Law and modern biotechnology

Selected issues of relevance to food and agriculture

FAO LEGISLATIVE STUDY 78

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FOREWORD

The rapid progress of modern biotechnology has given rise to new legislative needs, in order to safeguard human health and the environment while at the same time taking advantage of the opportunities offered by biotechnology. Recent years have seen important new legislation being adopted, and older law amended in order to respond to the new challenges.

Considerable public debate has taken place over some of these technologies, in particular genetic engineering. While direct risks and benefits have been the main focus of that debate, other issues, social and ethical, have also been part of it. Therefore, it seemed opportune not only to study the way in which new legislation handles risk assessment and licensing for new technologies or products derived therefrom, but also the way in which other considerations are taken into account, and how the general public is given an opportunity to participate in the decision-making process.

The important ethical dimension of modern biotechnology has been considered by FAO in its Ethics Series publication "Genetically modified organisms, consumers, food safety and the environment", and by the Panel of Eminent Experts on Ethics in Food and Agriculture. The Panel requested FAO to review the status of regulations in different countries concerning the application of biotechnology and GMOs. FAO then commissioned a paper by Mr Lyle Glowka of Biodiversity Strategy International, which was used as background material for the Second Session of the Panel in March 2002. Following the Panel Session, the study was expanded by Ms Antonella Ingrassia (Legal Consultant, FAO).

The study has benefited at various stages from the comments and contributions of a number of people, including: 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), 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). Colleagues at FAO who contributed to the preparation of the study include David Byron, José T. Esquinas-Alcázar, Daniele Manzella, Ali Mekouar, Marta Pardo-Leal, Alan Randell and Margret Vidar.

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Contents

List of abbreviations

ACNFP	Advisory Committee on Novel Foods and Processes of the United Kingdom
AIA	Advanced Informed Agreement
ANFZA	Australia New Zealand Food Authority
ASEAN	Association of Southeast Asian Nations
CBAC	Canadian Biotechnology Advisory Committee
CBD	Convention on Biological Diversity
CEC	Commission of the European Communities
CFIA	Canadian Food Inspection Agency
CTNBio	National Technical Biosafety Committee of Brazil
DNA	Deoxyribose Nucleic 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
NAGM	National Authority on Genetic Modification
OAU	Organization for African Unity (African Union)
OECD	Organization 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 Organization
WHO	World Health Organization
WTO	World Trade Organization

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 around the world.

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 realize 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 is designed around a number of thematic areas that may contribute to assisting societies to realize 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 II describes the nature of the instruments addressing biotechnology. Public participation, including access to information and labelling, is a major tool for realizing the potential and avoiding the risks of modern biotechnology. How the instruments reviewed address public participation is described in Section III. 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 IV.

Finally, section V 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.

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.

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 realize 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 recognized 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 cooperation 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 the biosafety area no international instruments specifically address labelling**.** 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 organizations 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 harmonize standards. For food, harmonization 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.

Oversight Mechanisms

The oversight process may contribute to maximize 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, maximizing the benefits and minimizing 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 (IBCs). 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 legislation and 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, namely "substantial equivalence" in the food safety area. The concept is intended to identify similarities and differences between new food and conventional counterparts in order to focus the safety assessment procedure on identified differences. 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 emphasizes 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 practised 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 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 minimizing 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**.**

INTRODUCTION

I. 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 operationalized. Recent years have seen rapid technological advances 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 realize the potential and avoid the risks of modern biotechnologies, including GMOs.

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

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

1.1. Methodology of the Study and Format

The study is comparative in nature. It reviews legal instruments at international, regional 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. A selected subset of countries is referenced in the study following the "FAO Member Nations by region" classification.

The study is designed around a number of thematic areas that may contribute to assisting societies to realize 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 II describes the nature of the instruments addressing biotechnology. Public participation, including access to information and labelling, is a major tool for realizing the potential and avoiding the risks of modern biotechnology. How the instruments reviewed address public participation is described in section III. 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 IV.

Finally, section V 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.

II. 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 minimize 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 victimized 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 Organization (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 Organization (FAO) International Plant Protection Convention (IPPC) (1997), Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters (1998), the CBD Cartagena Protocol on Biosafety (2000) and the International Treaty for Plant Genetic Resources for Food and Agriculture (2001).

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 Organization (UNIDO) Voluntary Code of Conduct for the Release of Organisms into the Environment (1991), 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 December 2002), 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 Revized 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 finalized 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 twenty-two countries and regions were reviewed for this study. Twenty 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 applied "voluntary" guidelines.

