October 2002

منظمة الأغذية والزراعة للأمم المتحدة | 联合国粮食及农业组织 | Food and Agriculture Organization of the United Nations | Organisation des Nations Unies pour l'alimentation et l'agriculture | Organización de las Naciones Unidas para la Agricultura y la Alimentación

E

COMMISSION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE

THE ROLE OF LAW IN REALISING THE POTENTIAL AND AVOIDING THE RISKS OF MODERN BIOTECHNOLOGY

SELECTED ISSUES OF RELEVANCE TO FOOD AND AGRICULTURE

Lyle Glowka, Biodiversity Strategies International

This draft study was prepared by Mr. Lyle Glowka, consultant, at the request of FAO, following the first session of the FAO Panel of Eminent Experts in Food and Agriculture, which "underlined the advisability of conducting a comparative study of national regulations concerning biotechnology, including GMOs, exploring the possibility and desirability of harmonizing such regulations".

The study is put at the disposal of the Commission on Genetic Resources for Food and Agriculture, for its deliberations on Genetic Resources for Food and Agriculture and related biotechnologies, specially in the context of the requested Code of Conduct on Biotechnology.

Any opinions expressed in this document are those of the author, and do not necessarily represent the views of the FAO, or its Members.

The Legal Office intends to publish a revised version in the FAO Legislative Studies series.

Foreword

Ethics in food and agriculture has been identified by FAO as a Priority Area for Interdisciplinary Action, in order to allow the Organization to address ethical questions of relevance to its work in a holistic and cross-sectorial manner. FAO has established a series of publications on ethics in food and agriculture, and has established a Panel of Eminent Experts on Ethics in Food and Agriculture to advise the Organization.

At its First Session in September 2000, the Panel considered, among other subjects, the question of genetically modified organisms (GMOs), and, in its report, considered specific issues concerning the use of GMOs for food and agriculture:

- the risks, uncertainties, and doubts involved in the use of GMOs;
- the potential benefits and the problems faced; and
- the enabling conditions needed to realise the potential and avoid the risks of modern biotechnologies, including GMOs.

The Panel then requested FAO to prepare an update on the status of regulations in different countries concerning the application of biotechnology and GMOs.

In order to respond to the request, as a first step towards a more comprehensive legislative study, and as background material for further discussion by the Panel at its Second Session to be held from 18-20 March 2002, FAO commissioned the present study from Mr Lyle Glowka.

Giuliano Pucci
Legal Counsel.

José T. Esquinas-Alcázar
Chair, Sub-Committee on Ethics in Food and Agriculture

Acknowledgments

A number of people took time out of their busy schedules to provide me with materials and helpful comments and advice on earlier drafts of this study. In particular I would like to acknowledge: Don Anton (Canberra, Australia), Mark Christensen (Christchurch, New Zealand), Worku Damena (Montreal, Canada), Laurent Granier (Paris, France), Erningsih Haryadi (Jakarta, Indonesia), Porter Hoagland (Woods Hole, USA), Peter Jenkins (Washington DC, USA), Julian Kinderlerer (Sheffield, United Kingdom), Anni Lukacs (Bonn, Germany), Kent Nnadozie (Lagos, Nigeria), Alan Randell (Rome, Italy), Cyrie Sendashonga (Montreal, Canada), Birgitta Simon (Bonn, Germany), Stephen Stec (Budapest, Hungary), Robyn Stein (Johannesburg, South Africa), Xueman Wang (Montreal, Canada) and Tomme Young (Bonn, Germany).

I am particularly grateful to José T. Esquinas-Alcázar, Ali Mekouar and Margret Vidar of FAO for asking me to undertake this project.

My thanks go to all of these people and others for their assistance in making this study possible.

I am responsible for any weaknesses that remain.

Table of contents

List of Acronyms

ACNFP	Advisory Committee on Novel Foods and Processes of the United Kingdom
AIA	Advanced informed agreement
ANFZA	Australia New Zealand Food Authority
CBAC	Canadian Biotechnology Advisory Committee
CBD	Convention on Biological Diversity
CEC	Commission of the European Communities
CFIA	Canadian Food Inspection Agency
DNA	Deoxyribonucleic acid
EC	European Community
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GMO	Genetically modified organism
IBAC	Independent Biotechnology Advisory Council of New Zealand
IBC	Institutional Biosafety Committee
ICPM	Interim Commission on Phytosanitary Measures
IPPC	International Plant Protection Convention
IUCN	World Conservation Union
LMO	Living modified organism
OAU	Organisation for African Unity (African Union)
OECD	Organisation for Economic Co-operation and Development
PGR/WIS	FAO World Information and Warning System on Plant Genetic Resources
PGRs	Plant genetic resources
PGRFA	Plant genetic resources for food and agriculture
PIC	Prior informed consent
PNTs	Plants with novel traits
PRA	Pest risk analysis
RCGM	Royal Commission on Genetic Modification of New Zealand
SPMs	Sanitary and Phytosanitary Measures
TBT	Technical Barriers to Trade
UNCLOS	United Nations Convention on the Law of the Sea
UNECE	United Nations Economic Commission for Europe
UNEP	United Nations Environment Programme
UNESC	United Nations Economic and Social Council
UNIDO	United Nations Industrial Development Organisation
WHO	World Health Organisation
WTO	World Trade Organisation

Executive Summary

Overview

In considering the use of modern biotechnologies, in particular GMOs, for food and agriculture, the FAO Panel of Eminent Experts on Ethics in Food and Agriculture noted that there were still uncertainties, risks and doubts, but recognized, as well, that there were important potential benefits. It recommended a comparative study of regulations concerning biotechnology, including GMOs, exploring the possibility and desirability of harmonizing such regulations. Such regulations balance a multitude of interests and reflect the legal traditions of the countries concerned. However, a comparison of legislation of relevance can assist in identifying major trends and gaps, and in understanding the state of the current regulatory framework.

The purpose of this study is to indicate the extent to which international agreements and a small selected group of national laws may already be assisting societies to realise modern biotechnology's potential and avoid its possible risks.

The study reviewed three categories of legal instruments at international and national levels in the areas of biosafety, food safety and consumer protection. The study can only be considered indicative because of the small sampling of national level instruments undertaken. However, when combined with a wider sampling of international instruments, a number of trends and gaps were evident in two key areas: public participation and oversight mechanisms.

The study is designed around a number of thematic areas that may contribute to assisting societies to realise the potential and avoid the risks of modern biotechnologies. Examples are provided to help illustrate a particular concept. To maintain the study's brevity, general descriptions of the legal instruments reviewed are found in Table I (International Instruments) and Table II (National Instruments).

Section 2.0 describes the nature of the instruments addressing biotechnology. Public participation, including access to information and labelling, is a major tool for realising the potential and avoiding the risks of modern biotechnology. How the instruments reviewed address public participation is described in Section 3.0. Oversight mechanisms, including institutions, safety assessment, and decision-making are the primary tools countries use to examine the merits of GMOs and these are described in section 4.0.

Finally, Section 5.0 briefly suggests some general conclusions on major gaps and trends of existing biotechnology-related legislation. This section also identifies areas for possible further work that might be addressed by supplementary or supporting mechanisms such as a future FAO Code of Conduct on Biotechnology.

Public Participation in Policy and Regulatory Decision-making

Whether at the international or national levels, the biosafety instruments examined were generally found to be more specific on public participation than the food safety or consumer protection instruments examined. This demonstrates that the general principle of public participation is well established in the biosafety field.

However the extent to which public participation is actually facilitated or exists in a country is difficult to determine from a simple review of the country's biotechnology related legislative

instruments. For example, general references to public participation may not translate into actual participation if additional criteria are not provided on the form public participation can take. Also the best public participation provisions may not be used if the public does not have the capacity to effectively participate. Finally, the lack of specific public participation provisions in, for example, a biosafety law does not necessarily mean that the public is barred from participation. It must be kept in mind that generic laws on public participation may already exist in the country and that the necessary criteria are applicable to the policy making and regulatory decision making processes addressing modern biotechnology.

The general lack of references to public participation in the food safety area, at least in what could be considered the first generation of laws at the national level, was striking because it appeared to be across the board, regardless of whether a country was developed or developing. However, some countries such as the United Kingdom are beginning to open the food safety assessment process up to greater public participation and scrutiny.

While consumer protection instruments examined did not promote public participation *per se,* they did promote access to information to enable consumers to make informed choices and to prevent fraud.

Access to information is an important cornerstone of public participation and is one tool that could help to realise the benefits and avoid the risks of modern biotechnology.

International instruments address access to information with varying degrees of specificity. The Aarhus Convention is perhaps the standard against which to judge other instruments at international and national levels. Though its reach is limited to the region in which it applies it is an important source of principles from which international negotiators and national level lawmakers could draw.

In general, those countries with legislation that were reviewed had more references to public participation and access to information than countries relying on voluntary guidelines. Developed countries typically have legislation on biosafety. However, many of the developed countries examined do not appear to be any more progressive in terms of substance than those developing countries examined. This is despite the fact that developed countries have been working on biosafety issues far longer than developing countries, may have a better informed public and constantly urge developing countries to increase public participation and transparency within their decision making processes.

Still it must be kept in mind again that generic public participation laws may pre-empt the need for specific references to public participation and access to information in the sectoral legislation. This may explain the situation in Canada where none of the five sectoral laws examined had explicit provisions on public participation in general and access to information in particular. In contrast, two of these laws did have explicit confidentiality provisions.

The review indicates that confidentiality provisions have proliferated at both international and national levels. There may be a need to further study confidentiality provisions to determine how countries use them and, in particular, whether the application of such provisions impedes the public's access to relevant information on modern biotechnologies. It may be particularly important for future international and national instruments to supply principles to guide the use of confidentiality provisions by decision-makers.

The review reveals that the principle of providing information to neighbouring States is increasingly recognised at the international level. Notwithstanding this, no national level instrument examined

made specific reference to access to information by other States. Bridging this gap could be foreseen as an important contribution to international co-operation and could help to avert transboundary incidents involving GMOs.

Labelling, especially in the food safety and consumer protection areas, is being increasingly addressed at international and national levels. The issue of when labels can or should be applied to products that may or may not contain GMOs is a major issue that is being tackled. In contrast, in the biosafety area no international instruments address labelling, though the AAarhus Convention is examining the issue. Notwithstanding this lack of international action on biosafety related labelling, the review did reveal that some States and regional economic integration organisations are addressing the biosafety and labelling nexus.

The primary concern in all labelling areas is that a proliferation of standards at international, regional and national levels will create barriers to trade and ultimately confuse consumers and other end-users. Therefore there is a need to harmonise standards. For food, harmonisation is taking place at the international level within the Codex Alimentarius. In the biosafety area, there does not appear to be any international process other than an examination of the issue within the AAarhus Convention. An important threshold issue to more action at the international level is determining the need for labelling GMOs and GMO-related products in the biosafety context.

With regard to public participation in policy-making, no international instruments specifically mention the need for public participation in strategic processes focussing on modern biotechnology. In addition, the countries examined do not appear to have participatory policy-making processes within which all aspects of modern biotechnology could be addressed. The most important possibility for public input appears to occur on a case-by-case basis as promoters of individual genetically modified organisms attempt to gain approval through a regulatory process.

Notwithstanding this the review found that some countries are indeed taking a new approach. They are creating broad-based stakeholder processes on certain aspects of modern biotechnology such as the release of GMOs. These processes help the government to gauge public opinion, generate dialogue, gather useful information and develop awareness within their populations on modern biotechnology. New Zealand is a particularly good example.

Because of the dearth of specific references to public participation in policy-making at the international level specific to modern biotechnology, it may be useful for future international instruments, such as the forthcoming FAO Code of Conduct on Biotechnology, to unambiguously refer to the desirability of creating such processes.

Public participation in decision-making is a more familiar concept at international and national levels than public participation in policy-making. Still only four international instruments reviewed address the issue, the standard again being the AAarhus Convention. Examples of varying specificity do exist at the national level specific to GMOs.

Some important considerations include the mechanism through which the public is notified (e.g., public notice) and can provide inputs (in writing or via a public hearing) and the time period within which the comments must be received. However, it is really not enough simply to give the public an opportunity to participate and provide information. Most importantly the competent authority must take those views into consideration. In the best case, the competent authority may also be required to justify why a particular viewpoint was accepted or not. Work on future international or national level instruments should keep this in mind.

Oversight Mechanisms

The oversight process may contribute to maximise the benefits and avoid the risks of modern biotechnology. Three mechanisms were examined: institutions; safety assessment; and decision making.

Oversight and advisory institutions are the most obvious oversight components addressed at international and national levels. The generality with which institutional issues have been treated at international level does not seem to have impeded the establishment of institutional oversight nationally. All countries examined have some form of institutional oversight in place.

What does vary between countries is whether bodies have been created to provide advice to competent authorities tasked with decision-making responsibilities. A multidisciplinary and/or multi-stakeholder advisory body could have an important role to play in assisting a competent authority in its examination of the merits of GMOs and, consequently, maximising the benefits and minimising the risks of modern biotechnology. With the exception of the FAO preliminary draft International Code of Conduct on Plant Biotechnology, no international instrument reviewed refers to the desirability of creating advisory bodies. Future instruments could include provisions on advisory bodies.

Another potentially important institutional consideration is creating institutional biosafety committees. These can be given the ultimate responsibility within an institution working with GMOs to ensure the safety of any GMO-related work before and after regulatory oversight. In fact, IBCs appear to be widely referenced in voluntary guidelines promulgated at the national level. It is unclear whether the concept of IBCs originated with an existing international instrument. Those reviewed for the study did not mention them. Nonetheless negotiators and lawmakers may wish to consider the concept for future instruments.

Safety assessment (e.g., hazards identification, risk assessment and risk management), the second oversight mechanism, is referred to in all national oversight systems examined. It is also referenced in all international instruments examined dealing with biosafety and food safety.

While the need for risk assessment is undisputed, one concept in particular is coming under greater scrutiny. The application of the substantial equivalence concept in the food safety area is the primary example in this regard. Future negotiators of international instruments that may refer to substantial equivalence may wish to provide guidance on its proper application so that the concept does not simply become a decision threshold to exempt genetically modified products from rigorous safety assessments.

Greater attention is also being given to factors other than environmental protection and human health in the oversight process. For example, an emerging trend is the consideration of socio-economic considerations. Governments may need assistance, particularly capacity building and technical guidance, in assessing socio-economic impacts.

Finally, risk communication is a new area of risk assessment that emphasises effective communication in all aspects of risk assessment and risk management. Negotiators and lawmakers may wish to consider it in their work in order to better integrate the public's access to information and participation in the safety assessment process.

In the risk management area the precautionary approach is being referenced more frequently in post-Rio international instruments. The extent to which the precautionary approach is actually practiced at the national level is unknown. However, the small collection of second-generation biosafety and food safety laws that were reviewed do tend to refer to it explicitly. Guidance for applying a precautionary approach to modern biotechnology may need to be promulgated at the international level to ensure a consistent application worldwide.

Post-approval monitoring is a risk management technique referred to in a number of international instruments reviewed. It was not explicitly mentioned in the majority of national level instruments reviewed, but this may be a function of its application in permit conditions. Post-approval monitoring will be important to minimising the risks of modern biotechnology and should be addressed specifically in sectoral instruments at the national level.

Traceability is an emerging risk management tool within the biosafety and food safety areas. It could be useful where illegal export, import or release is suspected, where environmental damage has occurred or where unforeseen food toxicity is identified. It is just being referred to at international and national levels and, where technically feasible, may be useful for negotiators and lawmakers to consider as they create new legal instruments.

Decision-making is the third common component of any oversight mechanism. One important aspect of decision-making consists of the extent to which considerations other than environment and human health are used by decision-maker to reach a decision concerning a GMO. Based on the instruments reviewed it appears that a trend may be emerging to the extent that other factors, such as socio-economic and ethical considerations, are beginning to be considered. A more holistic approach to decision-making may result in a more accurate consideration of costs and benefits in the regulatory decision-making process. Negotiators and lawmakers may wish to consider this broader approach in their work.

A second important aspect of decision-making is mechanisms to ensure greater accountability in the decision-making process. Greater accountability can be supported by criteria for decision-making, publicly available rationales to the decisions taken and the possibility for judicial or administrative review of decisions. Each of these areas is underrepresented in international instruments and only a handful of the national level instruments reviewed refer to all of them. Therefore, negotiators and lawmakers may wish to consider these points in their work**.**

1.0 Introduction

1.1 Basis for the Study

Modern biotechnology for food and agriculture raises a wide variety of ethical questions, including in relation to the need to ensure food security for present and future generations, to conserve and sustainably use natural resources, to respect human rights, and to share the benefits of technology in an equitable manner. National legislation and international law constitute one of the ways in which such concerns are operationalised. Recent years have seen rapid techonlogical advance and regulatory changes at the international and national levels.

The FAO Panel of Eminent Experts on Ethics in Food and Agriculture held its first session from 26-28 September 2000. The Panel addressed three issues among them biotechnology, including genetically modified organisms (GMOs) (FAO, 2001).

In its report, the Panel examined three aspects of the biotechnology issue as it relates to food and agriculture:

- Risks, uncertainties, and doubts in the use of GMOs;
- Potential benefits and problems faced; and
- Enabling conditions to realise the potential and avoid the risks of modern biotechnologies, including GMOs.

Law is one of the enabling mechanisms through which society can realise the potential and avoid the risks of modern biotechnologies.

The purpose of this study is to indicate the extent to which international and a small selected group of national laws may already be assisting societies to realise modern biotechnology's potential and avoid its possible risks. The study is designed to fulfil the Panel's request that FAO "prepare an update on the status of regulations in different countries concerning the application of biotechnology and GMOs" (FAO, 2001).

1.2 Methodology of the Study and Format

The study is comparative in nature. It reviews legal instruments at international and national levels.

It should be kept in mind that biotechnology is a very broad topic. Some of the intersecting thematic areas include biosafety, food and feed safety, consumer protection, intellectual property, seed certification, bio-ethics, as well as access to genetic resources and benefit-sharing. The study does not attempt to review all of these different thematic areas. To narrow the study's scope three categories of legal instruments have been reviewed: those dealing with biosafety, food safety and consumer protection.

Biotechnological techniques can be described as conventional or modern. To narrow the study's scope further, and to parallel worldwide trends, the study's primary focus is on "modern" biotechnology. Modern biotechnology encompasses the techniques of recombinant DNA or genetic engineering. Therefore the study's focus is on genetically modified organisms (GMOs).

The primary research for the study was undertaken with the assistance of the FAO Legal Office. The Legal Office suggested a number of possible countries to review in different regions around the world. It provided primary and secondary source materials, including legislation and literature. These materials were then supplemented with additional Internet-based research. Only a selected subset of the countries suggested by FAO are actually referenced in the study because they provide what was considered by the author to be good illustrative examples.

The study is designed around a number of thematic areas that may contribute to assisting societies to realise the potential and avoid the risks of modern biotechnologies. Examples are provided to help illustrate a particular concept. To maintain the study's brevity, general descriptions of the legal instruments reviewed are found in Table I (International Instruments) and Table II (National Instruments).

Section 2.0 describes the nature of the instruments addressing biotechnology. Public participation, including access to information and labelling, is a major tool for realising the potential and avoiding the risks of modern biotechnology. How the instruments reviewed address public participation is described in Section 3.0. Oversight mechanisms, including institutions, safety assessment, and decision-making are the primary tools countries use to examine the merits of GMOs and these are described in section 4.0.

Finally, Section 5.0 briefly suggests some general conclusions on major gaps and trends of existing biotechnology-related legislation. This section also identifies areas for possible further work that might be addressed by supplementary or supporting mechanisms such as a future FAO Code of Conduct on Biotechnology.

2.0 The Nature of Instruments Addressing Biotechnology

The instruments reviewed for this study include those on biosafety, food safety and consumer protection.

Biosafety instruments represent the primary source of law on modern biotechnology in the world today. Biosafety instruments address the risks posed to the environment and human health when GMOs are released into the environment either for research (e.g., small scale or field-testing) or for commercial purposes. Biosafety instruments also address contained use of GMOs. This area has not been reviewed for the study.

Food safety instruments address the risks posed to humans by genetically modified foods. The general goal of these instruments is to minimise risks to humans presented by GMOs or their products used as foods themselves or as ingredients in food. Ideally the entire human food chain is examined moving from the farm to the kitchen table.

A related area that was not specifically reviewed is animal feed safety. This area is mentioned within the study in isolated instances. A new trend, exhibited by new instruments being developed in the European Union, is to make no distinctions between regulating food or feed derived from GMOs when feed could find it is way into the human food chain.

Consumer protection instruments address a range of issues primarily in that area of biotechnology related to food or feed products. The labelling of end products resulting from genetic engineering, such as food or animal feed, is the primary area addressed. In general these instruments are designed to (1) protect the consumers' right to know and the right to make informed choices and (2) ensure fair trade practices to ensure that consumers are not victimised by false or misleading claims about a product.

At the international level there is no single comprehensive legal instrument that addresses all aspects of GMOs or the products of modern biotechnology. Some of the existing instruments are "hard" law or binding. Others are non-binding "soft" law type documents.

In the biosafety area there are at least fifteen instruments. The major instruments are described in Table I which supplements this study. Binding instruments include the United Nations Convention on the Law of the Sea (1982), Convention on Biological Diversity (CBD) (1992), the World Trade Organisation (WTO) Agreement on the Application of Sanitary and Phytosanitary Measures (1994), the WTO Agreement on Technical Barriers to Trade (1994), the UN Food and Agriculture Organisation (FAO) International Plant Protection (1997), Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (1998) and the CBD Cartagena Protocol on Biosafety (2000)

Non-binding codes of practice and technical guidance documents include the World Conservation Union (IUCN) Position Statement on Translocation of Living Organisms (1987), Agenda 21, Chapter 16 (Environmentally Sound Management of Biotechnology) (1992), Organisation for Economic Co-operation and Development (OECD) Safety Considerations for Biotechnology (1992), the FAO preliminary draft International Code of Conduct on Plant Biotechnology as it Affects the Conservation and Utilization of Plant Genetic Resources (1992), the United Nations Industrial Development Organisation (UNIDO) Voluntary Code of Conduct for the Release of Organisms into the Environment (____), the FAO Code of Conduct on Responsible Fisheries (1995), the UNEP

Technical Guidelines (1995) and the FAO Code of Conduct for the Import and Release of Exotic Biological Control Agents (1996).

In the food safety area the Codex Alimentarius is the primary collection of internationally adopted food standards (Codex, 1999). The Codex Commission is the primary forum in which the food safety aspects of GMOs are presently being addressed.

There are six relevant instruments. The Codex instruments are described in Table II which supplements this study. Of these (as of October 2001), only the Codex Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods (1999), which refer to GMOs, have been adopted.

Instruments still being developed include the Proposed Draft Guidelines for the Labelling of Foods Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering, the Proposed Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology, the Codex Alimentarius Proposed Revised Code of Ethics for International Trade in Food and the Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA Plants. In addition, in the animal feed area, the Codex Commission is developing a proposed Code of Practice on Good Animal Feeding.

Of the three primary groups of instruments, those dealing with consumer protection and modern biotechnology are the least developed at the international level. Only two instruments appear to exist at the international level. Both of these are non-binding soft law instruments.

The first instrument is the UN Guidelines on Consumer Protection (1985). The Guidelines are currently being revised within the Commission on Sustainable Development process to address sustainable consumption patterns including references to GMOs. These may be finalised at the World Conference on Sustainable Development. The second instrument is the Codex Alimentarius Proposed Revised Code of Ethics for International Trade in Food (1985).

The legal instruments from fifteen countries and regions were reviewed for this study. Thirteen of these are actually referred to in the study. As might be expected, at the national level the legal systems applying to modern biotechnology in the biosafety, food safety and consumer protection areas vary from country to country. If the countries reviewed are any indication, there does not appear to be any single law addressing all aspects of biotechnology. Instead, the primary focus is on GMOs.

Perhaps the most obvious distinction is that a country can have specific laws on GMOs or it can rely on existing non-specific laws that apply through an expanded interpretation. Australia relies on specific legislation.

For example, the Gene Technology Act (2000) consolidates the country's treatment of GMOs and genetically modified products (GM products). All "dealings" with GMOs are regulated and a "gene technology regulator" is established. The gene technology regulator is set-up as the competent authority overseeing the law's implementation.

The United States of America represents the approach taken at the opposite end of the spectrum. The United States does not have a specific law on GMOs. Instead, existing laws on agricultural pests, toxic chemicals and food, have been adapted through administrative regulations to address GMOs. The regulations have been promulgated in a "loosely" co-ordinated framework (Jenkins, 2001) that is overseen by existing institutions. Gaps remain. Several classes of GMOs lack specific regulations or

enforceable guidelines, for example, arthropods and fish, and in those and other cases, the applicability of existing statutes is unclear and in debate among the agencies that potentially have oversight (Jenkins, 2001).

Some countries do not appear to rely on any legislation at all. Instead they have developed and apply "voluntary" guidelines.

For example, as of October 2001, Thailand does not have in place comprehensive laws to address biosafety. Other laws apply in part, but a set of guidelines is the primary instrument applicable. The Guidelines are considered "soft law based on voluntary action". However, the Plant Quarantine Act prohibits GMO imports without a permit from the Department of Agriculture and when imports are allowed this can only be for experimental purposes.

The extent to which a voluntary system helps to realise the benefits while avoiding the risks of modern biotechnology is unclear. The success of voluntary systems (or mandatory systems for that matter) very much depends on the national situation of the country(ies) involved (Young, 2001). The most important aspects of a voluntary system are (1) ensuring compliance and (2) issues of accountability, including liability, when the guidelines are breached and/or damage occurs. Without assurances of accountability, such as legal enforcement, the risks of modern biotechnology could be shifted to third parties.

As might be expected, developed countries tend to have the most comprehensive and specific legal and institutional systems in all three thematic areas examined. Some developed countries, such as those in the European Union, or Australia, are developing second-generation laws.

Second generation laws tend to be more comprehensive than those that they replace. They move away from sectoral treatment that may have created gaps in the past. A more comprehensive regulatory approach may result in greater possibilities to capture biotechnology's benefits while minimising its risks. A number of characteristics may contribute to this. The most important may be the consistency of approach that comes from the use of a single competent authority entrusted with review and decision-making.

The legal and institutional systems of developing countries are best represented in the biosafety area. Within this group the systems vary in comprehensiveness.

For example, some systems address the complete spectrum of GMO uses - from research and field-testing to commercialisation. Other systems may only apply to research. In some countries, a step-wise approach to developing and implementing a regulatory system may be taken.

In Egypt, for example, the regulatory programme appears to be based solely on voluntary guidelines. It will be expanded to include commercialisation of GMOs when the need arises.

The extent to which a step-wise approach helps to realise the benefits and avoid the risks of modern biotechnology is unclear. However, a step-wise approach may help to strategically focus limited resources and capacity into areas most in need, such as risk assessment and risk management. While resources may always be limited, the knowledge, experience and capacity developed in a step-wise approach could be adapted and shifted to other areas needing attention as the circumstances present themselves. However, it would appear that a step-wise approach needs to be carefully tied to a suitable regulatory framework that can also be adapted as the circumstances change.

The prescriptive nature of the rules governing biosafety also varies with the country. For example, as alluded to earlier, a number of countries have adopted biosafety "guidelines". The guidelines may or may not be supported by accompanying implementation legislation calling into question whether they are legally binding or simply voluntary. The aspirational tone of some of the guidelines reviewed could be problematic because their obligatory nature is left unclear.

Developing countries also tend not to have laws that specifically address the food safety or consumer protection aspects of GMOs. That more specific instruments do not exist may be due to the lack of capacity to focus on GMOs. Another reason could be a different cultural perspective on the risks posed by GMOs, particularly with regard to food safety (Aerni, *et al.*, 1999).

In the absence of specific laws, developing countries for example may rely on the product approvals issued by countries with more developed laws. Depending on the circumstances, this may or may not be appropriate for the particular country at issue. For example, the assessments upon which the other country's competent authority based its decision may not be specific enough for the importing countries own unique circumstances.

General laws on food safety and consumer protection do exist but they may not have been developed with GMOs in mind. General laws on food safety and consumer protection could be applied to GMOs as stopgap measures as the situation arises. However, where there is a need, and the goals are to realise the potential and avoid the risks of modern biotechnology, it may be better to develop more specific legislation tailored to the country's particular needs. This is an important point because without specific references to GMOs in the general laws it may be difficult to motivate governmental oversight agencies to act.

2.1 Regulatory Trigger: Process versus Product

The instruments examined are also distinguishable according to their regulatory trigger. In other words, does the process that was used to create an end product (such as the techniques of modern biotechnology) trigger the application of a legal instrument? Or, regardless of the process used, is the trigger the potential risks posed by the end product itself?

The majority of instruments examined are product-oriented. That is, the risks posed by the end-product trigger review, regardless of the techniques used to produce the end product.

Notwithstanding this, a distinction is still made between non-GMOs and GMOs in product-oriented systems, whereby non-GMOs are typically not regulated. For example, most countries do not formally evaluate new seed varieties produced by traditional breeding methods for their food safety or environmental safety. This is primarily because the breeding process is premised on the familiarity with the varieties being released. Traits that might pose a threat to the environment or to human health are typically identified in the breeding process and eliminated.

Interestingly, Canada takes a different, and possibly unique, product-based approach. Canada does not distinguish between organisms and products made from recombinant DNA techniques and more traditional techniques such as plant breeding. Instead, the regulatory trigger is whether a new organism or product has a novel trait or characteristic that sets it apart from other similar, but non-modified organisms or products, regardless of the process used. This is most apparent for plants.

In Canada, plants with novel traits (PNTs) are varieties or genotypes. They are regulated because they or their characteristics are not considered to be "familiar" or "substantially equivalent" to those in a

distinct, stable population of cultivated species of seed in Canada and have been intentionally selected, created or introduced through a genetic change (CFIA, 1994). “Familiarity” is “the knowledge of the characteristics of a plant species and experience with the use of that plant species in Canada” (CFIA, 1994).

“Substantial equivalence” is the equivalence of a novel trait within a particular plant species, as it relates to the novel plant’s use and safety for humans, the environment [and animals - in the case of feeds], compared to plants of the same species that are used and generally considered safe in Canada (CFIA, 1994).

3.0 Public Participation in Policy Making and Regulatory Decision Making

One of the most useful legal tools for realising the potential and avoiding the risks of modern biotechnology may be legally requiring public participation in the policy making and regulatory decision-making processes. Opening decision making processes up to the public may help to ensure that decision makers have the best information at their disposal in order to evaluate the benefits and risks that modern biotechnology could present. Public participation could also help to ensure better transparency and accountability in decision-making.

Of course a necessary pre-condition to public participation is the public's capacity to meaningfully participate (Young, 2001). The mere will to participate is not enough even where the legal regime is conducive. For example, for NGOs to act as biosafety watchdogs requires sustained efforts, financial resources and trained personnel. Other important elements include access to information (section 3.1) and access to the judicial system (section 4.3.2.3).

3.1 Access to Information

Access to accurate information related to biotechnology in general and GMOs in particular is a cornerstone of any system to realise modern biotechnology's benefits and avoid its risks. The accessible information could include permit applications, environmental and other assessment results, the results of consultations with the public, as well as information on consents and denials

Access to information is especially important because GMO releases generally take place on a case-by-case basis. Therefore it is through the regulatory process that the public may have the most direct access to information on modern biotechnology.

A sub-area of access to information is the extent to which a permit applicant may withhold confidential information and prevent its dissemination to the public during the regulatory review and decision-making process. The possibility to withhold commercially sensitive information is found in almost all instruments examined whether international or national.

The more advanced instruments provide principles against which a request to withhold confidential information is weighed by competent decision making authority. Many times an instrument will stipulate which pieces of information must remain part of the public record.

A second sub-area of access to information relates to that provided between States. A number of international instruments provide the basis to ensure information transfer.

Finally, product labelling can provide consumers with information. Product labelling is presented here as a third sub-area.

3.1.1 International Treatment of Access to Information

Many international instruments address the public's access to information in relation to GMOs.

The Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (Aarhus Convention) is probably the standard against which other international and national instruments can be measured. It has recently entered into force, But AarhusA is only a regional convention. Therefore, though it may be a good example, its reach may be limited.

The AarhusA Convention specifically mentions GMOs in the context of decision-making (article 6(11)), but its broader or more general provisions could be interpreted to apply to GMOs as well.

The Convention is premised upon the principle that every person of present and future generations has the right "to live in an environment adequate to his or her health and well-being" (art.1). One-way to ensure this is for governments to "guarantee the rights of access to information, public participation in decision-making and access to justice in environmental matters" pursuant to the Convention's provisions (art. 1). The 20th recital in the preamble recognises "the concern of the public about the deliberate release of genetically modified organisms into the environment and the need for increased transparency and greater public participation in decision-making in this field".

Environmental information is defined to include any information in any media on *inter alia* (1) the state of elements of the environment, including GMOs and (2) factors affecting or likely to affect the elements of the environment, cost/benefit and other economic analysis and assumptions upon which environmental decision-making is based. A person may access environmental information without an interest having to be stated (art. 4(1)(a)). The information should be made available as soon as possible (art. 4(2)). Requests for access may be refused according to enumerated criteria (art. 4(3)). In addition, access to environmental information may be refused for reasons of commercial confidentiality (art. 4(4)(d)), but the grounds for refusal are to be interpreted restrictively, taking into account the public interest served by disclosure (art. 4(4)).

There is an affirmative obligation on public authorities to possess and update environmental information relevant to their functions (art. 5(1)((a)). Public authorities are to establish systems to ensure an adequate flow of information on proposed and existing activities (art. (1)(b)). Public authorities also must ensure the availability of information to enable the public to take steps to mitigate harm where there is an imminent threat to human health (art. 5(1)(c)).

The manner in which public authorities make information available to the public is to be transparent and environmental information is to be effectively available (art. 5(2)). The progressive availability to the public of easily accessible electronic sources of information is required, including environmental legislation (art. 5(3)(b)). Operators undertaking activities with a significant environmental impact are to be encouraged to regularly inform the public of the environmental impact of their activities and products (art. 5(6)). Parties are also to develop mechanisms to ensure that sufficient product information is available to the public to enable consumers to make informed environmental choices (art. 5(8)).

The public participation provisions of the Convention on Biological Diversity are comparatively weak to those of the Aarhus Convention. The only explicit call for public participation is in the context of environmental impact assessment and this is qualified "as appropriate" (art. 14(1)(a)). The CBD, however, is strong in the transboundary context.

The CBD has general provisions to promote notification, information exchange and consultation regarding activities under a party's jurisdiction or control which are likely to significantly affect adversely the biodiversity of other States or areas beyond the limits of national jurisdiction (art. 14(1)(c)). These provisions can be interpreted to apply to GMOs.

In addition, where it does not ratify or accede to the Biosafety Protocol, a CBD party still needs to implement article 19(4). Article 19(4) creates a bilateral obligation for a contracting party to provide information on an LMO prior to providing it to another CBD party. This information includes (1) any

available information on the regulatory measures taken by the exporting CBD Party and (2) any available information on the "potential adverse impact" of a particular LMO.

The Cartagena Protocol on Biosafety contains explicit provisions on access to information. Contracting parties shall promote and facilitate public awareness, education and participation concerning safe transfer, handling and use of LMOs in relation to biodiversity conservation and sustainable use (taking into consideration risks to human health) (art. 23(1)(a)).

The contracting parties are to endeavour to ensure public awareness and education encompasses access to information on LMOs identified by the Protocol that may be imported (art. 23(1)(b)). Finally, each contracting party is to endeavour to inform its public about access to information through the Biosafety Clearinghouse (art. 23(3)).

Confidential information is explicitly addressed in the Protocol. For example, the contracting party of import is to permit the notifier to identify information submitted under Protocol procedures or required by the contracting party of import for AIA to be treated as confidential (art. 21(1)). The notifier must justify this upon request.

The party of import is to consult the notifier if the information identified does not qualify for confidential treatment and inform the notifier prior to disclosure. The party must provide reasons on request and an opportunity for consultation and internal review of decision prior to disclosure (art. 21(2)).

Each contracting party is to protect the confidential information that it receives. Each party is also to ensure that it has procedures to protect confidentiality and shall protect this information no less favourably than confidential information for domestically produced LMOs (national treatment) (art. 21(3)). The party of import is not to use the confidential information for commercial purposes except with written consent of the notifier (art. 21(4)). When the notifier withdraws or the notification is withdrawn, the contracting party must respect the confidentiality of commercial and industrial information (R&D included) and information where there is disagreement as to confidentiality (art. 21(5)).

Under the Protocol, some information cannot be made confidential: (a) the notifier's name and address; (b) the general description of the LMO; (c) a summary of the risk assessment; and (d) methods and plans for emergency response (art. 21(6)).

The most significant provisions of the Biosafety Protocol focus on the evaluation and notification between parties for LMOs slated for export and subsequent import. Advance informed agreement (AIA), in other words, notification and subsequent approval of a first-time import (an intentional transboundary movement), applies to LMOs that are intended for intentional introduction into the environment where they may have adverse effects on the conservation and sustainable use of biodiversity (art. 7-10 and 12). For a first time import of an LMO slated for release into the environment, the Protocol sets up a notification procedure between the exporting contracting party (or an exporter that is a legal or natural person) and an importing contracting party (art. 8 and 9).

AIA does not apply to LMOs intended for direct use as food or feed, or for processing. Instead, the contracting party that makes a final decision on an LMO for domestic use must notify the Biosafety Clearing-house created under the Protocol when the LMO could find its way into international trade (art. 11). The notification, at minimum, must contain information required under Annex II. The exemption for AIA does not apply to decisions on field trials.

In both cases, lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of potential adverse effects shall not prevent the contracting party of import from taking a decision, as appropriate, in order to avoid or minimise potential adverse effects (art. 10(6)).

The Protocol also addresses access to information in another transboundary context. Affected or potentially affected States are to be notified when an occurrence may lead to an unintentional transboundary movement (art. 17(1)).

The WTO Agreement on Sanitary and Phytosanitary Measures (SPS Agreement) has a number of provisions on stakeholder participation – as between WTO member States. For example, a member State is entitled to an explanation from another member State when the former believes a specific sanitary or phytosanitary measure (SPM) is or could constrain its exports (art. 5(8)). This only applies when the SPM is not based on an international standard, guideline or recommendation. Furthermore, members are to notify changes in their SPM according to an annex to the SPS Agreement (art. 7). These procedures include (1) publishing a notice to interested member States; (2) notifying member States through the SPS Secretariat; (3) providing copies of the proposed SPM to members on request; and (4) allowing reasonable time for members to make comments, discuss the comments upon request and take the comments and discussion results into account (Annex B, para. 5(a-d)). Some of these steps can be omitted in emergencies (Annex B, para. 6). Other means to ensure transparency are also provided. These include (1) prompt publication of new regulations (Annex B, para. 1); (2) allowing reasonable time for other members to adapt their systems to the new requirements (Annex B, para. 2); and (3) providing one "enquiry point" responsible for answering questions (Annex B, para. 3).

Similar provisions are made under the WTO Agreement on Technical Barriers to Trade. In addition, confidential information does not have to be disclosed (Annex B, para. 11).

The UNEP Technical Guidelines on Biosafety were adopted in 1995. They were designed and adopted as a contribution to the implementation of Agenda 21 (Chap. 16) (which incidentally makes very limited reference to public participation). They provide the possibility for States to voluntarily develop mechanisms for evaluating the biosafety of "organisms with novel traits" and to identify, assess and manage the risks associated with the use of biotechnology.

The Guidelines suggest that oversight authorities are responsible for encouraging public participation, through access to information on which decisions are based, while respecting confidential business information. Annex 7 highlights examples of how the public may be involved. This could include *inter alia*, establishing a register of information on organisms with novel traits, giving interested groups the opportunity to comment, publishing a newsletter, encouraging proponents to inform local people and encouraging dialogue between the public and companies and academic institutions.

The Guidelines also apply to information exchange between States in a transboundary context. For example, where transboundary impacts could occur, the potentially affected country should be notified of the intended use and should be given the opportunity to determine whether risk management measures will protect its interests (para. 42). The potentially affected country should be informed immediately when adverse effects could affect it.

The Guidelines also provide a framework to exchange information related to transboundary transfer or organisms with novel traits (para. 44). The framework is premised on a user in an exporting country providing information to a user or focal point in the importing country, prior to transfer. This is much

like the concept of "advance informed agreement" in the CBD Biosafety Protocol. It is particularly intended to assist those countries without fully operational regulatory programmes

UNIDO Voluntary Code of Conduct for the Release of Organisms into the Environment provides general principles governing standards of practice for all parties involved with the introduction of organisms or their products/metabolites into the environment (sec. II-A-1(a)). It covers GMOs in all stages of research, development and disposal while focussing on release into the environment (sec. I-B). The Code is founded upon a number of general principles.

For example, national authorities, industries and researchers have the responsibility to make safety information available to the public (sec. II-C-1((e)). Furthermore, maximum disclosure of information necessary for risk assessment may be balanced by respect for confidential business information (sec. C-2-(h)). The local community should be informed of a planned introduction prior to release and appropriate educational materials should be provided (sec. II-C-2(i)). In addition, public access to information upon which decisions regarding use or release of organisms should be ensured (sec. II-C-2(j)). Finally, information on anticipated consequences, which may be transboundary in nature, needs to be provided to those countries that may be affected (sec. II-C-1(l)).

The FAO Code of Conduct for the Import and Release of Exotic Biological Control Agents does not specifically mention GMOs. However, because a GMO could act as a biological control agent the Code could be interpreted to apply, even though a first time import for environmental release would now be likely be covered by the Biosafety Protocol.

Curiously, an importer is only to make information publicly available relating to safety and environmental impact *after* import and release (art. 8.1.2). A "free and frank" exchange of information, not subject to commercial confidentiality, is to be maintained.

Article 16 of the FAO preliminary draft International Code of Conduct on Plant Biotechnology as it Affects the Conservation and Utilization of Plant Genetic Resources addresses public information. Article 16.1 provides that the public should be informed about possible risks to the environment and health. In addition, governments and competent authorities should "apply transparent procedures in risk assessment, giving access to all the information that could be of public interest" (art.16.1). Governments and public authorities should inform and consult the public (art. 16.2).

The UN Guidelines for Consumer Protection were adopted in 1985 as UN General Assembly Resolution 39/248 (9 April 1985). The guidelines were incepted as "a comprehensive policy framework outlining what governments can do to promote consumer protection in such areas as safety, economic interests of consumers, quality and distribution of goods and services, consumer education and information and redress" (UNESC, 1998). The Guidelines are most relevant to food safety issues. They form one foundational group of principles underpinning the Codex Alimentarius.

The UN Commission on Sustainable Development (CSD) established an international work programme on changing consumption and production patterns in 1995. In 1995, the CSD recommended expanding the consumer protection guidelines to include guidelines on sustainable consumption patterns (UNESC, 1998).

The UN Economic and Social Council requested the Secretary General to work on this through the creation of an interregional expert group meeting (UNESC, 1998). The expert group, which met in 1998, made specific recommendations for submission to Council through the Commission on Sustainable development at its sixth session (UNESC, 1998). The expert group focussed on

identifying the issues related to sustainable consumption that should be incorporated into consumer protection policy (UNESC, 1998).

The expert group's recommendations include various specific references to GMOs in relation to food. In addition, some of its general recommendations could be more generally applied to GMOs. For example, governments should encourage all concerned to participate in the free flow of accurate information on all aspects of consumer products (sec. B, para. 12).

3.1.2 National Level Treatment of Access to Information

The States examined have treated access to information at the national level in a number of ways. There is a great variation between instruments, whether in developed or developing countries, but some general patterns can be discerned.

