approval. In such circumstances it is hard to be proactive.

Currently, there is no significant national environmental effects research program that takes a proactive or anticipatory approach to creating a knowledge base for assessing new substances. However, the potential scope of environmental effects research that is needed to aid assessments is so wide that it would be hard to know where to begin defining such a program. Certainly, its scope would be much larger than could reasonably be addressed by an in-house research program, given the additional resources that are likely, in our opinion, to be available to the department. Clearly, some alternative to a large in-house research capacity is required.

In our opinion, the initial solution lies in building up the national capacity for GMO environmental effects research so that Environment Canada can draw upon those resources and expertise in assessing new substances. This will probably require the development of one or more environmental effects research networks, very likely in partnership with other government departments and agencies, the Granting Councils, and possibly with companies or industry associations. Thus, in our opinion, one of the priorities of EC's *Canadian Environmental Research Networks* project should be to foster the creation of a GMO environmental effects network(s)[42].

While EC's current GMO role focuses on new substance assessment, one can envisage future situations arising in which EC would also become an active developer of or investor in new GMOs - for example if a microbe were identified which had the potential to aid the cleanup of toxic spills. In such a situation the department might find it compelling to support the development of such an organism. This example highlights the GMO regulator-vs.-GMO developer role that already confronts some other departments.

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[41] In exceptional circumstances extensions to the review period are permitted.

[42] A promising line of inquiry for such a research network might be on vectors of gene transfer.

Now is the time for Environment Canada to draft its own detailed stewardship framework for the environmental effects of GMOs. With the current volume of GMO assessment activity at a comparatively low level, EC has the opportunity to sort out its GMO stewardship plans in a comprehensive way. An important dimension of stewardship frameworks is that they allow organizations to document their plans, and thereby demonstrate to stakeholders that they are acting as responsible stewards of the public interest. In our opinion, the federal government (and Environment Canada) has in place many of the stewardship values, tools and capacities needed to effectively carry out its stewardship responsibilities. For the most part, though the government has not documented its efforts so that they present a convincing argument that an appropriate safety net is in place.

Developing an in-depth Environment Canada stewardship framework for GMOs necessitates the following actions:

1. Specifying the principles, values and ethics that will underlie the framework;

2. Delineating Environment Canada's stewardship responsibilities at each stage of the GMO life cycle;

3. Ensuring that the appropriate tools and activities that will support stewardship are in place;

4. Building a national capacity for environmental effects assessment to support Environment Canada's obligations; and,

5. Liaising with OGDAs so that respective departmental stewardship frameworks work together to create a robust national stewardship framework.

8.0 GMO STEWARDSHIP - A COLLABORATIVE FEDERAL APPROACH

A number of different federal departments and agencies have direct or indirect responsibility for stewardship of GMOs in the environment. Federal legislation gives direct responsibility for assessing environmental effects of new substances to three departments - Environment Canada, the Canadian Food Inspection Agency, and Health Canada (see table following). These departments are responsible for assessing the safety of new GM substances.

Federal GMO Stewardship - Organizations With Direct Responsibilities

APPLICABLE LEGISLATION AND REGULATIONS	DEPARTMENT/ AGENCY	NEW SUBSTANCE
Seeds Act and Seeds Regulations	Canadian Food Inspection Agency	• All plants with novel (new) traits (PNT) including food crops, trees, horticultural, and marine plants, intended for planting in the environment
Feeds Act and Feeds Regulations	Canadian Food Inspection Agency	• All new livestock feeds, including new feed ingredients
Health of Animals Act and Health of Animals Regulations	Canadian Food Inspection Agency	• All novel veterinary biologics (i.e. live veterinary product like certain animals vaccines and test kits)
Fertilizers Act and Fertilizers Regulations	Canadian Food Inspection Agency	• All new fertilizers (i.e. chemicals) and new novel supplements (i.e. organisms)
Pest Control Products Act and Regulations	Health Canada, Pest Management Regulatory Agency	• All new substances in pest control products
Canadian Environmental Protection Act, 1999, and New Substances Notification Regulations	Environment Canada and Health Canada	• All remaining new substances including: • New industrial chemicals, biochemicals, polymers and biopolymers, and organisms • Imports of plant material with novel (new) traits (PNT) intended for direct use as food, non-livestock feed, or for processing into food or industrial products • Genetically modified microorganisms not covered by a CEPA listed Act and Regulation • Novel feeds for non-livestock animals • Transgenic animals and fish • New substances in fertilizers and novel supplements manufactured for export only • New substances used as intermediates to manufacture pest control products • New substances in drugs (human and veterinary), human biologics, cosmetics, medical devices

From a public policy perspective, the key issue that all SBDAs are trying to address is how to avoid approving new GM substances which could have unintentional and unforseen large-scale environmental consequences. It is feared that negative environmental consequences could arise if genetic material were transferred from GMOs to related or unrelated naturally-occurring species in an ecosystem, either from a single GMO or from the cumulative impacts of multiple

GMOs[43]. The preferred approach is to anticipate the future (negative) ecosystem effects of such substances before they are licensed for release into the environment. Increasingly, it is becoming apparent that gene transfer between and among GM and non-GM organisms is the norm, rather than the exception. What is not known is:

- Whether and under what circumstances gene transfers will cause harm to the environment;
- What constitutes "environmental harm";
- What level of harm or risk of harm, if any, is acceptable;
- How to predict the harmful effects of GMOs;
- What technical or management safeguards (e.g. "terminator" or "exterminator" technology) could prevent or minimize harm;
- How to reverse genetic harm to the environment in situations where it might inadvertently occur.