For example, as of December 2002, 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 Plant Variety Protection Act set rules for the registration of a new plant variety derived from genetic modification which can be registered as new plant variety only upon a successful result of a safety appraisal with regard to environment, health or public welfare.

The extent to which a voluntary system helps to realize 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.

An example at the regional level is the "Biodiversity Regional Strategy" which has been recently developed by the Andean Community. The Andean Community is a sub-regional organization with international legal status composed of Bolivia, Colombia, Ecuador, Peru and Venezuela and the Andean Integration System (AIS). The Biodiversity Regional Strategy contains provisions on biosafety dealing with living modified organisms (LMOs). The need to develop a regional approach to biosafety arises from the lack of uniform regulatory mechanisms. Recognizing the validity of existing legal instruments, new ones concerning the implementation of the Regional Strategy could be established and developed by the Andean Community Secretariat through Resolutions and/or Decisions.

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 commercialization. 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 commercialization of GMOs when the need arises.

The extent to which a step-wise approach helps to realize 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 generally 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 country's own unique circumstances.

General laws on food safety and consumer protection do exist in developing countries 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 realize 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?

A legal instrument is product-oriented when 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).

III. PUBLIC PARTICIPATION IN POLICY-MAKING AND REGULATORY DECISION-MAKING

One of the most useful legal tools for realizing 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 (sect. 3.1) and access to the judicial system (sect. 4.4.2.3).

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 realize 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 Aarhus is only a regional convention. Therefore, though it may be a good example, its reach may be limited.

The Aarhus Convention specifically mentions GMOs in the context of decision-making (art. 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 recognizes "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 Clearing-house (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 (arts. 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 (arts. 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 minimize 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 (sect. II-A-1(a)). It covers GMOs in all stages of research, development and disposal while focussing on release into the environment (sect. 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 (sect. II-C-1((e)). Furthermore, maximum disclosure of information necessary for risk assessment may be balanced by respect for confidential business

information (sect. C-2(h)). The local community should be informed of a planned introduction prior to release and appropriate educational materials should be provided (sect. II-C-2(i)). In addition, public access to information upon which decisions regarding use or release of organisms should be ensured (sect. 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 (sect. 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 (sect. 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 (sect. III(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)).

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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 (sect. 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 (sect. 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 (sect. 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 (sect. 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 (sect. 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 (sect. 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 (sect. 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 (art. 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 authorization criteria in article 4(1), the application must include *inter alia* a dossier summary (art. 6(3)(l)). The Authority would make the applicant's dossier summary available to the public (art. 7(3)(c)). Favourable opinions by the Authority are to be made available to the public after deletion of confidential information (art. 7(7)).

The European Commission will prepare a draft decision. The authorized food is entered into the proposed Community Register of Genetically Modified Food and Feed and made available to the public (art. 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" (art. 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 (art. 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 (art. 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 (art. 11).

Part C (marketing and commercialzation) 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 (art. 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 commercialization (art. 15(3) and art. 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 (art. 18) are made accessible to the public (art. 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 (art. 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 (art. 25(1)). The notifier may indicate that information whose disclosure might harm his competitive position and which should be treated as confidential (art. 25(2)). He must provide verifiable justification. The competent national authority consults with the notifier and decides which information shall be kept confidential (art. 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 (art. 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 (art. 31(3)(a)). They are to also create registers for GMOs grown under Part C whose locations shall also be publicly available (art. 31(3)(b)).

The African Union has issued draft model legislation on 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)).

Another example of a draft law on GMOs is the one issued in Tunisia on the contained use, deliberate release and commercialization of GMOs . Public information requirements are reflected in article 7. A dossier containing all the information concerning the utilization of GMOs in public or private laboratories is to be made available to the public. The dossier is to contain, with the exception of information protected by trade and industrial secrets and by the law, general information on: (1) the activities of laboratories and the purposes of research; (2) GMOs to be used; (3) containment measures; (4) emergency plans in case of accidents, which have to be approved by the Biosafety National Commission; (5) traceability of GMOs; (6) consumers' information on the presence of GMOs in certain products; (7) a summary on the opinion of the Biosafety National Commission; and (8) the address of the Biosafety National Commission for any comment the public may wish to send. The right for any person to have information on the possible impact on the environment, biodiversity and human health which may be caused by a deliberate release of GMOs is also recognized. Notwithstanding this, access to information is subject to confidentiality provisions.