Perhaps the most explicit examples pertaining to access to information come from within the EU, despite the fact that first generation EU level legislation was comparatively weak in public participation. For example, in the United Kingdom applications for GMO release into the environment must be publicly advertised pursuant to the Environmental Protection Act (sec. 111(4)). The GMOs Regulation makes the applicant responsible for advertising the application for consent to release by publishing a notice in a newspaper or newspapers in the areas likely to be affected by the proposal (reg. 8(1)). The information is to include (a) the applicant's name and address; (b) the general description of the organisms to be released; (c) the release's location and general purpose; and (d) the foreseen release dates (reg. 8(1)(a-d)). The level of detail regarding the release's location must be that which appears in the public register created pursuant to the Environmental Protection Act. In addition, the applicant must specifically notify a number of individuals that he has made the application along with the information found in the public notice. These include *inter alia* (a) the owner or owners of the site when different from the applicant; (b) the local authority for the area of the proposed release; (c) a number of different councils and commissions; and (g) each member of the genetic modification safety committee that the applicant has established pursuant to the UK Genetically Modified Organisms (Contained Use) Regulations of 1992 (see generally reg. 3(a-h)).
.
The Environmental Protection Act establishes a public register system. The Secretary of State is to maintain the public register. The register is to include a wide variety of information. This includes (1) notifications for release under section 108 of the Act, (2) prohibition notices, (3) applications for consent and advice given by an appointed committee, (6) consents granted and information furnished pursuant to conditions of consent and (6) convictions for offences (section 122(1)). The register is to be open to the public, free of charge and is to afford the public facilities to obtain copies of register entries for reasonable charges (section 122(2)). The register shall not include (1) information contrary to national security interests, (2) information that could lead to environmental damage or (3) information that is commercially confidential (without consent of the information holder (section 123(1-3)). The register goes beyond EU requirements.

Confidential information is also explicitly addressed. The holder of commercially confidential information must apply to have the information excluded from the register (section 123(4)) and the Secretary of State decides upon the application and informs the applicant accordingly. When it has been obtained as a result of the law's implementation, the Secretary of State shall notify third parties of information that may be commercially confidential to give them a reasonable opportunity to object to its posting in the register (section 123(6)). The Secretary of State shall take the third party's representations into consideration before determining whether the information is commercially confidential. Information to be included in the register for notifications, consent applications and

consents granted is to include (1) name and address of person; (2) GMO description; (3) location of the GMOs; (4) purposes of importation, acquisition, keeping, release or marketing; (5) results of environmental risk assessment; and any other information "which the public interest requires" notwithstanding its commercial confidentiality (section 123(7)(a-e)). Confidential information can be excluded from the register for up to four years, at which time the holder needs to reapply (section 123(8)).

The UK takes a different approach to public participation and access to information in the food safety area where a combination of sectoral and generic instruments refer to public participation. Public participation through stakeholder involvement is not explicitly provided for in the food assessment process under the Novel Foods and Novel Foods Ingredients Regulations. However, amendments to the regulation, and their subsequent interpretation by the UK Food Standards Agency and the Advisory Committee on Novel Foods and Processes (ACNFP), change this. Another influencing factor is the UK Freedom of Information Act (2000). Finally, some of the shift to greater transparency may also be due to a series of food safety crises that have struck the United Kingdom and Western Europe in recent years.

The 1999 amendment to the UK Novel Foods Regulations increased the transparency of ACNFP's proceedings such that any information submitted to it under the European Commission Regulation 257/97 is discloseable to anyone who requests it. This is subject to three exceptions: (1) the information is not required by the EC Novel Foods Regulation; (2) ACNFP agrees with the information holder that the information is confidential because it would harm competitive position; or (3) the ACNFP agrees that the information is confidential because disclosure would harm intellectual property rights (UK Food Standards Agency, _____). Other aspects of stakeholder involvement such as public participation in decision-making are not clarified, although another UK law that has not been reviewed as part of this study, such as the UK Freedom of Information Act, could provide for this.

In contrast, European Union Regulation 258/97/EC (Concerning Novel Foods and Novel Food Ingredients) does not appear to have any requirements for public participation at the Community level, other than co-ordination between the Member States. In addition, there are no requirements for public participation at the national level.

The situation may improve slightly with the adoption of the proposed EU Regulation on Genetically Modified Food and Feed. An application process would be established by the proposed regulation (article 6). The application would be sent to the proposed European Food Authority. Along with a variety of other information, including a study demonstrating compliance with the authorisation criteria in article 4(1), the application must include *inter alia* a dossier summary (article 6(3)(l)). The Authority would make the applicant's dossier summary available to the public (article 7(3)(c)). Favourable opinions by the Authority are to be made available to the public after deletion of confidential information (article 7(7)).

The European Commission will prepare a draft decision. The authorised food is entered into the proposed Community Register of Genetically Modified Food and Feed and made available to the public (article 30).

Confidentiality provisions are similar to those in Directive 2001/18/EC. However, it is clarified that the Commission, Authority and the Member States are obliged to keep confidential all information identified as confidential "except for information which must be made public if circumstances so require, in order to protect human health, animal health or the environment" (article 31(5)).

The European Union is a little more progressive in its new directive on the Deliberate Release of GMOs into the Environment (2001/18/EC) with regard to access to information. Directive 2001/18 promotes transparency by emphasising the necessity of public consultation, either by the European Commission or the Member States (preamble para. 10).

In Part B (first release), article 9 applies to public information and consultation with respect to environmental releases. Member States are to make information available to the public on all GMO releases into the environment (article 9(2)). In addition, the Commission is to make available to the public the information contained in the system of information exchange between the Commission and the Member States' competent authorities (article 9(2), which includes summaries of the notifications received by the competent authorities, observations and a list of GMOs released within the Member States' territories (article 11).

Part C (marketing and commercialisation) of the Directive places the responsibility on the European Commission to inform the public of the application and its receipt. The Commission has the responsibility to make available to the public a dossier summary provided with the applicant's notification. (art. 24(1)). This is to happen immediately upon the notification's receipt. In addition, the assessment reports for GMOs attaining written consent, and the opinions of any Scientific Committees consulted, must also be made public (article 24(2)), but it is unclear who is to do this.

Part C also creates Member State requirements with regard to access to information. For example, the Member States' competent authority issues the written consent that allows the notifier (i.e., the applicant) to go ahead with marketing or commercialisation (article 15(3) and article 19). Member States are to take "all necessary measures" to ensure that the written consent, and decisions by a committee created to address Member State objections to a notification (article 18) are made accessible to the public (article 19(4)). In addition, the Member State is to take emergency measures, including providing public information, when the GMO or the product presents a severe risk after consent has been granted (article 23(1)).

The release of information to the public in all cases is subject to the confidentiality provisions of article 25. The Commission and competent national authorities shall not divulge to third parties confidential information notified or exchanged under the Directive (article 25(1)). The notifier may indicate that information whose disclosure might harm his competitive position and which should be treated as confidential (article 25(2)). He must provide verifiable justification. The competent national authority consults with the notifier and decides which information shall be kept confidential (article 25(4)). Information that cannot be kept confidential includes *inter alia* a general description of the GMO, monitoring methods and plans, emergency responses and environmental risk assessment (article 25(4)).

Finally, the Commission is to establish registers on genetic modification that "shall include a part which is accessible to the public" (art. 31(2)). Member States are also to create public registers with release site locations for Part B GMO releases (article 31(3)(a)). They are to also create registers for GMOs grown under Part C whose locations shall also be publicly available (article 31(3)(b)).

The African Union has issued draft model legislation on GMO biosafety that includes provisions on access to information. When an application is received, the information included is to be made available to the public and other governmental agencies by the competent authority (CA) (art. 5(1)). The information provided is subject to confidentiality restrictions for business purposes, after the applicant makes a claim for confidentiality to the CA (art. 11(1)). Information that cannot be kept

confidential includes (1) a description of the GMO or the product; (2) methods and plans for monitoring and emergency plans (3) evaluation of foreseeable effects (pathogenic or ecological) (art. 5(2)(a-c)). The CA may make the confidential information available if it decides that it is in the public interest to do so (art. 12(3)). The public may make comments within a period specified by the CA (art. 5(2)). Where the CA arranges for a public consultation it is to be announced in the media with national coverage for a given period of time (art. 5(3)). The CA is to make available to the public information on consents and denials as well as the risk assessment for the GMO or product of a GMO at issue (art. 5(5)).

Public access to information requirements were not identified in the instruments reviewed in Indonesia, Philippines and Thailand study.

The Indonesian Ministerial Decree on the Provisions on Biosafety of Genetically Engineered Agricultural Biotechnology Products (1997) does not appear to have any provisions for public participation, though another law may apply. The successful applicant has a number of rights and obligations.

For example, commercial confidentiality is available to the applicant over the genetically engineered agricultural biotechnology product, but it appears to be limited to situations where the approval has been issued (art. 40(1)). Confidentiality is extended to the application by the agency reviewing the application (art. 40(2)). No criteria are provided in either case for reviewing claims to confidentiality.

3.2 Labelling

The labelling of GMOs or products derived from GMOs is a sub-area of the access to information theme. Labelling is being considered, and in some cases is already being used, in the biosafety and food safety areas in order to provide consumers with information on the GMO or GMO-derived product that they are either considering to purchase or are already using. “Consumers” may be farmers, mass caterers or individuals (either wittingly or unwittingly).

One aspect of labelling is premised on the principle that the consumer has a right to know what he or she is purchasing and subsequently using. This principle has its origins in consumer protection. With the information that labels provide, consumers may make better, more informed choices about the products that they are thinking of buying. Furthermore, when products are properly labelled consumers can exercise their right to choose products that meet their particular economic, health, religious, ethical, moral or other needs. For these reasons, labels can become a market-based mechanism that can contribute to the marketplace’s acceptance of a product or the technology upon which the product is based.

A second aspect of labelling, related to the right to know, is protecting the consumer from false, misleading or deceptive practices. This is another consumer protection principle. Labelling may be able to ensure that the claims made about a product are indeed true and that the consumer really gets what is being advertised.

Finally, a third aspect of labelling is premised on consumer education. Consumer safety and environmental protection can be promoted when labels supply the appropriate information to consumers.

For example, a label's information may warn the consumer of product attributes that could endanger his or her health or threaten the environment if the product is used in a certain way. In this way, labels can be viewed as a risk management tool (see section 4.2.3.2 below).

When labels can or should be applied to products that may or not contain GMOs is a major issue that is being addressed at international and national levels. Labelling has been most prevalently used in relation to food derived from GMOs and food that producers would like to claim is GMO free. In the first instance, there is a trend worldwide to label food products that are clearly derived from GMOs.

In the second instance, some food producers would like to distinguish their products from those that are genetically modified. But, because *de minimis* or adventitious amounts of genetically modified ingredients may appear in otherwise normal materials, the issue then becomes what percentage of the modified materials can be allowed while enabling producers to still make the "GMO free" claim? In other words, what percentage of GMO products triggers labelling? This issue's resolution not only has market implications. It could also have an impact on food safety and the consumer's right to know, especially in relation to foods that may contain ingredients that have religious or ethical implications.

At the international level, the rules for GMOs and food are being developed within the Codex Alimentarius. In the biosafety area, no international instrument creates general rules on labelling. Perhaps sometime in the future the Aarhus Convention will play a large role in the biosafety arena as a task force has been examining the issue of labelling with regard to GMOs (UNECE, 2001). In the former two cases, when the products are in international trade, the World Trade Organisation's Agreement on Technical Barriers to Trade will ensure that labelling is not indiscriminately applied so as to create a trade barrier.

The TBT Agreement is relevant to biotechnology products because it generally applies to technical regulations and standards, including packaging, marking and labelling requirements. It also applies to conformity assessment procedures. The TBT Agreement recognises that "no country should be prevented from taking measures necessary" to ensure the quality of its exports; to protect human, animal or plant life or health, of the environment; or prevent deceptive practices. This can be at levels it considers appropriate provided the TBT Agreement's conditions are met (preamble, para. 6).

The TBT Agreement applies to all products (art. 1.3). It does not apply to sanitary and phytosanitary measures (art. 1.5)). Therefore, the WTO SPS Agreement would apply where a biotechnological product may be a risk to human, plant or animal health. The TBT Agreement would apply where, for example, a product is merely labelled as containing GMOs. The TBT is premised on a number of trade-related principles.

In general, imported products are to be accorded national treatment (art. 2.1). Technical regulations should not create unnecessary obstacles to international trade and should not be more trade-restrictive than necessary to fulfil a "legitimate objective, taking account of the risks of non-fulfilment" (art. 2.2). Legitimate objectives include *inter alia* preventing deceptive trade practices, protecting human health or safety, animal or plant life or health, or the environment. Relevant elements are suggested for assessing the risks.

3.2.1 Food Labelling at the International and National Levels

At the international level, the Codex Alimentarius Commission dominates the food safety and labelling area. The Commission is attempting to develop harmonised world wide labelling practices

related to foods derived from modern biotechnology in order to minimise the effects that food labelling could have on international trade.

Notably, the Codex Commission has yet to adopt an agreed definition of "genetically engineered/modified organisms" (Codex, 1999). However a number of subsidiary bodies are working on different aspects of genetically modified foods and food products.

In the food labelling area, the Codex Committee on Food Labelling is working to amend the Codex General Standard for Labelling Pre-packaged Foods: Labelling of Foods Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering (definitions and declaration of allergens) (steps 6 and 8 respectively). As part of the standard's amendment process, it is also working on Proposed Draft Guidelines for the Labelling of Foods Obtained through Certain Techniques of Genetic Modification/Genetic Engineering (step 3).

The Proposed Draft Guidelines are still in an early stage of development. Consequently, they are only generally described here. Many bracketed sections remain as of October 2001.

The Guidelines are proposed to apply to labelling of foods and food ingredients in three situations. These would be when they are: (1) [no longer equivalent/differ significantly from conventional counterparts]; (2) composed of or contain GM/GE organisms or contain protein or DNA resulting from gene technology; and (3) when they are produced from but do not contain GM/GE organisms, protein or DNA from gene technology (sec. 1, para. 1.1).

Labelling would describe those food characteristics or properties that are different than a corresponding conventional counterpart. Labels would declare the presence of allergens resulting from the GM process (sec. 3.0, paras. 3.1 and 3.2). Criteria would be provided for labelling the method of production (sec. 3.0, para. 3.4). Bracketed text exists on labelling in situations where substances exist that are absent from the corresponding conventional counterpart in situations that could raise ethical concerns (sec. 3.0, para. 3.5). Threshold levels for the presence of GM/GE organisms and the trigger for labelling are still under discussion (sec. 4.0). In general, all label declarations for pre-packaged food shall not be described in a manner that is false, misleading or deceptive or likely to create an erroneous impression regarding the product's character or safety (sec. 6.0).

In 1999, the Codex Commission adopted the Organic Foods Guidelines. The Guidelines provide an internationally agreed approach to produce, label and make claims about organically produced foods. The general aims of the guidelines include *inter alia* protecting consumers against deception and fraud, to protect organic producers against misrepresentation of other agricultural products as organic and ensuring that all stages of production, preparation, storage, transport and marketing are subject to inspection and comply with the guidelines (Foreword). The Guidelines are interpreted as a first step in efforts to harmonise internationally the requirements for organic production. Organic production claims and labelling are limited to operators certified by a certification body.

The Guidelines apply to products that carry or are intended to carry descriptive labelling referring to organic production (sec. 1.1). Products include (a) unprocessed plants and plant products and (b) processed products for human consumption derived from (a). The Guidelines declare that "all materials and/or products produced from genetically engineered/modified organisms (GE/GMO) are not compatible with the principles of organic production (either the growing, manufacturing or processing) and therefore are not accepted under these guidelines" (sec. 1.5). Therefore, the Guidelines take a process based, rather than a product based, approach to genetic manipulation.

In a footnote to the definition of GE/GMOs, the Guidelines note that the Codex Commission has yet to agree a definition. Therefore, a provisional definition is provided. GE/GMOs "are produced through techniques in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination" (sec. 2.2).

Criteria are listed as to when labelling and claims for a product may refer to organic production, including the need for ingredients of agricultural origin to meet certain specifications (sec. 3.3). Derogations are allowed when ingredients of agricultural origin do not satisfy the enumerated specifications (sec. 3.4). A five-percent threshold (total ingredients) is set. From the earlier statements in the Guidelines against GE/GMOs it appears a zero threshold is implicitly set for ingredients of GE/GMO origin.

The *Ad hoc* Intergovernmental Codex Task Force on Animal Feeding is developing a new Animal Feeding Code of Practice. As of October 2001, the elaboration procedure is at step 3. Though the Code is at a very early stage of development its general provisions are potentially relevant to the use of genetically modified or engineered materials in animal feeds.

The purpose of the Code is to establish a feed safety system that covers the whole " 'feed chain' from farm to table" (sec. 1). This will eliminate potential risks to human health, animal health and the environment. In addition to other substantive requirements, labelling of feedstuffs is to be clear and informative to allow the farmer to handle and use the feed correctly (sec. 4.2). It is also to ensure the traceability of the feeding stuffs. Presently, the Code specifically states that "Genetically modified organisms (GMO products) should be labelled".

The extent to which national measures are taking their cue from the Codex's work on food labelling and modern biotechnology is unclear because the majority of the Codex's work is still in the development phase. However, a number of the countries reviewed for this study have taken steps on food labelling issues and these can be categorised as either voluntary or mandatory.

For example, in Canada, food-labelling responsibilities are split between the Canadian Food Inspection Agency (CFIA) and Health Canada. CFIA handles general food labelling policies and regulations not related to health and safety such as misrepresentation and fraud along with basic food labelling requirements (CBAC, 2001). Health Canada's responsibilities relate to health and safety issues related to for example allergenicity.

The Food and Drug Act sets out the general requirements for food labelling in Canada. No person can label, package, treat, process, sell or advertise any food in a false, misleading, or deceptive manner or that is likely to create an erroneous impression regarding the food's character, value, quantity, composition, merit or safety (sec. 4). According to the CFIA *Guide to Food Labelling and Advertising* (CFIA, 1996), since 1993, there have been three major consultations on foods derived from genetic modification. Guidelines have been developed.

Mandatory labelling is required if there is a health or safety change or a signification change in nutrition or composition. In addition, any labelling must be understandable, truthful and not misleading. Finally, voluntary positive labelling (e.g., "does contain products from biotechnology") and negative labelling (e.g., "does not contain products from biotechnology") is permitted provided it is truthful and not misleading (CFIA, 1996).

There are no federal obligations to indicate that a food is a product of gene technology (Canadian General Standards Board, 2001). Because of the lack of federal regulations on this specific aspect of food labelling, an initiative is under way to create a voluntary national standard for labelling of foods derived from biotechnology. The Canadian General Standards Board oversees the standards development process. The process is open to the public and transparent (CFIA, ___a).

A first draft standard has been circulated in 2001 for public comment. The standard would apply to voluntary labelling and advertising of food in order to distinguish whether or not the food is a product of gene technology or contains or does not contain ingredients that are products of gene technology (sec. 1.1). It would not apply to the labelling of foods produced using processing aids, veterinary biologics or livestock feeds that are products of gene technology (sec. 1.2).

Distinctions are made between claims for single ingredient and multi-ingredient food (sec. 4). In general, it is proposed that claims that a single ingredient food is a product of gene technology can only be made for that food when it is obtained from sources of which more than 5% are products of gene technology (sec. 5.2). Similarly, a 5% threshold is proposed for multi-ingredient foods claimed to be produced from gene technology (sec. 5.3). Conversely, a threshold of less than 5% is proposed for single and multi-ingredient foods claimed not to be a product of gene technology (sec. 6).

Verification provisions are established. No claim is permitted if it cannot be verified (sec. 7.1). The person making the claim is responsible for providing the data necessary to verify the claim (sec. 7.2.2). Provisions on confidential information are proposed. The claimant must have in place a verification system (sec. 7.3). In addition, the claimant must have a plan that includes a detailed description of sources of food/ingredients and a description of the management system used to maintain integrity of the food/ingredient (sec. 7.3.2). The standard is equivocal on testing and detection methods (sec. 7.4).

Of the instruments reviewed, Indonesia had one of the most explicit in relation to religious claims and food. The Indonesian Food Act makes specific reference to genetic engineering in article 13. Persons who produce food or use foodstuffs, food additives or "other auxiliary material" in the "production activity or process of food" derived from genetic engineering must have the food examined before it is circulated (art. 13(1)).

The government is to set requirements and principles for research, development and use of the genetic engineering method in the food production activity or process (art. 13(2)). It will also lay down requirements to test food derived from the genetic engineering process.

These provisions build on the more general provisions on contaminated food. A person is prohibited from circulating (1) food containing materials which are toxic, dangerous or which may harm or endanger human health or life, and (2) food containing materials prohibited from use in food production or processes (art. 21(a) and (c)).

Pre-packaged food to be traded, either produced within Indonesia or imported, must have a label (art. 30(1)). Among other things, the label shall contain information on "halal" (allowable for Muslim consumption; relatedly but not required for listing is "haram" (forbidden)) (art. 30(2)(e)). The government may determine other information to be included in or withheld from the label (art. 30(3)). Persons are prohibited from providing untrue or misleading information through the label (art. 33). A person making a claim about a food's acceptability to the requirements of a religion or belief through a label or advertisement is responsible for the correctness of the statement based on the religion or belief (art. 34(1)).

Indonesia's Food Labels and Advertising Regulations have provisions related to labelling products derived from biotechnology. Primary source materials were not available for analysis.

As of October 2001, Thailand does not appear to have food safety laws in place for genetically modified foods. However, the government has committed to labelling by the end of 2001 (Greenpeace, 2001). No texts were available for review.

The present situation within the European Union on labelling and foods derived from GMOs is a little complex because there are a number of instruments addressing various aspects of the issue. The EU Novel Foods Regulation (258/97/EC) applies to the placing on the market for the first time of novel foods or novel food ingredients (i.e., "foods that have not hitherto been used for human consumption to a significant degree") (article 1(1 & 2)). This includes *inter alia* (1) foods and food ingredients containing or consisting of GMOs and (2) foods and food ingredients produced from, but not containing, GMOs (article 1(2)(a & b)).

Labelling requirements in addition to other Community labelling requirements can be specified for foodstuffs to ensure that the final consumer is informed. Among these, additional labelling is required when (1) any characteristic or food property no longer renders a novel food or food ingredient equivalent to an existing counterpart (based on scientific assessment and accounting for natural variations); (2) the presence of material not present in the existing counterpart and which may have human health implications for certain population sectors; (3) the presence of material not found in existing counterparts that gives rise to ethical concerns; and (4) the presence of GMOs (article 8(1)). Where an existing equivalent counterpart does not exist appropriate provisions are to be adopted to ensure that consumers are adequately informed of the nature of the food or food ingredient (article 8(2)).

Regulation 1139/98/EC (Labelling of Certain Foodstuffs Produced from GMOs), as amended, supplements Regulation 258/97/EC (Novel Foods). Regulation 1139/98 covers food and food ingredients which are delivered as such to the final consumer or mass caterers (e.g., restaurants) and are produced in whole or in part from GM soya beans (Decision 96/281/EC) and GM maize (Decision 97/98/EC). These foodstuffs are subject to labelling requirements in addition to those in Directive 79/112/EEC.

The labelling requirements do not apply when the protein or DNA resulting from the genetic modification is not present in the food ingredients individually considered or the food when it comprises a single ingredient (article 2(2)(a)). In addition, labelling is not required where the foodstuff contains GM soya beans and/or GM maize and any other material placed on the market pursuant to Regulation 258/97 (Novel Foods and Food Ingredients) derived from GMOs in a proportion no higher than 1 percent of the food ingredients (article 2(2)(b)). In other words, *de minimis* amounts of genetically modified materials up to 1 percent do not trigger additional labelling requirements. Operators must be in position to supply evidence to satisfy competent authorities that they have taken appropriate steps to avoid GMOs as a source.

Additional labelling requirements vary with the form the food product takes. For example, where the food consists of more than one ingredient, the words "produced from genetically modified soya" or "produced from genetically modified maize" are to appear in the list of ingredients in brackets immediately after the ingredient concerned or in a prominently displayed footnote (article 3(a)).

Regulation 50/2000 (Labelling of Foodstuffs and Food Ingredients Containing Genetically Modified Additives and Flavourings) fills in a gap created by Regulation 258/97 (Novel Foods and Food Ingredients) because it does not apply to GM additives and flavourings. Regulation 50/2000 applies to additives and flavourings used in foodstuffs that are, contain or are produced from GMOs (article 1(2)).

Labelling requirements, in addition to other Community labelling requirements, are to be specified for additives and flavourings to ensure that the final consumers and mass caterers are informed. Among these, additional labelling is required when (a) any characteristic or food property no longer renders a novel food or food ingredient equivalent to an existing counterpart (based on scientific assessment and accounting for natural variations); (b) material that is present is not present in the existing counterpart and which may have human health implications for certain population sectors; (c) the presence of material not found in existing counterparts gives rise to ethical concerns; or (d) GMOs are the present (article 2(a-d)).

Additives or flavourings are not equivalent if scientific assessment demonstrates that the characteristics assessed are different to traditional additives or flavourings taking into consideration accepted limits for natural variation (article 3).

Additives or flavourings with protein or DNA resulting from genetic modification are not considered equivalent. The labelling requirements vary with the form of the flavouring or additive and may include wording such as “produced from genetically modified…” (where a characteristic or food property is not equivalent to existing additives or flavourings) (article 4(1)) or “genetically modified” (where an additive or flavouring is or contains an organism modified by GM techniques (article 4(2)).

The proposed regulation of the European Parliament and the European Council on Genetically Modified Food and Feed flows from various proposals made in the Commission White Paper on Food Safety (COM (1999) 719 Final, 21 January 2000) and the adoption of Directive 2001/18/EC. It will consolidate existing Community level legislation and procedures on these issues and close gaps such as feed produced from GMOs and the evaluation of genetic modifications in additives and flavourings.

The proposed regulation is premised on three fundamental objectives: (1) to ensure a high level of consumer and animal health and life protection; (2) to facilitate the consumer’s and in the case of feed, the end user’s right to know to enable an informed choice; and (3) to ensure that the consumer or end user is not misled (CEC, 2001).

The proposed regulation would fit within a larger framework of food law that is being proposed for a regulation at the Community level in the aftermath of European food crises involving BSE and dioxin contaminated feed (see EC proposed regulation COM (2000) 716 Final – 2000/0286(COD)). The proposed legal framework would lay down general principles and requirements of food law, establish an independent European Food Authority and provide procedures for food safety. It will include a proposed regulation on traceability and labelling of GMOs and traceability of food and feed products produced from GMOs.

The proposed regulation would cover genetically modified food, livestock feed and additives and flavourings regardless of whether DNA or protein resulting from the genetic modification can be detected (CEC, 2001). In other words, it will apply to products *produced from a GMO*, rather than products *produced with a GMO* (CEC, 2001).

All products subject to the authorisation under the proposed regulation would also be subject to mandatory labelling (CEC, 2001). Under the proposal, labelling requirements will apply to foods "delivered as such to the final consumers or mass caterers which (1) consist or contain GMOs or (2) are produced from or contain ingredients produced from GMOs (article 13(1)). Labelling requirements will not apply to foods with material that contains, consists of or is produced from GMOs in a proportion no higher than the thresholds to be established provided the presence is adventitious or technically unavoidable (article 13(2)). This leaves open the possibility that labelling requirements may apply to a threshold of adventitious materials different than that set for authorisation (one percent). As with the procedures for GMO food authorisation, the operator must be in a position to supply evidence to satisfy the competent authorities that they have taken steps to avoid the presence.

The food labelling requirements vary with the form of the product and are not to prejudice other Community labelling requirements (article 14(1)). Generally, the words "genetically modified" or "produced from genetically modified [name of organism] but not containing a [GMO]" must appear (article 14(1)(a-c)). Food without pre-packaging must have similar wording displayed on or in connection with the food's display (article 14(1)(d)). The labelling must also mention any characteristic or property when (1) the food is not equivalent to its conventional counterpart (i.e., with regard to composition, nutritional value or nutritional effects, intended use, or implications for the health of certain sectors of the public) or (2) where the food gives rise to ethical or religious concerns (article 14(2)(a & b)). Where a food does not have a conventional counterpart the label is to include information about the food's nature and the characteristics (article 14(3)).

In contrast to the GM food labelling requirements, which only speak in terms of label content, article 27 proscribes a person from marketing GM feed without including a clearly visible, legible and indelible label, either on an accompanying document or on the packaging, container or on a label attached thereto (article 27(3)). For genetically modified feed the name shall be "genetically modified [name of feed]"; for feed produced from GMOs: "produced from genetically modified [name of the feed from which the feed is produced] but not containing a [GMO]"; for feed containing or consisting of GMOs the unique identifier assigned to the GMO shall accompany the name of the feed (article 27(3)(a & b)). As with the GM food labelling requirements, any characteristic not equivalent to its conventional counterpart needs to be also clearly indicated, including a characteristic or property that may give rise to ethical or religious concerns (article 27(3)(c & d)).

The Australia New Zealand Food Authority (ANZFA) develops and maintains a joint Australian New Zealand Food Standards Code pursuant to the Australia New Zealand Food Authority Act (1991). The Australian States and Territories and the government of New Zealand enforce the code and police food standards set according to it. The food standards have the force of law and must be read in conjunction with national and sub-national food legislation in the respective countries.

Standard 1.5.2 applies to food produced using gene technology (whether derived or developed from an organism that has been modified by gene technology – sec. 1). It does not apply to additives and processing aids derived from gene technologies, whose safety and pre-market approval, are regulated by a different standard. In general, Standard 1.5.2 prohibits the sale and use of foods produced from gene technology or classes of such foods, unless they have been assessed, approved and listed by ANZFA.

The Standard also applies to the labelling of food produced using gene technology. Genetically modified foods (i.e., food that is, or contains as an ingredient, including an additive or a processing aid, a food produced using gene technology which contains novel DNA and/or novel protein(s) or has

altered characteristics – sec. 4) must be labelled with an appropriate statement ("genetically modified") in conjunction with the name of the food or ingredient or processing aid (sec. 5). Exemptions may apply. For example, highly refined foods where the processing removes the novel DNA or novel protein (sec. 4(1)(c)). In addition, a threshold is set whereby genetically modified food unintentionally present in a food, ingredient or processing aid in a quantity no more than 10g/kg (1%) does not trigger the labelling requirement (sec. 4(1)(f)). Additional labelling requirements may be needed in situations where a genetic modification "raises significant ethical, cultural and religious concerns regarding the origin of the genetic material used in the genetic modification" (sec. 7(e)).

3.2.2 Labelling Related to Biosafety at International and National Levels

At the international level, the CBD Biosafety Protocol does not address labelling in a consumer protection sense. Instead, article 18(2) is about the identification of LMOs in documentation accompanying their transboundary movement. Therefore the labelling envisioned in this instance is primarily for the information of transport operators and customs people (Damena, 2001) as a means to manage risks during transport (see section 4.2.3.2).

For example, each contracting party must take the necessary measures such that LMOs subject to intentional transboundary movement within the Protocol's scope are handled, packaged and transported under safety conditions (considering relevant international rules) in order to avoid adverse effects on biodiversity conservation and sustainable use (accounting for risks to human health) (art. 18(1)). In particular, each contracting Party is to take measures to require documentation that:

(a) Clearly identifies LMOs intended for direct use as food or feed, or processing with the words "may contain" LMOs and "not intended for intentional introduction into the environment" and contact point; the COP/MOP is to decide within two years of entry into force on detailed requirements especially on identity and unique identification;

(b) Clearly identifies LMOs destined for contained use and specifies any requirements for safe, handling, storage, transport and use; contact point; and consignee; and

(c) Clearly identifies LMOs intended for intentional introduction into the environment of the party of import; specifies identification and traits/characteristics, requirements for safe, handling, storage, transport and use; contact point; name/address of importer/exporter; and a declaration that the movement conforms to the Protocol's requirements applicable to the exporter (art. 18(2)(a-c)).

The Protocol's meeting of parties is to consider the need for modalities to develop standards on identification, handling, packaging and transport practices in consultation with other relevant bodies (art. 18(3)).

Of the biosafety instruments reviewed at the national level, only those in the African Union and the European Union have provisions related to labelling.

The OAU Draft Model Legislation on Safety in Biotechnology applies to the import, contained use, release or placement on the market of any GMO or products from GMOs (art. 2). Any GMO or product of a GMO is to be clearly identified and labelled as such (art. 11(1)). Identification is to specify the relevant traits and characteristics in sufficient detail for purposes of traceability. In addition, any product of a GMO is to be clearly labelled and packaged using words that will be specified in a subsequent annex to the model law that is unavailable. The CA may require additional information in particular whether the product may cause reactions, allergies or other risks (art. 11(2)).

Within the European Union, Directive 2001/18/EC will act as a reference for GMOs as or in products authorised by other Community legislation *inter alia* with regards to environmental risk assessment, risk management, labelling, monitoring and public information (preamble para. 27). In general, GMOs, whether individually or in combinations, intended for placing on the market as or in products must have been subjected to satisfactory field testing in the research and development stage in ecosystems that could be affected by their use (preamble para. 25). The general procedures for notification of and consent by the competent national authorities are similar to those for release into the environment (Part B).

Notification is sent to the competent national authority of the Member State in which the product will be marketed for the first time. Notifications are to include a technical dossier including a full environmental risk assessment and, for products, precise information for use and proposed labelling and packaging (preamble para. 33; article 13(2)(f) and (g)). The proposed labelling must include the words "this product contains genetically modified organisms" clearly displayed either on a label or in accompanying documentation (preamble para. 40; article 13(2)).

Member States are to ensure that labelling and packaging of GMOs placed on the market as or in products comply with the conditions of consent (article 21(1)). Where adventitious or technically unavoidable traces of authorised GMOs cannot be excluded, minimum thresholds may be established below which the products require no labelling (article 21(2)). Thresholds will be product specific and will be established through the EC committee procedure laid down in article 30(2).

3.3 Public Participation in Policy and Decision Making

Participation in policy and decision-making on modern biotechnology is another example of how the public can help to realise the benefits and avoid the risks of modern biotechnology. Public input can provide policy and decision makers with valuable information and perspectives that may not be accessible otherwise.

The public's access to information supports its participation in policy and decision-making. However, without explicit provisions providing for public participation in the policy and decision making process information cannot be used to the fullest potential.

3.3.1 Public Participation in Policymaking

Policymaking is a strategic exercise that attempts to create a framework within which regulatory and other decisions can be made. Policymaking includes developing law. Provisions for public participation in governmental policymaking, especially with regard to law making, may generically exist in a number of countries.

At the international level, no international instruments specifically mention the need for public participation in the strategic processes focussing on all aspects of modern biotechnology.

Instead, there are only more general calls for stakeholder participation in those strategic processes involved with biodiversity conservation, environmental protection and sustainable development. The Aarhus Convention explicitly mentions the need for public participation in strategic processes, such as planning and programming (art. 7), as well as in law making and the promulgation of regulations (art. 8). The FAO preliminary draft International Code of Conduct on Plant Biotechnology provides another more comprehensive example.

According to the draft Code, governmental action at the national level should be framed through policies and programmes in agriculture and food biotechnologies (art. 6). In particular, governments should establish committees for appropriate biotechnology or similar fora. Their membership should be multi-disciplinary and represent "related interests that can assess the needs for and likely benefits and other impacts of relevant biotechnologies and their influence on the productivity and sustainability of prevailing agricultural systems" (art. 6.1).

At the national level, no country examined appears to have established a participatory policy making process to address the benefits and risks of modern biotechnology *in toto*, and early-on, as the technology emerged over the last twenty years. And thus far, none of the laws reviewed appears to require the establishment of a publicly accessible process within which the merits of modern biotechnology could be discussed as a single issue.

This does not mean that generic laws on public participation in policy making do not exist, only that the laws examined do not specifically provide for such processes with regard to biotechnology. Certainly some countries do promote and consider public comments on all proposed environmental regulations regardless of the thematic area being addressed or allow the public to participate in strategic environmental planning exercises. Some governments may also have the power to convene special commissions to examine particular topics. However, it seems apparent from the countries reviewed that, assuming the public can participate in governmental decision making, the most important possibility for public input tends to occur on a case by case basis as promoters of individual genetically modified end-products seek regulatory approval.

It may be useful to have on-going dialogues with stakeholders as a country develops and adapts it policies on modern biotechnology. Such dialogues could gauge public opinion and build awareness within and outside the government. The dialogues could be part of a stand-alone policymaking process on modern biotechnology or they could be incorporated into existing environmental policy-making processes such as those on sustainable development, the environment or biodiversity conservation.

The sole reliance on case by case review may be ebbing and giving way as some countries face their first commercial GMO releases, begin to develop second generation laws or as their public becomes more interested and knowledgeable in or concerned about modern biotechnologies. Possibilities are emerging for broader based stakeholder processes to provide inputs into policy-making processes. In this regard, independent commissions or councils can be used to facilitate dialogue within a country. Perhaps the best examples of this are from New Zealand.

New Zealand has established two bodies within the last three years. Within their mandates each is to inform the government on public opinion and to supplement the internal policy making process on modern biotechnology.

In May 1999, the New Zealand Government set up the Independent Biotechnology Advisory Council (IBAC) "to help New Zealanders explore and consider issues in biotechnology" (IBAC, 2000). IBAC does not have legislative or regulatory responsibility (IBAC, ____). It reports directly to the Minister of Research, Science and Technology in order to provide independent advice to the New Zealand Government on the environmental, economic, ethical, social and health aspects of biotechnology.

IBAC's main role is described as stimulating dialogue and enhancing public understanding about biotechnology (IBAC, _____). IBAC has looked at a range of issues including biotechnology applied

in the agricultural, food, medical and environmental contexts. Among other things, IBAC found:

- A need for balanced, factual and accessible information on biotechnology within New Zealand; and

- General support for IBAC's role of facilitating dialogue and providing advice on biotechnology (IBAC, 2000).

The IBAC was originally commissioned for two years. A monitoring and evaluation process is to determine how to proceed after this period is completed.

The New Zealand Royal Commission on Genetic Modification was created in 2000 by the government through a warrant (specialised law). Its mandate was to (1) research and report on the strategic options available to New Zealand on genetic modification, GMOs and products and (2) any changes considered desirable to the current legislative, regulatory, policy or institutional arrangements for addressing genetic modification, GMOs and products in New Zealand (RCGM, 2000). Some of the relevant matters that the Royal Commission could investigate and receive representations on included (1) the risk of and benefits to be derived from the use or avoidance of genetic modification, GMOs or products and (2) the key strategic issues drawing on ethical, cultural, environmental, social and economic risks and benefits (RCGM, 2000).

Because of the treaty obligations the New Zealand government holds, the Royal Commission also consulted with New Zealand's aboriginal peoples, the Maori. The warrant directs the Commission to consult and engage with Maori in a manner that specifically provides for their needs.

Among its conclusions, the Royal Commission noted that New Zealand's regulatory system is appropriate. However, because the values held by Maori add special emphasis to the ethical and cultural objections many people have on biotechnology, it was clear that existing regulatory bodies were not best equipped to address these types of issues (RCGM, 2001). Therefore, the Royal Commission recommended setting up a specialist body on bioethics in which matters could be debated.

Also, the Commission emphasised the need for a strong overall biotechnology strategy to guide New Zealand in the use of all new biotechnologies in the field. Finally, it recommended that a single, independent institution, such as a Parliamentary Commissioner on Biotechnology, undertake the general auditing of biotechnological applications (RCGM, 2001).

3.3.2 Public Participation in Decision Making

Public participation and decision making is more clearly addressed by international and national instruments than in the policy-making area.

At the international level five instruments refer to public participation in decision-making. The Aarhus Convention may again be the standard against which other instruments are judged.

The public is to be informed early on in the decision making process of *inter alia* the proposed activity, the technical details of the decision making process itself and whether a national or transboundary environmental impact assessment is necessary (art. 6(2)(a), (d) and (e)). The procedures should include reasonable time frames (art. 6(3)). Prospective applicants are encouraged to meet early with stakeholders before applying for a permit (art. 6(5)).

Competent national authorities are to give the public access to all information relevant to the decision-making, subject to certain exceptions (art. 6(6)). Procedures are to allow the public to submit any comments, information, analyses or opinions considered relevant to the proposed activity (art. 6(7)). Each contracting party is also to ensure in the decision that due account is taken of the outcome of public participation (art. 6(8)).

When a decision is taken the public is to be promptly informed. A text of the decision and the reasons and considerations upon which the decision is based are also to be made publicly available (art. 6(9)). Whenever a decision is reconsidered after the fact, the same procedures for the original decision as specified in the Convention are to be followed (art. 6(10)).

Under the CBD, the only reference to public participation is in the context of environmental impact assessment for activities that adversely affect biodiversity (art. 14(1)(a))

Under the Biosafety Protocol contracting parties are directed to consult with the public in the decision-making process regarding LMOs. They are also to make decisions available to the public, but respect confidential information (art. 23(2)). But the Biosafety Protocol is equally as equivocal on public participation as the CBD, if not more so. It qualifies that these actions are to be "in accordance with [the Parties'] respective laws and regulations". This qualification builds-in an enormous amount of discretion for governments and does not require changes to a status quo that may be inadequate at present.

Under the recently adopted FAO International Treaty on Plant Genetic Resources for Food and Agriculture (2001), contracting parties are "to take steps to minimize or, if possible, eliminate threats to PGRFA" (art. 5.2). Public participation in decision-making could be envisioned to flow from this and this is foreshadowed in article 9 dealing with Farmers' Rights.

National governments have the responsibility for realizing Farmers' Rights (art. 9.2). The right to participate in decision making at the national level on matters related to the conservation and sustainable use of PGRFA is among the measures to protect and promote Farmers' Rights (art. 9.2(c)). This could be interpreted to include the right of farmers to participate in biosafety decision-making processes and to have access to information.

The FAO preliminary draft Code of Conduct on Plant Biotechnology does not specifically mention public participation in decision-making. However, article 16 (Public Information) suggests governments and public authorities should inform and consult the public, particularly local and farming communities that could be affected, about specific deliberate releases (art. 16.2).

Despite the scarcity of international instruments addressing public participation in decision-making, national level instruments do address the issue in varying degrees of specificity.

The Australian Gene Technology Act demonstrates how access to information and public participation go hand in hand. When an intentional release is involved, and the Regulator is satisfied that it may pose significant risks to human health and safety or the environment, he must publish a notice on the application in the official Gazette, a national newspaper and on the Regulator's website (sec. 49). Criteria are provided for the public notice including inviting submissions on whether the license should be issued along with a closing date for submissions (sec. 49, para. 3). Once an assessment and plan are completed, the Regulator must again notify the public that they are available for comment (sec. 52, para. 2). The Regulator may also hold public hearings (sec. 53).

Persons may request copies of the application and the risk assessment or risk management plan (sec. 54, para. 1). However, confidential commercial information so declared by the Regulator is not to be shared (sec. 54, para. 2).

The applicant must apply to the Regulator for a declaration of confidential commercial information (sec. 184). Criteria are provided to guide the Regulator's decision making (sec. 185). The Regulator may refuse a declaration when the public interest in disclosure outweighs the prejudice disclosure would cause to the information holder (sec. 185, para. 2). The Regulator must refuse a declaration of confidential information if the information relates to one or more locations at which GMO field trials would occur, unless the Regulator is satisfied that significant damage to human health and safety, the environment or property would likely occur if the locations were disclosed (sec. 185, para. 2a). The Regulator must make publicly available a statement of reasons for making the declaration (sec. 185, para. 3a).

In any licensing decision – whether for release or otherwise - the Regulator cannot issue a license without being satisfied that risks posed by the dealings proposed to be authorised by the license can be managed to protect human health and safety and the environment (sec. 56). Guidelines are provided to guide the Regulator's decision-making process. For example, the Regulator must be *inter alia* guided by submissions received from the public (Sec. 56, para. 2).]