The life cycle approach favoured in this report highlights the need for the federal government to take a more holistic approach to GMO stewardship than the product-approval approach now required by CEPA and other legislation. It argues that stewardship needs to be exercised by all stakeholders, at each stage of the biotech life cycle. As such, the following table indicates which SBDAs might lead federal stewardship efforts at different stages of the life cycle.

Sample Federal Biotech Stewardship Roles	
LIFE CYCLE ELEMENT	**SAMPLE STEWARDSHIP ROLE**
Laboratory Research	Granting Councils, Health Canada, Federal GMO developers
Research Tools Development	Granting Councils, Health Canada, Industry Canada
Standards Development	Environment Canada, Health Canada, DFO, AAFC, CFIA, Others
Regulatory Development	Environment Canada, Health Canada, DFO, AAFC, CFIA, Others
Screening & Baseline Monitoring	Environment Canada, Health Canada, DFO, AAFC, CFIA
Field Trials	Environment Canada, Health Canada, DFO, AAFC, CFIA, Others
Field Trials Monitoring	Environment Canada, Health Canada, DFO, AAFC, CFIA, Others
Approvals	Environment Canada, Health Canada, CFIA

[43]There are obvious parallels between the environmental GMO issue and the exotic or alien species issue, but there are also fundamental differences. The exotic/alien species issue differs from the GMO issue in that exotic/alien species are whole genomes which do occur in nature, but happen not to be native to a particular habitat or ecosystem. The fear is not that exotic species will transfer their genes to other species, but that they themselves will take over their ecosystem into which they are introduced, due to their superior adaptive characteristics. In contrast, the environmental GMO issue concerns the potential transfer of exotic genetic material to native species - or even non-native, exotic species - in the ecosystem. This may not result in a situation where new GM species take over the ecosystem, per se, but rather one where gene transfer will alter the genetic integrity of species in the ecosystem, which in turn could produce indirect or direct negative environmental consequences for other species, humans, wildlife, etc.

Sample Federal Biotech Stewardship Roles	
LIFE CYCLE ELEMENT	**SAMPLE STEWARDSHIP ROLE**
Production/Manufacturing	Industry Canada, Provinces, Others
Community Awareness	All
Storage	AAFC, CFIA, Others
Distribution/Transportation	Transport Canada, Others
Application/Use	Provinces/Territories
Long Term Monitoring/Assessment	Environment Canada, Health Canada, DFO, AAFC, CFIA, Others
Emergency Response/Repatriation	Environment Canada,
Enforcement	Environment Canada, Others
Disposal	Environment Canada, Others
Reporting	All

The life cycle approach is not directive; it does not necessarily require federal intervention at every stage of the life cycle. Rather, it calls for a thorough assessment of the need for stewardship at the different stages; following such an assessment SBDAs may conclude that their direct intervention is not needed, and that the lead on stewardship should come from another stakeholder. What is important is to be able to document to the public that SBDAs have properly assessed their stewardship roles and made the appropriate determination as to whether action is or is not required.

8.1 EEGMO - SBDAs Working Together

At the present time a number of SBDAs (Environment Canada, AAFC, The cfia, Canadian Museum of Nature, DFO, Health Canada, NRC, NRcan, Parks Canada) are working together to develop a joint EEGMO (environmental effects of GMO) research strategy; a strategy on the potential long term ecosystem effects of GMOs. SBDAs have 2 shared objectives:

- Improving understanding of (I) ecosystems likely to be affected by GMOs, and (ii) mechanisms by which various ecosystems, wildlife and biodiversity, and human health may be directly or indirectly affected by GMOs and their products, and (iii) cumulative effects of multiple GMOs or GMOs in combination with other potential stressors;

- Improving capacity to monitor ecosystem health and change, to identify the presence and direct and indirect effects of GMOs and their products in the environment and to reduce and mitigate potentially harmful effects. This includes but is not limited to GMOs in agriculture, forestry, aquaculture, industrial effluents and sewage treatment plant effluents, and GMOs in Canada that may originate from transport or migration across boundaries.

The intention is that SBDAs should avoid research duplication and act in a complementary way[44]. MOUs will be developed to clarify roles and responsibilities. Collaborative research efforts are expected to focus on 4 ecosystem themes: Aquatic, Agricultural, Forest, and Wildlife. The anticipated research program will emphasize 4 issues:

- Increasing existing knowledge on the exchange of genetic material;
- Understanding the process by which ecosystems are affected;
- Developing and validating monitoring and predictive tools; and,
- Communicating knowledge and research results.

Improving understanding of ecosystems, mechanisms and cumulative effects will inevitably be a long term undertaking, as these types of effects only emerge over extended periods of time. Improving capacity to monitor ecosystem health and change has two dimensions: federal (government) monitoring capacity and national monitoring capacity.