Similarly, access to information is addressed in a certain number of laws in the Latin American countries analyzed. According to Law No. 27104 on the prevention of risks derived from biotechnology issued in Peru, anyone wanting to introduce into the national territory LMOs to be used for research, production, manipulation, transfer, conservation, commercialization, contained use and release, must submit a formal application to the competent authority. The application is to include all the information necessary for carrying out a risk assessment. When the application is received, an informative summary is published at the national level. The information contained in the application is subject to confidentiality restrictions that are actionable by the claimant to avoid unfair use. Information that cannot be kept confidential includes: the name of the applicant, the objectives of the activities to be realized, where these will be realized, methods and plans of monitoring, emergency plans and risk assessment reports. Confidentiality restrictions cannot be authorized when the application concerns activities which may cause damage to human health, the environment and biodiversity.

In Costa Rica, Law 7788 on Biodiversity regulates the import, export, trials, and release into the environment, commercialization and use of GMOs. A permit is required prior to carrying out these activities. Anyone realizing activities of genetic manipulation is to be registered with the Technical Bureau of the National Technical Commission on Biosafety. The Technical Bureau is to organize and update a register of rights to access to genetic and biochemical elements. The Director of the Technical Bureau will also act as Director of the Register and is responsible for the safe-keeping and authenticity of the registered information. Such information will be public except for that protected by industrial secrets. If public disclosure is due to biosafety reasons trade secrets can not be invoked as a reason to maintain confidentiality.

Decree No. 190 on Biological Safety issued in Cuba includes provisions on the development of an information policy. Representatives of the State Central Administration, as well as researchers involved in this field, upon consultation with the Ministry of Science, Technology and Environment, are responsible for developing a policy on public information that is to be mainly addressed to people directly or indirectly involved with the release. The policy is to be developed in collaboration with the National Health System, political organizations and mass media (art. 9).

Under the Mexican Law on Sustainable Rural Development the Federal Government is to establish mechanisms and instruments for biosafety related to the production, import, handling, propagation, release, consumption, use and general development of such organisms, their products and sub-products, providing sufficient information to the consumers (art. 97).

In Brazil, pursuant to Law No. 8974 any organization using genetic engineering techniques and methods shall create an Internal Biosafety Commission/CIBio (art. 9). A CIBio will be responsible for, *inter alia*, providing to employees and to the community information on possible effects caused by activities related to GMOs, including information related to health, safety and to procedures to be followed in the event of accidents.

In relation to the Asian region, public access to information is not addressed in the ASEAN Guidelines on Risk Assessment of Agriculture-related Genetically Modified Organisms (1999). Public access to information requirements were not identified in the instruments reviewed in Indonesia, Philippines and Thailand.

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 sect. 4.4.3.2 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, no general rules on labelling are in place. The rules for GMOs and food are being developed within the Codex Alimentarius. In the biosafety area, the Cartagena Protocol on Biosafety to the CBD sets out in article 18 the obligations of Parties concerning the identification of living modified organisms (LMOs). Article 18 provides different obligations for LMOs intended for direct use as food or feed or for processing (LMO-FFPs) (subpara. (a)), LMOs destined for contained use (subpara. (b)), and LMOs intended for intentional introduction into the environment (subpara. (c)).

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 Organization's Agreement on Technical Barriers to Trade will ensure that labelling is applied according to the principles of necessity and proportionality so as not 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 recognizes 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 to 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 harmonized world wide labelling practices related to foods derived from modern biotechnology in order to minimize 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, step 6). 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 December 2002.

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/different significantly from conventional counterparts; (2) no longer equivalent/different significantly from conventional counterparts; (3) 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 (sect. 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 (sects. 3, paras. 3.1 and 3.2). Criteria would be provided for labelling the method of production (sect. 3, 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 (sect. 3, para. 3.5). Threshold levels for the presence of GM/GE organisms and the trigger for labelling are still under discussion (sect. 4). 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 (sect. 6).

In 1999, the Codex Commission adopted Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Food. 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 harmonize 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 (sect. 1.1). Products include (a) unprocessed plants and plant products, livestock and livestock 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 (growing, manufacturing or processing) and therefore are not accepted under these guidelines" (sect. 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" (sect. 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 (sect. 3.3). Derogations are allowed when ingredients of agricultural origin do not satisfy the enumerated specifications (sect. 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 December 2002, 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" (sect. 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 (sect. 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 categorized 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 (sect. 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.