Other instruments do not go into as much detail as the Australian Gene Technology Act but nonetheless are interesting to describe here. Under the OAU draft model legislation the public may make comments within a period specified by the competent authority (art. 5(2)). Where the CA arranges for a public consultation it is to be announced in the media with national coverage for a given period of time (art. 5(3)). The CA is to take the public's views and concerns into consideration when it is making or reviewing its decisions (art. 5(4)).

In relation to first releases, Part B of European Union Directive 2001/18/EC requires the Member States to consult with the public, including groups. They are to create arrangements for consultation, including reasonable time periods for the public to "express an opinion" (article 9(1)). On the other hand, Part C allows the public to "make comments" to the Commission within 30 days on the public summary provided by the notifier to the Member State's competent authority pursuant to article 13(2)(h) and forwarded to the Commission (article 24(1)). The public can also only provide "comments" on the assessment reports (article14(3)(a)) which comprise the competent authority's assessment of the notification and which is also forwarded to the Commission (article 24(1)). While the distinction between "opinions" and "comments" is not clarified, it could be that opinions are actually taken into greater consideration by the Commission and the Member States than comments.

Of the three Asian countries reviewed only the Indonesian Food Act (1996), which addresses genetically modified food in a handful of specific articles, has public participation provisions. The Act provides the "community" with the opportunity to participate in realising the protection of any natural person consuming food (art. 51). The community may submit "problems, inputs and/or the solution for matters in the field of food" in the framework of improving and upgrading the food system (art. 52). It is unclear how participation is to be realised. The extent to which this means the public can participate in regulatory decision making is also unclear. No criteria are provided on the extent to which governmental decision makers must consider the comments and other inputs that are provided.

4.0 Oversight Mechanisms

Oversight mechanisms are the primary tools that countries use to examine the merits of a GMO in the areas of biosafety, food safety or consumer protection. The oversight mechanisms that have been established around the world are generally premised on a GMO's "first time" use in a particular context: importation, in-country research or commerce/marketing and, sometimes, export. Legal and non-legal instruments describe the oversight process and various institutions that may be involved with implementation and oversight.

Requirements to submit to oversight are either mandatory and typically described in legislation, or they are "voluntary" and described in guidelines.

Common components of oversight mechanisms are (1) the designation or establishment of institutions to undertake the review and/or provide advice; (2) safety assessment; and (3) decision making. In the systems examined, stakeholder participation is only a common element of mandatory oversight mechanisms promulgated by law.

The following sections describe those components of the oversight process that may contribute to maximise the benefits and avoid the risks of modern biotechnology.

4.1 Designating Existing or Establishing New Institutions

The international instruments reviewed tended to address institutional issues in only the most general way. Typically when there is a particular reference to institutions it is only to require the designation or establishment of a competent national authority, in other words, an institution with decision-making authority. In some cases institutional responsibilities are enumerated.

At the international level, only the biosafety-related instruments reviewed mention competent national authorities. For example, the Plant Protection Convention requires its contracting parties "to make provision for" an official national plant protection organisation (art. IV(1)). A list of responsibilities is enumerated including *inter alia* surveillance of growing plants, wild flora and plants and products in storage or transportation, inspection of international consignments for plant pests, disinfestation or disinfection and the conduct of pest risk analyses (art. IV(2)(a, b, d and f).

The CBD Biosafety Protocol requires each of its contracting parties to designate one or more competent national authorities (art. 19(1)). These are to be authorised to be responsible for performing the administrative functions required by the Protocol.

The FAO Code of Conduct on Biological Control Agents lists some of the responsibilities of competent authorities in situations before and upon release including *inter alia* "critical assessment", encouraging monitoring and ensuring corrective action where necessary (art. 7.1).

In its chapter on biosafety and environmental concerns, the FAO preliminary International Code of Conduct on Plant Biotechnology suggests that governments should designate "competent national authorities to review, assess, implement and monitor biosafety and other concerns such as genetic erosion and agroecological disruption" from the introduction of biotechnological products (art. 11). Multi-disciplinary and multi-interest "national committee[s] on biosafety and other environmental concerns" could contribute to the competent national authority's work (art. 11.1).

National instruments dealing with biosafety address institutional issues in far greater detail than

international instruments. For example, the instruments examined either establish new institutions or designate existing institutions and give them new responsibilities related to GMOs.

Where existing line ministries or their agencies are tasked with regulatory oversight they do so within their traditional areas of competence. In Indonesia, for example, the category of organism determines the agency within the Ministry of Agriculture that reviews the application.

Where new national level institutions are created they may be interdisciplinary or inter-agency in nature and either have an oversight function or an advisory function to the competent authority that ultimately makes the decisions on a GMO. Institutions with an inter-agency character will typically include representatives from other governmental agencies. In some countries, representatives may also be from the academic and scientific communities and other major stakeholder groups. Bringing an interdisciplinary and, ideally, an independent, perspective to the oversight review process could strengthen the determination of where the benefits and risks of the particular GMO lie.

For example, in France, the National Commission on the Release of the Biomolecular Products is a cross-sectoral body involved with risk assessment, as well as defining the conditions of commerce and labelling of GMOs and the products that contain them (art. 3(II)). It is composed of scientists, parliamentary members, representatives of environmental and consumer protection groups, professionally concerned groups and representatives of employee groups. The National Commission generally undertakes risk evaluation and supplies an opinion to the minister of the relevant competent national authority reviewing the application for authorisation.

Another example is in the Philippines. Executive Order 430 created a national committee on biosafety (NCBP) that is attached to the Department of Science and Technology (sec. 1).

The NCBP has a multi-disciplinary membership including various scientists, a social scientist, citizens and representatives from various governmental agencies (sec. 2). The NCBP has a number of functions. These include *inter alia* (1) identifying and evaluating potential hazards related to initiating genetic engineering experiments, the introduction of new species and GMOs and recommending risk minimisation measures; (2) formulating and reviewing national biosafety policies and guidelines; (3) formulating and reviewing national policies and guidelines on risk assessment; (4) publishing the results of internal deliberations; holding public deliberations on proposed national policies, guidelines and other biosafety issues; and (5) assisting in the formulation of laws (sec. 4). The Department of Science and Technology provides the NCBP's secretariat (sec. 4).

The NCBP created the Philippine National Biosafety Guidelines in 1991. The NCBP must review and approve any work covered by the Guidelines. However, institutions and involved scientists have the primary responsibility to enforce biosafety rules and regulations and this is accomplished through institutional biosafety committees (see below) and biosafety officers. The NCBP has the power to impose sanctions on erring personal and institutions.

Other countries establish advisory bodies to focus on particular issue areas. Australia offers an example where a new competent national authority has been created and is advised by three newly created committees.

The Gene Technology Act establishes the Gene Technology Regulator as an administrative office within the Ministry of Health and Aged Care to administer the legislation and make decisions pursuant to it (sec. 26). Among its responsibilities, the Regulator performs functions in relation to issuing GMO licences, develops draft policy principles and codes of practice and provides advice to

the public, other regulatory agencies and the Australian Ministerial Council (sec. 27).

The Act also establishes (1) a scientific committee (Gene Technology Technical Advisory Committee), (2) a community committee (Gene Technology Community Consultative Committee) and (3) an ethics committee (Gene Technology Ethics Committee) (part 8). The committees are interdisciplinary and share cross membership. On matters within their competence, the committees provide advice upon request to the Regulator and the Ministerial Council. Providing advice on the need for policy principles and codes of practice is a function common to all three committees.

The Ethics Committee is to provide advice on ethical issues relating to gene technology, the need for and content of codes of practice in relation to ethics and conducting dealings with GMOs and the need for a content of policy principles in relation to dealings with GMOs that should not be conducted for ethical reasons (sec. 112). All committee members are subject to disclosure and conflict of interest rules.

Under the South African Genetically Modified Organisms Act, the Ministry of Agriculture oversees implementation. The Minister of Agriculture shall appoint an interagency Executive Council for GMOs composed of representatives from various governmental agencies (sec. 3). The Council is to advise the Minister on all aspects concerning activities within the law's scope of application and ensure that all activities are performed according to the Act (sec. 4). The Council has the power to *inter alia* (1) require a permit for the use of facilities to develop, produce, use or apply GMOs or to release GMOs into the environment, to submit through a registrar a risk assessment and where required an environmental impact assessment of these activities (sec. 5(a)); (2) require a registrar to examine an application's conformity with the Act (sec. 5(b)); and (3) approve the use of facilities or a release (sec. 5(g)). The Council may also inform any other country of an accident that may have an impact on that country's environment (sec. 5(i)) and approve and publish guidelines for all GMO uses (sec. 5(l)).

The Act establishes an Advisory Committee whose members are appointed by the Minister after recommendation by the Council (sec. 10(1)). The Committee's membership is to reflect representation from all fields of expertise involved with GMOs (sec. 10(2)). The Committee is to act as the national advisory body on all matters related to genetic modification of organisms (sec. 11).

Advice may include that related to GMO introductions into the environment, proposals for specific activities or projects, contained use, importation and exportation and proposed regulations and guidelines (sec. 11(1)(b)). The Committee may advise upon request (or upon its own initiative) the Minister, the Council, other Ministries and bodies. It may also invite written comments from knowledgeable persons on any aspect of genetic modification of organisms (sec. 11(1)(d)). Committee members are to recuse themselves when the Committee considers subjects in which they have direct or indirect interest (sec. 13).

Some instruments, particularly those that are voluntary guidelines, also require all institutions that work with GMOs to create institutional biosafety committees (IBC). IBCs are typically given the ultimate responsibility to ensure the safety of any GMO-related work within the institution.

When used effectively, IBCs could have a particularly important role in maximising the benefits and minimising the risks of GMOs. This is because projects could be screened early on at the level of the researcher or institution before government oversight is more formally applied.

The Philippines experience is particularly interesting because of the breadth of responsibilities that

IBCs are given and the interaction that occurs with the National Committee on Biosafety. In the Philippines, all institutions engaged in genetic engineering are to create institutional biosafety committees (sec. B). IBCs have the responsibility to evaluate and monitor the biosafety aspects of their institution's biological research. IBCs need to have the collective expertise to supervise and assess planned field releases. The Guidelines outline additional expertise to be represented on IBCs (sec. B, para 1.1). IBCs may have consultants on call that are knowledgeable in a variety of issues, including standards of professional conduct and practice and community attitudes (sec. B, para 1.2).

Among its functions an IBC is to review work conducted or sponsored by the institution and recommend research proposals (sec. B, para. 2.1). Reviews are to include holding discussions on the comparative ecological, economic and social impacts of alternative approaches to attain the purposes of the genetic engineering product or services (sec. B., para. 2.1.3). An IBC should also formulate and adopt emergency plans and notify the National Committee on Biosafety about significant problems (sec. B, paras. 2.4 and 2.5).

Procedurally, IBCs review proposals made by the principal investigator (sec. C, para. 1.1 and 1.3). The IBC assesses the project and sends the proposal and its evaluation to the NCBP for its assessment (sec. C, para. 1.3).

4.2 Safety Assessment

A cornerstone of all oversight systems examined - whether voluntary or mandatory - is to assess the GMO for safety. Biosafety regimes attempt to identify the risks posed by the GMO to the environment and human health. Food safety regimes attempt to identify the risks posed by the GMO to human health.

Safety assessment generally consists of (1) hazards identification, (2) risk assessment and (3) risk management (UNEP, 1995). Only risk assessment and risk management are discussed here.

4.2.2 Risk Assessment

The underlying principle of risk assessment is to prevent harm by identifying the probability that particular hazards will occur. Because case-by-case risk assessment is quite burdensome other principles such as "familiarity" and "substantial equivalence" have evolved with which certain assumptions can be made about the GMO under scrutiny in order to facilitate the review.

The principle of familiarity is used primarily in the biosafety area to determine the level of oversight applied to a particular GMO. It is premised on knowledge and experience with the host and recipient organisms. This then can be used to extrapolate the potential risks of the modified organism.

The UNEP Biosafety Guidelines note that familiarity does not imply that an organism is safe, while unfamiliarity does not imply that an organism is necessarily unsafe (para. 19). Unfamiliarity means however that an organism should be assessed on a case-by-case basis. With experience and knowledge, a risk assessment may apply to a group of organisms for characteristics functionally equivalent on a physiological level. The development of generic risk assessment approaches or exemptions in one country does not necessarily mean that other countries will apply similar approaches. Monitoring can provide knowledge and experience on the use of organisms with novel traits (para. 24).

The principle of substantial equivalence is used primarily in the food safety area where, because of the

complex nature of food and the inadequacy of traditional risk assessment techniques, there is a need for a targeted approach. Substantial equivalence is primarily applied to foods derived from genetically modified plants and it attempts to take into account both intended and unintended changes in the plant or foods derived from it (WHO, 2000).

The Codex Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA Plants points out that substantial equivalence is not a safety assessment *per se*. Rather, it is a way to structure food safety assessments relative to a conventional counterpart (sec. 3, para. 12). Substantial equivalence is used to identify similarities and differences between the new food and the conventional counterpart acknowledging that, for the foreseeable future, foods derived from modern biotechnology will not be used as conventional counterparts. The safety assessment then assesses the safety of identified differences, taking into consideration unintended effects due to genetic modification (sec. 3, para. 16). Risk managers subsequently judge this and design risk management measures as appropriate.

The proper application of familiarity and substantial equivalence, in particular the assumptions upon which both principles are founded and applied, is an outstanding issue that may determine the extent to which the risks of GMOs can be accurately identified and subsequently minimised or eliminated. In particular, some uses of substantial equivalence are becoming increasingly criticised.

For example, the Royal Society of Canada Panel on the Future of Food Biotechnology rejected "the use of substantial equivalence as a decision threshold to exempt new [genetically modified] products from rigorous safety assessments on the basis of superficial similarities because such a regulatory approach is not a precautionary assignment of the burden of proof" (Royal Society of Canada, 2001). The Royal Society went on the say that "[w]hen substantial equivalence is invoked as an unambiguous safety standard (and not as a decision threshold for risk assessment), it stipulates a reasonably conservative standard of safety consistent with a precautionary approach to the regulation of risks associated with [genetically modified] foods".

Similarly, the European Union has recognised the problems with applying substantial equivalence. Consequently, the proposed new Novel Foods and Feed Regulation would eliminate the simplified notification procedure provided in the current Novel Foods Regulation (97/258/EC) for GM foods which are "substantially equivalent" to existing foods. According to the explanatory memo accompanying the proposal, the substantial equivalent concept has been controversial in the Community. It has been recognised internationally only as a key step in the safety process of GM foods, but not a safety assessment in itself, as it has been used as a regulatory shortcut.

International law has imparted additional principles to guide the risk assessment process. For example, the concept of "science-based" risk assessment is referred to in international instruments. The reference to science may be an attempt to ensure that an assessment is objective in order to minimise arbitrary assessment approaches.

The UNIDO Voluntary Code of Conduct states that risk assessment should be based on "sound scientific principles" involving the participation of experts from appropriate disciplines (sec. II-C-1(h)). International trade law also appears to be a source of the guiding principle that risk assessment should be "science based".

The WTO Agreement on the Application of Sanitary and Phytosanitary Measures applies to all sanitary and phytosanitary measures which may directly or indirectly affect international trade (art. 1). The SPS agreement does not explicitly mention GMOs. However, when GMOs are in international

trade, and may pose a threat to human, animal or plant life or health in an importing country, the SPS Agreement would apply to national sanitary or phytosanitary measures (SPMs) designed to address the threats prior to import.

WTO member States must ensure that sanitary and phytosanitary measures are based on an assessment of risks to human, animal or plant life or health (art. 5(1)). Risk assessment techniques developed by relevant international organisations must be taken into account. Risks are to be assessed taking into account a number of enumerated factors including "available scientific evidence" (art. 5(2)).

In the food safety and trade area, the Codex Statements of Principle Concerning the Role of Science in the Codex Decision-making Process and the Extent to Which Other Factors Are Taken Into Account states that Codex instruments are to be based on the principle of "sound scientific analysis and evidence" (Codex, 1995).

International law also provides a basis for the consideration of socio-economic factors in risk assessment. The FAO preliminary draft International Code of Conduct on Plant Biotechnology appears to be the most comprehensive in this regard.

For example, one of the draft Code's eight objectives is "to help assess and minimize possibly adverse socio-economic effects of biotechnology in agriculture and the food industry on farming communities" and developing countries' economies (art. 1.6). From this flows one of the key provisions of the draft Code: promoting the transfer and development of "appropriate biotechnologies" applied to PGRs (art. 5.1). "Appropriate biotechnologies" include those "which contribute to sustainable development" (art. 3). Criteria for identifying appropriate biotechnologies are provided and include those that are: (1) technically feasible; (2) bring tangible benefits to users; (3) are environmentally safe; and (4) socio-economically and culturally acceptable (art. 3).

Additionally, the draft Code emphasises preventing and mitigating possible negative effects of agro- and food biotechnologies. To this end, the draft Code first emphasises foreseeing and preventing possible negative socio-economic effects of agro and food biotechnologies (art. 8.1). Governments and international organisations should, as part of their technology assessment procedures, monitor and assess the socio-economic impacts of biotechnologies.

Under the WTO SPS Agreement Member States can also take "relevant economic factors" into account when assessing the risk, and establishing risk management measures (i.e., establishing the appropriate level of protection as manifested by a sanitary or phytosanitary measure). Economic measures include (1) the potential damage to production or lost sales; (2) costs of control or eradication; and (3) relative cost effectiveness of alternative approaches to limit risks (art. 5(3)). It is unclear whether this is an exhaustive list.

The Guidelines for Plant Risk Analysis promulgated under the FAO Plant Protection Convention emphasise that the potential economic importance of the pest is a key determinant in the assessment process. It is in this determination that potential environmental damage is assessed along with other criteria such as perceived social costs (sec. 2.2.3). If the pest has sufficient economic importance and introduction potential (i.e., there is sufficient risk) then phytosanitary measures are justified – in other words pest risk management should be considered. The Guidelines highlight which options could be taken and suggest the efficacy and impact of the options should be evaluated (secs. 3.1 and 3.2).

The Biosafety Protocol, which has yet to enter into force, appears to establish the most comprehensive

collection of criteria with which a risk assessment is to comply. While acknowledging that a risk assessment must be undertaken in a "scientifically sound manner", the assessment must also take account of "recognised risk assessment techniques" (art. 15(1)).

Risk assessment should be based on "existing scientific evidence" in order to "identify and evaluate" the possible adverse effects of GMOs on the conservation of biodiversity, taking into account risks to human health (art. 15(1)). Annex III adds that the risk assessment must be undertaken in a manner that is "transparent" and on a "case by case basis". The lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk or an acceptable risk (annex III).

Like the Biosafety Protocol, the FAO preliminary draft International Code of Conduct on Plant Biotechnology acknowledges the need to conduct risk assessment for deliberate releases on a "scientifically sound basis" (art. 13.3). What the draft code adds is the principle that countries should ensure that there is a "full review and risk assessment by both the proposer and the competent authority" (art. 13.1). Review and risk assessment should be undertaken on case-by-case basis (art. 13.5).

The draft Code also adds that risk assessment should proceed on a "step-by-step" basis. The step-by-step approach involves evaluating each step of the deliberate release (i.e., laboratory, small scale release, and adequate tests prior to marketing the novel product) (art. 13.6). Containment measures may be reduced gradually in each step, but only if the tests conducted in the previous step justify it. The details and depth of information required for the authorisation is to be proportional to the estimated degree of risk.

"Risk communication" is one final principle related to risk assessment that may soon be introduced more into international instruments. Risk communication an area related to public participation and access to information. Within the food safety area, the risk communication principles found in the Codex Proposed Draft Principles for Risk Analysis of Foods Derived from Modern Biotechnology are premised on the belief that effective communication is essential in all phases of risk assessment and management (sec. 3, para. 22).

Risk communication is to be an interactive process involving all interested parties. Processes should be transparent, fully documented and open to public scrutiny while respecting legitimate concerns for confidential commercial information. Safety assessment reports and other aspects of the decision-making process should be available to the public (sec. 3, para. 23). Responsive consultation processes should be created (sec. 3, para. 24).

The extent to which the principles reflected in international instruments are actually applied at the national level is unclear from a simple review of the instruments examined. While all instruments reviewed require safety assessment and typically refer to risk assessment few details are provided within the instruments themselves to guide the risk assessment process.

The most explicit references relate to substantial equivalence and familiarity, which provide a basis for oversight. The principle of case-by-case review is the next most referred to principle. Only the OAU draft Model Legislation on Safety in Biotechnology explicitly refers to "an assessment of risks to the environment, biodiversity and health, including socio-economic conditions" (art. 8(2)).

Who actually undertakes the risk assessment depends on the country and may have a bearing on realising modern biotechnology's potential and avoid its possible risks. For example, in Canada the

risk assessment is undertaken by the proponent and reviewed by the regulatory agency. In contrast, the Australian Office of the Gene Regulator undertakes the risk assessment based upon information supplied by the proponent. In the food safety area, the Australia New Zealand Food Authority assesses, approves and lists foods produced from gene technology that may be imported into the two countries.

It is difficult to ascertain which approach will be more effective in minimising the risks presented by a GMO, especially in developing countries. Both approaches assume that an oversight agency either has the capacity, in the first instance, to critically review the risk assessment presented to it or, in the second instance, has the capacity to actually undertake the risk assessment itself.

4.2.3 Risk Management

The underlying principle of risk management is to identify and take steps to eliminate or minimise to an acceptable level risks identified in the risk assessment. Risk management is typically practised at the level of the regulatory decision maker who must process risk assessment data along with other factors that may be required to then determine whether approval should granted or denied.[1]

The decision maker must determine what is an acceptable risk for society in relation to other possible benefits and costs. This is an inherently political decision (CEC, 2000).

Risk management strategies vary with circumstances and can embrace a number of techniques ranging from an outright ban to softer approaches that might include educating users of the proper application of an end product. In particular, post-approval monitoring, labelling and traceability can be used within risk management strategies and are described below.

A cornerstone of risk management practice, at least in toxicity studies related to human health, has been to build in a safety factor to ensure that risks are truly minimised, if not eliminated. The evolution of this practice to a wider number of applications such as GMOs may be reflected in part now by the precautionary principle, which should be applied by decision makers where there is scientific uncertainty. The recognition of the need for a precautionary approach is greatest at the international level.

In the biosafety area, the Cartagena Protocol on Biosafety is, at the moment, the foremost international instrument referring to a precautionary approach. In its preamble, the protocol "reaffirms" the "precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development" (4th recital). The precautionary approach is also referred to in article 1 (Objective). Under the Protocol, decisions of the contracting party importing a GMO destined for first-time release into the environment (and where necessary for GMOs intended for direct use as food or feed, or for processing) must be according to a risk assessment (art. 10). However, lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of potential adverse effects shall not prevent the contracting party of import from taking a decision, as appropriate, in order to avoid or minimise potential adverse effects (arts. 10(6)).

[1] Another aspect of risk management is practised at the level of the researcher. At the researcher level, especially where mandatory oversight by a governmental agency may not exist, well-designed risk management practices may be particularly important. The 1992 OECD Safety Considerations for Biotechnology are an example of guidance designed to promote safer small-scale research involving field trials. The Safety Considerations are intended to apply to the second stage of the continuum of research on GMOs - small-scale basic and initial applied research involving genetically modified plant and microorganisms – and how to ensure the environmental safety of this work. The GDPs provide guidance to researchers "on selecting organisms, choosing the research site and designing appropriate experimental conditions" (OECD, 1992).

In the food safety area, it appears the Codex Commission is embracing a precautionary approach, even if the term is not explicitly referred to in the Codex itself. For example, the Codex Proposed Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology state that risk managers are to account for the uncertainties identified in the risk assessment and manage the uncertainties (sec. 3, para. 18).

In the area of trade, the WTO SPS Agreement provides some flexibility for member States to provisionally adopt sanitary and phytosanitary measures (SPMs) when scientific evidence for the measures is insufficient (art. 5(7)). Provisional SPMs can be adopted on the basis of "available pertinent information" derived from a variety of sources. However, member States must subsequently seek additional information to more objectively assess the risk and to review the SPM within a reasonable period of time.

Article 5(7) has been commonly referred to as evidence that the SPS Agreement reflects a "precautionary approach" (Charnowitz, 2000), even without specifically saying so. Even so, the ultimate burden to justify an SPS measure is placed on the importing country – even in the face of uncertainty (Jenkins, 2001). Indeed, this could be interpreted as contrary to a precautionary approach where such a burden would normally be placed on the exporter (Jenkins, 2001).

While risk assessment is itself a contribution to a precautionary approach, the explicit or implicit reference to precaution as a decision making principle has found its way only into a handful of instruments at the national level that were examined. For example, the precautionary principle is reflected in article 6(7) of the OAU Model Legislation on Safety in Biotechnology: where threats of serious damage exist, lack of scientific evidence should not be used as a basis for not taking preventative measures.

Within the European Union, the precautionary principle is to be considered in the implementation of Directive 2001/18/EC (Deliberate Release of GMOs into the Environment) (preamble, 8th recital). An earlier Communication from the Commission on the precautionary principle seeks to harmonise the interpretation of the precautionary principle within the European Union (CEC, 2000). The Communication provides guiding principles for applying the precautionary principle.

In Australia, the Gene Technology Act refers to the concepts embodying the precautionary principle. The objectives of the Act are to be achieved through a regulatory framework premised *inter alia* on the precautionary principle: "where there are threats of serious or irreversible environmental damage, a lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation" (sec. 4(aa)). The term "precautionary principle" is not used in the Act and it is unclear whether this is a policy principle for purposes of the Act. This is an important point because, according to the law, the Gene Technology Regulator must not issue a license if it would be inconsistent with a policy principle in force (sec. 57).

As is the case with risk assessment, additional principles have been recognised by the international community that provide a framework for the application of risk management, especially as it relates to international trade.

The need for risk management measures to be "necessary" and where implemented, "proportional" to the risks identified are two principles that share the widest recognition at the international level. Calls for necessity and proportionality are common to both biosafety and food safety instruments.

Another common principle is the need for risk management measures to be scientifically or technically justified. This qualifier attempts to inject objectivity into the decision making process in order to limit arbitrary decisions.

Three principles are closely related to trade-related issues. The principle of non-discrimination means that comparable situations should not be treated differently (CEC, 2001). In a trade context, GMOs from one country should not be treated differently than their domestic counterparts. The principles of taking the "least trade restrictive" measures and measures that afford the "minimum impediment" to trade require the decision maker to consider the impacts of the risk management measures on trade.

In the biosafety area, the FAO Plant Protection Convention has the most comprehensive collection of principles affecting risk management. The IPPC provides that phytosanitary measures can be taken for quarantine pests and regulated non-quarantine pests, but not non-regulated pests (art. VI). Phytosanitary measures must meet minimum requirements: they must be non-discriminatory. They must be "necessitated" by phytosanitary considerations and be "proportional". They must be "technically justified". They must represent the "least trade restrictive" measures available. Finally, they must result in the "minimum impediment" to the international movement of people, commodities and conveyances (arts VI(1) and VII(2)(g)). Emergency measures are justified but must be evaluated as soon as possible after their application to justify their continued application (art. VII(6)).

The IPPC principles parallel those found in the WTO SPS Agreement. Each WTO member State has the right to take sanitary and phytosanitary measures (SPMs) "necessary" to protect human, animal, plant life or health, provided these measures are not inconsistent with the SPS Agreement (art. 2(1)). A member State's SPMs: (1) must only be applied to the extent necessary; (2) be based on scientific principles; and (3) must not be maintained without sufficient scientific evidence (art. 2(2)). SPMs must also not "arbitrarily or unjustifiably discriminate between member States" and SPMs cannot be applied in manner that would constitute a disguised restriction on international trade (art. 2(3)).

Member States are directed to base their SPMs on international standards, guidelines and recommendations, where they exist in order to harmonise SPMs as widely as possible (art. 3(1)). However, a member State can introduce an SPM resulting in a higher level of protection than that offered by an international standard, guideline or recommendation (art. 3(3)). This is conditioned on the existence of one of two things: (1) scientific justification or (2) if the State deems the SPM to be "appropriate" (art. 3(3)). This last point is subject to the further conditions in article 5. Nonetheless, all measures that differ from international standards must be consistent with the SPS Agreement. Other factors to take into consideration when establishing the "appropriate" level of protection (1) "should" include "minimising negative trade effects" (art. 5(4)); (2) "avoiding arbitrary or unjustifiable distinctions" in the levels it considers appropriate in different situations (if they result in discrimination or a disguised restriction in international trade) (art. 5(5)); and (3) ensuring SPMs are "not more trade-restrictive than required" for an appropriate level of protection (art. 5(6)).

The CBD Biosafety Protocol specifies general risk management measures and criteria. Any measures based on risk assessment should be proportionate to the risks identified (i.e., to the extent necessary to prevent adverse effects within the Party of import) (art. 16(2)). Measures to minimise the likelihood of unintentional transboundary movement of LMOs are to be taken (art. 16(3)).

The UNEP Technical Guidelines on Biosafety reflect the principle that risk management should be proportional to the level of risk and the scale of the operation (paras. 30 and 31). Risk management measures should be taken until risks have been minimised to acceptable levels. If risk cannot be minimised either the intended operation should not proceed, or a risk/benefit analysis could be used to

determine whether the higher level of risk is acceptable (para. 30).

The UNIDO Voluntary Code of Conduct for the Release of Organisms into the Environment states that safety precautions and monitoring procedures should be proportional to the level of assessed risk (sec. I-C-1(d)).

The provisions of the FAO preliminary draft International Code of Conduct on Plant Biotechnology reflect a number of risk management principles already elaborated upon earlier. For example, when it is approved, "the release must be conducted and implemented…to minimize the possible negative effects and the dispersal of transgenic plants, parts of plants, pollen, and organisms which affect plant genetic resources" (art. 14.1).

Interestingly, the draft Code suggests applying the step-by-step principle to risk management (art. 14.2). In other words the various aspects of the release should match the potential risks. Any scale-ups should be evaluated and authorised on the basis of results of experiments conducted in the previous steps (art. 14.2).

Governments and competent authorities should inform the competent authority of countries that could be affected by negative and unexpected consequences of a deliberate release (art. 14.4). Finally, Governments should also consider establishing technical and financial assistance to farming communities and countries to mitigate adverse socio-economic effects from biotechnological developments (art. 8.4).

In the food safety area, the Codex Proposed Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology state that risk management measures are to be proportional to the risk. These should take into account where relevant "other legitimate measures" (sec. 3, para. 16) according to general decisions of the Codex Commission and the Codex Working Principles on Risk Analysis.

When they are mentioned in the international or national instruments examined, risk management measures have rarely been elaborated upon. This may be because risk assessment is typically undertaken on a case-by-case basis, and therefore risk management measures need to be prescribed on a case-by-case basis as well. Notwithstanding this, three measures are typically mentioned: (1) post-approval monitoring and other responsibilities; (2) labelling; and (3) traceability.

4.2.3.1 Post Approval Monitoring and Other Responsibilities

Post-approval monitoring is a mechanism to ensure compliance after a permit is issued, to gather general information and to identify unexpected consequences resulting from an approval. Post-approval monitoring therefore may be an important way to minimise the risks of modern biotechnology.

After receiving consent, the authorisation holder may be required to comply with certain conditions related to the release or marketing of a GMO that contribute to risk management. Monitoring may be one such condition. Another may be for the authorisation holder to notify authorities when a problem occurs and to take corrective action.

Monitoring may also take place in a strategic manner. This would take place for all releases within a country over a period of time.

The FAO preliminary draft International Code of Conduct on Plant Biotechnology addresses both strategic and post-approval monitoring. For example, governments and international organisations should monitor and assess socio-impacts of biotechnologies as a part of their technology assessment programmes (art. 8.2). Technology assessment procedures should include monitoring and long-term assessment of environmental impact (art. 8.2). Finally, a proposer must ensure adequate and proportional monitoring of the actual effects that the organisms had on the environment as part of technology assessment procedures; suggestions made as to what information should be recorded (art. 14.3)).

A number of international instruments in the biosafety and food safety areas only refer to post-approval monitoring in a very general way. These instruments include the Codex Proposed Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (risk management measures could include post-marketing monitoring (sec. 3, para. 19)), the Pest Risk Analysis Guidelines of the Plant Protection Convention (the effectiveness of phytosanitary measures should be monitored and risk management options should be reviewed if necessary (sec. 3.3)), the Convention on Biological Diversity (identify processes and categories of activities which have or are likely to have significant adverse impacts on biodiversity and monitor their effects (art. 7(c)) and the UNIDO Voluntary Code of Conduct for the Release of Organisms into the Environment (researchers/proposers have the general responsibility to notify unexpected or adverse public health or environmental impacts to the appropriate national authorities (sec. II-C-3(e))).

The FAO Biological Control Agents Code of Conduct is more explicit with regard to other post-approval responsibilities. For example, the importer should ensure that the persons involved in distributing their biological control agents are trained adequately so that they can provide users with advice on efficient use (para. 8.1.1). Information related to safety and environmental impact of the biological control agents should be made publicly available and a "free and frank" exchange of information, not subject to commercial confidentiality, is to be maintained (para. 8.1.2). Finally, the importer has the responsibility to notify authorities when a problem occurs and to voluntarily take corrective action when requested (art. 8.1.4).

At the national level, post-approval monitoring and the responsibilities of the holder of authorisation were not explicitly evident in most instruments reviewed. This is not to say that they do not exist. Rather, they may be buried in the more general requirement for risk management or permit compliance. The exceptions are described here.

In Indonesia, pursuant to the Ministerial Decree on the Provisions on Biosafety of Genetically Engineered Agricultural Biotechnology Products, the person holding the approval is obliged to submit a periodic report every six months or any time there is an "event of biosafety harm" (art. 43). The oversight agency appears to be responsible for monitoring use (art. 44(2)).

Monitoring is referred to in the European Union's new directive on biosafety and the proposed regulation on food safety. In the biosafety area, the 20th preambular recital of EU Directive 2001/18/EC notes that monitoring should be undertaken after release. In addition, Part C (Placing on the Market as or in Products) states that when the competent national authority may provide its consent in writing it may stipulate conditions that are to include monitoring and the public release of subsequent results to ensure transparency (art. 20(4)).

In the food safety area under the proposed EU regulation on genetically modified foods, all authorisation holders will have supervisory obligations to undertake post-market monitoring and report to the European Food Authority (article 10(1)). The Authority will be informed of new

scientific or technical information that may influence the food's safety evaluation and will be informed of any prohibition or restriction imposed by the competent authority of a third country in which the food is placed on the market (article 10(3)).

In the United Kingdom, every consent issued for importation, acquisition, keeping, releasing or marketing of GMOs comes with specific and implied conditions. The specific conditions will vary with the circumstances. The implied conditions generally include (1) keeping informed of any risks of environmental damage from the permitted activity, (2) notifying the Secretary of State of any new information regarding the risks of environmental damage being so caused and the effects of any releases especially those when it appears the risks are more serious than apparent when the consent was first granted and (3) using best available techniques, not entailing excessive costs, to prevent environmental damage as a result of the activity (section 112 of the 1990 Environmental Protection Act as amended by regulation 9 under the GMO Deliberate Release Regulations of 1992)).

4.2.3.2 Labelling

Labelling has a dual role as a mechanism to provide access to information and as a means to manage risks. Labelling as an informational tool has been described earlier in section 3.1 (Access to information).

As a risk management tool, the information that labels can provide to end-users can refer to a GMO or GMO product's food toxicity or environmental safety. Consequently, with this information, the end user can take appropriate steps to minimise or avoid the risks specified for example by following the instructions on the label. Labelling and associated documentation may also provide important information to intermediate handlers of GMOs, for instance when they are in transit through the postal system. This latter role is being further examined under the Biosafety Protocol pursuant to article 18(2) in cooperation with other fora.

4.2.3.3 Traceability

Traceability - the ability to track a GMO - is an emerging issue within the biosafety and food safety areas. The concept behind traceability is to create a system to ensure that information is available on the origin of a genetically modified product as it moves from its point of manufacture or production to the end user. The system established would enable authorities to trace the organism back to those responsible for the import and export, as well as those responsible for the GMO's original development.

Traceability could be applied in instances where illegal export, import or release is suspected. It could also be applied where environmental damage has occurred from intentional and unintentional releases. Finally, it may be applied to situations where unforeseen food toxicity is identified.

A unique identifier assigned to approved GMOs would facilitate tracing. Methods to detect or identify GMO based products would need to be developed perhaps using molecular techniques.

In the instruments reviewed, provisions on traceability are usually associated with those on labelling. But it should be kept in mind that labelling is likely to be only one tool in a comprehensive traceability system. International and national level food safety and biosafety instruments reference traceability.

At the international level, the Codex Committee on Food Import and Export Inspection and

Certification Systems is examining the general concept of "traceability" within the systems that it oversees (Codex, 2000a). Traceability as a risk management measure is still under consideration by the Codex *Ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology (Codex, 2001e).

The Codex Proposed Draft Code of Practice on Good Animal Feeding links labelling to traceability. Labelling of feedstuffs is to be clear and informative for proper handling and use (sec. 4.2). It is also to ensure the traceability of the feeding stuffs. Presently, the Code specifically states "Genetically modified organisms (GMO products) should be labelled". Traceability of raw materials, minerals, vitamins and feed additives in feedstuffs is to be ensured by proper labelling and record keeping (sec. 4.3). Records are to be maintained to allow tracing in emergency situations.

The Biosafety Protocol does not specifically mention traceability. However, in the context of labelling the Meeting of Parties is to decide within two years of entry into force on detailed requirements especially on identity and unique identification (art. 18(2)(a)).

At the national level, the OAU Model Legislation makes a general reference to the need for the identity of any GMO product to specify the relevant traits and characteristics in sufficient detail for the purposes of traceability (art. 11(2)).

Under EU Directive 2001/18/EC (Deliberate Release of GMOs into the Environment), a system will be designed to assign a unique identifier to GMOs (preamble para. 41). In all stages of placing on the market, traceability of the GMO as or in products is to be ensured by the Member State (preamble para. 42, article 4(6)). This will take account of international developments. Monitoring plans are required to trace and identify any direct or indirect, immediate, delayed or unforeseen effects on human health or the environment of GMOs as or in products after their placement on the market (preamble para. 43).

A system will be designed to assign a unique identifier for GMOs (preamble para. 41). In all stages of placing on the market, traceability of the GMO as or in products is to be ensured by the Member State (preamble para. 42, article 4(6)). This will take account of international developments. Monitoring plans are required to trace and identify any direct or indirect, immediate, delayed or unforeseen effects on human health or the environment of GMOs as or in products after their placement on the market (preamble para. 43).

The proposed EU Regulation on Genetically Modified Food and Feed will be part of the suite of GMO-related instruments that will include a proposed regulation on traceability and labelling of GMOs and traceability of food and feed products produced from GMOs. Unique codes or identifiers will be developed under the traceability and labelling regulations. The proposed GM Food regulation will facilitate these future instruments by requiring in the application process for a novel food or feed a method to detect and identify the transformation event in the food and/or foods produced (arts. 6(3)(i) and 19(3)(i)).

In France under the Decree 95-487 (Applications for Genetically Modified Animals), authorisation cannot be made if the GM animal and its descendants cannot be traced (art. 22). Animals must be kept under surveillance for diseases and behaviour.

4.3 Decision Making

Decision-making is the third common component of any oversight system related to GMOs.

The primary role of the oversight body is to review applications on GMOs and decide whether or not to approve them. There are two aspects of decision making that may contribute to realising the benefits and minimising the risks of modern biotechnology: (1) decision making considerations other than environment and human health and (2) mechanisms to ensure greater accountability in decision making.

4.3.1 Decision Making Considerations Other Than Environment and Human Health

Judging from the instruments reviewed it appears that oversight decisions related to GMOs primarily are made on the risks posed to the environment and human health. There are some exceptions to this in the sanitary and phytosanitary areas with regard to safety assessment. For example, both the WTO SPS Agreement and the FAO Plant Protection Convention allow socio-economic factors to be considered in risk assessment and risk management measures.

But for the most part, decision makers apparently have not begun to more widely factor other considerations into their decision-making outside of the traditional realm of environmentally oriented safety assessment. Other considerations may include socio-economic, cultural, religious or ethical implications of commercialisation. Consumer protection issues may also be applicable.

This said, a trend might be emerging whereby decision makers are beginning or will begin to consider other factors in addition to environment and human health. Other considerations could be addressed in broader assessments, such as socio-economic impact analysis or cost/benefit analysis.

At the international level, with the exception of the Biosafety Protocol, there are more soft law instruments than hard law instruments that refer to other considerations.

In the food safety area, the Codex Committee on General Principles has been working to further elaborate “other legitimate factors relevant to the health protection of the consumer and for the promotion of fair practices” (Codex, 2001c). According to the Codex Statements of Principle Concerning the Role of Science in the Codex Decision-making Process and the Extent to Which Other Factors Are Taken Into Account, the Commission should consider “other legitimate factors” as it develops and adopts food standards.

The Committee on General Principles has developed and agreed general criteria for considering other legitimate factors (Codex, 2001c). Other Codex committees are feeding into this Committee’s work including those on Food Additives and Contaminants, Residues of Veterinary Residues and Drugs in Foods and Pesticide Residues.

During the Biosafety Protocol negotiations, there was a debate on the extent to which socio-economic considerations should be considered in the risk assessment. The adopted version of the Protocol states that contracting parties reaching import decisions under the Protocol or under domestic legal measures implementing the Protocol may account for socio-economic considerations arising from the impact of LMOs on biodiversity conservation and sustainable use (especially with regard to value of biodiversity to indigenous and local communities) (art. 26(1)). In other words, decision-making may only account for the socio-economics related to potential biodiversity loss and not more generally.

Furthermore, it is implied that socio-economics should not be addressed in identification of hazards and assessment of risk. Instead, it appears socio-economic considerations may be considered as an additional decision making criterion.

The FAO Code of Conduct on Responsible Fisheries specifically applies to genetically altered stocks used in aquaculture. Its more general provisions do not specifically refer to GMOs but they could be interpreted to apply. The Code suggests that conservation and management decisions should be based on the best scientific evidence, taking into account traditional knowledge, as well as environmental, economic and social factors (art. 6.4).

Agenda 21 addresses environmentally sound management of biotechnology in Chapter 16. Agenda 21 sets out a five point programme: (a) increasing the availability of food, feed and renewable raw materials; (b) improving human health; (c) enhancing environmental protection; (d) enhancing safety and developing international mechanisms for co-operation; and (e) establishing enabling mechanisms to develop and apply biotechnology in an environmentally sound manner.

The development of appropriate safety procedures, taking into account programme area "D", is common to all programme areas. Programme area "D" suggests that ethical considerations should be taken into account.

In programme area "A", governments are called on to improve plant and animal breeding and microorganisms both through traditional and modern biotechnologies. This should be undertaken taking into account the needs of farmers, the modifications' socio-economic, cultural and environmental impacts. Furthermore, work should proceed to promote sustainable social and economic development while "paying particular attention to how the use of biotechnology will impact on the maintenance of environmental integrity (para. 16.4).

The basis for action in programme area "E" stresses the need for strengthened endogenous capacities in developing countries in order to facilitate accelerated development and application of biotechnology (para. 16.37). Mention is made of the needs for socio-economic assessment and safety assessment. The basis for action also recognises that biotechnological research and its application could have significant positive and negative socio-economic and cultural impacts and that these should be identified early in the development phase to appropriately manage them (para. 16.38).

The UNEP Technical Guidelines on Biosafety acknowledge the importance of assessing socio-economic and other impacts of new biotechnologies. Unfortunately, the Guidelines do not address these issues.

Finally, the FAO preliminary draft International Code of Conduct on Plant Biotechnology should also be noted. If finalised and adopted the draft Code could help to influence a broadening of the considerations upon which decisions are made because it focuses on a triad of issues: the safe, responsible and equitable use of biotechnologies for food and agriculture. Socio-economic impacts are particularly emphasised.