8.1.1 EEGMO Research Governance

EEGMO research poses another in a long line of challenges for horizontal management of federal S&T. As such it raises the customary questions, including:

- Who will take the lead on the whole research program and on individual projects?
- Which federal and non-federal organizations will participate in the research?
- How will research priorities be determined?
- Who will pay for the research?
- How will research funding be administered?
- Who will perform the research?
- How can partnerships be formed with outside organizations?
- How can limited financial resources be leveraged?
- Who will assess the progress of the research?
- How will under-performing research be dealt with?
- Who will report on results and impacts?

None of these matters is especially new to federal S&T managers, and by now there is a body of experience to draw upon in framing the federal response. Appropriate implementation models might include TSRI, PERD, FINE, CESN, MEND, and similar initiatives. Whatever model is chosen, it should address the S&T governance issues raised in the federal government's *Framework for Science and Technology Advice* - especially because there is a great deal of public concern over EEGMOs. The

[44]For example, Environment Canada will undertake research at the interface of other SBDAs' responsibilities.

Framework advances a set of principles that should be incorporated into federal EEGMO research and decision making. In particular:

Inclusiveness:	*Advice should be drawn from a variety of scientific sources and from experts in relevant disciplines, in order to capture the full diversity of scientific schools of thought and opinion.*
Transparency and Openness:	*The government is expected to employ decision-making processes that are open, as well as transparent, to stakeholders and the public.*
Review:	*Subsequent review of science-based decisions is required to determine whether recent advances in scientific knowledge have an impact on the science advice used to reach the decision.*

The **inclusiveness** principle implies that a federal (EEGMO) research program needs to have mechanisms to draw knowledge from different scientific sources and different experts. The **transparency and openness** principle implies that there should be stakeholder and public involvement in the design and implementation of the research program. The **review** principle implies that periodic reviews of past decisions be taken, as new knowledge becomes available. Thus, whatever EEGMO governance mechanism is selected, it should incorporate these 3 principles.

To address these multiple issues, we suggest that SBDAs consider adopting a 3-tier research management model (see figure at right). EEGMO research would be governed by a Board of Directors composed of multiple stakeholders. The Board would have overall management responsibility, and the ability to allocate resources to individual projects and overall program management. The Board should include senior SBDA representatives, as well as

external representatives of the higher education sector and non-government stakeholders.

A Research Program Committee would be responsible for developing a multi-year research program and submitting the program to the Board for approval. The Committee would outline a set of research themes. It would also manage the approved research projects and regularly report on their progress. The Committee would be headed by a Research Director. Other members would include Leaders of individual research projects, as well as a number of Outside Advisors.

Each approved project would be headed by a Project Leader. Working with the Leader would be Researchers from SBDAs and universities, and possibly from industry and NGOs as well. Projects should be selected through a competitive process, beginning with a Call for Proposals in which researchers and research teams are invited to propose projects that would address priority research themes (e.g. GMO transfer through effluents). Each proposed project is assessed for relevance, excellence, management, and potential impact.

8.1.2 EEGMO Research Coordination

Whereas the preceding discussion (8.1.1 - Research Governance) is concerned with the stewardship of EEGMO research across government departments, our interviews with officials responsible for GMO stewardship within different departments and agencies indicates that there are similar coordination challenges that need to be addressed within departments. In many respects the internal coordination issues mirror the external (horizontal) coordination issues. Thus, it is possible to pose similar questions for intra-departmental coordination of GMO activities as for inter-departmental coordination:

- Who will take the lead on the department's/agency's research program and on individual projects?
- Which departmental organizations will participate in the research?
- How will departmental research priorities be determined?
- Who will pay for the research?
- How will research funding be administered?
- Who will perform the research?
- How can partnerships be formed with outside organizations?
- How can limited financial resources be leveraged?
- Who will assess the progress of the research?
- How will under-performing research be dealt with?
- Who will report on results and impacts on behalf of the department/agency?

Each department or agency can be viewed as a microcosm of the federal government as a whole. In many instances more than one branch or unit within a department has GMO

responsibilities, interests or expertise. Likewise, (GMO) decisions taken elsewhere in a department/agency or in another part of government can have a bearing on the activities of the branch or unit, and vice versa. For this reason, each department or agency would be well advised to review its internal policy and research systems to ensure that it can adequately address its own EEGMO responsibilities, and effectively contribute to the national dialogue.

8.1.3 EEGMO Research Capacity

The research model suggested above is meant to address the management aspects of the federal EEGMO research agenda that is emerging from interdepartmental discussions, and to be consistent with various approaches to horizontal research management (e.g. FINE, TSRI, PERD, etc.). A separate but related issue is building long term research capacity. Capacity has three key elements:

- Expertise: access to scientific expertise for research, assessment and advice;
- Infrastructure: access to research facilities and equipment; and,
- Linkages: ability to source external knowledge and infrastructure.