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 (sect. 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 (sect. 1.2).

Distinctions are made between claims for single ingredient and multi-ingredient food (sect. 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 percent are products of gene technology (sect. 5.2). Similarly, a 5 percent threshold is proposed for multi-ingredient foods claimed to be produced from gene technology (sect. 5.3). Conversely, a threshold of less than 5 percent is proposed for single and multi-ingredient foods claimed not to be a product of gene technology (sect. 6).

Verification provisions are established. No claim is permitted if it cannot be verified (sect. 7.1). The person making the claim is responsible for providing the data necessary to verify the claim (sect. 7.2.2). Provisions on confidential information are proposed. The claimant must have in place a verification system (sect. 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 (sect. 7.3.2). The standard is equivocal on testing and detection methods (sect. 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 December 2002, Thailand does not appear to have food safety laws in place for genetically modified foods. However, a regulation was drafted by the Food and Drug Administration (FDA) for mandatory labelling of genetically modified food (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") (art. 1(1) and (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 (art. 1(2)(a) and (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 (art. 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 (art. 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 (art. 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 (art. 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 (art. 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 (art. (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 (art. 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 (art. 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) (art. 4(1)) or "genetically modified" (where an additive or flavouring is or contains an organism modified by GM techniques (art. 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 authorization 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 (art. 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 (art. 13(2)). This leaves open the possibility that labelling requirements may apply to a threshold of adventitious materials different than that set for authorization (one percent). As with the procedures for GMO food authorization, 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 (art. 14(1)). Generally, the words "genetically modified" or "produced from genetically modified [name of organism] but not containing a [GMO]" must appear (art. 14(1)(a)–(c)). Food without pre-packaging must have similar wording displayed on or in connection with the food's display (art. 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 (art. 14(2)(a) and (b)). Where a food does not have a conventional counterpart the label is to include information about the food's nature and the characteristics (art. 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 (art. 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 (art. 27(3)(a) and (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 (art. 27(3)(c) and (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 – sect. 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 – sect. 4) must be labelled with an appropriate statement ("genetically modified") in conjunction with the name of the food or ingredient or processing aid (sect. 5). Exemptions may apply. For example, highly refined foods where the processing removes the novel DNA or novel protein (sect. 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 percent) does not trigger the labelling requirement (sect. 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" (sect. 7(e)).

3.2.2. Labelling Related to Biosafety at International and National Levels

At the international level, the Cartagena Biosafety Protocol to the CBD does not address labelling in a clearly specified 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 sect. 4.3.3.2). Notwithstanding this, it is important to note that article 11 refers to LMOs intended for direct use as food or feed, or processing. As these labelling provisions cover also such LMOs, they may be interpreted as indirectly protecting consumers.

According to the Protocol, 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 legislation reviewed at the regional and national level, only those in the African Union, Mexico, Tunisia 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)).

The Official Mexican Standard NOM-056-FITO-1995 establishes the phytosanitary requirements for interstate movement, import and conduct of field trials with regard to GMOs. Transgenic products must be identified and labelled as such when released, moved and/or imported. Labels must be visible on the container or package and have, *inter alia*, information on: (1) the general nature and quantity of the content; (2) on the country and/or place where the product was collected, developed, manufactured, cultivated or reproduced; (3) on the name and address of the carrier and sender and (4) on the number of the plant health certificate for release and/or import.

In Tunisia, pursuant to the draft Law Concerning the Import and Transfer of GMOs, any product imported into or transiting through the national territory is to be packed in a safe manner. Labels specifying the presence of GMOs are to be visible on the package. Informative notification facilitating control procedures is to accompany the package.

Within the European Union, Directive 2001/18/EC will act as a reference for GMOs as or in products authorized 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; arts. 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; art. 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 (art. 21(1)). Where adventitious or technically unavoidable traces of authorized GMOs cannot be excluded, minimum thresholds may be established below which the products require no labelling (art. 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 realize 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 Policy-Making

Policy-making 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 its 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 few 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 (specialized 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 emphasized 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. Under the Aarhus Convention 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 (arts. 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)).

It is important to note that public participation in decision-making is strengthened by the provisions of article 9, according to which the substantive and procedural legality of any decision, act or omission taken under Article 6 can be challenged by members of the public concerned through a review procedure before a court and or another impartial body (art. 9(2)).

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)).