At the national level, there are also emerging examples of decision making taking other considerations into account. The Indonesian Ministerial Decree on the Provisions on Biosafety of Genetically Engineered Agricultural Biotechnology Products regulates and supervises the use of "genetically engineered agricultural biotechnology products" (GEABP) (art. 2(1)) "to ensure the safety and health of humans, biosafety and the environment related to the use of GEABPs" (art. 2(2)). It applies to (1) transgenic animals and fish and materials originating from them, (2) transgenic plants and their parts and (3) transgenic microorganisms (art. 4).

The use of GEABPs must meet general and category-specific requirements (arts. 10-33) enumerated

in the decree. For example, in general, both domestic and foreign GEABPs must "pay attention to and take into consideration" religious, ethical, socio-cultural and aesthetic norms (art. 9(1)). The Decree leaves unclear how this is actually ensured.

European Union Directive 2001/18/EC (Deliberate Release of GMOs into the Environment) states that Member States may consider ethical aspects when GMOs are released into the environment or placed on the market (preamble para. 9). Furthermore, at its own initiative, or upon request of the European Parliament, the Council of Ministers or a Member State, the European Commission may consult any committee it has created to obtain advice on the ethical implications of biotechnology, such as the European Group on Ethics in Science and New Technologies (article 29(1)). This is without prejudice to the competence of Member States on ethical issues. The consultation is to be based upon openness, transparency and accessibility to the public (article 29(2)). Results shall be publicly available.

The Commission will also submit a report to the European Parliament every three years to report on the experience of Member States. The upcoming report for 2003 will include an assessment of *inter alia* the socio-economic implications of deliberate GMO releases and subsequent marketing (article 31(7)(d)). Finally, the Commission will report annually to the Council and the Parliament on ethical issues (article 31(8)), including proposals to amend the Directive.

If adopted, the proposed EU Regulation on Genetically Modified Food and Feed would require the applicant to submit as part of the application "either a reasoned statement that the food does not give raise to ethical or religious concerns or a proposed labelling scheme to address these concerns (art. 6(3)(g)). In addition, the references in the proposed regulation to "other legitimate factors" indicate that the Commission, as decision maker, may in making its decision rely on other factors in addition to the scientific risk assessment undertaken by the European Food Authority and provided for in the Authority's written opinion. The draft decision produced by the Commission is to take account of Community law and "other legitimate factors relevant to the matter under consideration" (art. 8(1)).

4.3.2 Mechanisms to Ensure Greater Accountability in Decision Making

4.3.2.1 Criteria for Decision Making

Requirements that GMOs not damage the environment or adversely affect human health are features typical of many of the instruments reviewed. For example, GMOs cannot usually be introduced into the environment without a risk assessment and risk management plan.

However, many of the instruments reviewed do not provide criteria to guide decision makers in their decisions. Without greater specification and additional guidance, decision makers may have too much discretion to decide in favour of an application. Too much discretion could lead to poor, even arbitrary decision making. This in turn could impede efforts to realise the potential and avoid the risks of modern biotechnologies such as GMOs.

Decision making criteria in addition to environmental and human health criteria do not appear to be incorporated into the international instruments reviewed at all. However, in article 3 the FAO preliminary draft International Code of Conduct on Plant Biotechnology indirectly provides some criteria in its definition of "appropriate biotechnology". For example, "appropriate biotechnologies" include those "which contribute to sustainable development" (art. 3). Criteria for identifying appropriate biotechnologies are provided. These include those that are: (1) technically feasible; (2) bring tangible benefits to users; (3) are environmentally safe; and (4) are socio-economically and culturally acceptable (art. 3).

At the national level, some countries have provided their decision makers with more guidance that consequently limits their discretion.

In the African Union, under the OAU Draft Model National Legislation on Safety in Biotechnology, approval cannot be issued unless the CA considers and duly determines that the GMO or product of GMOs poses "no risks to the environment, biological diversity or health" (art. 6(6)). In addition, no approval is to be given unless the activity will (a) benefit the country, (b) contribute to sustainable development, (c) not have adverse socio-economic effects and (d) "accord with ethical values and concerns of communities and does not undermine traditional knowledge and technologies" (art. 6(8)).

Decision making in the Philippines is guided by a single overarching principle that applies to approvals. The Biosafety Guidelines provide that "[g]enetic manipulation of organisms should be allowed only if the ultimate objective is for the welfare of humanity and the natural environment and only if it has been clearly demonstrated that there is no existing or foreseeable alternative approaches to servicing the welfare of humanity and the natural environment" (sec. C, para 1.4).

Finally, in any Australian licensing decision – whether for release or otherwise - the Regulator cannot issue a license without being satisfied that risks posed by the dealings proposed to be authorised by the license can be managed to protect human health and safety and the environment (sec. 56). Additional guidelines are provided to guide the Regulator's decision-making process.

For example, the Regulator must be guided by the risk assessment and management plan, submissions received from the public and any policy guidelines in force related to risks and ways to manage them (Sec. 56, para. 2). However, the Regulator must also not issue a license if it would be inconsistent with a policy principle in force or if the applicant is not suitable to hold a license (sec. 57).

4.3.2.2 Publicly Available Rationale

The public's access to information and participation in policy and decision-making are important tools to ensure accountability. The public availability of the rationale for a decision is a complementary requirement. A rationale could accompany any decision whether an approval or a denial. Few of the international and national level instruments reviewed provide for a publicly available rationale.

At the international level only two instruments were found to require a publicly available rationale. As between parties of the FAO Plant Protection Convention, the imposition of phytosanitary measures should be supported by an available rationale (art. VII(2)).

Under the Aarhus Convention when a decision is taken the public is to be promptly informed. In addition, a text of the decision and the reasons and considerations upon which the decision is based are also to be made publicly available (art. 6(9)).

At the national level, in Indonesia only denials are to be accompanied by a rationale under the Ministerial Decree on the Provisions on Biosafety of Genetically Modified Agricultural Biotechnology Products (art. 39(3)).

In the Philippines, the Biosafety Guidelines state that the national committee on biosafety has the responsibility to publish the results of its internal deliberations (sec. 4). It is unclear whether this includes a rationale for its decisions.

In the food safety area the United Kingdom provides an interesting example that contributes to greater public accountability. The UK Food Standards Agency is to prepare and publish a statement of general objectives that it intends to pursue and the general practices that it intends to adopt to carry out its functions (section 22(1)). The statement is to include as one of the Agency's objectives "securing the records of its decisions, and the information upon which they are based, are kept and made available" to enable the public to make informed judgments about the manner in which the Agency carries out its functions (section 22(2)(c)).

4.3.2.3 Access to Judicial or Administrative Review

Perhaps the ultimate tool to ensure accountability in decision-making is public access to judicial or administrative review. Judicial or administrative review provisions may be found in the instrument itself or they may be part of more general instruments dealing with civil procedure or administrative procedures. Therefore the absence of these procedures in GMO-related instruments may not mean that the procedures are denied in other more generally applicable laws.

Of the international instruments reviewed for the study only the Aarhus Convention addresses judicial or administrative review of decisions. Contracting parties are to provide access to a review procedure to those people who consider that their requests for information (under article 4) have been ignored, wrongfully refused or otherwise not dealt with (art. 9(1)). In addition, a review procedure is to be provided before *inter alia* a court of law to people with "sufficient interest" or an "impairment of right" in order to challenge the substantive and procedural legality of any decision, act or omission (subject to article 6) (art. 9(2)).

At the national level, of the instruments reviewed, only the Philippines provided access to administrative review. The Philippine Biosafety Guidelines note that a decision to deny a permit can be appealed (sec. ___, para. 1.1.6).

5.0 General Conclusions on Gaps and Trends and Areas for Possible Future Work

The study can only be considered indicative because of the small sampling of national level instruments undertaken. However, when combined with the wider sampling of international instruments a number of trends and gaps were evident in two key areas: public participation and oversight mechanisms. These are described below.

5.1 General Conclusions on Gaps and Trends and Areas for Possible Future Work With Regard to Public Participation

Whether at the international or national levels, the biosafety instruments examined were generally found to be more specific on public participation than the food safety or consumer protection instruments examined. This demonstrates that the general principle of public participation is well established in the biosafety field.

However the extent to which public participation is actually facilitated or exists in a country is difficult to determine from a simple review of the country's biotechnology related legislative instruments. For example, general references to public participation may not translate into actual participation if additional criteria are not provided on the form public participation can take. Also the best public participation provisions may not be used if the public does not have the capacity to effectively participate. Finally, the lack of specific public participation provisions in, for example, a biosafety law does not necessarily mean that the public is barred from participation. It must be kept in mind that generic laws on public participation may already exist in the country and that the necessary criteria are applicable to the policy making and regulatory decision making processes addressing modern biotechnology.

The general lack of references to public participation in the food safety area, at least in what could be considered the first generation of laws at the national level, was striking because it appeared to be across the board, regardless of whether a country was developed or developing. However, some countries such as the United Kingdom are beginning to open the food safety assessment process up to greater public participation and scrutiny.

While consumer protection instruments examined did not promote public participation *per se,* they did promote access to information to enable consumers to make informed choices and to prevent fraud.

Access to information is an important cornerstone of public participation and is one tool that could help to realise the benefits and avoid the risks of modern biotechnology.

International instruments address access to information with varying degrees of specificity. The Aarhus Convention is perhaps the standard against which to judge other instruments at international and national levels. Though its reach is limited to the region in which it applies it is an important source of principles from which international negotiators and national level lawmakers could draw.

In general, those countries with legislation that were reviewed had more references to public participation and access to information than countries relying on voluntary guidelines. Developed countries typically have legislation on biosafety. But surprisingly, many of the developed countries examined do not appear to be any more progressive in terms of substance than those developing countries examined. This is despite the fact that developed countries have been working on biosafety

issues far longer than developing countries, may have a better informed public and constantly urge developing countries to increase public participation and transparency within their decision making processes.

Still it must be kept in mind again that generic public participation laws may pre-empt the need for specific references to public participation and access to information in the sectoral legislation. This may explain the situation in Canada where none of the five sectoral laws examined had explicit provisions on public participation in general and access to information in particular. In contrast, two of these laws did have explicit confidentiality provisions.

The review indicates that confidentiality provisions have proliferated at both international and national levels. There may be a need to further study confidentiality provisions to determine how countries use them and, in particular, whether the application of such provisions impedes the public's access to relevant information on modern biotechnologies. It may be particularly important for future international and national instruments to supply principles to guide the use of confidentiality provisions by decision-makers.

The review reveals that the principle of providing information to neighbouring States is increasingly recognised at the international level. Notwithstanding this, no national level instrument examined made specific reference to access to information by other States. Bridging this gap could be foreseen as an important contribution to international co-operation and could help to avert transboundary incidents involving GMOs.

Labelling, especially in the food safety and consumer protection areas, is being increasingly addressed at international and national levels. The issue of when labels can or should be applied to products that may or may not contain GMOs is a major issue that is being tackled. In contrast, in the biosafety area no international instruments address labelling, though the Aarhus Convention is examining the issue. Notwithstanding this lack of international action on biosafety related labelling, the review did reveal that some States and regional economic integration organisations are addressing the biosafety and labelling nexus.

The primary concern in all labelling areas is that a proliferation of standards at international, regional and national levels will create barriers to trade and ultimately confuse consumers and other end-users. Therefore there is a need to harmonise standards. For food, harmonisation is taking place at the international level within the Codex Alimentarius. In the biosafety area, there does not appear to be any international process other than an examination of the issue within the Aarhus Convention. An important threshold issue to more action at the international level is determining the need for labelling GMOs and GMO-related products in the biosafety context.

With regard to public participation in policy-making, no international instruments specifically mention the need for public participation in strategic processes focussing on modern biotechnology. In addition, the countries examined do not appear to have participatory policy-making processes within which all aspects of modern biotechnology could be addressed. The most important possibility for public input appears to occur on a case-by-case basis as promoters of individual genetically modified organisms attempt to gain approval through a regulatory process.

Notwithstanding this the review found that some countries are indeed taking a new approach. They are creating broad-based stakeholder processes on certain aspects of modern biotechnology such as the release of GMOs. These processes help the government to gauge public opinion, generate dialogue, gather useful information and develop awareness within their populations on modern

biotechnology. New Zealand is a particularly good example.
Because of the dearth of specific references to public participation in policy-making at the international level specific to modern biotechnology, it may be useful for future international instruments, such as the forthcoming FAO Code of Conduct on Biotechnology, to unambiguously refer to the desirability of creating such processes.

Public participation in decision-making is a more familiar concept at international and national levels than public participation in policy-making. Still only four international instruments reviewed address the issue, the standard again being the Aarhus Convention. Examples of varying specificity do exist at the national level specific to GMOs.

Some important considerations include the mechanism through which the public is notified (e.g., public notice) and can provide inputs (in writing or via a public hearing) and the time period within which the comments must be received. However, it is really not enough simply to give the public an opportunity to participate and provide information. Most importantly the competent authority must take those views into consideration. In the best case, the competent authority may also be required to justify why a particular viewpoint was accepted or not. Work on future international or national level instruments should keep this in mind.

5.2 General Conclusions on Gaps and Trends and Areas for Possible Future Work With Regard to Oversight Mechanisms

The oversight process may contribute to maximise the benefits and avoid the risks of modern biotechnology. Three mechanisms were examined: (1) institutions; (2) safety assessment; and (3) decision making.

Oversight and advisory institutions are the most obvious oversight components addressed at international and national levels. The generality with which institutional issues have been treated at international level does not seem to have impeded the establishment of institutional oversight nationally. All countries examined have some form of institutional oversight in place.

What does vary between countries is whether bodies have been created to provide advice to competent authorities tasked with decision-making responsibilities. A multidisciplinary and/or multi-stakeholder advisory body could have an important role to play in assisting a competent authority in its examination of the merits of GMOs and, consequently, maximising the benefits and minimising the risks of modern biotechnology. With the exception of the FAO preliminary draft International Code of Conduct on Plant Biotechnology, no international instrument reviewed refers to the desirability of creating advisory bodies. Future instruments could include provisions on advisory bodies.

Another potentially important institutional consideration is creating institutional biosafety committees. These can be given the ultimate responsibility within an institution working with GMOs to ensure the safety of any GMO-related work before and after regulatory oversight. In fact, IBCs appear to be widely referenced in voluntary guidelines promulgated at the national level. It is unclear whether the concept of IBCs originated with an existing international instrument. Those reviewed for the study did not mention them. Nonetheless negotiators and lawmakers may wish to consider the concept for future instruments.

Safety assessment (e.g., hazards identification, risk assessment and risk management), the second oversight mechanism, is referred to in all national oversight systems examined. It is also referenced in all international instruments examined dealing with biosafety and food safety.

While the need for risk assessment is undisputed, one concept in particular is coming under greater scrutiny. The application of the substantial equivalence concept in the food safety area is the primary example in this regard. Future negotiators of international instruments that may refer to substantial equivalence may wish to provide guidance on its proper application so that the concept does not simply become a decision threshold to exempt genetically modified products from rigorous safety assessments.

Greater attention is also being given to factors other than environmental protection and human health in the oversight process. For example, an emerging trend is the consideration of socio-economic considerations. Governments may need assistance, particularly capacity building and technical guidance, in assessing socio-economic impacts.

Finally, risk communication is a new area of risk assessment that emphasises effective communication in all aspects of risk assessment and risk management. Negotiators and lawmakers may wish to consider it in their work in order to better integrate the public's access to information and participation in the safety assessment process.

In the risk management area the precautionary approach is being referenced more frequently in post-Rio international instruments. The extent to which the precautionary approach is actually practiced at the national level is unknown. However, the small collection of second-generation biosafety and food safety laws that were reviewed do tend to refer to it explicitly. Guidance for applying a precautionary approach to modern biotechnology may need to be promulgated at the international level to ensure consistency application worldwide.

Post-approval monitoring is a risk management technique referred to in a number of international instruments reviewed. It was not explicitly mentioned in the majority of national level instruments reviewed, but this may be a function of its application in permit conditions. Post-approval monitoring will be important to minimising the risks of modern biotechnology and should be addressed specifically in sectoral instruments at the national level.

Traceability is an emerging risk management tool within the biosafety and food safety areas. It could be useful where illegal export, import or release is suspected, where environmental damage has occurred or where unforeseen food toxicity is identified. It is just being referred to at international and national levels and, where technically feasible, may be useful for negotiators and lawmakers to consider as they create new legal instruments.

Decision-making is the third common component of any oversight mechanism. One important aspect of decision-making consists of the extent to which considerations other than environment and human health are used by decision-maker to reach a decision concerning a GMO. Based on the instruments reviewed it appears that a trend may be emerging to the extent that other factors, such as socio-economic and ethical considerations, are beginning to be considered. A more holistic approach to decision-making may result in a more accurate consideration of costs and benefits in the regulatory decision-making process. Negotiators and lawmakers may wish to consider this broader approach in their work.

A second important aspect of decision-making is mechanisms to ensure greater accountability in the decision-making process. Greater accountability can be supported by criteria for decision-making, publicly available rationales to the decisions taken and the possibility for judicial or administrative review of decisions. Each of these areas is underrepresented in international instruments and only a handful of the national level instruments reviewed refer to all of them. Therefore, negotiators and lawmakers may wish to consider these points in their work.

Table I – International Instruments Related to Modern Biotechnology				
Instrument	**Application**	**Biotech Product Movement**	**Oversight Mechanisms**	**Selected Legal Annotations and Comments**

	Environment and Human Health?	Food Safety?	Consumer Protection?	Traceability?	Labelling?	Commerce/Marketing?	Transport?	Export?	Import?	Safety Assessment?	Cross-sectoral Coordination/Advice?	Stakeholder Participation and other information-related considerations?	Other Considerations (e.g., socio-economics or ethics)?	

Biotechnology Industry Organisation (United States of America)													
Statement of Principles (1999)	Y	Y				Y				Y		Y		The Biotechnology Industry Organisation (BIO) is the primary US-based trade group representing the biotechnology industry. According to the Statement's preamble, BIO represents biotechnology companies, academic institutions, state biotechnology centres and related organisations in the US and in other countries. BIO recognises that biotechnology needs to by approached with an appropriate mixture of enthusiasm, caution and humility. The first principle acknowledges respect for the power of biotechnology and the intent to apply it for the benefit of humankind. The members of BIO will avoid technological applications that do not respect human rights or carry risks that outweigh potential benefits. BIO members affirm that they will "listen carefully" to those who are concerned about the implications of biotechnology and respond to their concerns (principle 2). BIO members also affirm that they help to educate the public about biotechnology, its benefits and implications (principle 3). BIO's highest priority is health, safety and environmental protection in the use of its members' products through science-based regulation (principle 4). It also respects animal welfare (principle 6). Principle 10 affirms that BIO's members will develop their agricultural products to enhance the world's food supply, and to promote sustainable agriculture with attendant environmental benefits. Finally, BIO supports the conservation of biodiversity (principle 13).
Food and Agriculture Organization of the United Nations and World Health Organization													
Codex Alimentarius														The Codex Alimentarius is a collection of internationally adopted food standards presented in a uniform manner (Codex, 1999). Codex standards ensure that consumers receive products that meet internationally accepted minimum acceptable quality levels, are safe and do not present a health hazard (FAO/WHO, 1999). Standards are prescribed for individual foods and food groups. General standards have also been adopted, for example, for labelling pre-packaged foods. In addition to specific standards, the Codex also includes "related texts". Related texts include advisory instruments: statements of principle, codes of practice, guidelines and codes of technological practice. Some of these instruments apply to food and food products that have been derived from biotechnology (genetically modified). The Codex Alimentarius Commission, an intergovernmental body, develops and keeps under review the Codex. The Joint FAO/WHO Food Standards Programme administers the Codex Commission. The highest priority of the Codex Commission is to protect the health of consumers and ensure fair practices in food trade according to article 1 of the Codex Statute (Codex, 2000c). The Codex Commission, and the Codex itself, also facilitates international trade in food through the elaboration and harmonisation of definitions and requirements for food. In this regard, the Codex Commission has been

														recognised as an international standard setting body for purposes of implementing the World Trade Organisation's Agreement on Sanitary and Phyto-sanitary Measures (SPS Agreement). The Codex itself is recognised as an international standard for purposes of the SPS Agreement. As part of its work, the Codex Commission also keeps under review its relationship with other international intergovernmental organisations such as the Convention on Biological Diversity, and the Cartagena Protocol on Biosafety. Subsidiary bodies undertake the bulk of the standard setting and the development of related texts. Subsidiary bodies can include codex committees, *ad hoc* intergovernmental task forces, as well as working groups. Joint FAO/WHO expert consultations help to supplement the technical content of the Codex work on an as needed basis. The overall elaboration of the Codex instruments is guided by the Procedures for the Elaboration of Codex Standards and Related Texts (Codex, 2000d). The uniform procedures are outlined as a series of steps. In general, subsidiary bodies develop standards and related texts. During their development they are submitted periodically for review to the Codex Commission and to member States for comment and ultimate adoption. The instruments can be elaborated and adopted in pieces. The Codex Commission keeps all instruments under review. The instruments relevant to genetically modified foods are in various stages of development within the Codex Commission. Notably, the Codex Commission has yet to adopt an agreed definition of "genetically engineered/modified organisms" (Codex, 1999). As of October 2001, the Codex Commission, through its subsidiary bodies, was working on a number of issues relevant to genetically modified organisms and foods either explicitly or more generally such as *inter alia* traceability, labelling, identification and risk assessment. More specifically, the following subsidiary bodies are working on different aspects of genetically modified foods and food products: (1) Codex Committee on Food Labelling (Amendments to the Codex General Standard for Labelling Pre-packaged Foods: Labelling of Foods Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering (definitions and declaration of allergens) (steps 6 and 8 respectively) (Codex, 2001b); and Proposed Draft Guidelines for the Labelling of Foods Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering: Proposed Draft Guidelines (step 3) (Codex, 2001b); (2) *Ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology (Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology (step 6); Draft Guidelines for the Conduct of Food Safety Assessments of Foods Derived from Recombinant DNA Plants (step 6); Draft Guidelines for the Conduct of Food Safety Assessment of Recombinant-DNA Micro-organisms in Food (step 1) (Codex, 2001e)); (3) Codex Committee on Methods of Analysis and Sampling (General co-ordinating role on the development of methods to analyse foods derived from biotechnology especially in the context of detection) (Codex, 2001f); (4) Codex Committee on Food

														Import and Export Inspection and Certification Systems (Examines the general concept of "traceability" within the systems that it oversees) (Codex, 2000a); (5) Codex Committee on General Principles (Develops the concept of precaution and other aspects of risk analysis within the Codex System – see below) (Codex, 2001c); (6) Codex Committee on Pesticide Residues (Agreed to a "case by case" approach to be followed in establishing "maximum residue limits" for genetically modified crops and metabolic residues) (Codex, 2001d); and (7) the *Ad hoc* Intergovernmental Task Force on Good Animal Feeding (Proposed Code of Practice on Good Animal Feeding) (Codex, 2000b). The Committee on General Principles has been working on two issue areas that are relevant to genetically modified foods and food products as applied to the Codex's mode of operation. The first issue area deals with risk analysis in the work of Codex. Working principles are to be developed and included in the Codex Procedural Manual. Work is on going. The 24th Session of the Codex Commission clarified that when there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Codex Commission should not elaborate a standard (Codex, 2001a). Instead, it should consider elaborating a related text that should itself be supported by available scientific evidence. In addition, other Codex Committees are working on risk analysis and these will be presented to the Commission in a single consolidated document (Codex, 2001a). The Committee on General Principles has also been working on further elaborating "other legitimate factors relevant to health protection of consumer and for the promotion of fair practices". In general, the Codex Statements of Principle Concerning the Role of Science in the Codex Decision-making Process and the Extent to Which Other Factors Are Taken Into Account states that Codex instruments are to be based on the principle of "sound scientific analysis and evidence" (Codex, 1995). According to the General Principles, the Commission should also consider "other legitimate factors" as it develops and adopts food standards. The Committee on General Principles has developed and agreed general criteria for considering other legitimate factors (Codex, 2001c). Other Codex committees are feeding into this Committee's work including those on Food Additives and Contaminants, Residues of Veterinary Residues and Drugs in Foods and Pesticide Residues.
Codex Alimentarius Proposed Draft Guidelines for the Labelling of Foods Obtained Through Certain Techniques of Genetic Mod./Genetic		**Y**	**Y**		**Y**	**Y**		**Y**	**Y**	**Y**			**Y**	The Codex Committee on Food Labelling has been working on Proposed Draft Guidelines for the Labelling of Foods Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering as an amendment to the General Standard for the Labelling of Pre-packaged Foods. The Guidelines were early on called Recommendations but this was changed. The Proposed Draft Guidelines are currently at step 3 in the Codex elaboration procedure. Two parts of the work to amend the General Labelling Standards (work on definitions and on the declaration of allergens) have been separated from the main body of work. The work on these parts is at a more advanced stage in the Codex elaboration

Engineering													procedure. The Draft development of an amended set of definitions is at step 6 in the Codex procedure. The Draft Amendment to the General Standards for the Labelling of Pre-packaged Foods: Labelling of Foods Obtained Through Certain Techniques of Genetic Modification/Genetic Engineering: Declaration of Allergens was adopted by the 24th Session of the Codex Commission (step 8). Because the Draft Guidelines are still in an early stage of development they are only generally described here. Many bracketed sections remain. The Guidelines are proposed to apply to labelling of foods and food ingredients in three situations when they are: (1) [no longer equivalent/differ significantly from conventional counterparts]; (2) composed of or contain GM/GE organisms or contain protein or DNA resulting from gene technology; and (3) when they are produced from but do not contain GM/GE organisms, protein or DNA from gene technology (sec. 1, para. 1.1). Labelling would describe those food characteristics or properties that are different than a corresponding conventional counterpart. Labels would declare the presence of allergens resulting from the GM process (sec. 3.0, paras. 3.1 and 3.2). Criteria would be provided for labelling the method of production (sec. 3.0, para. 3.4). Bracketed text exists on labelling in situations where substances exist that are absent from the corresponding conventional counterpart in situations that could raise ethical concerns (sec. 3.0, para. 3.5). Threshold levels for the presence of GM/GE organisms and the trigger for labelling are still under discussion (sec. 4.0). In general, all label declarations for pre-packaged food shall not be described in a manner that is false, misleading or deceptive or likely to create an erroneous impression regarding the product's character or safety (sec. 6.0)
Codex Alimentarius Guidelines for the Production, Processing Labelling and Marketing of Organically Produced Foods (1999)		**Y**	**Y**	**Y**	**Y**	**Y**		**Y**	**Y**				The Codex Organic Foods Guidelines provide an internationally agreed approach to produce, label and make claims about organically produced foods. The general aims of the guidelines include *inter alia* protecting consumers against deception and fraud, to protect organic producers against misrepresentation of other agricultural products as organic and ensuring that all stages of production, preparation, storage, transport and marketing are subject to inspection and comply with the guidelines (Foreword). The Guidelines are interpreted as a first step in efforts to harmonise internationally the requirements for organic production. They are seen as a tool to help countries develop national regimes on organic production. Principles of organic production are set out at the farm, preparation, storage, transport, labelling and marketing stages. Accepted inputs are specified. Organic production claims and labelling are limited to operators certified by a certification body. The Guidelines are interesting because they focus on a product whose character, and the claims made about it, are dependent on the production process used to create it. This distinguishes organic produce from other products in international trade where production process distinctions are not and should not be emphasised to ensure non-discriminatory trade practices. In short, the focus is on regulating the process rather than the final product *per se* (Foreword).

														The Guidelines apply to products that carry or are intended to carry descriptive labelling referring to organic production (sec. 1.1). Products include (a) unprocessed plants and plant products and (b) processed products for human consumption derived from (a). The Guidelines declare, "all materials and/or products produced from genetically engineered/modified organisms (GE/GMO) are not compatible with the principles of organic production (either the growing, manufacturing or processing) and therefore are not accepted under these guidelines" (sec. 1.5). Therefore, the Guidelines take a process rather than a product based approach with regard to genetic manipulation. In a footnote to the definition of GE/GMOs, the Guidelines note that the Codex Commission has yet to agree a definition. Therefore, a provisional definition is provided. GE/GMOs "are produced through techniques in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination" (sec. 2.2). Criteria are listed as to when labelling and claims for a product may refer to organic production, including the need for ingredients of agricultural origin to meet certain specifications (sec. 3.3). Derogations are allowed when ingredients of agricultural origin do not satisfy the enumerated specifications (sec. 3.4). A five-percent threshold (total ingredients) is set. From the earlier statements in the Guidelines against GE/GMOs it appears a zero threshold is implicitly set for ingredients of GE/GMO origin. In addition, transition periods are specified during which time farms can or cannot make organic claims about the agricultural products that they produce while they move to organic production methods. In addition to maintaining strict organic agricultural practices, the authenticity of a product claimed as organic is maintained by establishing strict handling, storage, transportation, processing and packaging requirements. In other words, authenticity must be maintained throughout the "organic food or supply chain" to the final consumer. For example, organic products must not be co-mingled with non-organic products; bulk stores should be separate from conventional product stores (Annex 1). When in international trade, imports are dependent on the issuance of a certificate of inspection by the exporting country. The certificate is to demonstrate that the lot meets the minimum standards of the Guidelines (sec. 7). After import, authenticity through the supply chain must be maintained.
Codex Alimentarius Proposed Draft Principles for the Risk Analysis of Foods Derived from Modern		**Y**		**Y[2]**		**Y**				**Y**	**Y**	**Y**		The Codex *Ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology is developing the Proposed Draft Principles (Codex, 2001e). In May 2001, the 24th Session of the Codex Commission agreed to advance the Draft Principles from step 5 to step 6. The introduction to the principles acknowledges that risk analysis approaches to assess chemical hazards for substances such as pesticide residues, contaminants,

[2] As of October 2001, text addressing traceability in the draft Principles is still under consideration.

Biotechnology														food additives and processing aids were not specifically designed to address whole foods (para. 2). These techniques are focused on discrete hazards that may be present in foods. A risk analysis approach can be applied to foods, but must be modified when applied to whole foods because of their complexity. The Draft Principles supplement the general Codex Working Principles on Risk Analysis that are being developed by the Codex Committee on General Principles. The Draft Principles are to provide a framework for risk analysis on the safety and nutritional aspects of foods derived from modern biotechnology (sec. 2, para. 7). The Draft Principles do not address the environmental, ethical, moral and socio-economic aspects of research, development, production and marketing of foods derived from modern biotechnology (sec. 2, para. 8). The definition of modern biotechnology is taken from the Cartagena Biosafety Protocol (under the Convention on Biological Diversity). Principles include *inter alia* those on risk assessment, risk management and risk communication (including advice and stakeholder participation). The risk assessment principles clarify that risk assessment includes a safety assessment designed to identify whether a hazard, nutritional or other safety concern is present and, if so, to gather information on its nature and severity (sec. 3, para. 10). The principles reflect the concept of substantial equivalence whereby the safety assessment should include, but should not be substituted for, a comparison between the food derived from modern biotechnology and its conventional counterpart (sec. 3, para. 11). The comparison should determine similarities and differences between the two. A safety assessment should (1) account for intended and unintended effects; (2) identify new or altered hazards; and (3) identify changes relevant to human health in key nutrients (sec. 3, para. 11). Safety assessment should take place on a case-by-case basis (sec. 3, para. 12). Risk management measures are to be proportional to the risk. These should take into account where relevant “other legitimate measures” (sec. 3, para. 16) according to general decisions of the Codex Commission and the Codex Working Principles on Risk Analysis. Different risk management measures can meet the same objective. Risk managers are to account for the uncertainties identified in the risk assessment and manage the uncertainties (sec. 3, para. 18). Risk management measures could include food labelling, conditions on marketing approvals, post marketing monitoring and development of methods to detect or identify foods derived from modern biotechnology (sec. 3, para. 19). Traceability may also be a risk management measure but is still under consideration. The risk communication principles are premised on the ideal that effective communication is essential in all phases of risk assessment and management (sec. 3, para. 22). It is to be an interactive process involving all interested parties. Processes

														should be transparent, fully documented and open to public scrutiny while respecting legitimate concerns for confidential commercial information. Safety assessment reports and other aspects of the decision-making process should be available to the public (sec. 3, para. 23). Responsive consultation processes should be created (sec. 3, para. 24).
Codex Alimentarius Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant DNA Plants		**Y**				**Y**		**Y**	**Y**	**Y**				The Codex *Ad hoc* Intergovernmental Task Force on Foods Derived from Biotechnology is developing the proposed Draft Guideline (Codex, 2001e). In May 2001, the 24th Session of the Codex Commission agreed to advance the Draft Guidelines from step 5 to step 6. The Draft Guideline is designed to support the Proposed Draft Principles for the Risk Analysis of Foods Derived from Modern Biotechnology. The Guideline describes the recommended approach for making a safety assessment of foods derived from r-DNA plants where a conventional counterpart exists. "'Conventional counterpart' means a related plant variety, its components and/or products for which there is experience of establishing safety based on a common use as food" (sec. 2, para. 7). The Draft Guideline reflects the concept of substantial equivalence (see below). The techniques described in the Draft Guideline may in theory be applied to foods derived from plants that have been altered by techniques other than modern biotechnology (sec. 1, para. 6). The Draft Guideline provides an introduction and rationale for food safety assessment, drawing distinctions between it and toxicological risk assessment for individual compounds that rely on animal studies. The "goal of the assessment is a conclusion as to whether the new food is as safe as and no less nutritious than the conventional counterpart against which it is compared" (sec. 5, para. 57). The discussion is based on a treatment of the concept of substantial equivalence undertaken by the Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology. The Expert Consultation noted that a more focused approach, substantial equivalence, is needed to judge the safety of foods derived from all plants taking into account both intended and unintended changes in the plant or foods derived from it (WHO, 2000). The Draft Guideline points out that substantial equivalence is not a safety assessment *per se*. Rather it is a way to structure food safety assessments relative to a conventional counterpart (sec. 3, para. 12). Substantial equivalence is used to identify similarities and differences between the new food and the conventional counterpart, acknowledging that for the foreseeable future foods derived from modern biotechnology will not be used as conventional counterparts. The safety assessment then assesses the safety of identified differences, taking into consideration unintended effects due to genetic modification (sec. 3, para. 16). Risk managers subsequently judge this and design risk management measures as appropriate. The Draft Guideline outlines a stepwise procedure for conducting safety assessments.

Codex Alimentarius Proposed Revised Code of Ethics for International Trade in Food		**Y**	**Y**			**Y**		**Y**	**Y**				**Y**	The Codex Alimentarius Proposed Revised Code of Ethics for International Trade in Food builds on the original Code adopted by the Codex Commission in 1985. The Codex Committee on General Principles is revising the Code. As of October 2001 the elaboration procedure is at step 3. The scope of application of the Revised Code remains to be determined but it will apply at least to governments. In addition, the relationship of the Code with WTO Agreements such as SPS and TBT and the implications for national implementation remain to be determined. The Code establishes standards of ethical conduct food in international trade. The Code makes only one reference to foods derived from biotechnology, though its general provisions can be interpreted to apply to these foods. The Code is premised on a number of general principles including *inter alia* consumer protection, food safety and fair trade practices (art. 4, para. 4.1). It takes into account various Codex Standards and related texts as well. The Code specifies that no food should be in international trade which "has in it or on it any substance in any amount which renders food poisonous, harmful or otherwise injurious to health unless the food is subject to further processing so as to address those risks" (art. 4, para. 4.2(a)), and is "labelled or presented in a manner that is false, misleading or deceptive or that may adversely affect the safety of the food" (art. 4, para 4.2(d)). It calls for the establishment of national food standards based on risk analysis (art. 5, para. 5.1) and adequate labelling of pre-packaged and bulk foods (art. 5, para. 5.3). Food additives and pesticide residue limits should follow codex standards and principles (art. 5, paras. 5.4 and 5.5). Foods derived from biotechnology are also to take into consideration Codex standards and related texts (art. 5, para. 5.9). Implementation measures are suggested for exports and imports (art. 6, paras. 6.1 and 6.3). Finally, provisions are suggested for exceptional circumstances – such as famines or other emergencies - where application of the Code may not be fully possible or desirable (art. 8). In these situations, due regard is still be given to food safety and those principles enumerated as may be applicable in such circumstances.
Codex Alimentarius Proposed Draft Code of Practice on Good Animal Feeding		**Y**	**Y**	**Y**	**Y**	**Y**				**Y**				The *Ad hoc* Intergovernmental Codex Task Force on Animal Feeding is developing a new Animal Feeding Code of Practice. As of October 2001, the elaboration procedure is at step 3. Though the Code is at a very early stage of development its general provisions are potentially relevant to the use of genetically modified or engineered materials in animal feeds. The purpose of the Code is to establish a feed safety system that covers the whole "'feed chain' from farm to table" (sec. 1). This will eliminate potential risks to human health, animal health and the environment. It will apply to the production and use of all materials of animal, plant and marine origin used in animal feed at all levels, whether produced industrially or on the farm (sec. 2). The Code's objectives will be to encourage adherence to Good Animal Feeding Practice (GAFP) at the farm level and Good Manufacturing Practice (GMP) during procurement, handling, storage, processing and distribution of animal feedstuffs. This is to ensure food safety for humans. It only applies to animal welfare issues to the extent that issues of animal

														health arise. In addition to other substantive requirements, labelling of feedstuffs is to be clear and informative to allow the farmer to handle and use the feed correctly (sec. 4.2). It is also to ensure the traceability of the feeding stuffs. Presently, the Code specifically states "Genetically modified organisms (GMO products) should be labelled". Traceability of raw materials, minerals, vitamins and feed additives in feedstuffs is to be ensured by proper labelling and record keeping (sec. 4.3). Records are to be maintained to allow tracing in emergency situations. The Code calls for the establishment of official regulatory programmes to ensure foods of animal origin produced for human consumption are safe and wholesome (sec. 4.4) with inspection systems designed around objective risk assessment. Feeding stuffs generally should be marketed when wholesome, unadulterated and of merchantable quality. They should not be dangerous to human or animal health and should not be marketed in a misleading manner (sec. 4.5.3). Undesirable substances such as pesticides should be minimised (sec. 4.5.4). The Code assigns ultimate responsibility to the producer or manufacturer of feeds to ensure the safety and wholesomeness of feed (sec. 5).
Food and Agriculture Organization of the United Nations														
International Treaty on Plant Genetic Resources for Food and Agriculture (2001)	**Y**									**Y**		**Y**		The FAO International Treaty on Plant Genetic Resources for Food and Agriculture was adopted by the FAO Conference in 2001 and opened for signature. The Treaty's objectives are the conservation and sustainable use of plant genetic resources for food and agriculture (PGRFA) and the fair and equitable sharing of the benefits arising out of their use (art. 1.1). It applies to all PGRFA (art. 3). The treaty's application to modern biotechnologies, such as genetically modified organisms, is not direct. In fact, the term "modern biotechnologies" is only referred to once and this is in the preamble's 6th recital. This paragraph acknowledges that PGRFA are indispensable as raw material for crop genetic improvement including that through modern biotechnologies. The conservation provisions of the Treaty are found in Article 4 (Conservation, Exploration, Collection, Characterisation, Evaluation and Documentation of PGRFA). Each contracting party is to promote an integrated approach to exploration, conservation and sustainable use of PGRFA (art. 5.1). Cooperation should be promoted to develop and transfer appropriate technologies leading to an efficient and sustainable system of ex situ conservation (art. 5.1(e)). This could include the use of modern biotechnologies. Finally, contracting parties are "to take steps to minimize or, if possible, eliminate threats to PGRFA" (art. 5.2). Though there are potentially many threats to PGRFA, this provision could be interpreted to apply to the threats posed by modern biotechnology such as GMOs especially in centres of origin or diversity. Flowing from this would be the need to undertake safety assessments prior to release. Stakeholder participation might also be envisioned. This is foreshadowed in article 9

													dealing with Farmers' Rights. National governments have the responsibility for realizing Farmers' Rights (art. 9.2). The right to participate in decision making at the national level on matters related to the conservation and sustainable use of PGRFA is among the measures to protect and promote Farmers' Rights (art. 9.2(c)). This could be interpreted to include the right of farmers to participate in biosafety decision-making processes and to have access to information. The Treaty creates a Multilateral System of Access and Benefit-sharing (MLS) in article 10. Access is to be facilitated to PGRFA that are part of the MLS. Access to those PGRFA that are included in the MLS is provided "solely for the purpose of utilisation and conservation for research, breeding and training for food and agriculture" (art. 12.3(a)). These uses are not to include those for the purpose of chemical, pharmaceutical and/or other non-food/feed industrial uses. The benefit sharing provisions of the Treaty will not be elaborated upon here. However, it should be noted that benefits might include the sharing of modern biotechnologies that use or incorporate PGRFA.
International Plant Protection Convention (1997)	**Y**					**Y**	**Y**	**Y**	**Y**	**Y**		**Y**	**Y**	The FAO International Plant Protection was originally adopted in 1951. It has been subsequently revised with the latest revision adopted in 1997 (described here). The IPPC regulates plant pests. It also regulates "any organism, object or material capable of harbouring pests or spreading pests that affect plants or plant products" (art. I(4)). The purpose of regulation is to prevent "the spread and introduction of these pests and promoting measures for their control" (ICPM, 2001a). IPPC provides a framework to develop and apply harmonised phytosanitary measures through the elaboration of international standards, the creation or management of national plant protection organisations. A "phytosanitary measure" is "any legislation, regulation or official procedure…to prevent the introduction and/or spread of pests" (art. II(1)). "Pests" are "any species or biotype of plant, animal or pathogenic agent injurious to plants or plant products" (art. II(1)) (including fungi) (ICPM, 2001b). Therefore, the IPPC's scope of application is broad enough to include genetically modified organisms, or living modified organisms/products of modern biotechnology that may directly or indirectly damage plants. Damage to plants is not necessarily limited to cultivated plants. The IPPC can be interpreted to apply to all plants – whether cultivated or wild – though in actual operation many contracting parties have limited its application to the former. The IPPC creates a Commission on Phytosanitary Measures (art. XI(1)). Until the 1997 revision enters into force, the Commission meets as the Interim Commission on Phytosanitary Measures (ICPM). The Commission is tasked with *inter alia* establishing and keeping under review the arrangements to develop and adopt international standards on phytosanitary measures (ISPMs) (art. XI(2)(b)). ISPMs are "the standards, guidelines and recommendations recognised as the basis for

														phytosanitary measures applied by Members of the World Trade Organisation under the Agreement on the Application of Sanitary and Phytosanitary Measures" (ICPM, 2001a). The development and application of ISPMs contributes to minimising phytosanitary measures as barriers to international trade. A suite of ISPMs has been developed under the IPPC. Perhaps the most relevant are the Guidelines for Pest Risk Analysis. The PRA Guidelines describe the three stages of PRA: (1) initiating the process for analysing risk presented by a pest; (2) assessing the pest risk and (3) managing the pest risk (IPPC, 1996b). As described in the Guidelines, initiating the process begins with identifying the pests or pathways for which the PRA is needed. A pest risk assessment then determines whether the pest identified is a quarantine pest. A quarantine pest is characterised in terms of the likelihood of entry, establishment, spread and economic importance. Pest risk management involves developing, evaluating, comparing and selecting options for reducing risk. The potential economic importance of the pest is a key determinant in the assessment process. It is in this determination that potential environmental damage is assessed along with other criteria such as perceived social costs (sec. 2.2.3). If the pest has sufficient economic importance and introduction potential (i.e., there is sufficient risk) then phytosanitary measures are justified – in other words pest risk management should be considered. The Guidelines highlight which options could be taken and suggest the efficacy and impact of the options should be evaluated (secs. 3.1 and 3.2). The IPPC provides that phytosanitary measures can be taken for quarantine pests and regulated non-quarantine pests, but not non-regulated pests (art. VI). Phytosanitary measures must meet minimum requirements. They must be non-discriminatory. They must be necessitated by phytosanitary considerations and be proportional. They must be technically justified. They must represent the least trade restrictive measures available. Finally, they must result in the minimum impediment to the international movement of people, commodities and conveyances (arts VI(1) and VII(2)(g)). Emergency measures are justified but must be evaluated as soon as possible to justify their continued application (art. VII(6)). In general, import requirements must comply with minimum stakeholder related requirements (as between IPPC parties). Some of these include publication and transmission of import requirements and the availability of a rationale (art. VII(2)). At its second session, the ICPM established the Exploratory Open-ended Working Group on Phytosanitary Aspects of GMOs, Biosafety and Invasive Species to review among other things the relationship between IPPC and the plant pest concerns that may be presented by LMOs/products of modern biotechnology. The Working Group noted that the IPPC was relevant to and adequate for managing the plant pest risks posed by LMOs/products of modern

														biotechnology (ICPM, 2000). Based on the Working Group's recommendation, the ICPM at its third session decided to create an Open-ended Expert Working Group for the Development of a Detailed Standard Specification on the Plant Pest Risks Associated with LMOs/Products of Modern Biotechnology (ICPM, 2001a).
Code of Conduct for the Import and Release of Exotic Biological Control Agents (1996)	**Y**							**Y**	**Y**	**Y**		**Y**		Another IPPC instrument that may be relevant to GMOs used in or having an effect on plant protection is the Code of Conduct for the Import and Release of Exotic Biological Control Agents. The Code's Outline notes that the Code could be applied to the handling and release into the environment of strains of organisms created artificially by genetic engineering techniques (IPPC, 1996a). In general, the code applies to exotic biological control agents (1) imported for research; (2) imported and released for biocontrol; and (3) imported and released for use as biological pesticides. The Code aims to facilitate safe import, export and release of exotic biological control agents by introducing internationally acceptable procedures for public and private entities (art. 1.1). It provides standards that *inter alia* encourage responsible and generally accepted trade practices (art. 1.1). The Code promotes the assessment of risks to the environment and human and animal health prior to import (at first import: identification of potential hazards, the risks posed and proposed mitigating procedures) (art. 4.3) and prior to release (where not already to in an import permit) (art. 7.1.1). Responsibilities for authorities are also described for situations before and upon release including *inter alia* encouraging monitoring (art. 7.1.3) and ensuring corrective action when problems arise (art. 7.1.4). Curiously, an importer is only to make information publicly available relating to safety and environmental impact after import and release (art. 8.1.2). A "free and frank" exchange of information, not subject to commercial confidentiality, is to be maintained. Finally, the importer has the responsibility to notify authorities when a problem occurs and to voluntarily take corrective action when requested (art. 8.1.4).