Common to different SBDAs' EEGMO requirements is timely access to knowledge - that is, to information, expertise and infrastructure - to meet their policy needs. Whether the needed resources are internal to the federal government or external is another matter. In our view, only if a case can be made that timely access to knowledge is important but not available through external linkages, should SBDAs try to build in-house capacity. In any event, capacity requirements need to be directly linked to agreed research priorities; capacity should be acquired only when it supports agreed research programs/themes and projects. In other words, SBDAs should strive to build capacity for specific priority purposes (just-in-time) and not to meet unspecified future requirements (just-in-case).

The federal government is making considerable investments in genomics through CFI, CIHR, NSERC, and other federal initiatives. SBDAs' principal objective should be gaining timely access to the expertise, information and infrastructure resulting from these investments, to support federal policy and related research priorities. A complementary objective is to influence the national EEGMO research agenda by initiating and participating in EEGMO research projects, programs and networks.

Throughout, officials should bear in mind that the vast majority of the knowledge required will be produced outside of Canada, and that efforts should be made to avoid duplicating "generic knowledge" that can be applied here. Efforts should be devoted to generating knowledge for unique Canadian needs; for example, knowledge related to unique Canadian ecosystems.

9.0 SUMMARY AND CONCLUSIONS

The main purpose of this report is to help Environment Canada fulfill its responsibility to ensure sound stewardship of the effects of genetically modified organisms (GMOs) on the environment by outlining a life-cycle based stewardship framework. GMOs include plants, animals and microbes that have undergone artificial gene transfer, and are therefore classed as "animate products of biotechnology" under federal legislation. A related purpose is to provide some guidance to EC and other SBDAs on how to work together to achieve shared GMO stewardship objectives.

Fig. 1 Elements of a Stewardship Framework

A variety of legislation and regulations provide the federal government with broad authority to address "pollution" issues as they relate to the products of biotechnology (i.e. GMOs). The various Acts takes a preventative approach by requiring that substances be identified and assessed, prior to market introduction, to determine whether they are "toxic" or capable of becoming toxic. Toxicity refers to risk to human health, the environment or its biological diversity.

The report proposes adoption of a comprehensive stewardship model that takes into account social values, institutional roles, stewardship tools and capacity requirements. The report also recognizes that Environment Canada shares responsibility for GMOs in the environment with other federal departments and agencies[45]. This suggests the need for a harmonized government-wide approach to environmental effects stewardship.

The report reaches a number of conclusions concerning stewardship frameworks and how they should be applied, to ensure their safe use in the environment. Following are the principal conclusions:

9.1 Stewardship frameworks must be formalized and documented

[45]The report does not address the question of federal–provincial responsibilities, but acknowledges that these are important.

Organizations cannot truly claim to have a stewardship framework in place unless the framework has been formalized and documented. The literature on stewardship frameworks is replete with passing references to stewardship ideals and stewardship frameworks, but relatively few organizations have developed formal frameworks. We have concluded that a true stewardship framework needs to be formalized and documented. Otherwise, it cannot provide the safeguards that society wants to see in place to manage the safe use of the products of biotechnology.

9.2 Stewardship embraces values, roles, tools and capacities

A stewardship framework is a social system that encourages individuals and organizations to account for the values, roles, tools and capacities needed to address a public policy issue; in this instance, eliminating or minimizing the unwanted environmental effects of new GMOs.

A sound stewardship system requires that its adherents specify a base of clearly-expressed values, principles and ethics. For example: "Protection of people and the environment is paramount", or "The precautionary principle should guide risk management". It is important to express what society is trying to protect and why. Stewardship frameworks need to declare the values on which they are based, and where necessary, to sort through competing values (e.g. promotion of biotechnology benefits versus the precautionary principle).

Sound stewardship also requires that individuals and organizations in the private, public and higher education sectors understand their own and other stakeholders' roles and responsibilities for sound stewardship, and act on them.

Implementing stewardship frameworks requires that organizations have access to a suite of science and policy tools that support stewardship. These tools include standards, codes, guidelines, regulations, etc., which are instruments that allow organizations to exercise their stewardship.

Finally, to implement stewardship frameworks organizations require a certain level of capacity. Capacity includes their own expertise and infrastructure, together with linkages to the larger national and international capacity.

9.3 Stewardship must be applied at each stage of the biotech life cycle

Stewardship frameworks need to be applied in a comprehensive way, which is to say that they must apply at each stage of the GMO life cycle, from laboratory research through to recycling of unwanted materials. Gaps in applying sound stewardship at any stage of the life cycle can lead to unwanted problems or unexpected consequences. For example, standards for safely transporting GMOs would be meaningless unless there were also standards for safely storing them. The GMO life cycle is a continuum and stakeholders need to exercise sound stewardship throughout the continuum.

9.4 Knowledge is the "currency" of stewardship

The "currency" of stewardship is knowledge. Acquiring scientific knowledge to meet the government's assessment and policy development needs is a key objective of federal S&T efforts in support of GMO stewardship. There are a number of valid strategies for gaining timely access to knowledge. Bearing in mind that the majority of the relevant EEGMO knowledge will be produced outside of Canada, then robust information gathering and assessment mechanisms are called for. Recognizing that substantial Canadian expertise and infrastructure resides outside of government, mechanisms are required to utilize and coordinate those resources. Acknowledging that different SBDAs have expertise and infrastructure that can support federal stewardship, then well-coordinated internal efforts to work together are essential.