The Cartagena Protocol on Biosafety to the CBD contains provisions on public participation in decision-making. The Parties shall in accordance with their respective laws and regulations, consult the public in the decision-making process regarding LMOs and shall make the results of such decisions available to the public, while respecting confidential information (art. 23). The qualification ('in accordance with their respective laws and regulation') 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 (v. 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 (sect. 49, para. 3). Once an assessment and plan are completed, the Regulator must again notify the public that they are available for comment (sect. 52, para. 2). The Regulator may also hold public hearings (sect. 53).

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

The applicant must apply to the Regulator for a declaration of confidential commercial information (sect. 184). Criteria are provided to guide the Regulator's decision-making (sect. 185). The Regulator may refuse a declaration when the public interest in disclosure outweighs the prejudice disclosure would cause to the information holder (sect. 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 (sect. 185, para. 2(a)). The Regulator must make publicly available a statement of reasons for making the declaration (sect. 185, para. 3(a)).

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 authorized by the license can be managed to protect human health and safety and the environment (sect. 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 (sect. 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" (art. 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 (art. 24(1)). The public can also only provide "comments" on the assessment reports (art. 14(3)(a)) which comprise the competent authority's assessment of the notification and which is also forwarded to the Commission (art. 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 four 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 realizing 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 realized. 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.

Of the remaining developing countries analyzed, none specifically addresses the issue.

IV. 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 maximize 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 International Plant Protection Convention requires its contracting parties "to make provision for" an official national plant protection organization (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 Cartagena Biosafety Protocol to the CBD requires each of its contracting parties to designate one or more competent national authorities (art. 19(1)). These are to be authorized 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 agro-ecological 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. For example, the ASEAN Guidelines on Risk Assessment of Agriculture-related Genetically Modified Organisms (1999) require each member country to establish a National Authority on Genetic Modification (NAGM) which consists of representatives from national agencies involved in agriculture, trade, economics, environment, health, science, technology and any other sectors that are deemed appropriate by the respective NAGMs.

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. It also defines the conditions of commerce and labelling of GMOs and the products that contain them (art. 3(II)). The Commission 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 authorization.

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 (sect. 1).

The NCBP has a multi-disciplinary membership including various scientists, a social scientist, citizens and representatives from various governmental agencies (sect. 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 minimization 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 (sect. 4). The Department of Science and Technology provides the NCBP's secretariat (sect. 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 (sect. 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 (sect. 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 (sect. 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 (sect. 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 (sect. 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 (sect. 5(a)); (2) require a registrar to examine an application's conformity with the Act (sect. 5(b)); and (3) approve the use of facilities or a release (sect. 5(g)). The Council may also inform any other country of an accident that may have an impact on that country's environment (sect. 5(i)) and approve and publish guidelines for all GMO uses (sect. 5(l)).

The Act establishes an Advisory Committee whose members are appointed by the Minister after recommendation by the Council (sect. 10(1)). The Committee's membership is to reflect representation from all fields of expertise involved with GMOs (sect. 10(2)). The Committee is to act as the national advisory body on all matters related to genetic modification of organisms (sect. 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 (sect. 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 (sect. 11(1)(d)). Committee members are to recuse themselves when the Committee considers subjects in which they have direct or indirect interest (sect. 13).

Under the Peruvian 'Law on the Prevention of Risks Derived from Biotechnology' an Environment National Council (CONAM) is established. It functions as the competent authority for the coordination of matters in the field of conservation and sustainable exploitation of biodiversity. CONAM promotes, through the Framework of Environmental Management, coordination among the various authorities involved in the field of safety in biotechnology (art. 5.1). The National Commission on Biological Diversity (CONADIB) is the advisory body for matters of safety in biotechnology. It supports CONAM in the proposal of guidelines on living modified organisms (art. 5.2).

In Mexico, pursuant to the Official Standard NOM-056-FITO-1995, the General Directorate for Plant Health is the responsible authority which issues the certificates for genetically manipulated products to be released into the environment (Annex 3). Certificates can only be issued upon a favourable opinion from the National Agricultural Biosafety Committee. The General Directorate submits the application to the Committee for review. A copy of the application and of the Committee's opinion is sent to the relevant governmental office and, in the case of exports, to the pertinent governmental authority of the country in which the GMOs will be released. The governmental office and/or the government of the country shall have a maximum of 30 calendar days to send comments to the head of the General Directorate for Plant Health (3.2.2).