Code of Conduct for Responsible Fisheries (1995)	**Y**									**Y**		**Y**	**Y**	The FAO Code of Conduct is a voluntary set of principles and standards applicable to the conservation, management and development of all fisheries (preface and article 1.3). Some of its provisions reflect existing international law. It is global in scope and applies to all governments, fisheries organisations, non-governmental organisations and the private sector (art. 1.2). The Code's general provisions generally apply to release and use of GMOs without specifically mentioning these types of organisms. For example, conservation and management decisions should be based on the best scientific evidence, taking into account traditional knowledge, as well as environmental, economic and social factors (art. 6.4). Furthermore, the precautionary approach is to be applied to the conservation, management and development of living aquatic resources (art. 6.5). Finally, decision-making should be transparent and stakeholder participation should be facilitated (art. 6.13). The Code's aquaculture provisions are most directly applicable to GMOs because GMOs will likely be released in the context of aquaculture operations. Of the different obligations, two stand out. First, States should ensure that the livelihoods of local communities, and their access to fishing grounds, are not negatively affected by aquaculture developments (art. 9.1.4). This could be applied in situations where, for example, a genetically altered fish displaces wild species. Second, States in general should conserve genetic diversity and maintain the integrity of aquatic communities and ecosystems through management. Specifically, States are to minimise the harmful effects of introducing "genetically altered stocks" used in aquaculture, including culture-based fisheries, into waters (art. 9.3.1). This is especially important where there is significant potential for these stocks to spread into the waters of other States (art. 9.3.1).
International Code of Conduct on Plant Biotechnology as it Affects the Conservation and Utilization of Plant Genetic Resources (1992) (preliminary draft)	**Y**					**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	The FAO Commission on Plant Genetic Resources originally accepted in 1992 the preliminary draft of the FAO International Code of Conduct on Plant Biotechnology as it Affects the Conservation and Utilization of Plant Genetic Resources. Further work on the Code was postponed owing to other work priorities within the Commission, namely the renegotiation of the International Undertaking on Plant Genetic Resources. With the adoption of the International Treaty on Plant Genetic Resources, and the earlier adoption of the CBD Biosafety Protocol, the renamed Commission on Genetic Resources has turned its attention back to the draft Code. The draft Code is a holistic document that goes beyond mere biosafety issues to address a wide range of issues involving plant genetic resources (PGRs) and biotechnology. It attempts to address technical, economic, social, ecological, ethical and legal developments on biotechnology as it relates to biotechnology and PGRs. It lists eight objectives. Three of these are perhaps the most relevant to this study. The first objective is providing "recommendations for the safe, responsible and equitable use of biotechnologies for agriculture and food by researchers and

														commercial users in the public", private governmental sectors (art. 1.2). Another relevant objective is "to help assess and minimize possibly adverse socio-economic effects of biotechnology in agriculture and the food industry on farming communities" and developing countries' economies (art. 1.6). A third relevant objective is ensuring "the environmental impact of innovations in biotechnology in agriculture and food industry (*sp*.) are (*sp*.) fully assessed and measures taken to minimize and mitigate them (art. 1.7). The draft Code applies to new (or modern) biotechnologies "as they affect the conservation and utilization of plant genetic resources" (art. 2). As a result the draft Code applies to all plant biotechnologies. It also applies to all other biotechnologies if they affect or are likely to affect the conservation and utilisation of PGRs. This includes whether or not the plants or other organisms have been modified using the new biotechnologies. The draft Code is voluntary in nature (art. 4.1). It is addressed primarily to governments. It also addresses international organisations, researchers and research institutions, the agro and biotechnology industries, the seed trade, trade associations, local communities, farmers and public sector groups (art. 4.3). One of the key provisions of the draft Code is promoting the transfer and development of "appropriate biotechnologies" applied to PGRs (art. 5.1). "Appropriate biotechnologies" include those "which contribute to sustainable development" (art. 3). Criteria for identifying appropriate biotechnologies are provided and include those that are: (1) technically feasible; (2) bring tangible benefits to users; (3) are environmentally safe; and (4) socio-economically and culturally acceptable (art. 3). Governmental action at the national level should be framed through policies and programmes in agriculture and food biotechnologies (art. 6). In particular, governments should establish committees for appropriate biotechnology or similar fora. Their membership should be multi-disciplinary and represent "related interests that can assess the needs for and likely benefits and other impacts of relevant biotechnologies and their influence on the productivity and sustainability of prevailing agricultural systems" (art. 6.1). The draft Code also addresses preventing and mitigating possible negative effects of agro- and food biotechnologies. To this end, the draft Code first emphasises foreseeing and preventing possible negative socio-economic effects of agro and food biotechnologies (art. 8.1). Governments and international organisations should, as part of their technology assessment procedures, monitor and assess the socio-economic impacts of biotechnologies. Governments and international organisations should also act to foresee and prevent possible negative long-term environmental effects of biotechnologies (art. 8.2). Genetic erosion and the narrowing of the genetic basis of cultivated crops are emphasised. This is to be accomplished through

														adequate monitoring and long-term assessment of environmental impact as part of normal procedures for technology assessment. Governments should also consider establishing technical and financial assistance to farming communities and countries to mitigate adverse socio-economic effects from biotechnological developments (art. 8.4). Article 9 addresses access to PGRs and related biotechnologies; intellectual property rights and compensation for informal innovators. These provisions are not elaborated upon here. The FAO World Information and Early Warning System on Plant Genetic Resources (PGR/WIS) will be the focal point for the exchange of information related to the draft Code's implementation (art. 10.1). By disseminating information, the PGR/WIS will support the development of appropriate biotechnologies for the sustainable use of PGRs and biodiversity (art. 10.2). One way it will do this is by promoting research to define more precisely criteria and indicators on biotechnology's contribution "to sustainability in agriculture and use of plant genetic resources…[s]uch criteria should include both scientific (i.e., protection and development of biodiversity) and socio-economic aspects (i.e., whether innovations fit local farming systems)" (art. 10.2.1). In addition, the PGR/WIS will *inter alia* assess possible future developments and highlight possible adverse effects, identify crops and farming communities at risk and notify governments of the eventual risks for crops, farming communities, and human and animal health (art. 10.3). The draft Code's most extensive chapter addresses biosafety and other environmental concerns. Article 11 focuses on environmental risks from the application of plant biotechnologies. Governments should designate "competent national authorities to review, assess, implement and monitor biosafety and other concerns such as genetic erosion and agroecological disruption" from the introduction of biotechnological products (art. 11). The creation of a multi-disciplinary and multi-interest "national committee on biosafety and other environmental concerns" is suggested (art. 11.1). The elaboration of specific new laws and regulations is also suggested while ensuring that existing legislation has "adequate mechanisms for guaranteeing biosafety is also an option (arts. 11.2 and 11.3). A mechanism is also suggested to control and monitor deliberate releases, and to ensure the enforcement of biosafety laws and regulations (art. 11.5) International co-operation is urged in consideration that plants and other organisms (whether modified by genetic engineering or not) could adversely affect PGRs on other countries (art. 12.1). The draft Code proposes together in article 13 risk assessment and authorisation procedures for biotechnological applications to PGRs and the deliberate release of transgenic organisms that could adversely affect PGRs. Countries should ensure that

														there is a “full review and risk assessment by both the proposer and the competent authority” (art. 13.1). The review should precede authorisation by the national authority (art. 13.2). The review and risk assessment should be “conducted on a scientifically sound basis and consider possible negative consequences for human and animal health and the environment (including agro-ecosystems, possible PGRs erosion and biodiversity) (art. 13.3). The draft Code also suggests a number of bits of information that a proposer should include in any request for authorisation (art. 13.4). Case by case review is suggested to consider risks associated with each deliberate release (art. 13.5). Risk assessment should also proceed on a step-by-step basis – evaluating each step of the deliberate release (i.e., laboratory, small scale release, and adequate tests prior to marketing the novel product) (art. 13.6). Containment measures may be reduced gradually in each step only if the tests conducted in the previous step justify it. The details and depth of information required for the authorisation is to be proportional to the estimated degree of risk. The authorisation from the competent national authority should also include liability provisions for “eventual environmental damages due to the deliberate release of a transgenic organism” (art. 13.9). Article 14 of the draft Code also suggests various risk management and monitoring steps that should be taken. For example, when it is approved, “the release must be conducted and implemented…to minimize the possible negative effects and the dispersal of transgenic plants, parts of plants, pollen, and organisms which affect plant genetic resources” (art. 14.1). Interestingly, the draft code suggests applying the step-by-step principle to risk management (art. 14.2). In other words the various aspects of the release should match the potential risks. Any scale-ups should be evaluated and authorised on the basis of results of experiments conducted in the previous steps (art. 14.2). The proposer must ensure adequate and proportional monitoring of the actual effects that the organisms had on the environment and suggestions are made as to what information should be recorded (art. 14.3). Governments and competent authorities should inform the competent authority of countries that could be affected by negative and unexpected consequences of a deliberate release (art. 14.4). Governments and competent authorities should ensure adequate containment during transport. (art. 15.1). Import of transgenic organisms intended for release that could affect PGRs should be 15,prohibited without the importing country’s advanced informed agreement/prior informed consent (art. 15.2). AIA/PIC should take place independently of risk assessment and authorisation for release in the exporting country. It should be subject to *inter alia* (1) a preliminary risk assessment by the competent authority of the exporting country; (2) a notification from the competent authority of the exporting country along with all information to properly assess the risk and (3) the full authorisation of the importing country’s competent national authority

														(arts. 15.2.1, 15.2.2 and 15.2.4). In addition, a preliminary risk assessment should be proportional to the expected degree of risk (art. 15.2.3). A government that does not authorise handling or release of a transgenic plant or other organism should notify among others the Commission on Plant Genetic Resources (art. 15.3). A transgenic plant, or micro-organism that could adversely affect PGRs, that has not been authorised because of its pathogenic effects on human health, animals or plants (independently of the environment), could be exported only following a specific request from the importing country's competent authority (art. 15.4). Unauthorised exports should be notified to the Commission on Plant Genetic Resources (art. 15.5). A database of actions taken by member governments will be developed under the PGR/WIS so the information can be provided to national competent national authorities and international organisations (art. 15.6). Article 16 addresses public information. Article 16.1 provides that the public should be informed about possible risks to the environment and health. In addition, governments and competent authorities should "apply transparent procedures in risk assessment, giving access to all the information that could be of public interest" (art.16.1). Governments and public authorities should inform and consult the public, particularly local and farming communities that could be affected, about specific deliberate releases (art. 16.2). Governments should also organise adequate public education and information on plant biotechnologies (art. 16.3). Governments should inform the Commission on positive results and any negative effects, both environmental and socio-economic, from the applications of new biotechnologies (art. 17.2). Finally, non-observance of the rules and regulations of a host country regarding the safe, responsible and equitable use of agro and food biotechnologies should be provided to the Commission with copies to the transgressor (art. 17.3). The Code is to be reviewed and updated periodically to take into account technical, economic, social, ecological, ethical and legal developments (art. 18.1).
Organisation for Economic Co-operation and Development														
Safety Considerations for Biotechnology (1992)	**Y**									**Y**				The 1992 OECD Safety Considerations follow earlier OECD work in 1986 that set out the first safety guidelines for biotechnology applications to industry, to agriculture and to the environment (OECD, 1992). The 1986 Recombinant-DNA Safety Considerations provided guidance to be used in assessing field research involving GMOs. The 1992 Safety Considerations address two issues: biotechnological industrial production (good industrial large-scale practice of fermentation-derived biotechnology products) and, for field experiments, "Good Developmental Principles" (GDP). GDPs are proposed to contribute to "design…safe small scale field research with plants and micro-organisms with newly introduced traits" (OECD, 1992). Only the second aspect is described here.

														The Safety Considerations are intended to apply to the second stage of the continuum of research on GMOs - small-scale basic and initial applied research involving genetically modified plant and microorganisms – and how to ensure the environmental safety of this work. The GDPs provide guidance to researchers "on selecting organisms, choosing the research site and designing appropriate experimental conditions" (OECD, 1992). GDPs are premised on three working assumptions. First, that "certain general scientific principles related to the organism, the research site and experimental conditions have varied relative importance in determining whether an experiment is of low or negligible risk" (OECD, 1992). Second, is that an experiment's risk can be determined "by evaluating the relevant factors and their interaction under conditions of the experiment…" (OECD, 1992). Third and finally, "the interaction of these factors is easier to address in small-scale field experiments…because of their limited scope, which permits closer monitoring, generally easier assessment and analysis and the possibility of more effective containment measures" when something unforeseen happens (OECD, 1992). "Three "key" safety factors are described. The first is the characteristics of the organism. It is acknowledged that some organisms may have characteristics that present low or negligible risk under a broad range of conditions. Organisms with known adverse effects may still be able to be used when the experimental design allows the reduction of the likelihood of adverse effects through mitigation and/or confinement to a restricted research site. The first key safety factor recognises higher plants can be more readily mitigated and confined than microorganisms. The characteristics of the research site are the second key safety factor. The research site is to be "chosen both to design field trials of low or negligible risk, and to meet the objectives of the research" (OECD, 1992). The experimental conditions are the third key safety factor. Careful experimental design is a precondition to "acceptable and environmentally sound field research" (OECD, 1992). Some of the many considerations provided in the document include: (1) choosing an appropriate site in relation to the proximity of significant biota that could be affected; (2) characterising the site; (3) developing suitable safety and handling procedures for application and contingency plans; (4) keeping introduced organisms to the lowest practicable level appropriate for the experiment; (5) limiting dispersal; (6) adequate monitoring and preparedness to apply control or mitigation measures to avoid unintended adverse environmental effects; and (7) appropriate training for all involved personnel. The Safety Considerations also provide guidance on the application of GDP to plants and microorganisms, as well as scientific considerations for small-scale research with plants and microorganisms.

United Nations Commission on Economic Co-operation in Europe														
Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (1998)	**Y**		**Y**		**Y**							**Y**		The Aarhus Convention has not yet entered into force. The Convention specifically mentions GMOs in the context of decision-making (article 6(11)), but its broader or more general provisions could be interpreted to apply to GMOs as well. When the Convention was first adopted, the signatories requested that the first meeting of contracting parties develop further the application of the Convention with respect to GMOs. The first meeting of signatories established the Task Force on Genetically Modified Organisms (UNECE, 2000). The Task Force met twice in 2000. At its first meeting the Task Force generally agreed that article 6(11) of the Convention "left it unclear to what extent and in what situations the provisions of article 6 should be applied to decision-making on GMOs" (UNECE, 2000). At its second meeting, the Task Force sought to identify possible procedural options to clarify the Convention's application to GMOs (e.g., developing an annex or a set of guidelines); to clarify the definition of "deliberate release"; and to review the means, including labelling, of providing information on products containing GMOs, products derived from GMOs and products obtained by using GMOs (UNECE, 2001). The Convention is premised upon the principle that every person of present and future generations has the right "to live in an environment adequate to his or her health and well-being" (art.1). One aspect of ensuring this is for governments to "guarantee the rights of access to information, public participation in decision-making and access to justice in environmental matters" pursuant to the Convention's provisions (art. 1). The 20th recital in the preamble recognises "the concern of the public about the deliberate release of genetically modified organisms into the environment and the need for increased transparency and greater public participation in decision-making in this field". Environmental information is defined to include any information in any media on *inter alia* (1) the state of elements of the environment, including GMOs and (2) factors affecting or likely to affect the elements of the environment, cost benefit and other economic analysis and assumptions upon which environmental decision-making is based. A person may access environmental information without an interest having to be stated (art. 4(1)(a)). The information should be made available as soon as possible (art. 4(2)). Requests for access may be refused according to criteria enumerated (art. 4(3)). In addition, access to environmental information may be refused for reasons of commercial confidentiality (art. 4(4)(d)), but the grounds for refusal are to be interpreted restrictively, taking into account the public interest served by disclosure (art. 4(4)). There is an affirmative obligation on public authorities to possess and update environmental information relevant to their functions (art. 5(1)((a)). They must establish systems to ensure an adequate flow of information on proposed and existing activities; (art. (1)(b) and the availability of information enabling the public to take steps to mitigate harm where there is an imminent threat to human health (art. 5(1)(c)). The way in which public authorities make information available to

														the public is to be transparent and environmental information is to be effectively available (art. 5(2)). The progressive availability to the public of easily accessible electronic sources of information is required, including environmental legislation (art. 5(3)(b)). Operators undertaking activities with a significant environmental impact are to be encouraged to regularly inform the public of the environmental impact of their activities and products (art. 5(6)). Parties are also to develop mechanisms to ensure that sufficient product information is available to the public that enables consumers to make informed environmental choices (art. 5(8)). Public participation in decision-making is to take place for activities enumerated in Annex I (art. 6). However, the provisions of article 6 are specifically to be extended "to decisions on whether to permit the deliberate release of GMOs into the environment (art. 6(11)). For example, the public is to be informed early on in the decision making process of *inter alia* the proposed activity, the technical details of the decision making process itself and whether a national or transboundary environmental impact assessment is necessary (art. 6(2)(a), (d) and (e)). The procedures should include reasonable timeframes (art. 6(3)). Prospective applicants are encouraged to meet early with stakeholders before applying for a permit (art. 6(5)). Competent national authorities are to give the public access to all information relevant to the decision-making, subject to certain exceptions (art. 6(6)). Procedures are to allow the public to submit any comments, information, analyses or opinions considered relevant to the proposed activity (art. 6(7)). Each contracting party is also to ensure in the decision that due account is taken of the outcome of public participation (art. 6(8)). When a decision is taken the public is to be promptly informed; a text of the decision and the reasons and considerations upon which the decision is based are also to be made publicly available (art. 6(9)). Whenever a decision is reconsidered after the fact, the same procedures for the original decision as specified in the Convention are to be followed (art. 6(10)). The Convention also includes provisions on public participation in strategic processes such as planning and programming (art. 7), as well as in law making and the promulgation of regulations (art. 8). Contracting parties are to provide access to a review procedure to those people who consider that their requests for information under article 4 have been ignored, wrongfully refused or otherwise not dealt with (art. 9(1)). In addition, a review procedure is to be provided before *inter alia* a court of law to people with "sufficient interest" or an "impairment of right" in order to challenge the substantive and procedural legality of any decision, act or omission subject to article 6 (art. 9(2)). The public is to have access to administrative or judicial procedures to challenge acts or omissions by private persons and public authorities (art. 9(3)). Finally, adequate and effective remedies, including injunctive relief, are to be provided as well (art. 9(4)).
United Nations Commission on Sustainable Development														
Agenda 21, Chapter 16,	**Y**					**Y**	**Y**		**Y**	**Y**		**Y**	**Y**	Agenda 21 addresses the environmentally sound management of biotechnology in chapter 16. The programme is to help foster the application of internationally agreed

Environmentally Sound Management of Biotechnology (1992)														principles to ensure environmentally sound management; "to engender public trust and confidence"; to promote development of sustainable biotechnological applications; and establish appropriate enabling mechanisms (para. 16.1). Agenda 21 sets out a five point programme: (a) increasing the availability of food, feed and renewable raw materials; (b) improving human health; (c) enhancing environmental protection; (d) enhancing safety and developing international mechanisms for co-operation; and (e) establishing enabling mechanisms to develop and apply biotechnology in an environmentally sound manner. Only programme areas A, C, D and E are summarised here. The development of appropriate safety procedures taking into account programme area D, while "taking account of ethical considerations" is common to all programme areas. Programme area "A" puts into perspective the need not just to increase food supply through biotechnology, but also to improve food distribution and putting agriculture on a more sustainable footing (para. 16.2). It highlights that productivity gains have benefited only industrialised countries where biotechnology has been concentrated and that this imbalance needs to be rectified. Of the proposed activities in this programme area, those related to management may be most important in the context of this study. For example, governments are called on to improve plant and animal breeding and microorganisms both through traditional and modern biotechnologies. But this should be undertaken taking into account the needs of farmers, the modifications' socio-economic, cultural and environmental impacts; the need to promote sustainable social and economic development while "paying particular attention to how the use of biotechnology will impact on the maintenance of environmental integrity (para. 16.4). The primary aim programme area "C" is to prevent, halt and reverse environmental degradation through the appropriate use of biotechnology in conjunction with the use of other technologies (para. 16.22). Some of the management-related activities that governments are foreseen to undertake include *inter alia*: (b) developing applications to minimise the use of unsustainable synthetic chemical inputs; (f) increasing the availability of planting materials particularly indigenous varieties, for afforestation and reforestation and to improve sustainable yields from forests; (g) developing applications to increase the availability of stress-tolerant planting materials for land rehabilitation and soil conservation; (h) promoting the use of integrated pest management based on judicious use of bio-control agents; (i) promoting the use of bio-fertilisers within national fertiliser programmes (para. 16.23). The basis for action on programme area "D" includes many of the concepts reflected in the literature, fora and instruments reviewed thus far in these summary tables. These include: the need for internationally agreed principles on risk assessment and management; the need for adequate and transparent safety and border-control procedures to build confidence in biotechnology and lay the foundation for the community at large to accept potential risks and benefits of biotechnology; the primary

														consideration of the organism in safety assessment; the application of the principle of familiarity in a "flexible framework" considering national requirements, and logical progression within "a step-by-step and case-by-case approach"; the evolution to a more comprehensive approach based on the experiences of the first period leading to streamlining and categorising; complementary consideration of risk assessment and risk management; classification into contained use and release into the environment (para. 16.29). The aim of the programme area is "to ensure safety of biotechnology development, application, exchange and transfer through international agreement on principles to be applied on risk assessment and management, with particular reference to health and environment considerations, including the widest possible public participation and taking into account ethical considerations" (para. 16.30). The activities proposed were to be built upon planned or existing activities (para. 16.31). Among the management-related activities, governments should: (a) make existing safety procedures widely available and adapt them to local needs; (b) further develop existing safety procedures; (c) compile a framework of internationally agreed principles as a basis for guidelines on biosafety; and (e) exchange information on safety procedures and assist in emergency situations (para. 16.32). The basis for action in programme area "E" stresses the need for strengthened endogenous capacities in developing countries in order to facilitate accelerated development and application of biotechnology (para. 16.37). Mention is made of the needs for socio-economic assessment and safety assessment. Mention is also made of the need for "national mechanisms to allow for informed comment by the public with regard to biotechnology research and application". The basis for action also recognises that biotechnological research and its application could have significant positive and negative socio-economic and cultural impacts and that these should be identified early in the development phase to appropriately manage them (para. 16.38). One of the programme area objectives is to raise public awareness on the beneficial aspects of and risks related to biotechnology (para. 16.39(a)(iii)).
United Nations Environment Programme														
Convention on Biological Diversity (1992)	**Y**					**Y**		**Y**	**Y**	**Y**		**Y**		The CBD addresses biosafety in two articles: Article 8(g) and Article 19(3) and (4). Article 8(g) requires each contracting party to domestically regulate or manage the risks associated with the use and release of living modified organisms (LMOs) resulting from biotechnology likely to have adverse environmental impacts that could affect the conservation and sustainable use of biological diversity. Risks to human health are also to be taken into account but it is unclear in what context. For example, should risks to human health be considered in the purest sense or only in the context of biodiversity conservation and sustainable use? No further details are given. Other principles reflected in the CBD preamble and other CBD articles could be interpreted to apply to the use and release of LMOs. The principles of prevention and precaution, reflected in the CBD's preamble, are examples of the former case. In the latter case, contracting parties are to introduce appropriate procedures to

														require impact assessment of proposed projects likely to have significant adverse effects on biodiversity (art. 14(1)(a)). The objective is to avoid or minimise such effects. "Where appropriate" public participation in the procedures is to be allowed. Other relevant obligations include those on reciprocity, notification, exchange of information with other States and international organisations where activities in one party may adversely affect the biodiversity of another party or an area beyond the limits of any national jurisdiction (art. 14(1)(c and d)). Parties are to create emergency response arrangements at national level and joint contingency plans with other States (art. 14(1)(e)). Finally, there is a general obligation for parties to transfer environmentally sound technology (including biotechnology) relevant to the conservation and sustainable use of biodiversity (art. 16(1)). Domestic measures may benefit from international measures. The Biosafety Protocol, the need for which the CBD COP was required to consider under Article 19(3), now provides the basis for international measures related to the trade in LMOs. Prior to the Biosafety Protocol (see below), there was no global legally binding instrument to address the transfer, safe handling and use of LMOs resulting from modern biotechnology in the context of adverse effects on the environment that could subsequently adversely effect biodiversity. Whether it ratifies or accedes to the Protocol or not, a CBD party must still fulfil its obligations to implement CBD Article 8(g). In addition, where it does not ratify or accede to the protocol, a CBD party still needs to implement CBD Article 19(4). CBD Article 19(4) creates a bilateral obligation for a CBD party to provide information on an LMO prior to providing it to another CBD party. This information includes (1) any available information on the regulatory measures taken by the exporting CBD Party and (2) any available information on the "potential adverse impact" of a particular LMO.
Cartagena Protocol on Biosafety to the Convention on Biological Diversity (2000)	**Y**			**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**		**Y**	**Y**	The Biosafety Protocol was adopted in 2000. It has yet to enter into force. Along with the adoption of the Biosafety Protocol, the CBD COP Extraordinary Meeting established the Open-ended Ad Hoc Intergovernmental Committee for the Cartagena Protocol on Biosafety (ICCP). The ICCP has the mandate to prepare for the first meeting of the Protocol Parties. The ICCP's first meeting was in late 2000. The CBD Secretariat has proposed an additional meeting in 2001. The objective of the Protocol is to contribute to ensuring adequate levels of protection in the field of safe transfer, handling and use of LMOs (from modern biotechnology) that may have adverse effects on the conservation and sustainable use of biodiversity (accounting for human health risks) (art. 1). The Protocol specifically applies to transboundary movement, transit, handling and use of LMOs that may have adverse effects on biodiversity conservation and sustainable use (accounting for risks to

														human health) (art. 4). The Protocol applies only to the movement of LMOs between contracting parties. There is only one exception to the scope of the Protocol. It does not apply to the transboundary movement of LMOs that are pharmaceuticals for human use that are addressed by other relevant international agreements or organisations (article 5) (Sendashonga, 2001). In general, each party (1) is to take the necessary and appropriate legal, administrative and other measures to implement the protocol's obligations; and (2) is to ensure the development, handling, transport, use transfer and release of LMOs is undertaken in a manner that prevents or reduces risks to biodiversity (accounting for human health risks) (art. 2(1 and 2). Each party can take more protective action to conserve and sustainably use biodiversity, provided action is consistent with the Protocol (art. 2(4)). The most significant provisions of the Biosafety Protocol focus on the evaluation and notification between parties for LMOs slated for export and subsequent import. Advanced informed agreement (AIA), in other words, notification and subsequent approval of a first-time import (an intentional transboundary movement), applies to LMOs that are intended for intentional introduction into the environment where they may have adverse effects on the conservation and sustainable use of biodiversity (art. 7-10 and 12). The Protocol sets up a notification procedure between the exporting contracting party (or an exporter that is a legal or natural person) and an importing contracting party (art. 8 and 9). Criteria are provided for decision making on importation (art. 10). Most notably, decisions of the contracting party of import must be according to a risk assessment. It is important not to confuse the exceptions to AIA procedure with exceptions to the Protocol's scope of application (Damena, 2001; Sendashonga, 2001). In the case of the latter, there is only one exception: pharmaceuticals intended for human use that are already addressed by another international instrument or organisation). In the case of the former there are four categories of exceptions: (1) LMOs in transit (art. 6(1)); (2) LMOs for contained use (art. 6(2)); (3) LMOs identified in a decision of the Conference of Parties/Meeting of Parties as not likely to have adverse effects on biodiversity conservation and sustainable use (art. 7(4)); and (4) LMOs intended for direct use as food, feed or for processing (art. 11). For LMOs intended for direct use as food or feed, or for processing, the contracting party that makes a final decision for domestic use must notify the Biosafety Clearing-house created under the Protocol when the LMO could find its way into international trade (art. 11). The notification, at minimum, must contain information required under Annex II. The exemption for AIA does not apply to decisions on field trials. Even though AIA does not apply, a contracting party may still take an import decision under its domestic regulatory framework, provided this is consistent with the Protocol (art. 11(4)). Lack of scientific certainty due to insufficient relevant scientific information and

														knowledge regarding the extent of potential adverse effects shall not prevent the contracting party of import from taking a decision, as appropriate, in order to avoid or minimise potential adverse effects (art. 10(6)). When it lacks a domestic regulatory framework, a developing country contracting party, or a party with a transition economy, can declare through the Biosafety Clearinghouse that its decision on the first import of an LMO for direct use as food, feed or for processing will be pursuant to a risk assessment (art. 11(6)). Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of potential adverse effects shall not prevent the contracting party of import from taking a decision, as appropriate, in order to avoid or minimise potential adverse effects (art. 11(8)). Risk assessment and risk management are key requirements in both situations covered by the Protocol. In both cases, the risk assessment must be consistent with criteria enumerated in an annex (art. 15). For example, the risk assessment must be undertaken in a manner, which is scientifically sound and transparent and on a case-by-case basis (annex III). The lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk or an acceptable risk (annex III). The criteria reflect the principle of substantial equivalence though the term is not specifically used. For example, risks posed by an LMO or products thereof (of LMO origin with detectable novel combinations of replicable genetic material obtained through use of modern biotechnology) should be considered in the context of risks posed by the non-modified recipients or parental organisms in the likely receiving environment (annex III). While risk assessment is to be carried out by competent national decision making authorities, the exporter may be required to undertake the assessment (art. 15(2)). The importing party may require the notifier to pay for the risk assessment (art. 15(3)). The Protocol specifies general risk management measures and criteria. Any measures based on risk assessment should be proportionate to the risks identified (i.e., to the extent necessary to prevent adverse effects within the Party of import) (art. 16(2)). Measures to minimise the likelihood of unintentional transboundary movement of LMOs are to be taken (art. 16(3)). Affected or potentially affected States are to be notified when an occurrence may lead to an unintentional transboundary movement (art. 17(1)). During the Protocol negotiations, there was a debate on the extent to which socio-economic considerations should be considered in risk assessment. The adopted version of the Protocol states that contracting parties reaching import decisions under the Protocol or under domestic legal measures implementing the Protocol may account for socio-economic considerations arising from the impact of LMOs on biodiversity conservation and sustainable use (especially with regard to value of biodiversity to indigenous and local communities) (art. 26(1)). In other words,

														decision-making may only account for the socio-economics related to potential biodiversity loss and not more generally. Furthermore, it is implied that socio-economics should not be addressed in identification of hazards and assessment of risk. The parties are encouraged to co-operate on research and information exchange on any socio-economic impacts of LMOs, especially on indigenous and local communities (art. 26(2)). The Protocol contains explicit public participation provisions. Contracting parties shall: (a) promote and facilitate public awareness, education and participation concerning safe transfer, handling and use of LMOs in relation to biodiversity conservation and sustainable use (taking into consideration risks to human health) (art. 23(1)(a)). The contracting parties are to endeavour to ensure public awareness and education encompasses access to information on LMOs identified by the Protocol that may be imported (art. 23(1)(b)). In addition, the Parties shall consult the public in the decision-making process regarding LMOs and shall make decisions available to public (in accordance with respective laws), but respecting confidential information (art. 23(2)). Finally, each Party is to endeavour to inform its public about access to information on Biosafety Clearinghouse (art. 23(3)). Confidential information is explicitly addressed in the Protocol. For example, the contracting party of import is to permit the notifier to identify information submitted under Protocol procedures or required by the contracting party of import for AIA to be treated as confidential (art. 21(1)). The notifier must justify this upon request. The party of import is to consult the notifier if the information identified does not qualify for confidential treatment and inform notifier prior to disclosure; the party must provide reasons on request and opportunity for consultation and internal review of decision prior to disclosure (art. 21(2)). Each contracting party is to protect confidential information that it receives; each Party is to ensure that it has procedures to protect confidentiality and shall protect this information no less favourably than confidential information for domestically produced LMOs (national treatment) (art. 21(3)). The party of import is not to use the confidential information for commercial purposes except with written consent of the notifier (art. 21(4)). When the notifier withdraws or the notification is withdrawn, the contracting party must respect the confidentiality of commercial and industrial information (R&D included) and information where there is disagreement as to confidentiality (art. 21(5)). Some information cannot be made confidential: (a) the notifier's name and address; (b) the general description of the LMO; (c) a summary of the risk assessment; and (d) methods and plans for emergency response (art. 21(6)). The Protocol also contains provisions on LMO handling, packaging and transportation. For example, each contracting party must take the necessary measures such that LMOs subject to intentional transboundary movement within the Protocol's scope are handled, packaged and transported under safety conditions (considering relevant international rules) in order to avoid adverse effects on

														biodiversity conservation and sustainable use (accounting for risks to human health) (art. 18(1)). In particular, each contracting Party is to take measures to require documentation that: (a) clearly identifies LMOs intended for direct use as food or feed, or processing with the words "may contain" LMOs and "not intended for intentional introduction into the environment" and contact point; the COP/MOP is to decide within two years of entry into force on detailed requirements especially on identity and unique identification; (b) clearly identifies LMOs destined for contained use and specifies any requirements for safe, handling, storage, transport and use; contact point; and consignee; and (c) clearly identifies LMOs intended for intentional introduction into the environment of the party of import; specifies identification and traits/characteristics, requirements for safe, handling, storage, transport and use; contact point; name/address of importer/exporter; and a declaration that the movement conforms to the Protocol's requirements applicable to exporter (art. 18(2)(a-c)). The meeting of parties is to consider the need for modalities to develop standards on identification, handling, packaging and transport practices in consultation with other relevant bodies (art. 18(3)). A process to address liability and redress for damage resulting from LMO transboundary movements is to be set up by the first meeting of the Protocol parties (art. 27). This is to take due account of ongoing processes and with the anticipated completion of the process within 4 years.
UNEP Technical Guidelines on Biosafety (1995)	**Y**					**Y**		**Y**	**Y**	**Y**		**Y**		The UNEP Guidelines were adopted in 1995. They were designed and adopted as a contribution to the implementation of Agenda 21 (Chap. 16). They provide the possibility for States to voluntarily develop mechanisms for evaluating the biosafety of "organisms with novel traits" and to identify, assess and manage the risks associated with the use of biotechnology. "Organisms with novel traits" are those organisms whose genetic make-up is unlikely to develop naturally (para. 21). The Guidelines acknowledge the importance of assessing socio-economic and other impacts of new biotechnologies but do not address these issues. The Guidelines draw from common elements and principles of regional and international instruments and national regulations and guidelines. They focus on human health and environmental safety for all applications of biotechnology, whether research, development or commercialisation. Safety assessment is premised on (1) hazard identification; (2) risk assessment; and (3) risk management (para. 18). Risk assessment and risk management can be based in part on knowledge and experience with an organism (familiarity) with the proviso that familiarity does not imply that an organism is safe, while unfamiliarity does not imply that an organism is necessarily unsafe (para. 19). Unfamiliarity means however that an organism should be assessed

														on a case-by-case basis. With experience and knowledge, a risk assessment may apply to a group of organisms for characteristics functionally equivalent on a physiological level. The development of generic risk assessment approaches or exemption in one country does not necessarily mean that other countries will apply similar approaches. Monitoring can provide knowledge and experience on the use of organisms with novel traits (para. 24). The user of the organism has the primary responsibility for the safe use or transfer of organisms with novel traits once adequate risk management strategies have been devised. The introduction of organisms with novel traits into centres of origin must be particularly considered in risk assessment and management. Annex 3 provides additional considerations for risk assessment. Annex 5 provides additional considerations for risk management. The Guidelines reflect the principle that risk management should be proportional to the level of risk and the scale of the operation (paras. 30 and 31). Risk management measures should be taken until risks have been minimised to acceptable levels. If risk cannot be minimised either the intended operation should not proceed, or a risk/benefit analysis could be used to determine whether the higher level of risk is acceptable (para. 30). Risk assessment and management needs to be undertaken within an institutional framework (para. 33). Multidisciplinary scientific expertise may be drawn upon (para. 36). The oversight authorities are responsible for encouraging public participation, through access to information on which decisions are based, while respecting confidential business information. Annex 7 highlights examples of how the public may be involved. Examples include *inter alia*, establishing a register of information on organisms with novel traits, giving interested groups the opportunity to comment, publishing a newsletter, encouraging proponents to inform local people and encouraging dialogue between the public and companies and academic institutions. Where transboundary impacts could occur, the potentially affected country should be notified of the intended use and should be given the opportunity to determine whether risk management measures will protect its interests (para. 42). The potentially affected country should be informed immediately when adverse effects could affect it. The Guidelines also provide a framework to exchange information related to transboundary transfer or organisms with novel traits (para. 44). The framework is premised on a user in an exporting country providing information to a user or focal point in the importing country, prior to transfer. This is much like the concept of “advanced informed agreement” in the CBD Biosafety Protocol. It is particularly intended to assist those countries without fully operational regulatory programmes.
United Nations General Assembly														

United Nations Convention on the Law of the Sea (1982)	**Y**													UNCLOS entered into force in 1994. Article 196 (Use of technologies or introduction of alien or new species) applies to biotechnological applications involving marine and coastal areas. It says "States shall take all measures necessary to prevent, reduce and control…the intentional or accidental introduction of species, alien or new, to a particular part of the marine environment, which may cause significant and harmful changes thereto". Although not specific, UNCLOS's provisions can be interpreted to support, for example, assessment of GMOs prior to their release into the marine environment.
UN Guidelines for Consumer Protection (1985)	**Y**	**Y**	**Y**		**Y**	**Y**				**Y**		**Y**		The UN Guidelines for Consumer Protection were adopted in 1985 as UN General Assembly Resolution 39/248 of 9 April 1985. The guidelines were incepted as "a comprehensive policy framework outlining what governments can do to promote consumer protection in such areas as safety, economic interests of consumers, quality and distribution of goods and services, consumer education and information and redress" (UNESC, 1998). They form one cornerstone group of principles underpinning the Codex Alimentarius. The UN Commission on Sustainable Development (CSD) established an international work programme on changing consumption and production patterns in 1995. In 1995, the CSD recommended expanding the consumer protection guidelines to include guidelines on sustainable consumption patterns (UNESC, 1998). The UN Economic and Social Council requested the Secretary General to work on this through the creation of an interregional expert group meeting (UNESC, 1998). The expert group, which met in 1998, made specific recommendations for submission to Council through the Commission on Sustainable development at its sixth session (UNESC, 1998). The expert group focused on identifying the issues related to sustainable consumption that should be incorporated into consumer protection policy (UNESC, 1998). It noted that sustainable consumption addresses the demand side of production processes, focusing on consumer choices of goods and services such as food, shelter, clothing, mobility and leisure in order to fulfil basic needs and improve the quality of life (UNESC, 1998). Its recommendations include various specific references to GMOs in relation to food. In addition, some of its general recommendations could be applied to GMOs. For example, governments should encourage all concerned to participate in the free flow of accurate information on all aspects of consumer products (sec. B, para. 12). Government policymaking should be conducted in consultation with business, consumer and environmental organisations and other concerned groups (sec. FF, para. FF2). The design development and use of products and services should take into consideration their full life cycle (sec. FF, para. FF5). In the food area, it was recommended to encourage governments to introduce controls on genetically engineered foods and crop varieties based on long-term risk assessment to ensure they are safe for people and the environment and are compatible with sustainable agriculture (sec. G, para. 39b). Furthermore, government controls should encompass the production process and the final product in an "open

														and transparent fashion". Products should be labelled taking consumer concerns into account (sec. G, para. 39b).
United Nations Industrial Development Organisation														
Voluntary Code of Conduct for the Release of Organisms into the Environment (____)	**Y**									**Y**	**Y**	**Y**		The UNIDO Code of Conduct provides general principles governing standards of practice for all parties involved with the introduction of organisms or their products/metabolites into the environment (sec. II-A-1(a)). It covers GMOs in all stages of research, development and disposal while focusing on release into the environment (sec. I-B). The Code is founded upon a number of general principles. For example, regulatory oversight and risk assessment should be focused on the characteristics of the resulting product rather than the molecular or cellular techniques used to produce it (sec. II-C-1(a)). Furthermore, safety precautions and monitoring procedures should be proportional to the level of assessed risk (sec. I-C-1(d)). Furthermore, national authorities, industries and researchers have the responsibility to make safety information available to the public (sec. II-C-1((e)) and unexpected or adverse public health or environmental impacts related to the GMO should be reported to appropriate authorities at national and international levels (sec. II-C-1(f)). Risk assessment should be based on "sound scientific principles" involving the participation of experts from appropriate disciplines (sec. II-C-1(h)). Systems to review proposed applications should remain flexible and adaptable in relation to the latest scientific information (sec. II-C-1(j)). Information on anticipated consequences, which may be transboundary in nature, needs to be provided to those countries that may be affected (sec. II-C-1(l)). The actions and responsibilities of governments are enumerated. These include *inter alia* (1) assuring the independence of the assessment process, (2) the use of multi-disciplinary scientific competence and using case by case evaluation as the rule unless sufficient experience and (3) an adequate body of knowledge is gathered to allow classifications and general experience on GMO behaviour (sec. II-C-2(a, c and d)). Maximum disclosure of information necessary for risk assessment may be balanced by respect for confidential business information (sec. C-2-(h)). The local community should be informed of a planned introduction prior to release and appropriate educational materials should be provided (sec. II-C-2(i)). In addition, public access to information upon which decisions regarding use or release of organisms should be ensured (sec. II-C-2(j)). Researchers/proposers have the general responsibility of evaluating risks at appropriate research and development stages (sec. II-C-3-(b)). Approvals should be secured prior to the conduct of any activity involving release (sec. II-C-3(d)) and unexpected or adverse public health or environmental impacts should be notified to the appropriate national authorities (sec. II-C-3(e)). Finally, the proposer should notify and suggest alternative review mechanisms where a regulatory procedure within a country is not yet in place (sec. II-C-3(g)).