9.5 All stakeholders have stewardship responsibilities

Responsibility for sound environmental stewardship of GMOs resides with all stakeholders: companies, industry associations, government departments, university researchers, non-governmental organizations, and so forth. Moreover, an effective stewardship framework requires the active involvement of all stakeholders. Each must understand its role and responsibilities and act on them accordingly.

9.6 Much can be learned from industry

Industry associations such as CropLife Canada and the Canadian Chemical Producers Association have developed what appear to be effective stewardship frameworks for biotech crops and chemicals, respectively. These frameworks are essentially voluntary, but do require independent third-party verification, and include limited sanctions. An impressive feature of these industry initiatives is that they commit CEOs to personally certify their company's adherence to the industry stewardship programs.

BIOTECanada, the industry association of private sector biotechnology developers, is developing a similar approach for its members. Government should apply industry stewardship best practices to its own GMO development activities. Government also needs to engage the biotechnology industry in developing a federal stewardship framework for the environmental effects of GMOs.

9.7 A mix of voluntary and mandatory measures is required

Inevitably, in our view, a Canadian stewardship system will need to rely on a mix of voluntary and mandatory measures to ensure that organizations with GMO responsibility carry out their responsibilities in a socially acceptable way. This reinforces the need for a partnership among stakeholders to ensure that the "GMO safety net" functions effectively, and that the right checks and balances are in place to reward good practice and penalize bad practice.

9.8 Third-party oversight provides an important safeguard

An attractive feature of a number of industry stewardship programs is that they require third-party verification or certification. These programs acknowledge that human and organizational nature being what they are, it is not enough to rely on declarations of compliance; third-party verification is an essential aspect of sound stewardship.

9.9 National research capacity needs to be reinforced

In our opinion, it will be difficult for any federal government organization to build in-house, all the capacity - that is, the knowledge, expertise and infrastructure - it will need to deal with the myriad of GMO science and policy issues that are likely to arise in the future, let alone those concerning the environmental effects of GMOs. At minimum, there needs to be a high level of aggregate national capacity - whether in industry, universities or government - that can be called upon when needed to address specific issues. In fact, the federal government is making extensive investments in university-based research, through such organizations as CFI, Genome Canada, Canada Research Chairs, and the Granting Councils. This calls for new institutional arrangements, such as (GMO environmental effects) research networks, that will harness existing capacities and address the capacity gaps that are found to exist.

9.10 International linkages should be expanded

As the vast majority of environmental effects knowledge needed for sound stewardship (we estimate around 95% of all the relevant knowledge) will be produced outside of Canada, federal organizations need to reinforce their linkages to international knowledge sources. These include international organizations, governments, universities, research networks, and so forth. International sources will produce far more environmental effects knowledge than we can on our own, and our challenge is to be able to access this knowledge in a timely way to meet our own science and policy needs.

9.11 Intra-Departmental Activities Should be Coordinated

Each department or agency faces similar challenges in coordinating its internal EEGMO activities across sectors, branches, work units, etc. as the federal government faces in coordinating inter-department/inter-agency EEGMO responses. Departments and agencies need to review their internal mechanisms to ensure they are operating smoothly and that they reinforce the ability of the parent department/agency to contribute to the national EEGMO endeavour.

9.12 Research investments should be focussed

Given the prospect of limited new funds becoming available for federal in-house research, it is apparent that research investments will need to be focussed. Much of the generic knowledge

needed to properly assess the environmental effects of GMOs will be produced outside of Canada. Where we need to concentrate national resources is on research related to environmental or ecological niches that are unique to Canada (e.g. Arctic, Pacific rainforest, etc.), or on products of biotechnology that are especially important to Canadians (e.g. canola, salmon). Another approach is to concentrate resources on the transmission vectors for GMOs, as these are the "gateways" which regulate the environmental effects of GMOs.

10.0 RECOMMENDATIONS

Based upon our findings and conclusions, we offer the following recommendations for your consideration.

10.1 Adopt the stewardship framework and life cycle models

As an initial step, we recommend that Environment Canada adopt the stewardship framework and life cycle models that are described in this report.

10.2 Elaborate specific values, roles, tools and capacity needs

Once the stewardship model is in place, then Environment Canada should work with its staff, the Science and Technology Advisory Board, and other stakeholders inside and outside of government to adapt the generic models to the department's specific requirements. This involves:

- Determining the principles, values, and ethics underlying EC's stewardship framework
- Specifying the stewardship role which EC will play at each stage of the GMO life cycle;
- Reviewing the stewardship tools and activities which are in place, strengthening those which are found lacking, and adopting any that might be missing; and,
- Analyzing the national and departmental environmental effects capacity requirements, and adopting measures to ensure a strong national capacity and effective institutional linkages.

10.3 Liaise with OGDAs

Sound federal stewardship requires a team effort. Environment Canada should share the results of this study with other government departments and agencies and determine whether there is consensus that the approach outlined here can serve the needs of individual organizations

(departmental stewardship frameworks), as well as those of the government as a whole (federal stewardship framework).

10.4 Open a dialogue with stakeholders

Industry, higher education, and NGOs should be consulted about the approach that the department decides to pursue.