World Conservation Union														
IUCN Position Statement on Translocation of Living Organisms (1987)	Y									Y		Y		The Statement sets out IUCN's position on translocation of living organisms covering introductions, re-introductions and re-stocking. The instrument was not drafted with genetically modified organisms in mind, however, some of the principles it embodies may be applicable to GMOs. The Statement establishes the general principle that alien species should only be considered if clear and well-defined benefits to man or natural communities could be foreseen. In addition, an alien species should only be considered if no suitable native species is available. Principles are also provided for assessment based on analysis of risk, especially to biodiversity. Special principles are provided for aquatic introductions, in particular that no introduction should be made for which a control does not exist. Principles are also provide for extensive introduction after experimental assessment introductions, including making all the results of all phases of introduction available to the public, while the person or organisation introducing the species, not the public, should bear the cost of control where problems arise. Specific references are made to biological control and "micro-organisms genetically altered by man" when they will be introduced into areas where they have not previously existed. In both cases, the same procedures and care should be used that are enumerated for other species introductions.
World Trade Organisation (WTO)														
Agreement on the Application of Sanitary and Phytosanitary Measures (1994)	Y	Y			Y	Y	Y	Y	Y	Y		Y	Y	The WTO oversees the implementation of the Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement). The SPS Agreement applies to all sanitary and phytosanitary measures which may directly or indirectly affect international trade (art. 1). The SPS agreement does not explicitly mention GMOs. However, when GMOs are in international trade, and may pose a threat to human, animal or plant life or health in an importing country, the SPS Agreement would apply to national sanitary or phytosanitary measures (SPMs) designed to address the threats prior to import. One of the primary goals of the SPS Agreement is to encourage the harmonisation of SPMs on the basis of international standards, guidelines and recommendations promulgated by international organisations. Consequently, the work of the Codex Alimentarius Commission, the International Office of Epizootics and the International Plant Protection Convention on GMOs is relevant to the SPS Agreement's implementation. In fact, an SPM measure conforming to an international standard promulgated by one of these international organisations is "deemed to be necessary" to protect human, animal or plant life or health and "presumed to be consistent" with the SPS Agreement and the GATT 1994 Agreement (art. 3(2)). In general, the SPS provides a multi-lateral framework of rules to guide development, adoption and enforcement of sanitary and phytosanitary measures to minimise their negative impacts on trade (preamble, para. 4). Each member State has the right to take SPMs "necessary" to protect human, animal, plant life or health, provided these measures are not inconsistent with

														the SPS Agreement (art. 2(1)). A member State's SPMs: (1) must only be applied to the extent necessary, (2) be based on scientific principles and (3) must not be maintained without sufficient scientific evidence (art. 2(2)). SPMs must also not "arbitrarily or unjustifiably discriminate between member States" and SPMs cannot be applied in manner that would constitute a disguised restriction on international trade (art. 2(3)). Member States are directed to base their SPMs on international standards, guidelines and recommendations, where they exist in order to harmonise SPMs as widely as possible (art. 3(1)). However, a member State can introduce an SPM resulting in a higher level of protection than that offered by an international standard, guideline or recommendation (art. 3(3)). This is conditioned on the existence of one of two things: (1) scientific justification or (2) if the State deems the SPM to be "appropriate" (art. 3(3)). This last point is subject to the further conditions in article 5 (see below). Nonetheless, all measures that differ from international standards must be consistent with the SPS Agreement. In general, member States must ensure that SPMs are based on an assessment of risks to human, animal or plant life or health (art. 5(1)). Risk assessment techniques developed by relevant international organisations must be taken into account. Risks are to be assessed taking into account a number of enumerated factors including "available scientific evidence" (art. 5(2)). Member States can also take "relevant economic factors" into account when assessing the risk, and establishing risk management measures (i.e., establishing the appropriate level of protection manifested by an SPM). Economic measures include (1) the potential damage to production or lost sales; (2) costs of control or eradication; and (3) relative cost effectiveness of alternative approaches to limit risks (art. 5(3)). It is unclear whether this is an exhaustive list. Other factors to take into consideration when establishing the appropriate level of protection (1) "should" include "minimising negative trade effects" (art. 5(4)); (2) avoiding arbitrary or unjustifiable distinctions in the levels it considers appropriate in different situations (if they result in discrimination or a disguised restriction in international trade) (art. 5(5)); and (3) ensuring SPMs are "not more trade-restrictive than required" for an appropriate level of protection (art. 5(6)). The SPS Agreement provides some flexibility for member States to provisionally adopt SPMs when scientific evidence for the measures is insufficient (art. 5(7)). Provisional SPMs can be adopted on the basis of "available pertinent information" derived from a variety of sources. However, member States must subsequently seek additional information to more objectively assess the risk and to review the SPM within a reasonable period of time. Article 5(7) has been commonly referred to as evidence that the SPS Agreement reflects a "precautionary approach" (Charnowitz,

													2000), even without specifically saying so. The SPS Agreement has a number of provisions on stakeholder participation – as between member States. For example, a member State is entitled to an explanation from another member State when the former believes a specific SPM is or could constrain its exports (art. 5(8)). This only applies when the SPM is not based on an international standard, guideline or recommendation. Furthermore, members are to notify changes in their SPM according to an annex to the SPS Agreement (art. 7). These procedures include (1) publishing a notice to interested member States; (2) notifying member States through the SPS Secretariat; (3) providing copies of the proposed SPM to members on request; and (4) allowing reasonable time for members to make comments, discuss the comments upon request and take the comments and discussion results into account (Annex B, para. 5(a-d)). Some of these steps can be omitted in emergencies (Annex B, para. 6). Other means to ensure transparency are also provided. These include (1) prompt publication of new regulations (Annex B, para. 1); (2) allowing reasonable time for other members to adapt their systems to the new requirements (Annex B, para. 2); and (3) providing one "enquiry point" responsible for answering questions (Annex B, para. 3). Confidential information does not have to be disclosed (Annex B, para. 11).
Agreement on Technical Barriers to Trade (1994)	**Y**		**Y**		**Y**	**Y**		**Y**	**Y**			**Y**	The WTO oversees the implementation of the Agreement on Technical Barriers to Trade (TBT Agreement). The TBT Agreement is relevant to biotechnology products because it generally applies to technical regulations and standards, including packaging, marking and labelling requirements. It also applies to conformity assessment procedures. The TBT Agreement recognises that "no country should be prevented from taking measures necessary" to ensure the quality of its exports; to protect human, animal or plant life or health, of the environment; or prevent deceptive practices. This at levels it considers appropriate provided the TBT Agreement's conditions are met (preamble, para. 6). The TBT Agreement applies to all products (art. 1.3). It does not apply to sanitary and phytosanitary measures (art. 1.5)). Therefore, the SPS Agreement would apply where a biotechnological product may be a risk to human, plant or animal health. The TBT Agreement would apply where, for example, a product is merely labelled as containing GMOs. In general, imported products are to be accorded national treatment (art. 2.1). Technical regulations should not create unnecessary obstacles to international trade and should not be more trade-restrictive than necessary to fulfil a "legitimate objective, taking account of the risks of non-fulfilment" (art. 2.2). Legitimate objectives include *inter alia* preventing deceptive trade practices, protecting human health or safety, animal or plant life or health, or the environment. Relevant elements are suggested for assessing the risks. Interestingly, developing country member States may adopt technical regulations, standards or conformity assessment procedures aimed at preserving "indigenous technology" and production methods compatible with their

														development needs. They are, therefore, not expected to use international standards as the basis to develop technical regulations or standards, which are not appropriate to their development, financial, and trade needs (art. 12.4). The meaning of "indigenous technology" is ambiguous. When member States require technical regulations they are to be based on international standards to the extent that this would be effective (art. 2.4). Whenever a technical regulation is based on an international standard, and is to be applied to one of the legitimate objectives listed, it is "rebuttably presumed not to create an unnecessary barrier to trade (art. 2.5). Where an international standard does not exist, or the technical content of a proposed technical regulation is not in accordance with the technical content of an existing international standard, and the technical regulation may have a significant effect on trade, the TBT Agreement requires the member State to engage in stakeholder participation type-activities with other member States (art. 2.9). These are similar to those enumerated for the SPS Agreement described above (e.g., written justification; notice; notification through the secretariat; making copies available; reasonable time for comments) (arts. 2.5 and 2.9). And like the SPS Agreement, some of these steps are omittable in emergency situations (art. 2.10). A Code of Good Practice for the Preparation, Adoption and Application of Standards is annexed to the TBT Agreement. This is to guide a member State's development of standards. Standardising bodies must not act contrary or inconsistent with the Code (art. 4.1). The application of standards by member States is premised on the same principles of international trade as for technical regulations: national treatment and non-discrimination; avoiding unnecessary obstacles to trade and proportionality (i.e., no more strict than necessary) (art. 5.1). Likewise, the preference is highlighted for deriving national standards from international standards, guidelines and recommendations (art. 5.4)

Table II – Selected National and Regional Instruments Related to Modern Biotechnology				
Instrument	**Application**	**Biotech Product Movement**	**Oversight Mechanisms**	**Selected Legal Annotations and Comments**

	Environment and Human Health?	Food Safety?	Consumer Protection?	Traceability?	Labelling?	Commerce/Marketing?	Transport?	Export?	Import?	SafetyAssessment?	Cross-sectoralCo-ordination/Advice?	StakeholderParticipationandotherinformation-relatedconsid	OtherConsiderations(e.g.,socio-economicsorethics)?	

African Union														
OAU Draft Model National Legislation on Safety in Biotechnology (revised) (2001)	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**		**Y**	**Y**	**Y**	**Y**	**Y**	**Y**	The draft OAU Model Law was developed over the course of two years. The latest revision, when finished, will be tabled for adoption at the next OAU Council of Ministers meeting. It follows in the footsteps of an earlier OAU model law on access to genetic resources and community knowledge. The draft law on biosafety could be developed into an African-wide framework for the development of biosafety laws. It could also provide the basis for a harmonised legislative approach. The extent to which African countries will use the model is unknown, but its inclusion here is illustrative of its many innovative features. The model law applies to the import, contained use, release or placement on the market of any GMO or products from GMOs (art. 2). Governments are to designate or establish a competent national authority (CA) (art. 3(1)) and establish a national biosafety committee (NBC) to provide the competent national authority with policy recommendations and guidelines (art. 3(2)). The NBC will include representatives from governmental and non-governmental institutions and the private sector (art. 3(2)(a)). The CA shall take account of the recommendations and guidelines in its decision making process (art. 2(1)). In addition, institutions undertaking the activities within the scope of the law are to create institutional biosafety committees (IBC) (art. 2(3)). No person shall import, make contained use, release or place on the market a GMO or product of GMOs (art. 4(1)). An application for approval must be submitted to the CA (art. 4(2)). It will include *inter alia* (b) a report on risks to the environment, biodiversity and health, including the consequences of unintentional releases, (d) information on previous approvals or rejections, (e) the place and purpose of the activities, (f) statement asserting that the information provided is correct (art. 4(3)(b, d, e-f)). When the application is received, the information included is to be made available to the public and other governmental agencies by the CA (art. 5(1)). The information provided is subject to confidentiality restrictions for business purposes, after the applicant makes a claim for confidentiality to the CA (art. 11(1)). Information that cannot be kept confidential includes (1) a description of the GMO or the product; (2) methods and plans for monitoring and emergency plans (3) evaluation of foreseeable effects (pathogenic or ecological) (art. 5(2)(a-c)). The CA may make the confidential information available if it decides that it is in the public interest to do so (art. 12(3)). The public may make comments within a period specified by the CA (art. 5(2)). Where the CA arranges for a public consultation it is to be announced in the media with national coverage for a given period of time (art. 5(3)). The CA is to take into consideration when it is making or reviewing its decisions the public's views and concerns (art. 5(4)). The CA is to make available to the public information on consents and denials as well as the risk assessment for the GMO or product of a GMO at issue (art. 5(5)). Criteria are provided for the CA's decision-making. Decisions must be in writing (art. 6(2)). Approvals are to state that the activity approved is to be carried out on a "step-by-step"

														basis and that risk assessment should be carried out at each step (art 6(4)), though the CA may waive this where there is no risk to environment, biodiversity or health. Approvals must require subsequent monitoring and evaluation of risks (art. 6(5)). Approval cannot be issued unless the CA considers and duly determines that the GMO or product of GMOs poses "no risks to the environment, biological diversity or health" (art. 6(6)). The precautionary principle is reflected in article 6(7): where a threat of serious damage exists, lack of scientific evidence should not be used as a basis for not taking preventative measures. In addition, no approval is to be given unless the activity will (a) benefit the country, (b) contribute to sustainable development, (c) not have adverse socio-economic effects and (d) "accord with ethical values and concerns of communities and does not undermine traditional knowledge and technologies" (art. 6(8)). Approvals may be revoked or subjected to conditions when new information arises or review of existing information indicates risks to the environment, biodiversity or health (art. 7(1)). Applicants are to notify the CA when information on possible risks becomes available after approval (art. 7(2)). Decisions shall not be made without an assessment of risks to the environment, biodiversity and health, including socio-economic conditions (art. 8(2)). Risk assessments are to be carried out on a case-by-case basis according to guidelines that will be annexed to the model law (art. 8(3)). The CA may undertake the risk assessment or cause it to be undertaken (art. 8(6)). Either the CA evaluates the assessment or causes it to be evaluated (art. 8(4)). The applicant may be required to bear the cost of assessment and/or evaluation (art. 8(7)). Where the assessment indicates that the risks cannot be avoided, the CA must refuse approval (art. 8(5)). The CA may impose a variety of risk management measures including prohibiting the activity, ordering cessation, ordering the limitation of damage and requiring restoration and taking measures in emergency situations at the cost of the person responsible and require periodic monitoring reports (art. 9). Information on safety measures is to be made available to persons likely to be affected by an accident (art. 10(1)). Applicants are to notify accidents immediately to the CA along with other information (art. 10(2)). Any GMO or product of a GMO is to be clearly identified and labelled as such (art. 11(1)). Identification is to specify the relevant traits and characteristics in sufficient detail for purposes of traceability. In addition, any product of a GMO is to be clearly labelled and packaged using words that will be specified in a subsequent annex to the model law that is unavailable. The CA may require additional information in particular whether the product may cause reactions, allergies or other risks (art. 11(2)). The draft model law includes provisions on export in article 13. It implicitly requires authorisation from the exporting country's CA prior to export. An exporter must provide to the CA of the exporting country written advanced informed agreement from the importing country's CA (art. 13(1)). No authorisation for export will be given if the exporting country bans the GMO or the product of GMOs (art. 13(4)).

														Liability and redress provisions are provided in article 14. Strict liability applies for any harm caused by a GMO or product of a GMO and harm is to be fully compensated (art. 14(1)). Liability attaches to the person responsible for the activity as well as the GMO provider, supplier or developer (art. 14(2)). Harm to the environment or biological diversity is to be compensated including costs of reinstatement, rehabilitation, clean-up measures, which are actually incurred, and the costs of preventive measures (art. 14(4)). Liability shall also extend to direct or indirect harm or damage caused to "the economy or social or cultural practices or the livelihood or indigenous knowledge systems or technologies of a community or communities" (art. 14(5)). Harm includes disruption or damage to production systems, agricultural systems, reduction in yields, soil contamination, damage to biological mass and damage to the economy of an area or community. Any person or group is entitled to bring a claim and seek redress in respect of any breach or threatened breach of the act, including damage to the environment, biodiversity and socio-economics (art. 14(7)). No costs are to be awarded against any person entitled to bring a claim if it was instituted "reasonably out of concern for the public interest or in the interesting in protecting the environment or biodiversity (art. 14(8)). Existing activities need to reapply for authorisation (art. 17(1)).
Egypt														
Biosafety Regulation and Guidelines (1994)[3]	**Y**	**Y**				**Y**			**Y**	**Y**	**Y**			The Ministry of Agriculture and Land Reclamation (MALR) through two decrees created the Egyptian Biosafety System. Ministerial Decree 85 (1995) establishes a National Biosafety Committee (NBC) and Ministerial Decree 136 (1995) adopted biosafety regulations and guidelines. It is unclear the extent to which the guidelines are legally binding. Procedures for commercialising GMO crops are established by Ministerial Decree 1648 (1998). It establishes the responsibilities of the Central Administration for Seeds (CAS) for the release of GM and conventional seeds; procedures for small scale release permits, registration and requirements for commercial release. Decree 242 (1997) applies to GM foods. Foodstuffs produced through GMOs may not be imported until safety is confirmed. A certificate should accompany any imported seeds from the country of origin confirming that the seeds were not produced from untested GM plants. The Egyptian biosafety system has been expanded in stepwise fashion (as the need arises). This may explain the lack of clarity in the system described by commentators in secondary literature. It also appears that the primary focus of the system, at the moment, is on GM crops. Institutionally, a number of organisations are involved in the system. New plant varieties

[3] With the exception of the Guidelines, only secondary source material was available. The information and annotations provided are taken directly from Madkour M., El Nawawy A. and Traynor P. 2000. Analysis of a National Biosafety System: Regulatory Policies and Procedures in Egypt. International Service for National Agricultural Research, The Hague.

														are controlled, tested and registered by the Central Administration for Seed Testing and Certification (CASC). CASC is within the Ministry of Agriculture. Food safety and food import permitting is handled by the Supreme Committee for Food Safety within the Ministry of Health. The Ministry of Industry within the Organisation undertakes standard setting for food and industrial products imported or locally produced for Standardisation and Quality Control. The Ministry of Trade and Supply oversees the control of product imports and exports. The Ministry of Environment oversees the implementation of the Environmental Protection Law. The Biosafety Guidelines have an aspirational tone. Words such as "would" and "should" are used throughout the document. Key principles are proposed. For example, regulatory review should focus on the characteristics and identified risks of the biotechnology products, not mainly on the process that created it. Also, the degree of familiarity with the behaviour of similar organisms when released into the environment should determine the level of regulation required depending on the hazard identified. The guidelines propose creating a National Biosafety Committee (NBC) comprising policy makers and designers, governmental and academic scientific experts in agriculture, health, industry and environment, the private sector and non-technical members representing the interest of the surrounding community with respect to health and environmental protection (para. 1.2). The NBC is to *inter alia*: (1) establish policies and procedures to govern the use of modern biotechnology in Egypt (para. 1.1); (2) formulate national biosafety guidelines for contained and uncontained use for laboratory practices, greenhouse facilities, small scale field trails and commercial release (para. 1.3(a)); (3) review new initiatives to evaluate the benefits and potential risks of research with GMOs and periodically review containment measures if a licence is issued (para. 1.3(b)); and (4) provide technical advice to regulatory authorities and institutions (para. 1.3(d)). The NBC is to request that all institutions conducting recombinant DNA research create Institutional Biosafety Committees (IBC) (para. 2.0). The IBC is to be responsible for ensuring that r-DNA research is carried in conformity with the NBC Guidelines (para. 2.1). Recommendations are made on the expertise that should be reflected in the IBC. An institutional biosafety officer is to be appointed. IBCs are to *inter alia* assemble a comprehensive set of research and containment oriented guidelines tailored to the institution's research activities, establish a programme to inspect the physical containment facility and report annually to the NBC (para. 2.3). The Biosafety Guidelines provide risk assessment recommendations. They suggest that any risk identified has to be balanced against the benefits in order to determine what is an "acceptable risk". Other guidelines are provided for laboratory practices, greenhouses and small scale field-testing. While the guidelines appear to indicate that the NBC has only an advisory role in decision-making, secondary literature reviewed in the absence of primary legislation indicates that

														the NBC actually issues permits. NBC is involved in research and field-testing, as well as commercial release of GM crop plants. Field test approval does not require the applicant to submit a report at its conclusion. The purpose of the field trials is to evaluate variety performance. Monitoring takes place to ensure compliance with biosafety requirements and not to collect biosafety information. According to commentators it is rare for a field test to generate valid biosafety data unless a risk assessment component is built into the tests. Applications for research or first release of GM crop plants are made to the NBC. A principal investigator, who is an NBC member, is tasked with reviewing the application. The NBC serves as lead agency and co-ordinates with secondary agencies for review; discusses the application; and decides whether or not to issue a permit. Risk management measures are determined prior to authorisation. NBC members who are applicants don't take part in the vote. Where genetically modified plant material is imported, an import permit must be obtained in advance from the Supreme Committee for Food Safety (SCFS) prior to importation Applications for commercialisation are made to NBC. Applications for plant varieties produced within Egypt must provide various types of information including data from food and feed safety studies and evidence to support a determination of low or negligible environmental risk. Upon approval the NBC forwards the application to a "Seed Registration Committee" (it is unclear from the literature whether the committee is within the CASC or is one of the three NBC subcommittees) for its approval to conduct field trials. The SRC assigns a team to supervise cultivation, ensure compliance with biosafety requirements, confirm new phenotypes and evaluate agronomic performance. With successful field trails and the submission of a report, NBC authorises the applicant to apply to the SRC for final approval to commercially release the variety. For imported plant materials, the applicant must first obtain an import license from the SCFS.
South Africa														
Genetically Modified Organisms Act (1997)	**Y**					**Y**		**Y**	**Y**	**Y**	**Y**			This act applies to (1) GMOs; (2) development, production, release, use and application of GMOs; and (3) use of gene therapy (though not gene therapy techniques) (sec. 2(1)). The Ministry of Agriculture oversees the Act's implementation. The Act is only enabling in nature and does not specify outright, for example, that a release must have a permit. The Act will be further elaborated upon via regulations. The Minister may make regulations *inter alia* on the application and issue of permits, procedures for risk assessment and environmental impact assessment, requirements for general release and marketing of GMOs and the importation/exportation of GMOs (sec. 20(1)). The Minister of Agriculture shall appoint an interagency Executive Council for GMOs composed of representatives from various governmental agencies (sec. 3). The Council is to advise the Minister on all aspects concerning activities within the law's scope of application and ensure that all activities are performed according to the Act (sec. 4). The

													Council has the power to *inter alia* (1) require a permit for the use of facilities to develop, produce, use or apply GMOs or to release GMOs into the environment, to submit through a registrar a risk assessment and where required an environmental impact assessment of these activities (sec. 5(a)); (2) require a registrar to examine an application's conformity with the Act (sec. 5(b)); and (3) approve the use of facilities or a release (sec. 5(g)). The Council may also inform any other country of an accident that may have an impact on that country's environment (sec. 5(i)) and approve and publish guidelines for all GMO uses (sec. 5(l)). The Minister shall appoint a qualified person to act as registrar, in consultation with the Council (sec. 8(1)). The registrar administers the Act (sec. 8(2)(a)). The registrar, subject to the instructions of the Council, *inter alia* (1) issues, amends and withdraws permits issued under the Act and (2) enforces the Act (sec. 9(a & b)). The registrar may appoint inspectors (sec. 15(1)) who are empowered to enter facilities or places with a warrant when there is a reason to believe the Act has been contravened (sec. 15(4)) and who undertake routine inspections (without a warrant) (sec. 16) The Act establishes an Advisory Committee whose members are appointed by the Minister after recommendation by the Council (sec. 10(1)). The Committee's membership is to reflect representation from all fields of expertise involved with GMOs (sec. 10(2)). The Committee is to act as the national advisory body on all matters related to genetic modification of organisms (sec. 11). Advice may include that related to GMO introductions into the environment, proposals for specific activities or projects, contained use, importation and exportation and proposed regulations and guidelines (sec. 11(1)(b)). The Committee may advise upon request (or upon its own initiative) the Minister, the Council, other Ministries and bodies. It may also invite written comments from knowledgeable persons on any aspect of genetic modification of organisms (sec. 11(1)(d)). Committee members are to recuse themselves when the Committee considers subjects in which they have direct or indirect interest (sec. 13). Users are to ensure that appropriate measures are taken to avoid adverse environmental impacts that may arise from the use of GMOs (sec. 17(1)). Liability for damage is borne by the user. The Act does not have public participation provisions, though these may exist in other South African laws. There are confidentiality provisions that apply (sec. 18(1)). The Council decides after consultation with the applicant which information is to be kept confidential (sec. 18(2)). Information that cannot be kept confidential includes the GMO description, methods and plans for monitoring GMOs and emergency plans and an evaluation of foreseeable impacts, particularly pathogenic or ecologically disruptive impacts (sec. 18(2)).
The Americas													
Canada													In Canada, the regulatory approval process for biotechnology products is based around at least ten different pieces of legislation (MacKenzie, 2000). Distinctions are not made between organisms and products made from recombinant DNA techniques and more

														traditional techniques such as plant breeding. Instead, the regulatory trigger is whether a new organism or product has a novel trait or characteristic that sets it apart from other similar, but non-modified organisms or products, regardless of the process used. This is most apparent for plants. Plants with novel traits (PNTs) are varieties or genotypes regulated because they or their characteristics are not considered to be "familiar" or "substantially equivalent" to those in a distinct, stable population of cultivated species of seed in Canada and have been intentionally selected, created or introduced through a genetic change (CFIA, 1994). "Familiarity" is "the knowledge of the characteristics of a plant species and experience with the use of that plant species in Canada" (CFIA, 1994). "Substantial equivalence" is the equivalence of a novel trait within a particular plant species, as it relates to the novel plant's use and safety for humans, the environment [and animals - in the case of feeds], compared to plants of the same species that are used and generally considered safe in Canada (CFIA, 1994). An environmental safety assessment for PNTs generally takes into consideration (1) weediness potential, (2) gene flow, (3) plant pest potential, (4) impact on non-target organisms and (5) impacts on biodiversity. Safety assessments are undertaken on a "case by case basis" as a part of a "continuum of research, development, evaluation and commercialisation" (CFIA, 1994). In general, each new application needs an assessment. Safety assessments are undertaken by the applicant and reviewed by the government regulator prior to authorisation (MacKenzie, 2000). Any subsequent authorisation must take into consideration potential risks and an applicant as specified in the authorisation must take risk management measures. Information from previous authorisations can be used to satisfy subsequent regulatory requirements for additional authorisations. The extent to which provincial regulatory requirements differ from those at the federal level is unclear, however a single window approach and harmonisation is sought (CFIA, 1994). At the federal level, the Canadian Food Inspection Agency (CFIA) has the primary responsibility for regulating PNTs. Within CFIA, the Plant Biosafety Office takes the lead responsibility. Co-ordination with other internal offices takes place depending on the future use of the product or organism regulated. In addition, Health Canada has the primary responsibility for assessing novel human foods prior to marketing. Food labelling responsibilities are split between CFIA and Health Canada. CFIA handles general food labelling policies and regulations not related to health and safety such as misrepresentation and fraud along with basic food labelling requirements (CBAC, 2001). Health Canada's responsibilities relate to health and safety issues related to for example allergenicity. Environment Canada regulates organisms that are not PNTs and uses not otherwise regulated pursuant to the Canadian Environmental Protection Act and the New Substances Notification Regulations (1999) (CBAC, 2001). All new substances, including products from

														biotechnology, are notified to Environment Canada and assessed for their potential to adversely effect the environment and human health. This is to take place prior to import or manufacture. Environment Canada assesses the environmental risk of new organisms derived from biotechnology. Until the Department of Fisheries and Oceans adopts new regulations, transgenic, aquatic organisms will be regulated under CEPA (CBAC, 2001). What follows are brief descriptions of some of the applicable legislation and regulations with regard to PNTs.
Plant Protection Act (1990) and Regulations (1995)	**Y**								**Y**	**Y**				The CFIA's Plant Health and Production Division issues permits to import PNTs and derived products pursuant to section 43 of the Plant Protection Regulations (CFIA, 1998). PNTs or products derived from them that have been subject to plant risk assessment (PRA), and that do not pose a plant pest risk, do not require an import permit (CFIA, 1998). Conversely, PNTs that do present a plant pest risk require a permit to import. Importers that are unclear about the status of a PNT are to submit an application to the Division (CFIA, 1998). The application's contents are kept confidential (CFIA, 1998). A permit shall be issued when the Division determines that the thing is imported for purposes of scientific research, educational, processing, industrial or exhibition purposes (sec. 43(1)(a)). The person must be able and willing to comply with permit conditions and "will take every precaution to prevent the spread of any pest or biological obstacle to the control of the pest" (sec. 43(1)(b)). Apparently, where these criteria cannot be met the permit is not to be issued. Packaging, transport, handling and control are to ensure that the pest is not introduced into Canada (sec. 43(2)). It appears that a PRA is conducted by the CFIA. PRAs determine whether the organism is a pest, could be infested or constitutes or could constitute a biological obstacle to control the pest (sec. 2). They also provide the basis for recommended actions to prevent introduction or control a pest; whether the thing assessed could have a significant adverse effect on the environment; and how to minimise degradation to Canadian flora (sec. 2). There does not appear to be any public participation process established by either instrument.
Seed Act (1985) and Regulations (1996)	**Y**					**Y**			**Y**	**Y**				The Seed Act and regulations (Part V) provide CFIA with the authority to regulate the release of seeds with novel traits (NT seed) into the environment, either for confined field trials or unconfined field trials. The CFIA Plant Biosafety Office administers the regulatory process. Two regulatory directives supplement the Act and regulations: 2000-07 (confined field trials) and 94-08 (unconfined field trials). According to the Seed Act, unless otherwise provided, no person shall sell, import or export any seed unless the seed conforms to prescribed standards and is marked and packed and the package is labelled (sec. 3(a)) and sell or import seed that is not registered properly (sec. 3(b)). A novel trait of a seed has two aspects. First, it is a characteristic that "has been intentionally selected, created or introduced into a distinct, stable population of cultivated seed of the same species through a specific genetic change" (reg. sec. 107(1)). Second, "based on a valid scientific rationale, it is not substantially equivalent, in terms of its

														specific use and safety…for the environment and for human health, to any characteristic of a distinct, stable population of cultivated seed of the same species in Canada. This is determined based on weediness potential, gene flow, plant pest potential, impact on non-target organisms and impacts on biodiversity (reg. sec. 107(1)). Essentially, seed that is substantially equivalent is exempt from regulation (reg. sec. 108(c)). A notification to CFIA and an authorisation is needed prior to any confined or unconfined release. (reg. sec. 109(1)(a and b)), though this is not necessary for registered seeds (reg. sec. 109(2)). Information to accompany the notification includes that on the novel trait and information and test data relevant to identifying the risk to the environment, including risk to human health (reg. sec. 110(1)(d and e)). Additional information requirements depend on the whether the release is confined or unconfined. For example, for confined releases, information on the confinement measures to mitigate establishment and spread (reg. sec. 110(2)(b)(i)) and for unconfined releases data describing the potential interaction of the seed or derived plants with other life forms, and an evaluation of the potential risk of harm posed to the environment, including the risk to human health (reg. sec. 110(3)). Where seed is intended for future commercialisation, the applicant for confined release is encouraged to undertake experiments designed to meet additional regulatory requirements for confined releases under the Directive 94-08. Information has been generated by CFIA on the biology of several agriculture plant species is available to the applicant for comparison purposes for use in the determination of substantial equivalence. The Minister evaluates the notification information, including the potential impact and risk to the environment (including human health) and either authorises the release (subject to conditions) or denies it (reg. sec. 111). Criteria are provided to guide the Minister's evaluation of the risks to the environment (reg. sec. 111(2)). For example, he is to consider the effects of the release on the environment and the magnitude of the environment's exposure to the seed and the seed's toxicity (reg. sec. 111(2)). When a person becomes aware of any new information regarding environmental/human health risks any time after the notification, the information is to be provided to the Minister (reg. sec. 112(1)). The information can be used by the Minister to re-evaluate the potential impact on and risk to the environment to subsequently change the conditions of the authorisation (reg. sec. 112(2)). No provisions for public participation are apparent. Confidential information is to be indicated by the applicant. The Plant Biosafety Office sends non-confidential information about each new field trial to designated provincial government contacts. Non-confidential information (decision documents) is also sent to the OECD and posted on the Plant Biosafety Offices WWW site. Where the NT seeds are intended for use in livestock feed or have pesticidal properties additional approvals may be required from CFIA's Feeds Section or from Health Canada's Pest Management Regulatory Agency. In addition, prior to commercialisation, the PNT may need to be evaluated as a novel food by Health Canada. Finally, the NT needs to fulfil the

														criteria for registration under the Seeds Act and Seeds Regulations (Part III). No variety may be registered if the variety or its progeny may be detrimental to human or animal health and safety or the environment when grown and used as intended (sec. 72(e)).
Feeds Act (___) and Regulations (1983)	**Y**	**Y**				**Y**			**Y**	**Y**				The Feed Regulations in part address the release of novel livestock feeds into environment. The implementation of the regulations is overseen by the CFIA, Feeds Section. The regulations are supplemented by a regulatory directive on the assessment of livestock feed from plants with novel traits. In short, where a PNT may be fed to livestock its safety and efficacy of the product as a novel feed. Novel feed means a feed made of an organism or organisms, or parts or products thereof that, *inter alia*, has a novel trait. There are two descriptors of "novel trait". First, the feed characteristic must have been intentionally selected, created or introduced into the feed through a specific genetic change (sec. 2). Second, the feed characteristic, based on a valid scientific rationale, is not substantially equivalent in terms of its specific use and safety both to the environment, human and animal health, to any characteristic of a similar feed (sec. 2). A novel livestock feed cannot be released without (1) notification, (2) a written undertaking by the developer taking responsibility for and assuming the costs of safe disposal and (3) and subsequent authorisation (sec. 4.1(1)(a-c)). Application information for a novel feed is to include *inter alia* identification and characterisation of the novel feed and all information and test data on the novel feed relevant to identifying environmental risks (sec. 4.2(1)(d and f)). The Minister makes a decision to authorise the release in particular after evaluating the potential impact on and risk to the environment, including potential impacts to human and animal health (sec. 4.3(1)). To guide decision making, the same criteria for evaluating the risk to the environment from PNTs are used for novel livestock feeds (sec. 4.3(2)). Likewise as with PNTs requirements are placed on the notifier to provide new information to the Minister when it arises (sec. 4.4). All feeds are to be registered (sec. 5). Some of the registration requirements include providing the CFIA with satisfactory evidence to permit an assessment or evaluation of the safety and efficacy of the feed in respect of livestock and its potential effect on humans and on the environment (sec. 8(1)). Labelling requirements for all feeds are specified (sec. 26), however there does not appear to be a specific requirement for novel feeds.

Food and Drugs Act (1985) and Regulations (___)	**Y**	**Y**	**Y**		**Y**	**Y**			**Y**	**Y**				Division 28 of the Food and Drugs Act apply to sale and advertisement of novel foods in Canada. The Canadian Food Inspection Agency will likely review the environmental and human health safety of confined and unconfined releases into the environment of, for example, a PNT to be used as a food pursuant to the Seeds Act. Health Canada oversees the assessment of novel food pursuant to the Food and Drug Act and Regulations. A novel food is "(a) a substance, including a micro-organism, that does not have a history of safe use as a food"; (b) a food "manufactured, prepared, preserved or packaged by a process that (i) has not been previously applied to that food, and (ii) causes the food to undergo a major change"; and (c) "a food derived from a plant, animal or micro-organism that has been genetically modified such that" (i) the organism exhibits characteristics that have not previously been observed in that organism; (ii) the organism no longer exhibits characteristics that have been previously observed in that organism; or (iii) one or more characteristics of the organism no longer fall within the anticipated range for that organism (sec. B.28.001). In general, no novel food can be sold or advertised in Canada without (i) notifying Health Canada and (ii) receiving authorisation (sec. B.28.002(1)). Notifications are to include *inter alia* a description of the novel food, details of the major change in the food, information relied on to establish the novel food's safety and the text of all labels (sec. B.28.002(2)(c and e)).
National Standard for Voluntary Claims About Foods That Are and Are Not Products of Gene Technology (July 2001 draft).														The Food and Drug Act sets out the general requirements for food labelling. No person can label, package, treat, process, sell or advertise any food in a false, misleading, or deceptive manner or that is likely to create an erroneous impression regarding the food's character, value, quantity, composition, merit or safety (sec. 4). According to the CFIA *Guide to Food Labelling and Advertising* (CFIA, 1996), since 1993, there have been three major consultations on foods derived from genetic modification. Guidelines have been developed. Mandatory labelling is required if there is a health or safety change or a signification change in nutrition or composition. In addition, any labelling must be understandable, truthful and not misleading. Finally, voluntary positive labelling ("does contain products from biotechnology") and negative labelling ("does not contain products from biotechnology") is permitted provided it is truthful and not misleading (CFIA, 1996). There are no federal obligations to indicate that a food is a product of gene technology (Canadian General Standards Board, 2001). Because of the lack of federal regulations on this specific aspect of food labelling, an initiative is under way to create a voluntary national standard for labelling of foods derived from biotechnology. The Canadian General Standards Board oversees the standards development process. The process is open to the public and transparent (CFIA, ___a). A first draft standard has been circulated in 2001 for public comment. The standard would apply to voluntary labelling and advertising of food in order to distinguish whether or not the food is a product of gene technology or contains or does not contain ingredients that are products of gene technology (sec. 1.1). It would not apply to the labelling of foods produced using processing aids, veterinary biologics or livestock feeds that are products of gene technology (sec. 1.2). Distinctions are made between claims for single ingredient and multi-ingredient food (sec. 4). In general, it is proposed that claims that a single ingredient food is

														a product of gene technology can only be made for that food when it is obtained from sources of which more than 5% are products of gene technology (sec. 5.2). Similarly, a 5% threshold is proposes for multi-ingredient foods claimed to be produced from gene technology (sec. 5.3). Conversely, a threshold of less than 5% is proposed for single and multi-ingredient foods claimed not to be a product of gene technology (sec. 6). Verification provisions are established. No claim is permitted if it cannot be verified (sec. 7.1). The person making the claim is responsible for providing the data necessary to verify the claim (sec. 7.2.2). Provisions on confidential information are proposed. The claimant must have in place a verification system (sec. 7.3). In addition, the claimant must have a plan that includes a detailed description of sources of food/ingredients and a description of the management system used to maintain integrity of the food/ingredient (sec. 7.3.2). The standard is equivocal on testing and detection methods (sec. 7.4).
Asia														
Indonesia														
Ministerial Decree on the Provisions on Biosafety of Genetically Engineered Agricultural Biotechnology Products (1997)	**Y**				**Y**	**Y**			**Y**	**Y**			**Y**	The Indonesian Ministry of Agriculture is responsible for implementing the decree. The decree's intent is to regulate and supervise the use of "genetically engineered agricultural biotechnology products" (GEABP) (art. 2(1)) and "to ensure the safety and health of humans, biosafety and the environment related to the use of GEABPs (art. 2(2)). It applies to (1) transgenic animals and fish and materials originating from them, (2) transgenic plants and their parts and (3) transgenic microorganisms (art. 4). The decree applies to the following uses: science, research, breeding, production and distribution including trading (art. 9(2)). The use of GEABP must meet general and category-specific requirements (arts. 10-33) enumerated in the decree. For example, in general, both domestic and foreign GEABPs must "pay attention to and take into consideration" religious, ethical, socio-cultural and aesthetic norms (art. 9(1)). How this is actually ensured is unclear. The more specific requirements enumerated relate to information that is to be supplied in an application to the Ministry of Agriculture for use, such as information on the organism's characteristics and potential threats to the environment. Written applications must be made to the Ministry of Agriculture (art. 34). The category of organism determines the agency within the Ministry that reviews the application. Upon receipt, the application is forwarded to and reviewed by a "biosafety commission" (art. 35(1)). The biosafety commission assists the Minister of Agriculture in compiling and determining biosafety policy for the use of a GEABP (art. 1(13)). A "biosafety technical team" assists the biosafety commission in evaluating the risks and appropriateness of a particular GEABP's use (art. 1(14)) by undertaking a technical study (art. 35(2)) and submitting a subsequent report to the biosafety commission (art. 35(3)). On the basis of the report the biosafety commission submits considerations or recommendations to the appropriate ministerial agency (art. 35(4)). The responsibilities of the biosafety commission and the biosafety technical team are to be enumerated in a subsequent (and unavailable)

														decree (art. 37). The biosafety technical team's evaluation report is used "as consideration" by the biosafety commission in its recommendation to the particular competent agency within the Ministry to either approve or deny the application (art. 39(1)). The commission's recommendations are to be used as the basis of the agency's determination (art. (39(2)). Denials are to be accompanied by a rationale (art. 39(3)). There do not appear to be any provisions for public participation, though another law may apply. The successful applicant has a number of rights and obligations. For example, commercial confidentiality is available to the applicant over the GEABP, but it appears to be limited to situations where the approval has been issued (art. 40(1)). Confidentiality is extended to the application by the agency reviewing the application (art. 40(2)). No criteria are provided in either case for reviewing claims to confidentiality. GEABPs that are destined for production and/or distribution activities must be labelled (art. 41(1)). The label must be fashioned so "a person could know that the commodity concerned is a GEABP" (art. 41(1)). The label is to be pasted on the packaging for the GEABP commodity concerned (art. 41(2)). "When the GEABP causes biosafety harm", the person who holds the approval is obligated to participate in the steps to "overcome" the harm (art. 42). Finally, the person holding the approval is obliged to submit a periodic report every six months or any time there is an "event of biosafety harm" (art. 43). The oversight agency appears to be responsible for monitoring the use (art. 44(2)).
Food Act (1996)		**Y**	**Y**		**Y**	**Y**		**Y**	**Y**	**Y**		**Y**	**Y**	The Food Act addresses GM food in a handful of specific articles. It states that food development is carried out to fulfil the basic needs of mankind which is provided on a "fair and equal basis based on self-determination and not contradictory to the conviction of the community" (art. 2). The Act also states that among the objectives regulating, developing and supervising food are ensuring its availability and fulfilling safety, quality and nutritional requirements in the interest of human health (art. 3(a)). Any materials used as a food additive and for which the human health impacts are unknown must be first examined for safety (art. 11). Use of such material production or process activities may only be carried out after approval from the government and subject to regulations. The Act makes specific reference to genetic engineering in article 13. Persons who produce food or use foodstuffs, food additives or "other auxiliary material" in the "production activity or process of food" derived from genetic engineering must have the food examined before it is circulated (art. 13(1)). The government is to set requirements and principles for research, development and use of the genetic engineering method in the food production activity or process (art. 13(2)). It will also lay down requirements to test food derived from the genetic engineering process. These provisions build on the more general provisions for contaminated food. A person is prohibited from circulating (1) food containing materials which are toxic, dangerous or which may harm or endanger human health or life, and (2) food containing materials prohibited from use in food production or processes (art. 21(a) and (c)). Pre-packaged food to be traded, either produced within Indonesia or imported, must have a label (art. 30(1)). Among other things, the label shall contain information on "halal"

														(allowable for Muslim consumption; relatedly but not required for listing is “haram” (forbidden)) (art. 30(2)(e)). The government may determine other information to be included in or withheld from the label (art. 30(3)). Persons are prohibited from providing untrue or misleading information through the label (art. 33). A person making a claim about a food’s acceptability to the requirements of a religion or belief through a label or advertisement is responsible for the correctness of the statement based on the religion or belief (art. 34(1)). Food imports are prohibited where the food does not fulfil the requirements of the Act (art. 36). The government may require that the imported food (1) has been examined and approved in the country of origin for safety by an authorised agency, (2) is supported by documents evidencing test results and (3) be tested in Indonesia determine safety, quality or nutrition before circulation (art. 37). Food importers are responsible for the safety, quality or nutrition of the food (art. 38). The government may require food exports to be tested before circulation for safety, quality, label requirements or nutrition content (art. 39). Liability attaches to a business venture or the individual within the business (art. 41(1)). Any natural person whose health is harmed as a direct consequence of consuming processed food is entitled to file a claim of indemnity against the responsible business venture or individual (art. 41(2)). The Act provides the “community” with the opportunity to participate in realising the protection of any natural person consuming food (art. 51). The community may submit “problems, inputs and/or the solution for matters in the field of food” in the framework of improving and upgrading the food system (art. 52). It is unclear how participation is to be realised. The extent to which this means the public can participate in regulatory decision making is also unclear. No criteria are provided on the extent to which governmental decision-makers must consider the comments and other inputs that are provided.