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Appendix 1A. Generic Stewardship Principles, Values & Ethics			
ITEM	**SAMPLE STEWARDSHIP PRINCIPLES, VALUES & ETHICS**		
	Biotech Industry	**Government**	**Higher Education**
Generic Principles, Values, Ethics (Apply to all sectors)	• Protection of people and the environment is paramount • Effective stewardship requires the involvement of all sectors and stakeholders • Stewardship principles should apply at all stages of the GMO life cycle • Stewardship should include voluntary and mandatory measures • Emphasis needs to be put on prevention • The precautionary principle should guide risk management • Stewardship ethics should apply both to organizations and to the individuals working in them • Stewardship includes an obligation for assessment • Stewardship involves ongoing review of past decisions based on new information • Principles and guidelines for federal S&T (e.g. Framework for S&T Advice, SAGE, BEST, etc.)		

Appendix 1B. Life Cycle Stewardship Principles, Values & Ethics

LIFE CYCLE ELEMENT	SAMPLE STEWARDSHIP PRINCIPLES, VALUES & ETHICS		
	Biotech Industry	**Government**	**Higher Education**
Laboratory Research	• Meet or exceed the spirit of current government regulations • Be seen to do the right (and wrong) thing • Operate with public consent • Manage risks to level acceptable to those affected • Include well-being in risk definitions • Consult with the public before deciding • Inform public of hazards, benefits, risks • Seek informed consent • Seek out, understand and address public concerns • Be our own whistle-blowers • Encourage mutual aid among companies and foster peer pressure to continuously improve • Inform employees of link between company programs and industry stewardship programs • Life cycle stewardship • Contribute positively to public policy • Seek advocates' input • Pursue continuous improvement to meet public expectations • Apply holistic decision making • Apply industry standards to suppliers	• Federal Regulatory Framework (1993): (1) Maintain high standards for the protection of the health of workers, the general public and the environment; (2) Use existing legislation and regulatory institutions to clarify responsibilities and avoid duplication; (3) Develop clear guidelines for evaluating products of biotechnology, which are in harmony with national priorities and international standards; (4) Provide a sound scientific database on which to assess risk and evaluate products; (5) Assure the development and enforcement of Canadian biotechnology regulations are open and include consultation; (6) 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 • The public interest is paramount • Separation of GM promotion from regulation roles • Burden of proof principle • Maintenance of genetic diversity • Meet or exceed sprit of current regulations in own GM activities • Operate with public consent • Inform public of hazards, benefits, risks • Manage risks to level acceptable to those	• Adherence to national guidelines on biotechnology research • Adherence to university guidelines on human, animal research • Publication in peer reviewed journals • Provide GELS training for all young researchers • Establish professional codes of conduct
Research Tools Development			
Standards Development			
Regulatory Development			
Screening & Baseline Monitoring			
Field Trials			
Field Trials Monitoring			
Approvals			
Production/Manufacturing			
Community Awareness			
Storage			
Distribution/Transportation			
Application/Use			
Long Term Monitoring/Assessment			
Emergency Response/Repatriation			
Enforcement			
Disposal			
Reporting			

Appendix 2. Stewardship Roles and Responsibilities

LIFE CYCLE ELEMENT	ROLES AND RESPONSIBILITIES		
	Biotech Industry	**Government**	**Higher Education**
Laboratory Research	Train/certify lab personnel Develop and apply best practices Advise on research guidelines	Establish GMO research guidelines Finance public good and commercial research Conduct public good research Train/certify (own) lab personnel Adopt best practices	Develop training programs Train/certify own personnel Train/certify third-party personnel Curriculum and program development Adopt best practices Conduct investigator-driven research Conduct sponsored research
Research Tools Development	Develop & apply research tools	Develop & apply research tools Fund tool development Certify tool performance	Develop & apply research tools Conduct investigator-driven research Conduct sponsored research
Standards Development	Advise on draft standards Apply standards (Self-)audit standards performance	Provide scientific input into standards Support standards development under CEPA Validate, harmonize standards Review emerging international standards	Provide scientific input into standards Safety/efficacy validation studies Conduct investigator-driven research Conduct sponsored research
Regulatory Development	Advise on draft regulations Adhere to regulations	Conduct regulatory research Develop science-based regulations Align domestic & international regs. Develop/amend regulations under CEPA	Provide scientific input into regulations Conduct investigator-driven research Conduct sponsored research
Screening & Baseline Monitoring	Baseline monitoring of new substance (environmental) impacts (local)	Baseline monitoring of local and regional environment	Conduct investigator-driven research Conduct sponsored research
Field Trials	Design field trials Conduct and report on field trials	Develop field trial guidelines Assess field trial reports	Develop field trial methodologies Study long term impacts of field trials Conduct investigator-driven research Conduct sponsored research
Field Trials Monitoring	Monitor field trials	Review field trials against design criteria	Conduct investigator-driven research Conduct sponsored research
Approvals	Submit novel products for approvals	Assess field trial data against standards Review and approve new substances under CEPA	Conduct investigator-driven research Conduct sponsored research