Consumer Protection Act (1999)			Y			Y			Y					The Consumer Protection Act does not make specific reference to genetically engineered products. It does, however, demonstrate some consumer protection principles that could be extended to genetically engineered products. The Act applies to all "goods" (anything that can be moved, used up or otherwise) and which can be traded, applied or used by consumers (art. 1(4)). Consumer protection is based on the principles of consumer benefit, justice, balance, security and safety and legal certainty (art. 2). Consumer protection is to be *inter alia* premised on a consumer protection system built additionally upon legal certainty, information transparency and access to information (art. 3(4)). Consumers have enumerated rights including *inter alia* the (1) right to comfort, security and safety in using goods and services and the (2) right to correct, clear and honest information about the condition and guarantee of goods and services (art. 4(c)). Business agents have enumerated obligations including *inter alia* (1) providing correct, clear and honest information about the condition and guarantee of goods and services and providing information about uses, as well as (2) guaranteeing the quality of goods or services provided. In addition, business agents are prohibited from producing or trading in goods and services which *inter alia*: (1) do not fulfil or conform to the standard required; (2) do not conform to the promise stated in a label or description; (3) do not comply with production requirements as permitted by "halal"; and (4) do not have a specified label (art. 8(1)(a, f, h and i)). Liability attaches to business agents for losses and other damages suffered (art. 19(1)). Every disadvantaged consumer may sue a business agent through an assigned dispute settlement agency (set up by the government – art. 49) or through a judicial process (art. 45). A national agency of consumer protection is established. Its regulatory powers are unclear (art. 31). Finally, the government shall recognise non-governmental institutions for consumer protection, which fulfil enumerated criteria (art. 44).
Food Labels and Advertising (Reg. 69/1999)														This regulation has provisions related to labelling of products derived from biotechnology. Primary source materials were unavailable for analysis.
Philippines														
Executive Order Constituting the National Committee on Biosafety (No. 430) (1990)												Y		Executive Order 430 creates a national committee on biosafety (NCBP) that is attached to the Department of Science and Technology (sec. 1). The NCBP has a multidisciplinary membership including various scientists, a social scientist, citizens and representatives from various governmental agencies (sec. 2). The functions of the NCBP include *inter alia* (1) identifying and evaluating potential hazards related to initiating genetic engineering experiments, the introduction of new species and GMOs and recommending risk minimisation measures; (2) formulating and reviewing national biosafety policies and guidelines; (3) formulating and reviewing national policies and guidelines on risk assessment; (4) publishing the results of internal deliberations; holding public deliberations on proposed national policies, guidelines and other biosafety issues; and (5) assisting in the formulation of laws (sec. 4). The Department of Science and Technology provides the NCBP's secretariat (sec. 4).
Philippine Biosafety Guidelines (1991)	Y				Y		Y		Y	Y				The National Committee on Biosafety (NCBP) formulated the Guidelines. The Guidelines reflect various national policies on biosafety. The Guidelines apply to all public and private, national or international research, production and manufacturing institutions engaged in

														genetic engineering. The Guidelines also cover the importation or introduction and/or breeding of plant pests and potentially harmful microorganisms. The NCBP must review and approve any work covered by the Guidelines. Institutions and involved scientists have the primary responsibility to enforce biosafety rules and regulations and this is accomplished through institutional biosafety committees and biosafety officers. The NCBP has the power to impose sanctions on erring personal and institutions. Monitoring is the institution's responsibility. Pest monitoring is the Government quarantine service's responsibility. All institutions engaged in genetic engineering are to create institutional biosafety committees (IBCs) (sec. B). IBCs have the responsibility to evaluate and monitor the biosafety aspects of their institution's biological research. IBC need to have the collective expertise to supervise and assess planned field releases. The Guidelines outline additional expertise to be represented on IBCs (sec. B, para 1.1). IBCs may have consultants on call that are knowledgeable in a variety of issues, including standards of professional conduct and practice and community attitudes (sec. B, para 1.2). Among its functions an IBC is to review work conducted or sponsored by the institution and recommend research proposals (sec. B, para. 2.1). Reviews are to include holding discussions on the comparative ecological, economic and social impacts of alternative approaches to attain the purposes of the genetic engineering product or services (sec. B., para. 2.1.3). An IBC should also formulate and adopt emergency plans and notify the NCBP about significant problems (sec. B, paras. 2.4 and 2.5). Procedurally, IBCs review proposals made by the principal investigator (sec. C, para. 1.1 and 1.3). The IBC assesses the project and sends the proposal and its evaluation to the NCBP for its assessment (sec. C, para. 1.3). A guiding principle for approval is provided: "Genetic manipulation of organisms should be allowed only if the ultimate objective is for the welfare of humanity and the natural environment and only if it has been clearly demonstrated that there is no existing or foreseeable alternative approaches to servicing the welfare of humanity and the natural environment. The use of domestic animals in tests involving products of genetic engineering is subject to approval of IBC and NCBP" (sec. C, para 1.4). Commercially sensitive information may be indicated as such for the IBC/NCBP and members of both bodies are to sign "deeds of confidentiality" (sec. C. para. 1.8). The NCBP conducts a biosafety assessment on the proposal (sec. C, para. 2.1). The risk assessment is to be based on the characteristics of the biological product and on the process by which it was obtained. A working group is formed to assess the proposal based on Procedures for Evaluation (included in the Guidelines as sec. 3; these vary depending on the organism) and submits recommendations to the NCBP (sec. C, para. 2.2). The assessment is sent to the IBC and any appropriate regulatory agencies (sec. C, para. 2.3). No member of the NCBP shall vote when deliberations involve projects in which he or she has an interest (sec. A para. 1.4). Procedures are also provided for introductions, movement and field releases of regulated materials covered by the Guidelines. Import permits are required from relevant regulatory

														agencies (sec. __, para. 1.1.1). The import application must respond to all information enumerated in the Guidelines. Applications for importation of organisms modified by rDNA techniques are to be referred to the NCBP by the regulatory agency involved (sec. ___, para. 1.1.3). Confidential information in the application can be so indicated (sec. ___. para. 1.1.4). NCBP reviews the application and if approved issues appropriate conditions (sec. ___, para. 1.1.5). Denied permits may be appealed (sec. ___, para. 1.1.6). The introduction and movement of GMOs within the Philippines must comply with packaging and container requirements. After movement from quarantine to research facility, no further movement may be made without authorisation (sec. ___, para. 1.2.3). Release into the environment requires a permit (sec. ___, para. 1.3.2). An IBC endorsed application and release procedure is submitted to the NCBP for review (sec. ___, para. 1.3.2). The application addresses all information enumerated in the Guidelines. Where other permits are required they are to be co-ordinated with the NCBP (sec. ___, para. 1.3.3). Periodic reports are required if the permit is granted (sec. ___, para. 1.3.4). The government's quarantine services monitor the progress of the work and report any significant outcome to the IBC for remedial action (sec. ___, para. 1.3.5). The Guidelines do not appear to apply to commercial releases.
Thailand														
Biosafety Guidelines in Genetic Engineering and Biotechnology (1992, revised in English 1996)	**Y**						**Y**	**Y**	**Y**	**Y**			**Y**	Thailand does not have in place comprehensive laws to address biosafety. Other laws apply in part but a set of guidelines is the primary instrument applicable. The guidelines consist of two parts. One part comprises the Guidelines in Genetic Engineering and Biotechnology for Laboratory Work for "viroids, viruses, cells or organisms, carrying novel genetic material which are either improbable to arise naturally or are potentially detrimental towards public safety and environmental health". The second part, described here, comprises the Guidelines in Genetic Engineering and Biotechnology for Field Work and Planned Release for plants and microorganisms. Both parts have common structure and content. For example, work related to GMOs is classified according to level of risk and safety. Three categories exist: (1) work bearing no risk; (2) work bearing low risk; and (3) work with high risk. Risk management and control is proportional to the organism/risk category at issue. Institutional arrangements in monitoring and control are also similar. For example, three groups of personnel and organisations are involved: (1) principal investigators and researchers; (2) institutional biosafety committees (IBC) and (3) the National Biosafety Committee (NBC). The Guidelines are considered "soft law based on voluntary action". However, the Plant Quarantine Act prohibits GMO imports without a permit from the Department of Agriculture and when imports are allowed this can only be for experimental purposes. According to the Guidelines, the fieldwork and release guidelines are meant to complement the guidelines on laboratory work because a natural extension of laboratory work is field-testing. Field-testing is meant to (1) confirm laboratory observations; (2) gather information on, for example, stability and gene expression under field conditions; (3) assess viability and (4) assess adaptive or evolutionary potential. In general, only GM plants that do not

														have a history of safe fieldwork require a preliminary risk assessment to determine the full range of possible environmental effects (sec. 2.1.3). Similar requirements apply to microorganisms (sec. 2.2.3). In terms of institutional review, distinctions are made based on a history of prior fieldwork. For example, an institutional biosafety committee must evaluate the sufficiency of biosafety provisions where experimental plants and microorganisms have a history of prior fieldwork (secs. 3.1.1 and 3.2.1). Work can begin only upon IBC endorsement. The IBC must also forward the proposal to the NBC for information. Where a plant or microorganism has no history of prior fieldwork, the work must proceed "under the advice, counsel and direction of the IBC and the NBC. Committee recommendations are to be grounded on biosafety concerns. Consent must be directly granted by the NBC (secs. 3.1.2 and 3.2.2). In January 1993, a national biosafety committee (NBC) was established under the National Centre for Genetic Engineering and Biotechnology (BIOTEC). BIOTEC was originally established in 1983 under the Ministry for Science, Technology and Energy and then was moved under the National Science and Technology Development Agency as an autonomous centre. The NBC has general responsibilities to *inter alia* (1) ensure that genetic manipulation work adheres to the Guidelines; (2) review and direct research methodologies; (3) recommend appropriate experimental conditions; and co-ordinate public information and education on biosafety issues and on proposed national policies (sec. 4.1.1). In the context of field research, the NBC *inter alia* (1) provides advice to Institutional Biosafety Committees, (2) suggests practical alternatives to high risk field procedures; and (3) protects and restricts access to commercially significant information (sec. 4.1.2). The NBC has direct responsibility for evaluating and endorsing enumerated proposals (sec. 4.1.3). IBCs must be established by all institutions, whether public or private, engaged, or with the intent to engage, in the purchase, construction, propagation or field release of GMOs or components (sec. 4.2). Smaller institutions with less capacity to establish their own IBC may request work with non-affiliated IBCs, upon notification of the NBC. In general, an IBC must be formally endorsed by the NBC (sec. 4.2.1) and is to be composed of no less than five members (e.g. with backgrounds in evaluation, ecology, engineering and biosafety (officer)). The IBC should also consider establishing relationships with people knowledgeable *inter alia* with ethics and community attitudes (sec. 4.2.2). In general with regard to field research, the IBC is to *inter alia* (1) assess all projects referred to it; (2) undertake risk assessment in co-operation with the research teams as necessary; and (3) suggest practical alternatives to any high-risk laboratory procedures (sec. 4.2.4). The guidelines also address movement of regulated materials within or between institutions (sec. 5.1). Exports of regulated materials are to be in compliance with international postal requirements and other national requirements (sec. 5.3). Finally, the guidelines apply sanctions even though they are to be voluntary (sec. 6). For example, scientists and institutions failing to enforce the provisions or intent of the Guidelines may be penalised

														through, for example, the withdrawal of government research grants and incentives. Scientist may be held accountable for all consequences resulting from failure or negligence in complying with the national biosafety guidelines. Apparently, Thailand does not have food safety laws in place for GE modified foods, though the government has committed to labelling by the end of 2001 (Greenpeace, 2001).
Plant Variety Protection Act (1999)	**Y**									**Y**				New plant varieties under the Act cannot be registered when they have severe adverse impacts, directly or indirectly, on the environment, health or public wealth (sec. 13). New plant varieties derived from genetic modification may be registered only upon "a successful result of a safety appraisal" on environment, health or public welfare conducted by the Department of Agriculture or another agency designated by the Plant Variety Protection Commission in accordance with a ministerial regulation.
European Union														
Directive 2001/18/EC (Deliberate Release of GMOs into the Environment)	**Y**		**Y**	**Y**	**Y**	**Y**			**Y**	**Y**	**Y**	**Y**	**Y**	This is the primary piece of horizontal EU legislation on GMOs and the environment. It addresses the release of GMOs into the environment for purposes other than placing on the market, as well as the placing on the market of GMOs. It will replace Directive 90/220/EEC on 17 October 2002 by which time Member States are to comply with it (article 34). Directive 90/220/EEC was supplemented by a collection of sectoral directives and regulations. The relationship between the existing sectoral legislation and the new Directive is unclear as the Directive refers to some and does not refer to others. The Commission is also bringing forward a number of proposals to rationalise the collection of legislation, especially in the food safety area. The Directive's preamble reflects the principles upon which the Directive's substantive provisions are based. The Directive derives from the principle embodied in the Treaty Establishing the European Community that Community action on the environment should based on preventative action (preamble para. 6). The precautionary principle is to be considered in the Directive's implementation (preamble para. 8). Member States may consider ethical aspects when GMOs are released into the environment or placed on the market (preamble para. 9). The Directive also promotes transparency by emphasising the necessity of public consultation, either by the European Commission or the Member States (preamble para. 10). Case by case environmental risk assessment is to be always carried out prior to release, in particular to identify long term effects (preamble para. 19; article 4(3)) and monitoring should be undertaken after release (preamble para. 20). Members and the Commission should ensure systematic and independent research into the potential risks of GMO release or marketing (preamble para. 21). **Deliberate Release of Viable GMOs for Purposes Other than Placing on the Market (Part B)** GMO introduction into the environment is premised on the "step by step" principle whereby GMO containment is reduced, and the release scale is gradually increased, but only if earlier human health and environmental evaluations of previous steps indicate the next step

														can be taken (preamble para. 24). Competent national authorities must be notified and provide consent before any deliberate release takes place (preamble para. 32 and 34; article 6(1)). Notifications are to include a technical dossier including a full environmental risk assessment (preamble para. 33; articles 6(2)). The period of consent for release is unclear. Notifiers must report on the result of the release in respect to any risk to human health or the environment with particular reference to any product that the notifier intends to notify at a later stage (article 10). Differentiated (exceptional or simplified) procedures can be proposed to the Commission by the competent national authority where sufficient experience has been obtained for certain GMOs proposed for release that meet specified criteria (article 7(1)). The Commission seeks observations and comments from other Member State competent national authorities and the public, respectively (article 7(2)(a) and (b)). It seeks an opinion from relevant Scientific Committees (article 7(2)(c)) as well. The Commission next decides the minimum amount of information necessary to evaluate foreseeable risks that is to be provided to the competent national authority (article 7(3)). [Commission Decision 93/584 outlines the criteria the Commission must use to decide on the application of simplified procedures, though it is unclear whether this decision is valid under the new directive]. The notifier then must comply with any conditions set forth by the competent national authority (article 7(5)). Other simplified procedures apply for genetically modified plants pursuant to Commission Decision 94/730/EC (article 7(6)). Article 9 applies to public information and consultation with respect to environmental releases. In general, Member States shall consult with the public, including groups. They are to create arrangements for consultation, including reasonable time periods for the expression of opinions (article 9(1)). In addition, Member States are to make information available to the public on all GMO releases into the environment (article 9(2)). In addition, the Commission is to make available to the public the information contained in the system of information exchange between the Commission and the Member States' competent authorities (article 9(2), which includes summaries of the notifications received by the competent authorities, observations and a list of GMOs released within the Member States' territories (article 11). These provisions are qualified by article 25 (Confidentiality). The Commission and competent national authorities shall not divulge to third parties confidential information notified or exchanged under the Directive (article 25(1)). The notifier may indicate that information whose disclosure might harm his competitive position and which should be treated as confidential (article 25(2)). He must provide verifiable justification. The competent national authority consults with the notifier and decides which information shall be kept confidential (article 25(4)). Information that cannot be kept confidential includes *inter alia* a general description of the GMO, monitoring methods and plans, emergency responses and environmental risk assessment (article 25(4)). Information exchange is to take place between competent national authorities and the Commission (article 11). A summary of each notification received by the Member State is

														to be provided to the Commission (article 11(1)). The Commission in turn forwards the summaries to other Member States who may make observations to the Commission or directly to the relevant competent national authority (article 11(2)). The competent national authorities of other Member States may subsequently request the full notification. It is unclear to what extent the article 25 confidentiality provisions may apply to another Member State's receipt of the full notification. The extent the observations from other Member States must be considered is also unclear. Competent national authorities must inform the Commission of the final decisions taken, including any reasons for rejection (article 11(3)). **Placing on the Market as or in Products (Part C)** Directive 2001/18/EC is to act as a reference for GMOs as or in products authorised by other Community legislation *inter alia* with regards to environmental risk assessment, risk management, labelling, monitoring and public information (preamble para. 27). In general, GMOs, whether individually or in combinations, intended for placing on the market as or in products must have been subjected to satisfactory field testing in the research and development stage in ecosystems that could be affected by their use (preamble para. 25). The general procedures for notification of and consent by the competent national authorities are similar to those for release into the environment (Part B). Notification is sent to the competent national authority of the Member State in which the product will be marketed for the first time. Notifications are to include a technical dossier including a full environmental risk assessment and, for products, precise information for use and proposed labelling and packaging (preamble para. 33; article 13(2)(f) and (g)). The proposed labelling must include the words "this product contains genetically modified organisms" clearly displayed either on a label or in accompanying documentation (preamble para. 40; article 13(2)). On the basis of results from Part B, or on other substantive, reasoned scientific grounds, a notifier may propose to the competent authority not to provide information required in the Directive Annex IV (B) (Additional Information) because the product posed no risk to human health and the environment (article 13(2)(h)). The competent national authority forwards a dossier summary immediately to other Member States and the Commission (article 13(1)). Upon a complete notification, the competent national authority prepares an assessment report indicating whether the GMO should or should not be placed on the market (article 14). Where the Commission or another Member State do not object to the marketing then the competent national authority may provide its consent in writing, subject to its conditions, and notifies the Commission and other Member States (article 13(3)). Conditions will *inter alia* include monitoring and the public release of subsequent results to ensure transparency (article 20(4)). Consent is given for 10 years (article 14(4)) with exceptions provided for GMOs intended only for the marketing of their seeds and forest reproductive material. Consent can be renewed subject to further review and additional conditions (article 17). In addition, the Member State is to take emergency measures, including providing public information, when the GMO or the product presents a severe risk after consent has been granted (article 23(1)).

														Where objections are lodged, a committee procedure under article 30 (Committee Procedure) is activated to resolve objections. The Commission drafts a decision reflecting the concerns of the Member States. A vote is taken. Where resolution is not possible, the Council of Ministers decides. If the Council fails to decide within three months, the Commission can adopt its decision. Member States are to take "all necessary measures" to ensure that the written consent, and decisions by the committee created to address Member State objections to a notification (article 18) are made accessible to the public (article 19(4)). The competent national authority or the Commission may propose derogations from the information requirements specified for notifications (article 16(1)) but "relevant scientific committees" must be consulted (article 16(2)). The Commission (article 16(3)) must notify proposals for derogations to the public. Public comments and an analysis are forwarded to a committee set-up to consider the derogations (article 16(3) and article 30). Member States are to ensure that labelling and packaging of GMOs placed on the market as or in products comply with the conditions of consent (article 21(1)). Where adventitious or technically unavoidable traces of authorised GMOs cannot be excluded, minimum thresholds may be established below which the products require no labelling (article 21(2)). Thresholds will be product specific and will be established through the EC committee procedure laid down in article 30(2). Where consent for marketing is provided in one Member State, other Member States may not prohibit, restrict or impede the GMO product's marketing (article 22). However, a Member State may provisionally restrict or prohibit a GMO's sale or use as or in a product within its territory when it has obtained new or additional information after consent has been given. The information is related *inter alia* to the environmental risk assessment or new scientific knowledge (article 23(1)). A decision is taken through the committee procedure outlined in article 30(2). In contrast to Part B's provision on public information where the burden is placed on the competent national authority, the Commission has the responsibility to make available to the public the dossier summary provided with the notification (article 24(1)). This is to happen immediately upon the notification's receipt. The public may make comments within 30 days and these are to be forwarded to the competent national authorities. In addition, the assessment reports for GMOs attaining written consent, and the opinions of any Scientific Committees consulted, must also be made public (article 24(2)), but it is unclear who is to do this. The release of information to the public in all cases is subject to the confidentiality provisions of article 25. A system will be designed to assign a unique identifier for GMOs (preamble para. 41). In all stages of placing on the market, traceability of the GMO as or in products is to be ensured by the Member State (preamble para. 42, article 4(6)). This will take account of

														international developments. Monitoring plans are required to trace and identify any direct or indirect, immediate, delayed or unforeseen effects on human health or the environment of GMOs as or in products after their placement on the market (preamble para. 43). **Miscellaneous and Final Provisions** The Commission shall consult "relevant scientific committees", on its own initiative or at the request of a Member State, when objections are raised to marketing a GMO based on risks to human health or the environment (article 28(1)). Relevant scientific committees shall also be consulted where an assessment report indicates GMO should not be marketed. Any other matters may also be put to the relevant scientific committee (article 28(2)). The procedure for actually creating a committee is unclear. At its own initiative, or upon request of the European Parliament, the Council of Ministers or a Member State, the Commission may also consult any committee it has created to obtain advice on the ethical implications of biotechnology, such as the European Group on Ethics in Science and New Technologies (article 29(1)). This is without prejudice to the competence of Member States on ethical issues. The consultation is to be based upon openness, transparency and accessibility to the public (article 29(2)). Results shall be publicly available. The Commission is to establish publicly accessible registers on genetic modification that "shall include a part which is accessible to the public" (art. 31(2)). Member States are also to create public registers with release site locations for Part B GMO releases (article 31(3)(a)). They are to also create registers for GMOs grown under Part C whose locations shall also be publicly available (article 31(3)(b)). The Commission will submit a report to the European Parliament every three years to report on the experience of Member States. The upcoming report for 2003 will include an assessment of *inter alia* of the socio-economic implications of deliberate GMO releases and subsequent marketing (article 31(7)(d)). Finally, the Commission will report annually to the Council and the Parliament on ethical issues (article 31(8)), including proposals to amend the Directive.
Regulation 258/97/EC (Concerning Novel Foods and Novel Food Ingredients)[4]	**Y**	**Y**	**Y**		**Y**	**Y**			**Y**	**Y**	**Y**		**Y**	This regulation applies to the placing on the market for the first time of novel foods or novel food ingredients (i.e., "foods that have not hitherto been used for human consumption to a significant degree") (article 1(1 & 2)). This includes *inter alia* (1) foods and food ingredients containing or consisting of GMOs, (2) foods and food ingredients produced from, but not containing, GMOs (article 1(2)(a & b)). The criteria for authorisation are the food and food ingredients must not (1) present a danger for the consumer; (2) mislead the consumer; or (3) differ from foods or food ingredients which they are intended to replace to such an extent that their normal consumption would be nutritionally disadvantageous for the consumer

[4] NB: The provisions on GMO foods and ingredients in Regulation 258/97/EC will be deleted if the Community adopts the proposal for a new Regulation on Genetically Modified Foods and Feed.

														(article 3(1)). Requests for authorisation are made to the Member State in which the product will be placed for the first time (article 4). The Commission receives a copy from the applicant. When the food or food ingredients contain or consist of a GMO additional information requirements for the application apply (article 9(1)). These include the written consent for the earlier deliberate release for research and development purposes and a technical dossier supplying information requested by Directive 90/220/EEC (now 2001/18/EC) on deliberate release with the environmental risk assessment. The Member State undertakes an initial assessment to determine whether an additional assessment (further review) is required (article 4(2)). The competent food assessment body preparing the assessment report is notified to the Commission (article 6(2)) and the Commission in turn provides the Member States with this information and the applicant's summary. The initial assessment is forwarded to the Commission and subsequently forwarded to the Member States (article 6(4)). The Commission and Member States may comment or present reasoned objections, which may also address labelling issues. Comments or objections are circulated to the Member States. Where an additional assessment is not needed and there are no objections to the application then the Member State notifies the applicant that it may place the food or food ingredient on the market (article 4(2)). Where an additional assessment is required or objections exist the authorisation decision takes place at the Commission level (article 7(1)). The procedure for the authorisation decision is specified in article 13 and includes using the Standing Committee for Food Stuffs to review and deliver opinions on draft measures to be taken (article 13(1-3)). The Commission can adopt the measures to be taken provided they are in accordance with the Committee's opinion (article 13(4)). The decision shall define the scope of the authorisation and establish conditions of use, the food or food ingredient's designation and specific labelling requirements (article (7)(2)). A Member State may subsequently temporarily restrict or suspend the trade in and use of the food or food ingredient within its territory (article 12(1)). This must be based on new information or reassessment of existing information that provides a Member State with detailed grounds to consider the use of the food or food ingredient endangers human health or the environment. The Commission examines the grounds in conjunction with the Standing Committee on Foodstuffs pursuant to the procedure in article 13. Labelling requirements in addition to other Community labelling requirements can be specified for foodstuffs to ensure that the final consumer is informed. Among these, additional labelling is required when (1) any characteristic or food property no longer renders a novel food or food ingredient equivalent to an existing counterpart (based on scientific assessment and accounting for natural variations); (2) the presence of material not present in the existing counterpart and which may have human health implications for certain population sectors; (3) the presence of material not found in existing counterparts

														that gives rise to ethical concerns; and (4) the presence of GMOs (article 8(1)). Where an existing equivalent counterpart does not exist appropriate provisions are to be adopted to ensure that consumers are adequately informed of the nature of the food or food ingredient (article 8(2)). A derogation procedure is available for food or food ingredients when the applicant believes they are "substantially equivalent" to existing foods or food ingredients. This determination is based on the criteria in article 3(1) described earlier. To support this the determination must be based on (1) available and generally recognised scientific evidence or (2) on the basis of a Member State's competent food assessment body (articles 3(4) and article 5). In this procedure the applicant notifies the Commission with relevant details and these are forwarded to Member States (article 5). The Standing Committee on Foodstuffs (article 13(1)) may assist the Commission. The Commission drafts a decision that is considered by the Committee (article 13(3)). The Commission adopts the measures when they are in accordance with the Committee's opinion (article 13(4)(a)). The Council of Ministers votes on the Commission draft where the Committee's opinion differs with Commission's measures. The Commission can adopt its measures when the Council fails to act (article 13(4)(b)) In this regulation there do not appear to be any requirements for stakeholder participation at the Community level, other than co-ordination between the Member States. In addition, there are no requirements of stakeholder participation at the national level.

Regulation 1139/98/EC (Labelling of Certain Foodstuffs Produced from GMOs) as amended[5]		**Y**	**Y**		**Y**	**Y**			**Y**		**Y**			Regulation 1139/98 derives from Directive 79/112/EEC (Approximation of the Laws of Member States Relating to Labelling, Presentation and Advertising of Foodstuffs). It was amended by Regulation 49/2000/EC. As amended, Regulation 1139/98 covers food and food ingredients that are delivered as such to the final consumer or mass caterers (e.g., restaurants) and are produced in whole or in part from GM soya beans (Decision 96/281/EC) and GM maize (Decision 97/98/EC). These foodstuffs are subject to labelling requirements in addition to those in Directive 79/112/EEC. The labelling requirements do not apply when the protein or DNA resulting from the genetic modification is not present in the food ingredients individually considered or the food when it comprises a single ingredient (article 2(2)(a)). In addition, labelling is not required where the foodstuff contains GM soya beans and/or GM maize and any other material placed on the market pursuant to Regulation 258/97 (Novel Foods and Food Ingredients) derived from GMOs in a proportion no higher than 1 percent of the food ingredients (article 2(2)(b)). In other words, *de minimis* amounts of genetically modified materials up to 1 percent do not trigger additional labelling requirements. Operators must be in position to supply evidence to satisfy competent authorities that they have taken appropriate steps to avoid GMOs as a source. Lists of products, ingredients or foods without DNA or protein from genetic modification, and therefore not subject to additional labelling requirements, are to be developed taking account of technical developments, the opinion of the EC Scientific Committee for Food and other relevant scientific advice (article 2(a)). Additional labelling requirements vary with the form the food product takes. For example, where the food consists of more than one ingredient, the words “produced from genetically modified soya” or “produced from genetically modified maize” are to appear in the list of ingredients in brackets immediately after the ingredient concerned or in a prominently displayed footnote (article 3(a)). Other requirements apply (article 3(b-d)).

[5] NB: This Regulation and its amendments would be repealed by the proposed regulation on genetically modified food and feed.

Regulation 50/2000/EC (Labelling of Foodstuffs and Food Ingredients Containing GM Additives and Flavourings)		**Y**	**Y**		**Y**	**Y**			**Y**				**Y**	Regulation 50/2000 fills in a gap created by Regulation 258/97 (Novel Foods and Food Ingredients) because it does not apply to GM additives and flavourings. Regulation 50/2000 applies to additives and flavourings used in foodstuffs that are, contain or are produced from GMOs (article 1(2)). Labelling requirements in addition to other Community labelling requirements are to be specified for additives and flavourings to ensure that the final consumers and mass caterers are informed. Among these, additional labelling is required when (a) any characteristic or food property no longer renders a novel food or food ingredient equivalent to an existing counterpart (based on scientific assessment and accounting for natural variations); (b) material that is present that is not present in the existing counterpart and which may have human health implications for certain population sectors; (c) the presence of material not found in existing counterparts gives rise to ethical concerns; and (d) GMOs are the present (article 2(a-d)). Additives or flavourings are not equivalent if scientific assessment demonstrates that the characteristics assessed are different to traditional additives or flavourings taking into consideration accepted limits for natural variation (article 3). Additives or flavourings with protein or DNA resulting from genetic modification are not considered equivalent. The labelling requirements vary with the form of the flavouring or additive. They may include wording such as “produced from genetically modified…” (where a characteristic or food property is not equivalent to existing additives or flavourings) (article 4(1)) or “genetically modified” (where an additive or flavouring is or contains an organism modified by GM techniques (article 4(2)).
Proposed Regulation on Genetically Modified Food and Feed	**Y**	**Y**	**Y**	**Y**	**Y**	**Y**			**Y**	**Y**	**Y**	**Y**	**Y**	The proposed regulation of the European Parliament and the European Council on Genetically Modified Food and Feed flows from various proposals made in the Commission White Paper on Food Safety (COM (1999) 719 Final, 21 January 2000) and the adoption of Directive 2001/18/EC. It will consolidate existing Community level legislation and procedures on these issues and close gaps such as feed produced from GMOs and the evaluation of genetic modifications in additives and flavourings. The proposed regulation is premised on three fundamental objectives: (1) to ensure a high level of consumer and animal health and life protection; (2) to facilitate the consumer’s and in the case of feed, the end user’s right to know to enable an informed choice; and (3) to ensure that the consumer or end user is not misled (CEC, 2001). The proposed regulation would fit within a larger framework of food law that is being proposed for a regulation at the Community level in the aftermath of European food crises involving BSE and dioxin contaminated feed (see EC proposed regulation COM (2000) 716 Final – 2000/0286(COD)). The proposed legal framework would lay down general principles and requirements of food law, establish an independent European Food Authority and provide procedures for food safety. It will include a proposed regulation on traceability and labelling of GMOs and traceability of food and feed products produced from GMOs. The European Food Authority would carry out the role of scientific committee envisioned in existing EU legislation (CEC, 2001). For example, the Authority would undertake risk

														assessments on GM food and feed under the proposal described here. The overall process envisioned is based on the "one door-one key" principle (CEC, 2001). This would streamline procedures and make it possible for an applicant to obtain approval for both the deliberate release of a GMO as well as its use in food and/or feed in one process. There would be a single risk assessment process overseen by the Authority. There also would be a single risk management process involving the Commission and the Member States (CEC, 2001). The proposed regulation would cover genetically modified food, livestock feed and additives and flavourings regardless of whether DNA or protein resulting from the genetic modification can be detected (CEC, 2001). In other words, it will apply to products *produced from a GMO*, rather than products *produced with a GMO* (CEC, 2001). According to the explanatory memo accompanying the proposed regulation, the determining criterion is whether or not material derived from the genetically derived starting material is present in the food or in the feed. Also the memo states that food or feed manufactured with the help of a genetically modified processing aid is not covered. Importantly, the proposed regulation would eliminate the simplified notification procedure provided in the Novel Foods Regulation (97/258/EC) for GM foods which are "substantially equivalent" to existing foods. According to the explanatory memo accompanying the proposal, the substantially equivalent concept has been controversial in the Community. It has been recognised internationally only as a key step in the safety process of GM foods but not a safety assessment in itself has it has been used as a regulatory shortcut. The references in the proposed Regulation to "other legitimate factors" indicates that the Commission, as decision maker, may in making its decision rely on other factors in addition to the scientific risk assessment undertaken by the Authority and provided for in the authority's written opinion. The reference may align the EU legislation with work being undertaken in the Codex Alimentarius Commission. **Genetically Modified Food (Chapter II)** **Authorisation** The proposed regulation would apply to (1) GMOs for food use (GMOs used as food or as source material – article 2(4)), (2) food containing or consisting of GMOs and (3) food produced from or containing ingredients produced from GMOs (article 3). The criteria for authorisation require that the food must not: (1) present a risk to human health or the environment; (2) mislead the consumer; and (3) differ from food that it is intended to replace to such an extent that its normal consumption would be nutritionally disadvantageous for the consumer (article 4(1)). "Genetically modified food or feed" means "food or feed containing, consisting or produced from [GMOs]" (article 2(3)). Marketing a genetically modified organism for food use or food requires prior authorisation (article 4(2)). Authorisation

														requires the applicant to demonstrate that the organism for food use or food meets the article 4(1) criteria. In other words, the applicant has the burden of demonstrating the safety of the organism or food. Authorisation may apply to (1) a GMO or foods containing or consisting of that GMO, as well as foods produced from or containing ingredients produced from that GMO or (2) a food produced from or containing an ingredient produced from a GMO as well as foods produced from or containing that food (article 4(4)). Food material that contains, consists of or is produced from GMOs in proportions of 1 percent or less does not require authorisation (article 5). However this is provided (1) the presence is "adventitious or technically unavoidable" and (2) the GM material has been subject to scientific risk assessment by the "relevant Scientific Committee(s)" or the European Food Authority. The assessment must conclude that the material does not present a risk to human health or the environment. Operators "must be in a position" to show "competent authorities" that the material is adventitious or technically unavoidable by demonstrating that they have taken steps to avoid the presence of the GMO or the products thereof. An application process would be established by the proposed regulation (article 6). The application would be sent to the Authority. Along with a variety of other information, including a study demonstrating compliance with the authorisation criteria in article 4(1), the application must include six additional points. These are *inter alia* (1) either an analysis that the food is not different to conventional food compared to the criteria enumerated in article 14(2)(a) (i.e., regarding composition, nutritional value or effects, intended food use and implications for the health of certain population sections) or a proposal for labelling in harmony with article 14(2)(a) and (3), (2) either a reasoned statement that the food does not give rise to ethical or religious concerns or a proposed labelling scheme, (3) a method to detect and identify the transformation event in the food and/or in the foods produced from it, (4) food and control samples, (5) where appropriate a post-market monitoring proposal and (6) a dossier summary (article 6(3)(f, g, i-l)). The Authority would consider the application and would prepare an opinion that is subsequently considered by the Commission and the Member States (article 7). The Authority would make the application and supplementary information available to the Commission and the Member States (article 7(3)(b)). The applicant's dossier summary would be made available to the public (article 7(3)(c)). The Authority may ask a food assessment body in a Member State to undertake a food safety assessment and a competent authority designated under Directive 2001/18/EC to undertake an environmental risk assessment (article 7(3)(d)). Confusingly, the Commission will publish a recommendation on the nature of the risk assessment that the Authority is to undertake (article 7(8)). The Authority may also request the Community reference laboratory to test and validate the detection and identification methods proposed by the applicant (article 7(3)(f)). The Authority would also validate the applicant's claims that the food's characteristics are different from its conventional food counterpart (article 7(3)(g)).

														The Authority's evaluation must respect the environmental safety requirements specified in Directive 2001/18/EC for GMOs or food containing or consisting of GMOs in relation to deliberate release or placing the product on the market (article 7(4)). The Authority is to consult with the bodies set-up under Directive 2001/18/EC by the Community and /or the Member States. Favourable opinions by the Authority are to include *inter alia* a labelling proposal, any conditions or restrictions such as post-market monitoring based on the risk assessment and a detection method (article 7(5)). The Authority would forward its opinion to the Commission and the Member States with a rationale (article 7(6)). The opinion would also be made available to the public after deletion of confidential information (article 7(7)). The public will be able to provide the Commission with comments within 30 days of the opinion's publication. There are no criteria proposed on the extent to which public comments need to be considered. The Commission will prepare a draft decision. The draft decision is to take account of Community law and "other legitimate factors relevant to the matter under consideration" (article 8(1)). A draft decision contrary to the Authority's opinion will need to provide an explanation of the differences. A final decision will be adopted according to Decision 1999/468/EC. Authorisation is valid for 10 years throughout the Community (article 8(5)). The authorised food is entered in a Register that is accessible to the public. Products authorised before the entry into force of the Regulation could remain on the market subject to a notification to the Authority which will include the information required in a first time notification described earlier under article 6(3) and (5) (article 9(a)). The process will lead to the product being placed on the Register (article 9(b)). All authorisation holders will have supervisory obligations to undertake post-market monitoring and report to the Authority (article 10(1)). The Authority will be informed of new scientific or technical information that may influence the food's safety evaluation and will be informed of any prohibition or restriction imposed by the competent authority of a third country in which the food is placed on the market (article 10(3)). According to the environmental assessment of the proposed regulation, GM food labelling within the EU is currently addressed by Regulation 258/97/EC (Novel Foods and Novel Food Ingredients) and Regulation 1139/98/EC (Compulsory Indication of the Labelling of Certain Foodstuffs Produced from GMOs Other than Those Provided for in Directive 79/112/EEC) as amended by Regulation 49/2000/EC and Regulation 50/2000/EC (Labelling of Foodstuffs and Food Ingredients Containing Additives and Flavourings that have been Genetically Modified or have been Produced from GMOs). The last three regulations would be repealed by the proposed regulation described here. It is important to note that the labelling requirements exist irrespective of the detectability of DNA or protein resulting from the genetic modification in the final the products (CEC, 2001). **Labelling**

														All products subject to the authorisation under the proposed regulation would also be subject to mandatory labelling (CEC, 2001). Under the proposal, labelling requirements will apply to foods "delivered as such to the final consumers or mass caterers which (1) consist or contain GMOs or (2) are produced from or contain ingredients produced from GMOs (article 13(1)). Labelling requirements will not apply to foods with material that contains, consists of or is produced from GMOs in a proportion no higher than the thresholds to be established provided the presence is adventitious or technically unavoidable (article 13(2)). This leaves open the possibility that labelling requirements may apply to a threshold of adventitious materials different than that set for authorisation. As with the procedures for GMO food authorisation, the operator must be in a position to supply evidence to satisfy the competent authorities that they have taken steps to avoid the presence. The food labelling requirements vary with the form of the product and are not to prejudice other Community labelling requirements (article 14(1)). Generally, the words "genetically modified" or "produced from genetically modified [name of organism] but not containing a [GMO]" must appear (article 14(1)(a-c)). Food without pre-packaging must have similar wording displayed on or in connection with the food's display (article 14(1)(d)). The labelling must also mention any characteristic or property when (1) the food is not equivalent to its conventional counterpart (i.e., with regard to composition, nutritional value or nutritional effects, intended use, or implications for the health of certain sectors of the public) or (2) where the food gives rise to ethical or religious concerns (article 14(2)(a & b)). Where a food does not have a conventional counterpart the label is to include information about the food's nature and the characteristics (article 14(3)). **Genetically Modified Feed (Chapter III)** The proposed regulation's provisions on genetically modified feed (marketing and labelling) generally parallel the provisions for genetically modified food. The following recounts some highlights. Directive 90/220/EEC and, when it enters, into force 2001/18/EC, presently regulate GM feed. Feed produced from GMOs but which does not contain them does not have to be labelled presently. The proposed regulation would change this. The authorisation procedure is the same as that for GM food. The proposed regulation will apply to (1) GMOs for feed use, (2) feed containing or consisting of GMOs and (3) feed produced from GMOs (article 16(1)). To gain authorisation, feed must not (1) present a risk to animal health, human health or the environment, (2) mislead the user, (3) harm the consumer by impairing the distinctive features of animal products and (4) differ from feed it was intended to replace to such an extent that it would be nutritionally disadvantageous for animals or humans (article 17(1)). The authorisation can apply to (1) a GMO and feed containing or consisting of that GMO as well as feed produced from the GMO or (2) feed produced from a GMO as well as feed produced from or containing the feed (article 17(4)).

														A 1 percent threshold is set for adventitious or technically unavoidable genetically modified material in feed with similar conditions shifting the burden on the operator to be in a position to demonstrate the steps taken to avoid the presence (article 18). The application for authorisation also refers to information (1) demonstrating the feed is not different than a conventional feed, (2) a reasoned statement that the feed does not give rise to ethical or religious concerns and (3) a method to detect and identify the transformation (article 19(3)(f, g & i). The Authority will conduct the application review and submit an opinion to the Commission and Member States with distribution to the public (article 20(3)(b & c)). The Commission will publish a recommendation on the nature of risk assessment that the authority will undertake (article 20(8)). In developing its draft decision the Commission is to take into account Community legislation and "other legitimate concerns" (article 21(1)). It will also include the unique code attributed to the GMO to be developed further under the proposed regulation on traceability and labelling (article 21(2)). Authorisation will be valid for 10 years throughout the Community (article 21(5)). In contrast to the GM food labelling requirements which only speak in terms of label content, article 27 proscribes a person from marketing GM feed without including a clearly visible, legible and indelible label, either on an accompanying document or on the packaging, container or on a label attached thereto (article 27(3)). For genetically modified feed the name shall be "genetically modified [name of feed]"; for feed produced from GMOs: "produced from genetically modified [name of the feed from which the feed is produced] but not containing a [GMO]"; for feed containing or consisting of GMOs the unique identifier assigned to the GMO shall accompany the name of the feed (article 27(3)(a & b)). As with the GM food labelling requirements, any characteristic not equivalent to its conventional counterpart needs to be also clearly indicated, including a characteristic or property that may give rise to ethical or religious concerns (article 27(3)(c & d)) **Common Provisions** Products likely to be used as food and feed shall be evaluated as a single application and will result in a single opinion by the Authority (article 29). A Community Register of Genetically Modified Food and Feed is to be created and made available to the public (article 30). Confidentiality provisions are similar to those in 2001/18/EC. However, it is clarified that the Commission, Authority and the Member States are obliged to keep confidential all information identified as confidential "except for information which must be made public if circumstances so require, in order to protect human health, animal health or the environment" (article 31(5)). The Community Reference Laboratory will be the Commission's Joint Research Centre (Annex). It will be assisted by a consortium of national reference laboratories to be referred to as the "European Network of GMO Laboratories". As with Directive 2001/18/EC, at its own initiative, or upon request of a Member State, the Commission may also consult the European Group on Ethics in Science and New Technologies to obtain its opinion on ethical issues (article 34(1)). The Commission will make the Group's opinions available to the public (article 34(2)).