Appendix 2. Stewardship Roles and Responsibilities

LIFE CYCLE ELEMENT	ROLES AND RESPONSIBILITIES		
	Biotech Industry	**Government**	**Higher Education**
Production/Manufacturing	Develop manufacturing standards Manufacture safely	Develop manufacturing standards Monitor manufacturing processes	Conduct investigator-driven research Conduct sponsored research
Community Awareness/Participation	Raise awareness of benefits of products	Raise awareness of stewardship "safety net"	Conduct investigator-driven research Conduct sponsored research
Storage	Establish storage standards Store safely	Develop storage standards Monitor safe storage	Conduct investigator-driven research Conduct sponsored research
Distribution/Transportation	Establish transportation standards Transport safely	Establish/validate transportation standards Monitor safe transportation	Conduct investigator-driven research Conduct sponsored research
Application/Use	Train/certify sales staff Train/certify end users Develop safe use guidelines	Develop safe use guidelines Validate training programs Monitor safe use	Conduct investigator-driven research Conduct sponsored research
Long Term Monitoring/Assessment	Long term monitoring of local environment (cf. field trials)	Long term monitoring of local and regional environment	Conduct investigator-driven research Conduct sponsored research
Emergency Response/Repatriation	Establish "cleanup"practices Train emergency response personnel	Participate in international standard development (e.g. repatriation) Adopt standards Establish "cleanup" guidelines/ regulations Monitor emergency response actions Take responsibility for "orphan product" response	Conduct investigator-driven research Conduct sponsored research
Enforcement	Avoid enforcement through compliance self-audits, third-party audits	Set audit standards Audit company/higher ed. compliance Self-audit own compliance Commission third-party compliance audits Enforce regulations	Conduct investigator-driven research Conduct sponsored research
Disposal	Establish surplus product disposal guidelines Establish safe container management practices	Establish standards for safe disposal Monitor safe disposal	Conduct investigator-driven research Conduct sponsored research
Reporting	Report to shareholders and employees Report to customers Report to public	Report to public	Conduct investigator-driven research Conduct sponsored research

Appendix 3. Stewardship Tools and Activities			
LIFE CYCLE ELEMENT	**SAMPLE STEWARDSHIP TOOLS AND ACTIVITIES**		
	Biotech Industry	**Government**	**Higher Education**
Laboratory Research	Professional code of conduct Professional training/certification R&D code of practice Controlled studies Health & safety guidelines Laboratory standards	Professional code of conduct Professional training/certification R&D code of practice Organizational code of conduct Health & safety guidelines Laboratory standards Laboratories Biosafety Guidelines Expert/peer review committees	Professional code of conduct Professional training/certification R&D code of practice Organizational code of conduct Health & safety guidelines Laboratory standards
Research Tools Development	Out-sourced technology development In-house technology development	In-house technology development Out-sourced technology development Validation of new research tools	In-house technology development Validation studies
Standards Development	Industry best practices Peer review Impact studies (environmental) Risk assessments Laboratory standards development Field trial standards development Greenhouse standards development Transportation standards development	International best practices studies GELS research (ethical, social, legal) Health & safety guidelines Refugia guidelines Peer review Risk assessments/assessment guidelines Safety/toxicological studies Genetic diversity studies Allergenicity assessments/standards Long term monitoring guidelines/ standards Transgenic animal standards Assisted human reproduction standards Xenotransplantation standards Production standards Protocols for testing GM foods in experimental diets GM plant nutrient profiles Record keeping guidelines Public consultation Advisory committees	Peer reviewed scientific/regulatory research Participation in expert panels

Appendix 3. Stewardship Tools and Activities			
LIFE CYCLE ELEMENT	**SAMPLE STEWARDSHIP TOOLS AND ACTIVITIES**		
	Biotech Industry	**Government**	**Higher Education**
Regulatory Development	Participation in regulatory development activities Industry review of draft regulations	Federal Regulatory Framework (1993) Regulatory research International monitoring and liaison Peer review Expert panels Public consultation	
Screening & Baseline Monitoring	Local baseline monitoring in preparation for field trials	Regional baseline monitoring studies (in-house) Regional baseline monitoring (third-party) Biological surveys, population studies Environmental impact studies Nutrient profile data bank	
Field Trials	Field trial design and implementation	Field trial protocol development	
Field Trials Monitoring	Monitoring of results Publication of results in peer-reviewed journals	Independent review of field trial data	
Approvals		New substance review & certification (CEPA)	
Production/Manufacturing	Manufacturing code of practice Environmental code of conduct Health & safety guidelines Process safety incident reports	Certification of production standards Health & safety monitoring	
Community awareness	Community awareness code of practice Outreach programs	Public consultation Advisory committees Open-source publication Risk communication workshops Arms-length stakeholder panels Websites Information kits Exhibit tours Brochures Public fora Magazine articles Other advertising and public relations	
Storage	Warehousing standards Personnel training	Storage standards development/ certification	