														In addition to that European legislation already mentioned, the proposed regulation would amend Regulation 258/97/EC (Novel Foods). It would do this by removing GM foods from its scope of application (article 38); Directive 82/471/EEC (Concerning Certain Products useful in Animal Nutrition) would be amended by removing products which act as direct or indirect protein sources that are within the scope of application of the proposed regulation (article 39); Directives 70/457/EEC (Common Catalogue of Varieties of Agricultural Plant Species) and 70/458/EEC (Marketing of Vegetable Seed) would be amended *inter alia* such that when the material derived from a plant variety is intended to be used in food within the scope of the proposed regulation, the variety will not be accepted unless it is approved in accordance with the proposed regulation (article 40(1) and article 41(1)); Directive 2001/18/EC would be amended with regard to the 1 percent threshold for adventitious presence of GMOs in products (article 42).
France														
Law 92-654 (Control of GMO Use and Spread (1992)	**Y**	**Y**				**Y**			**Y**	**Y**	**Y**	**Y**		Law 92-654 is the basic French law for research on and release of genetically modified organisms as they may affect the environment or human health. Title I provides for the National Commission on Gene Technology, a cross-sectoral body composed of scientists in fields related to genetics, public health and environmental protection and a representative from Parliament (Art. 3(I)). It is charged with evaluating risks posed by GMOs and proposes risk management measures. It also proposes necessary measures to adapt to technological changes. The National Commission on the Release of the Biomolecular Products is another cross-sectoral body involved with the risk assessment, defining the conditions of commerce and labelling of GMOs and the products that contain them (art. 3(II)). It is composed of scientists, parliamentary members, representatives of environmental and consumer protection groups, professionally concerned groups and representatives of employee groups. A simple reading of the law does not give the reader a clear indication of the roles of these two institutions. Subsequent legislation described below indicates that the National Commission on the Release of the Biomolecular Products generally undertakes the risk evaluation. It undertakes the risk evaluation and supplies an opinion to the Minister of the relevant competent national authority reviewing the application for authorisation. Title II applies to GMOs used in research applications. GMOs are classified according to risk (art. 4). A license is required for GMO research (art. 6(I)), except where the GMO is a non-disease causing organism or has been classified as not dangerous to public health or the environment (art. 6(II)). The license includes risk management measures (art. 6(I)). The application for first time authorisation is to include an “information file to the public” (art. 6(II) including general information on the planned activities, the classification of the GMOs and an address where the public can file objections. The address is that for the National Commission on Gene Technology. In general, the file is sent to and reviewed by the competent national authority responsible for the application’s authorisation, which may vary with the type of organism or product. Subsequent legislation described below clarifies which competent national authority is involved. In addition, the file must be sent to the local

														administration, mayor or city hall where the activity will take place. It is unclear whether this is purely for informational purposes or whether another regulatory process takes place at the local level. There are no other specific provisions on stakeholder involvement, but the information file submitted by the applicant must include an address to which the public can file objections to the proposal (art. 6(II)). Décret 93-773 describes the general administrative procedures and the conditions under which authorisation can be granted under Law 92-654, as well as information to the public on possible risks and emergency plans. In general, the proposer makes an application to the appropriate competent authority. As described above, a public notice at the local level (e.g., at the city hall) is to inform the public about the request (art. 7(II)).[6] Comments are made to the competent authority and the proposer then must address them. Title III applies to GMOs deliberately released into the environment for research or development purposes and GMOs placed into commerce. It does not apply to GMO transport (art. 9). All releases and related research, as well as placement into commerce, require a permit (art. 11 and 15). Permission is based *inter alia* on a risk evaluation (art. 11 and 15). The public has the right to access all files related to risk to public health or the environment (art. 12), but it is unclear how stakeholders can actually participate in this aspect. The application file must include an address to which the public can file objections to the proposal as described earlier (art. 6II). Commerce in GMOs requires a license. "Commerce" is defined as putting genetically modified products or products with GMOs at the disposal of third parties for free or for a fee (art. 14).
Decree 93-1177 (Application of Law 92-654 to GM Plants, Seeds and Seedlings) (1993)	**Y**	**Y**				**Y**			**Y**	**Y**	**Y**	**Y**		The Ministry of Agriculture is the competent national authority that provides authorisation to release GMOs related to plants, seeds and seedlings, after approval of the Ministry of Environment (art. 1). In addition to other information for the application, an information file for the public must be included. This is to include information on *inter alia*: goal of release, description of GMO; evaluation of risks and impact on human health and the environment; and emergency plans (arts. 2-11). The National Commission on the Release of the Biomolecular Products undertakes a risk evaluation and provides its opinion to the Minister who then makes a decision (arts. 2 and 3).

[6] NB: in later French laws described here the public notice procedure changes slightly with the relevant competent authority, such as the Ministry of Environment or Agriculture, sending the file to the local level. The local level administration then publishes the notice at city hall. In addition, the public may send objections and observations directly to the minister. The minister then informs the National Commission on the Release of the Biomolecular Products. (Décret 93-1177 Art.6 (GM plants); Décret 94-359 Art.34 (GM phytopharmaceuticals); Décret 95-487 Art.7 (GM animals); Décret 98-318 Art.6. (GM fertilisers). Décret 97-685 is different still. Here the Minster of Commerce does not inform the concerned local administration. Instead, it publishes the public notice granting authorisation in the official journal (art. 6).

Decree 94-359 (Control of Phyto-pharmaceutical Products)(1994)	**Y**	**Y**			**Y**	**Y**				**Y**	**Y**	**Y**		Phyto-pharmaceutical products include all substances, preparations containing active ingredients and products composed wholly or partially of GMOs for use *inter alia* as herbicides, pesticides or fertilisers (art. 1). Deliberate release or commerce in GMO phyto-pharmaceuticals requires a license issued by the Ministry of Agriculture after approval from the Ministry of Environment (art. 29). Information requirements are similar to those outlined in the previous decree and the main law, including various pieces of information for public information (art. 30). The National Commission on the Release of the Biomolecular Products undertakes a risk evaluation and provides its opinion to the Minister who then makes a decision (arts. 29. 46 and 49). When the Ministry of Agriculture authorises the release, it provides information to the local community where the release will take place, though it is unclear to what extent local approvals apply (art. 54). Labelling requirements are to follow the requirements laid out in an administrative order from 21 September 1994 (art. 64-66).
Decree 95-487 (Applications for GM Animals) (1995)	**Y**	**Y**		**Y**		**Y**				**Y**	**Y**	**Y**		Release of genetically modified animals must be authorised by the Ministry of Agriculture after the approval of the Ministry of the Environment (art. 2). Application information requirements are similar to earlier decrees, including a public information file (art.3). Similar authorisation is required for commerce in GM animals (art. 13-19). Authorisation in either case cannot be made if the GM animal and its descendants cannot be traced (art. 22). Animals must be kept under surveillance for diseases and behaviour. The minister will grant authorisation after the opinion and risk evaluation of the National Commission on the Release of Biomolecular Products (art. 3(III)).
Decree 97-685 (Animal Feed Stuff) (1997)	**Y**	**Y**				**Y**				**Y**	**Y**	**Y**		Chapter I provides rules for the release (testing) of products destined for animal feed composed partially or wholly of GMOs which are not plants, seeds seedlings or breeding animals. Release is permitted by a joint ministerial order issued from the Ministry of Consumer Protection and the Ministry of Agriculture after approval from the Ministry of Environment (art. 1). Application information requirements are similar to decrees described earlier including a public information file (art. 2(II)). The public may address all observations about the release to the Ministry of Consumer Protection. Upon a complete application, the Ministry of Consumer Protection submits the application to the National Commission on the Release of the Biomolecular Products and the National Commission on Animal Feed. The Commissions give their opinions to the Minister, based on a risk evaluation, who then decides to grant consent or reject the file (art. 3(II)).
Decree 98-318 (Control of Fertilisers and Cultivation Supporting Substances Wholly or Partially Containing GMOs) (1998)	**Y**	**Y**				**Y**				**Y**	**Y**	**Y**		Release of or commerce in fertilisers and cultivation supporting substances partially or wholly composed of GMOs requires Ministry of Agriculture authorisation after approval by the Ministry of the Environment (arts. 1 and 16). The National Commission on the Release of Biomolecular Products and a number of other commissions is involved in the review process and they provide their opinions to the Minister (arts. 1 and 16). Information requirements in the application are similar to those for other decrees (art. 2(III)). Commerce will be authorised when the product is (1) shown to be harmless to public health and the environment and effective and (2) if no EU country opposes the application (art. 17(I)).
United Kingdom														
Environmental	**Y**					**Y**			**Y**	**Y**	**Y**	**Y**		Part VI of the UK Environmental Protection Act, as amended, and The Genetically Modified

Protection Act (1990) as amended													Organisms (Deliberate Release) Regulation (1992), as amended, implement EC Directive 90/220/EEC (Deliberate Release and Marketing of GMOs). The designated Secretary of State from England, Wales and Scotland act to implement the legislation. Where a function of the Secretary of State is exercised in relation to a matter where the Minister of Agriculture, Fisheries and Food has competence the function is to be exercised acting jointly (as respects England)(section 126). No person may import, acquire (to be in a person's possession (section 217(1)), keep, release or market GMOs unless (1) a risk assessment of damage to the environment is carried out from the act and (2) the Secretary of State has been notified (section 108(1)& (3)). The Secretary of State may decide when consent is required by giving directions (section 108(8)). General duties of a person proposing to import, acquire, release or market GMOs or who is keeping GMOs vary with the circumstances (section 109). They include *inter alia*: (1) taking reasonable steps to identify the risks of damage to the environment when proposing to import or acquire GMOs and not importing or acquiring GMOs when there appears to be risk of damage to the environment, despite precautions taken (section 109(2)); (2) keeping informed of environmental damage caused by keeping GMOs, identifying risks of environmental damage caused by continued keeping, ceasing keeping of GMOs where there is risk of environmental damage from continued keeping and using best available techniques, not entailing excessive costs, to keep GMOs under control and preventing any environmental damage and disposing of GMOs properly; and (3) keeping informed of the risks of environmental damage as a result of GMO release, not releasing when there is a risk of environmental damage and using best available techniques, not entailing excessive costs, to prevent any environmental damage (section 109(2-4)). No person can import, acquire, keep, release or market a GMO without the consent of the Secretary of State (section 111(1) & (2)). Application requirements apply (section 111(3)). The application must also be advertised (section 111(4)) and must be advertised to such persons as may be prescribed (section 111(5)). Exemptions are possible (section 111(7)). The Secretary of State may, by notice, revoke or vary the consent at any time (section 111(10)). In addition to specific conditions applied to the consent (section 112), every consent includes implied general conditions applicable to the consent holder. These vary with the circumstances. The implied general conditions parallel the general duties described earlier. They generally include (1) keeping informed of any risks of environmental damage from the permitted activity, (2) notifying the Secretary of State of any new information regarding the risks of environmental damage being so caused and the effects of any releases especially those when it appears the risks are more serious than apparent when the consent was first granted and (3) using best available techniques, not entailing excessive costs, to prevent environmental damage as a result of the activity (section 112 as amended by reg. 9 of 1992)). The Secretary of State is to maintain a public register. The register includes (1) notifications under section 108, (2) directions under section 108(8), (3) prohibition notices, (4) applications for consent and advice given by an appointed committee, (5) consents granted

														and information furnished pursuant to conditions of consent, (6) any other information and (7) convictions for offences (section 122(1)). The register is to be open to the public, free of charge and is to afford the public facilities to obtain copies of register entries for reasonable charges (section 122(2)). The register shall not include (1) information contrary to national security interests, (2) information that could lead to environmental damage or (3) information that is commercially confidential (without consent of the information holder (section 123(1-3)). The register goes beyond EU requirements. The holder of commercially confidential information must apply to have the information excluded from the register (section 123(4)) and the Secretary of State decides upon the application and informs the applicant accordingly. When it has been obtained as a result of the law's implementation, the Secretary of State shall notify third parties of information that may be commercially confidential to give them a reasonable opportunity to object to its posting in the register (section 123(6)). The Secretary of State shall take the third party's representations into consideration before determining whether the information is commercially confidential. Information to be included in the register for notifications, consent applications and consents granted is to include (1) name and address of person; (2) GMO description; (3) location of the GMOs; (4) purposes of importation, acquisition, keeping, release or marketing; (5) results of environmental risk assessment; and any other information "which the public interest requires" notwithstanding its commercial confidentiality (section 123(7)(a-e)). Confidential information can be excluded from the register for up to four years, at which time the holder needs to reapply (section 123(8)). The Secretary of State is to appoint a committee to provide advice *inter alia* on consents and conditions and limitations on consents (section 124). The Advisory Committee on Releases to the Environment has been established and consists of independent experts. It advises the government on the safety of proposed releases and marketing of GMOs (and non-native species), biosafety research and GMO policy issues (UK Joint Regulatory Authority, *et al*., 2000). The Advisory Committee can take into consideration comments made as a result of listing in the public register and those made after the application has been notified in newspaper under the 1992 Regulations (see below) (UK Joint Regulatory Authority, et al., 2000).
The GMOs (Deliberate Release) Regulation (1992), as amended	**Y**					**Y**			**Y**	**Y**	**Y**	**Y**		The regulations, as amended, implement Part VI of the Environmental Protection Act of 1990. The regulations provide more detailed requirements. They are divided into different parts. Part II deals with marketing. To streamline the regulatory process, applications for release can address (1) one or more releases of one or more GMOs "of one or more descriptions" on the same site for the same purposes or (2) one or more releases of one description of GMOs on one or more sites for the same purposes (reg. 5(2)). The applicant is responsible for advertising the application for consent to release by publishing a notice in a newspaper or newspapers in the areas likely to be affected by the proposal (reg. 8(1)). The information is to include (a) the applicant's name and address; (b)

														the general description of the organisms to be released; (c) the release's location and general purpose; and (d) the foreseen release dates (reg. 8(1)(a-d)). The level of detail regarding the release's location must be that which appears in the public register created pursuant to the Environmental Protection Act. In addition, the applicant must specifically notify a number of individuals that he has made the application along with the information found in the public notice. These include *inter alia* (a) the owner or owners of the site when different from the applicant; (b) the local authority for the area of the proposed release; (c) the Nature Conservancy Council (England), Scottish Natural Heritage or the Countryside Council (Wales); (d) the Countryside Commission (England); (e) the Forestry Commission; (f) the National Rivers Authority or the regional islands council (Scotland); the water undertaker for the area of the proposed release or the river purification board or islands council (Scotland); and (g) each member of the genetic modification safety committee that the applicant has established pursuant to the UK Genetically Modified Organisms (Contained Use) Regulations of 1992 (reg. 3(a-h)). Under Part III for marketing, consent for marketing is required where the product is being marketed for the first time and where the product is intended for a use for which it had not previously been marketed (reg. 10(2)). In contrast to an application for consent to release, applications for consent to market do not appear to have detailed regulations on public announcement. Part IV enumerates various duties that are created after an application for consent is made. For example, the applicant's duties are listed in the Act but have been expanded to include notifying the Secretary of State before the application is granted or rejected of any new information to any risks of environmental damage from release or marketing (reg. 13). With regard to consents to release, the Secretary of State's duties include *inter alia* (1) forwarding the application's summary to the European Commission (reg. 14), (2) evaluating the risks posed by the proposed release, (3) carrying our tests and inspections as necessary for control purposes, (4) where appropriate, taking account of any comments made by the competent authorities of Member States and (5) recording his conclusions in writing (reg. 14). The Secretary of State may not grant consent to release as it relates to human health without the agreement of the Health and Safety Executive (reg. 15(1)) and likewise may not revoke or vary consent as it relates to human health without the Executive's agreement (reg. 15(5)). Consents must be notified to the European Commission and the competent authorities of the Member States (reg. 15(4)). Consent for marketing also entails duties for the Secretary of State. These include forwarding to the Commission *inter alia* (1) a statement of the conditions under which the Secretary of State proposes to consent to marketing, (2) details of any proposal by the applicant not to comply with certain information requirements (where acceded to by the Secretary of State) and (3) a favourable opinion (reg. 16(2)(a)) or informing the applicant that the application does not fulfil the necessary legal requirements (reg. 16(2)(b)). Favourable opinions must be forwarded to the Commission only with the agreement of the Health and Safety Executive (reg. 16(3)). Information received before or after consent is

														made is to be forwarded before or after granting consent (reg. 16(5)). The Secretary of State will grant consent where the Commission has taken a favourable decision under its procedures after a Member State objects (reg. 16(7)). Revocations or variations to a consent cannot be made as they relate to human health cannot be made without the agreement of the Health and Safety Executive (reg. 16(8)).
Novel Foods and Novel Food Ingredients Regulations (1997) as amended		**Y**	**Y**		**Y**	**Y**			**Y**	**Y**	**Y**		**Y**	Pursuant to the Food Safety Act of 1990, these regulations enable the enforcement and execution of certain obligations of EC Regulation 258/97/EC and other EC regulations. In the UK, requests to place a novel food or novel ingredient on the market (pursuant to article 4(1) of Regulation 258/97/EC) are made to the Minister of Agriculture, Fisheries and Food who acts jointly with the Secretary of State for Health as the UK food assessment body (reg. 3). However, these powers appear to be delegated to individual food authorities, designated by the UK Food Safety Act and operating at the local level, who are responsible when designated to enforce or execute the EC regulation. Therefore, separate but similar regulations have been promulgated for England, Northern Ireland and Wales. For example, the Genetically Modified and Novel Foods (Labelling) (England) Regulations 2000 implement the details of the EC regulations dealing with novel foods and food ingredients involving GMOs. It specifies *inter alia*: the general and specific requirements for the manner of marking or labelling foods and food ingredients, including additives and flavourings, containing GM maize and soya. Offences and penalties are also specified. It is not immediately apparent from the regulations reviewed how the process to make the initial assessment under Regulation 258/97/EC to market novel foods and novel ingredients operates within the UK. However, though not specifically referred to in the regulations, the Advisory Committee on Novel Foods and Processes (ACNFP) carries out the assessment of novel foods in the UK, The ACNFP is a non-statutory body of independent experts (UK Food Standards Agency, _____a.). A 1999 amendment to the Regulations increased the transparency of ACNFP's proceedings such that any information submitted to it under the European Commission Regulation 257/97 is discloseable to anyone who requests it. This is subject to three exceptions: (1) the information is not required by the EC Novel Foods Regulation; (2) ACNFP agrees with the information holder that the information is confidential because it would harm competitive position; or (3) the ACNFP agrees that the information is confidential because disclosure would harm intellectual property rights (UK Food Standards Agency, Other aspects of stakeholder involvement such as public participation in decision making are not clarified, although another UK law that has not been reviewed, such as the UK Freedom of Information Act (2000), could provide for this. The UK Food Standards Agency, created pursuant to the Food Standards Act of 1999, provides the ACNFP's secretariat.
Food Standards Act (1999)		**Y**	**Y**		**Y**	**Y**				**Y**	**Y**	**Y**		The Food Standards Agency is entrusted with protecting the public from risks that may arise from food consumption and to protect the interests of consumers with respect to food

														(section 1(2)). The risks from food consumption may include those risks caused by the way the food is produced or supplied. The Agency functions to develop food safety policies (section 6(a)), It also provides advice and information to the general public on food safety or other consumer related interests (section 7(1)), while ensuring that the public is kept adequately informed and advised in respect of matters that could significantly affect their capacity to make informed choices on food (section 7(2)). The Agency has similar functions with respect to animal feed stuffs (section 9). It is expected that the UK Food Standards Agency will eventually act as the competent authority within the UK for purposes of implementing EC Novel Foods Regulation 258/97/EC (ACNFP, 1997). The Agency is to prepare and publish a statement of general objectives that it intends to pursue and the general practices that it intends to adopt to carry out its functions (section 22(1)). The statement is to include as one of the Agency's objectives "securing that its activities are the subject of consultation with, or with representatives of, those affected and, where appropriate, with members of the public" (section 22(2)(a)). The statement is also to include as one of the Agency's objectives "securing the records of its decisions, and the information upon which they are based, are kept and made available" to enable the public to make informed judgments about the manner in which the Agency carries out its functions (section 22(2)(c)). When it carries out its functions, the Agency is to "pay due regard" to its statement of objectives (section 23(1)). When it considers whether or not to exercise its powers, or the manner in which it will exercise any power, the Agency is to take into account *inter alia* (1) the nature and magnitude of the risks to public health or other risks relevant to the decision (including "any uncertainty as to the adequacy or reliability of available information"), (2) the likely costs and benefits of the exercise and non-exercise of its powers and (3) "any relevant advice or information…[from] an advisory committee (whether or not requested) (section 23(2)(a-c)).
Oceania														
Australia														
Gene Technology Act (2000)	**Y**					**Y**	**Y**		**Y**	**Y**	**Y**	**Y**	**Y**	The Australian Gene Technology Act consolidates Australia's treatment of GMOs (e.g., an (living) organism modified by gene technology or an organism that that has inherited a gene technology derived trait from another organism – sec. 10) and GM products (i.e., a thing, other than a GMO, derived or produced from a GMO – sec. 10). The object of the Act is to (1) protect human health and safety and (2) protect the environment by identifying and managing risks posed by gene technology, by regulating "certain dealings" (i.e., activities) with GMOs (sec. 3). The Act has been supplemented by regulations (Gene Technology Regulations 2001). The objectives of the Act are achieved through a regulatory framework. The framework is premised *inter alia* on the precautionary principle: "where there are threats of serious or irreversible environmental damage, a lack of full scientific certainty should not be used as a reason for postponing cost-effective measures to prevent environmental degradation" sec. 4(aa). The term "precautionary principle" is not used and it

														is unclear whether this is a policy principle for purposes of the Act (see below). The Act is viewed as a component of a nationally consistent scheme to regulate certain dealings with GMOs (sec. 5). The Act works in conjunction, with and does not substitute for, other Commonwealth and State regulatory schemes relevant to GMOs and GM products (sec. 4(b)). In effect, this means that the Act applies to all dealings listed, including imports or intentional releases into the environment, and applies to those GM products not already regulated by an existing Australian agency. For example, food products with GM components and foods that are GMOs are regulated according to existing food laws in particular the Australia New Zealand Food Authority Act (1991) and accompanying standards. Similar treatment is accorded to agriculture and veterinary chemicals, industrial chemicals and therapeutic goods. Being a commonwealth, State laws are not displaced by the Act to the extent that they are compatible with it (sec. 16). The Act establishes the Gene Technology Regulator as an administrative office within the Ministry of Health and Aged Care to administer the legislation and make decisions pursuant to it (sec. 26). Among its functions, the Regulator performs functions in relation to issuing GMO licences, develops draft policy principles and codes of practice and provides advice to the public, other regulatory agencies and the Ministerial Council (sec. 27). The Act also establishes (1) a scientific committee (Gene Technology Technical Advisory Committee), (2) a community committee (Gene Technology Community Consultative Committee) and (3) an ethics committee (Gene Technology Ethics Committee) (part 8). The committees are interdisciplinary and share cross membership. On matters within their competence, the committees provide advice upon request to the Regulator and the Ministerial Council. Common to all three committees is *inter alia* providing advice on the need for policy principles and codes of practice. In particular, the Ethics Committee is to provide advice on ethical issues relating to gene technology, the need for and content of codes of practice in relation to ethics and conducting dealings with GMOs and the need for a content of policy principles in relation to dealings with GMOs that should not be conducted for ethical reasons (sec. 112). All committee members are subject to disclosure and conflict of interest rules. The Act prohibits persons from dealing (e.g., research, manufacture, production, commercial release and import) with GMOs unless the dealing is (1) exempt, (2) a "notifiable low risk dealing" (NLRD), (3) on the Register of GMOs or (4) licensed by the regulator. Offences can be penalised criminally and can be considered strict liability offences. The licensing system that is created applies to two kinds of dealings - those involving intentional release into the environment and those that do not (sec. 39). Applications are made to and reviewed by the Regulator. For those applications where the dealings do not involve release, the Regulator must *inter alia* prepare a risk assessment and risk management plan (sec. 47, para. 1). Criteria are provided for undertaking both the assessment and the management plan (sec. 47, paras. 2 and 3). The Regulator has the discretion to consult with those entities and persons listed including the Gene Technology

														Technical Advisory Committee (sec. 47, para. 4). When an intentional release is involved, and the Regulator is satisfied that it may pose significant risks to human health and safety or the environment, he must publish a notice on the application in the official Gazette, a national newspaper and on the Regulators website (sec. 49). Criteria are provided to guide the Regulator's determination of significant threat (sec. 49, para. 2). Criteria are also provided for the public notice including inviting submissions on whether the license should be issued along with a closing date for submissions (sec. 49, para. 3). Before a license for release can be issued the Regulator must prepare a risk assessment and a risk management plan, regardless of whether a public notice was required (sec. 50). (NB: this seems to mean that all applications for a license to release requires assessment, whether the threats foreseen are significant or not). The Regulator must also seek advice from those entities and persons listed, including the Gene Technology Technical Advisory Committee, on matters related to the risk assessment and risk management plan (sec. 50). Criteria are provided for what must be assessed. The Regulator is directed to "take into account" *inter alia* any risks to human health and safety and the environment, any submission made under the public notice and any advice from those entities enumerated, including the Gene Technology Technical Advisory Committee (sec. 51, para. 1). Similar criteria are specified for the risk management plan (sec. 51, para. 1). Once assessment and plan are completed, the Regulator must again notify the public that they are available for comment (sec. 52, para. 2) and again seek advice from enumerated entities (sec. 52, para. 3). The Regulator may also hold public hearings (sec. 53). Persons may request copies of the application and the risk assessment or risk management plan (sec. 54, para. 1). Confidential commercial information so declared by the Regulator is not to be shared (sec. 54, para. 2). The applicant must apply to the Regulator for a declaration of confidential commercial information (sec. 184). Criteria are provided to guide the Regulator's decision making (sec. 185). The Regulator may refuse a declaration when the public interest in disclosure outweighs the prejudice disclosure would cause to the information holder (sec. 185, para. 2). The Regulator must refuse a declaration of confidential information if the information relates to one or more locations at which GMO field trials would occur, unless the Regulator is satisfied that significant damage to human health and safety, the environment or property would likely occur if the locations were disclosed (sec. 185, para. 2a). The Regulator must make publicly available a statement of reasons for making the declaration (sec. 185, para. 3a). In any licensing decision – whether for release or otherwise - the Regulator cannot issue license without being satisfied that risks posed by the dealings proposed to be authorised by the license can be managed to protect human health and safety and the environment (sec. 56). Guidelines are provided to guide the Regulator's decision-making process. For example, the Regulator must be guided by the risk assessment and management plan, submissions received from the public and any policy guidelines in force related to risks and ways to manage them (Sec. 56, para. 2). However, the Regulator must also not issue a

														license if it would be inconsistent with a policy principle in force or if the applicant is not suitable to hold a license (sec. 57). In general, the Act makes an implicit distinction between policy principles and policy guidelines based on the way they are developed and to be applied. Policy principles are developed and adopted by the Ministerial Council in consultation with all three advisory committees, including the Ethics Committee, and other stakeholders within and outside government (sec. 22). Decision-making must not be inconsistent with policy principles, whereas policy guidelines are to be considered. The Ministerial Council may also issue codes of practice developed by the Regulator in a consultative process with the committees and other stakeholders (sec. 24). Low risk dealings are subject to another regulatory process based on a notification system. They don't require a license as such. Notifiable low risk dealings cannot involve intentional release into the environment (sec. 74). Regulations are to be developed specifying low risk dealings that qualify pursuant to criteria specified: (1) biological containment and the ability of the organism to survive without human intervention; (2) minimal risk to human health and safety and the environment; (3) whether no conditions or minimal conditions would be needed (sec. 74, para. 3). These are similar to class or general licences. The Act establishes a GMO Register, maintained by the Regulator (sec. 76). Once dealings with GMOs have been licensed for a certain period of time or a particular GMO involved is a GM product and the GMO has been defined by regulations, they may be entered into a register. GMOs can only be listed when the Regulator is satisfied that the risks posed are minimal and a person undertaking the dealing does not need regulatory oversight to protect human health and safety or the environment. Any person (sec. 81) may inspect the Register. The Regulator must also maintain a comprehensive record of GMO and GM product dealings (sec. 138). The information in the record is to include that of designated notifications to the Regulator related to dealings involving GM products under other laws, such as the Australia New Zealand Food Authority Act (1991).
Joint Australia New Zealand Food Standards Code, Standard 1.5.2 (Food Produced Using Gene Technology (2000)		**Y**	**Y**		**Y**	**Y**			**Y**	**Y**		**Y**	**Y**	The Joint Australia New Zealand Food Standard 1.5.2. was developed by the Australia New Zealand Food Authority (ANZFA). ANZFA develops and maintains a joint Australian New Zealand Food Standards Code pursuant to the Australia New Zealand Food Authority Act (1991). The Australian States and Territories and the government of New Zealand enforce the code and police food standards set according to it. The food standards have the force of law and must be read in conjunction with national and sub-national food legislation in the respective countries. The Act's objective is to ensure a high standard of public health protection throughout Australia and New Zealand through achieving *inter alia* a high degree of consumer confidence and the establishment of common rules for both countries (sec. 2A(a and b)). The Act created ANZFA. Among others, ANZFA's functions include developing draft standards and draft variations of standards, to make recommendations to the joint Ministerial Council and to review standards (sec. 7(1)(a)). Any body or person may apply to

														ANZFA to develop a standard or variation (sec. 12(1)). After making a preliminary assessment of the application, ANZFA decides whether to accept or reject the application. If it accepts, then a full assessment is undertaken (sec. 15). When the application is accepted, a public notice must be issued (sec. 14(1)(a)) and relevant government agencies are given written notice (sec. 14(1)(b)). The public notice invites written submissions. A public hearing may be held (sec. 29). With regard to approval, Standard 1.5.2 applies to food produced using gene technology (whether derived or developed from an organism that has been modified by gene technology – sec. 1). It does not apply to additives and processing aids derived from gene technologies, whose safety and pre-market approval, are regulated by a different standard. In general, Standard 1.5.2 prohibits the sale and use of foods produced from gene technology or classes of such foods, unless they have been assessed, approved and listed by ANZFA. Exemptions to the general prohibition on sale and use may apply. For example, if ANZFA has evidence that the food is lawfully permitted and sold or used as an ingredient or component by a food regulatory agency in one or more countries (sec. 3). The safety assessment is pursuant to ANZFA assessment criteria. Assessment generally addresses the safety for human consumption of each. The Standard also applies to the labelling of food produced using gene technology. Genetically modified foods (i.e., food that is, or contains as an ingredient, including an additive or a processing aid, a food produced using gene technology which contains novel DNA and/or novel protein(s) or has altered characteristics – sec. 4) must be labelled with an appropriate statement ("genetically modified"). This is to take place in conjunction with the name of the food or ingredient or processing aid (sec. 5). Exemptions may apply. For example, highly refined foods where the processing removes the novel DNA or novel protein (sec. 4(1)(c)). In addition, a threshold is set whereby genetically modified food unintentionally present in a food, ingredient or processing aid in a quantity no more than 10g/kg (1%) does not trigger the labelling requirement (sec. 4(1)(f)). Additional labelling requirements may be needed in situations where a genetic modification "raises significant ethical, cultural and religious concerns regarding the origin of the genetic material used in the genetic modification" (sec. 7(e)).

References

Aerni P., Anwander Phan-huy S. and Rieder P. 1999. *An Indication of Public Acceptance of Transgenic Rice in the Philippines.* BIOTECHNOLOGY AND DEVELOPMENT MONITOR No. 38. Obtained from the Biotechnology and Development Monitor WWW site (accessed July 2001).

Atkins H. 2000. *The Legal Aspects of Genetic Modification: Background Paper Submitted to the New Zealand Royal Commission on Genetic Modification.* Obtained from the New Zealand Royal Commission's WWW site (accessed July 2001).

Biotechnology Industry Organisation. 1999. STATEMENT OF PRINCIPLES. Obtained from the Biotechnology Industry Organisation WWW site (accessed October 2001).

Canadian Biotechnology Advisory Committee (CBAC). 2001. IMPROVING THE REGULATION OF GENETICALLY MODIFIED FOODS AND OTHER NOVEL FOODS IN CANADA: INTERIM REPORT TO THE GOVERNMENT OF CANADA BIOTECHNOLOGY MINISTERIAL CO-ORDINATING COMMITTEE. Obtained from the CBAC WWW site (Accessed August 2001).

Canadian Food Inspection Agency (CFIA). 2000. Regulatory Directive (2000-07): Regulatory Guidelines for the Release of Plants with Novel Traits Within Confined Field Trails in Canada. Obtained from the CFIA Plant Health and Protection WWW site (accessed September 2001).

CFIA. 1998. Regulatory Directive (revised D-96-13): Import Permit Requirements for Plants With Novel Traits (Including Transgenic Plants), and Their Products). Obtained from the CFIA Plant Health and Protection Division WWW site (accessed September 2001).

CFIA. 1996. GUIDE TO FOOD LABELLING AND ADVERTISING. Obtained from the CFIA WWW site (accessed September 2001).

CFIA. 1994. Regulatory Directive (Dir. 94-08): Assessment Criteria for Determining Environmental Safety of Plants with Novel Traits. Obtained from the CFIA Plant Health and Protection WWW site (accessed September 2001).

CFIA. _____. *Developing a Canadian Standard for the Voluntary Labelling of Foods Derived from Biotechnology* (date unknown). Obtained from the CFIA Office of Biotechnology WWW site (accessed September 2001).

Charnovitz S. 2000. *The Supervision of Health and Biosafety Regulation by World Trade Rules.* 13 TULANE ENVIRONMENTAL LAW JOURNAL 271. Tulane University School of Law, New Orleans.

Codex Alimentarius Commission. 2001a. *Report of the 24th Session of the Codex Alimentarious Commission (2-7 July 2001).* UN Doc. ____. Obtained from the Codex WWW site (accessed October 2001).

Codex Alimentarius Commission. 2001b. *Report of the 29th Session of the Codex Committee on Food*

Labelling (30 April-4 May 2001). UN Doc. ALINORM 01/22A. Obtained from the Codex WWW site (accessed October 2001).

Codex Alimentarius Commission. 2001c. *Report of the 16th Session of the Committee on General Principles (23-27 April 2001)*. UN Doc. ____. Summary obtained from the Codex WWW site (accessed October 2001).

Codex Alimentarius Commission. 2001d. *Report of the 33rd Session of the Codex Committee on Pesticide Residues (2-7 April 2001)*. UN Doc. ____. Summary obtained from Codex WWW site (accessed September 2001).

Codex Alimentarius Commission. 2001e. *Report of the 2nd Session of the Ad hoc Intergovernmental Task Force on Foods Derived from Biotechnology (25-29 March 2001)*. UN Doc. ALINORM 01/34A. Obtained from the Codex WWW site (accessed October 2001).

Codex Alimentarius Commission. 2001f. *Report of the 23rd Session of the Codex Committee on Methods of Analysis and Sampling*. UN Doc. ____. Summary obtained from Codex WWW site (accessed September 2001).

Codex Alimentarius Commission. 2000a. *Report of the 9th Session of the Codex Committee on Food Import and Export Inspection and Certification Systems (11-15 December 2001)*. UN Doc. ____. Summary obtained from Codex WWW site (accessed September 2001).

Codex Alimentarius Commission. 2000b. *Request for Comments on the Revised Proposed Draft Code of Practice on Good Animal Feeding*. UN Doc. CL 2000/30-AF. Obtained from the Codex WWW site (accessed October 2001).

Codex Alimentarius Commission. 2000c. *Statutes of the Codex Alimentarius Commission*, *in*: CODEX PROCEDURAL MANUAL (11th Edition) Obtained from the Codex WWW site (accessed October 2001).

Codex Alimentarius Commission. 2000d. *Procedures for the Elaboration of Codex Standards and Related Texts*, in: CODEX PROCEDURAL MANUAL (11th Edition). Obtained from the Codex WWW site (accessed October 2001).

Codex Alimentarius Commission. 1999. GUIDELINES FOR THE PRODUCTION, PROCESSING, LABELLING AND MARKETING OF ORGANICALLY PRODUCED FOODS. UN Doc. CAC/GL 32-1999. Obtained from the Codex WWW site (accessed October 2001).

Codex Alimentarius Commission. 1995. *Statements of Principle Concerning the Role of Science in the Codex Decision-making Process and the Extent to Which Other Factors Are Taken Into Account (decision of the 21st Session of the Codex Commission)*. UN Doc. ____. Summary obtained from the Codex WWW site (accessed October 2001).

Commission of the European Communities (CEC). 2001. *Proposal for a Regulation of the European Parliament and of the Council on Genetically Modified Food and Feed.* Obtained from the European Commission WWW site (accessed August 2001).

CEC. 2000. *Communication from the Commission on the Precautionary Principle.* Obtained from the European Commission WWW site (accessed August 2001).

Convention on Biological Diversity (CBD). 2000. CARTAGENA PROTOCOL ON BIOSAFETY TO THE CONVENTION ON BIOLOGICAL DIVERSITY: TEXTS AND ANNEXES. Montreal. Obtained from the CBD WWW site (accessed April 2001).

Damena W. 2001. Written communication from Worku Damena of the Secretariat to the Convention on Biological Diversity on 15 November 2001.

Food and Agriculture Organisation of the United Nations (FAO). 2001. REPORT OF THE PANEL OF EMINENT EXPERTS ON ETHICS IN FOOD AND AGRICULTURE (FIRST SESSION). FAO, Rome.

FAO Commission on Plant Genetic Resources. 1993. *Towards an International Code of Conduct for Plant Biotechnology as it Affects the Conservation and Utilization of Plant Genetic Resources.* UN Doc. CPGR/93/9.

FAO and World Health Organisation (WHO). 1999. UNDERSTANDING THE CODEX ALIMENTARIUS. FAO/WHO, Rome. Obtained from the Codex WWW site (accessed October 2001).

Greenpeace. 2001. GENETIC ENGINEERING: THE HIDDEN INGREDIENT IN THAI FOOD. Obtained from the Greenpeace WWW site (accessed July 2001).

Independent Biotechnology Advisory Council of New Zealand (IBAC). 2000. BIOTECHNOLOGY IN NEW ZEALAND: CONSULTATION REPORT. Wellington, New Zealand. Obtained from the IBAC WWW site (accessed July 2001).

IBAC. ____. What is IBAC? (date unknown). Obtained from the IBAC WWW site (accessed October 2001).

Interim Commission on Phytosanitary Measures (ICPM). 2001a. *Report of the Third Interim Commission on Phytosanitary Measures (2-6 April 2001)*. UN Doc. ICPM 01/Report. Obtained from Plant Protection Convention WWW site (accessed September 2001).

ICPM. 2001b. *Report of the Joint Consultation on the International Plant Protection Convention and the Convention on Biological Diversity (6-8 June 2001).* UN Doc. ____, in: Interim Commission on Phytosanitary Measures (ICPM). 2001a. *Report of the Third Interim Commission on Phytosanitary Measures (2-6 April 2001)*. UN Doc. ICPM 01/Report. Obtained from Plant Protection Convention WWW site (accessed September 2001).

ICPM. 2000. Statements of the ICPM Exploratory Open-ended Working Group on Phytosanitary Aspects of GMOs, Biosafety and Invasive Species (13-16 June 2000). UN Doc. ____, in: Interim Commission on Phytosanitary Measures (ICPM). 2001a. *Report of the Third Interim Commission on Phytosanitary Measures (2-6 April 2001)*. UN Doc. ICPM 01/Report. Obtained from the Plant Protection Convention WWW site (accessed September 2001).

International Plant Protection Convention (IPPC). 1996a. CODE OF CONDUCT FOR THE IMPORT AND RELEASE OF EXOTIC BIOLOGICAL CONTROL AGENTS. FAO, Rome.

IPPC. 1996b. GUIDELINES FOR PEST RISK ANALYSIS. FAO, Rome.

Jenkins P. 2001. Written communication from Peter Jenkins of the Center for Food Safety, International Center for Technology Assessment on 6 December 2001.

MacKenzie D. J. 2000. *International Comparison of Regulatory Frameworks: Report to the Canadian Biotechnology Advisory Committee Project Steering Committee on the Regulation of Genetically Modified Foods.* Obtained from the Canadian Biotechnology Advisory Committee WWW site (accessed August 2001).

Madkour M., El Nawawy A. and Traynor P. 2000. *Analysis of a National Biosafety System: Regulatory Policies and Procedures in Egypt.* International Service for National Agricultural Research, The Hague.

Organisation for Economic Co-operation and Development (OECD). 1992. SAFETY CONSIDERATIONS FOR BIOTECHNOLOGY. OECD, Paris.

Royal Commission on Genetic Modification of New Zealand (RCGM). 2001. REPORT OF THE ROYAL COMMISSION ON GENETIC MODIFICATION. Wellington, New Zealand. Obtained from the Royal Commission WWW site (accessed July 2001).

RCGM. 2000. *Appointment and Order of Reference*. Obtained from the Royal Commission WWW site (accessed October 2001).

Royal Society of Canada. 2001. *Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada. Report of the Expert Panel on the Future of Food Biotechnology.* Royal Society, Ottawa. Obtained from the Royal Society WWW site (accessed July 2001).

Sendashonga C. 2001. Written communication from Cyrie Sendashonga of the Secretariat to the Convention on Biological Diversity on 28 November 2001.

United Nations Economic Commission for Europe (UNECE) (Committee on Environmental Policy). 2001. REPORT OF THE SECOND MEETING OF THE TASK FORCE ON GENETICALLY MODIFIED ORGANISMS (UNDER THE AARHUS CONVENTION). UN Doc. CEP/WG.5/AC.3/2001/3. Obtained from the UN Economic and Social Council WWW site (accessed October 2001).

UNECE. 2000. REPORT OF THE FIRST MEETING OF THE TASK FORCE ON GENETICALLY MODIFIED ORGANISMS (UNDER THE AARHUS CONVENTION). UN Doc. CEP/WG.5/2000/6. Obtained from the UN Economic and Social Council WWW site (accessed October 2001).

United Nations Economic and Social Council (UNESC). 1998. *Report of the Secretary General: Consumer Protection: Guidelines for Sustainable Consumption*. UN Doc. E/CN.17/1998/5. Obtained from the UN Commission on Sustainable Development WWW site (accessed October 2001).

United Nations Environment Programme (UNEP). 1995. TECHNICAL GUIDELINES ON BIOSAFETY. UNEP, Nairobi.

United Kingdom Food Standards Agency. _____. *Openness* (date unknown). Obtained from the Food Standards Agency WWW site (accessed January 2002).

United Kingdom Joint Regulatory Authority, *et al*. 2000. *The Legal Framework for Decision-making on the Release and Marketing of GMOs in the European Union: Background Paper to the UK Agriculture and Environment Biotechnology Commission*. Obtained from the Agriculture and Environment Biotechnology Commission WWW site (accessed July 2001).

World Health Organisation (WHO). 2000. *Safety Aspects of Genetically Modified Foods of Plant Origin: Report of a Joint FAO/WHO Expert Consultation on Foods Derived from Biotechnology*. UN Doc. WHO/SDE/PHE/FOS/00.6. Obtained from the Codex WWW site (accessed September 2001).

Young T.R. 2001. Written communication from Tomme Young of the IUCN Environmental Law Centre on 17 December 2001.