Appendix 3. Stewardship Tools and Activities			
LIFE CYCLE ELEMENT	**SAMPLE STEWARDSHIP TOOLS AND ACTIVITIES**		
	Biotech Industry	**Government**	**Higher Education**
Distribution/Transportation	Transportation standards Transportation incident measurement reports Personnel training	Tracking/registration systems for novel substances Segregation standards development Training program certification	
Application/Use	Marketing standards code of conduct Sales representative training/ certification program End-user training/certification program	Training guidelines End-user certification programs	Design & deliver safe use training programs
Long Term Monitoring/Assessment	Impact studies Sample/record maintenance	After-market surveillance studies Tracking/registration systems Persistence studies Impact studies	
Emergency Response/Repatriation	Hazardous waste management standards	Emergency response planning Repatriation planning/implementation	
Enforcement	ISO-style record keeping	Documentation systems management Field enforcement	
Disposal	Hazardous waste management code of practice Emission/waste reduction plans Obsolete product disposal program Container disposal program Waste management contractor assessments	Segregation systems for transgenic & food animals Safe disposal guidelines Contractor certification	
Reporting	Self-assessment verification/audits Third-party verification/audits Milestone reports Commitment attained statements Re-commitment statements Re-verification (3 years)	Self-assessment verification/audits Third-party verification/audits Annual reports Special studies & analysis Interactive websites Monitoring & compliance reports	
Other	CEO commitment verification Code commitment/compliance verification Leadership groups Code coordinators	Interdepartmental coordinating committees Advisory committees Departmental (biotech standards) certifications	

Appendix 4. Stewardship Capacities

LIFE CYCLE ELEMENT	SAMPLE STEWARDSHIP CAPACITIES		
	Biotech Industry	**Government**	**Higher Education**
Laboratory Research		New substance development (crops, forests, fish, etc.) Toxicity testing Allergenicity testing	
Research Tools Development		Improved allergenicity testing technologies	
Standards Development		Scientific expertise for environmental impact assessment Occupational health and safety Transportation Storage Product labelling	
Regulatory Development		Legal expertise in biotechnology State-of-the-art genomics resources for major crops, farm animals and fish	
Screening & Baseline Monitoring		Central protein serum bank National research program on long-term environmental effects of GM organisms Multidisciplinary research program on environmental impacts of GM plants Wild-cultured fish interaction research program Baseline data program on the biology of agroecosystems and adjacent biosystems Vectors of genetic material transmission Environmental indicators	
Field Trials		Field trial design Field trial design review Field trial inspection	
Field Trials Monitoring		Scientific review	
Approvals		Field trial review expertise International research assessment Expert panel review	
Production/Manufacturing		Manufacturing plant inspection & enforcement Health and safety	
Community Awareness		Communication and consultation	

Appendix 4. Stewardship Capacities			
LIFE CYCLE ELEMENT	**SAMPLE STEWARDSHIP CAPACITIES**		
	Biotech Industry	**Government**	**Higher Education**
Storage		Inspection & enforcement expertise	
Distribution/Transportation		Inspection & enforcement expertise	
Application/Use		Inspection & enforcement	
Long Term Monitoring/Assessment		Research networks Long term studies Participation in international fora	
Emergency Response/Repatriation		Cleanup/remediation	
Enforcement		Personnel recruitment Training	
Disposal		Monitoring & enforcement	
Reporting		Communications	

Appendix 5
List of Individuals Consulted

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Science Policy Branch - Environment Canada

Working Paper Series

1 *Environment Canada's Scientific Research Publications in 1995*

2 *Science for Sustainable Development*

3 *Communicating Science at Environment Canada: A Brief Review of Lessons Learned from Communications on Acid Rain and the Depletion of the Stratospheric Ozone Layer*

4 *The Precautionary Principle, Risk-Related Decision Making, and Science Capacity in Federal Science-Based Regulatory Departments: A Discussion Document*

5 *Strengthening Environmental Research in Canada: A Discussion Paper*

6 *Environment Canada's Scientific Research Publications 1980-1997*

7 *Research & Development and Related Science Activities at Environment Canada*

8 *Measuring The Impacts Of Environment Canada's R&D: A Case Study of Pulp & Paper Effluent Research*

9 *Measuring The Impacts Of Environment Canada's R&D: A Case Study of Stratospheric Ozone Depletion Research*

10 *Measuring The Impacts Of Environment Canada's R&D: Notes On Methodology*

11 *Science Advice in Environment Canada*

12 *Environment Canada University Research Partnership Expansion Strategy: A Discussion Paper*

13 *Environment Canada's S&T: Expenditures & Human Resources, 1990-1999*

14 *National Environmental R&D Agenda-Setting: A Commentary on Issues, Options, and Constraints*

15 *Science in the Public Interest: Values and Ethics in the Management, Use and Conduct of Science at Environment Canada*

16 *Bibliometric Profile of Environmental Science in Canada: 1980-1998*

17 *Implementing the Principles and Guidelines of the Framework for Science and Technology Advice: A Guide for Science and Policy Managers*

18 *Role of a Renewed 5NR MOU in the Evolving Spectrum of Horizontal Federal S&T Management*

19 *Toward a Canadian Stewardship Framework for GMOs - A Discussion Paper*

20 *S&T Excellence in Environment Canada: A Self-Assessment Tool based on the CSTA STEPS report*

21 *Environment Canada's Research Laboratories: Institutional Change and Emerging Challenges - Three Case Studies*