Under the Mexican Law on Sustainable Rural Development the Federal Government is to establish a National System of Health and Food and Agricultural Quality. The Secretariat of Agriculture, Livestock, Rural Development, Fishery and Food will coordinate the activities of the National System (art. 92). An Inter-Secretariat Commission, with the participation of the Mexican Council, will propose to the Secretariat of External Relations, the adhesion to treaties and international instruments considered necessary in the field of genetically modified organisms. It may also promote agreements to harmonize phytosanitary requirements (art. 95).

In Tunisia, a Biosafety National Commission, *inter alia*, (1) provides technical opinions on any application for import, contained use, deliberate release and commercialization of GMOs; (2) verifies and analyzes documents prepared for risk analysis; (3) supervizes the risk analysis for the release and commercialization of GMOs; (4) sets limits for the presence of GMOs in food products, seeds and plants; establishes and updates the list of GMOs to be regularly controlled; (5) prepares a list of experts in the field of GMOs; (6) sets up the conditions and modalities for transport of GMOs within the national territory; (7) controls any GMOs imported or locally produced; and (8) gives advice on establishing national policy and assisting the competent organizations in establishing biotechnology regulations in the field of biotechnology and the competent institutions in implementing such regulations (art. 9).

Some instruments 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 (sect. 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 (sect. 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 (sect. B, para. 1.2).

Among its functions an IBC is to review work conducted or sponsored by the institution and recommend research proposals (sect. 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 (sect. B., para. 2.1.3). An IBC should also formulate and adopt emergency plans and notify the National Committee on Biosafety about significant problems (sect. B, paras. 2.4 and 2.5).

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

4.2.1. 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 (sect. 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 (sect. 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 minimized or eliminated. In particular, some uses of substantial equivalence are becoming increasingly criticized.

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 recognized 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 recognized 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 minimize 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 (sect. 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 organizations 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 emphasizes preventing and mitigating possible negative effects of agro- and food biotechnologies. To this end, the draft Code first emphasizes foreseeing and preventing possible negative socio-economic effects of agro- and food biotechnologies (art. 8.1). Governments and international organizations 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 emphasize 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 (sect. 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 (sects. 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 "recognized 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 authorization 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 is 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 (sect. 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 (sect. 3, para. 23). Responsive consultation processes should be created (sect. 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.

In some cases, the identification of risks is undertaken through classification according to the different levels of threat to human health and ecological environment. For example, China's Safety Administration Regulation on Genetic Engineering (1993) sets out four safety classes. Different responsibilities for undertaking the safety evaluation are associated with each class. Similarly, the French Decree No. 98-18 (1998) defines four risk levels in order to classify GMOs.

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. 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)).

In Costa Rica, the Plant Protection Law contains provisions on risk assessment. Risk assessment is to be carried out considering: (1) scientific evidence; (2) adequate processes and methods of production; (3) adequate methods of inspection; (4) the presence of pests; (5) the existence of area free of pests; (6) pertinent ecological and environmental conditions and (7) quarantine systems (art. 45). In such risk assessment explicit reference is made to the consideration of economic factors, such as the possible damage for lost production or sale in case of entry; propagation of diseases; the costs for the control or eradication within the national territory and the relation cost-efficacy of others possible methods to eliminate risks. The Peruvian Law on the Prevention of Risks Derived from Biotechnology provides criteria for risk assessment procedures to be carried out on a case-by-case basis (art. 13).

Who actually undertakes the risk assessment depends on the country and may have a bearing on realizing 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. Similarly, in China the risk assessment is completed by the institutions carrying out genetic engineering work and subsequently re-examined by relevant administrative departments at different levels. In contrast, the Australian Office of the Gene Regulator undertakes the risk assessment based upon information supplied by the proponent. In Cuba process of risk assessment concerning areas for release of GMOs is to be followed by owners and/or whoever is responsible for such areas. The Ministry of Science, Technology and Environment has supervisory functions. In the food safety area, the Australian New Zealand Food Authority assesses, approves and lists foods produced from gene technology that may be imported into the two countries. In the plant protection area, it is responsibility of Costa Rican State Phytosanitary Service to make sure that phytosanitary measures are based on an adequate assessment of the risks to human health and to the protection of plants.

It is difficult to ascertain which approach – assessment by the proponent or assessment by the regulator - 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.

4.2.2. Risk Management

The underlying principle of risk management is to identify and take steps to eliminate or minimize 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 minimized, 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 minimize potential adverse effects (arts. 10(6)).

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 (sect. 3, para. 18).

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[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 micro-organisms – 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 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 regional and national instruments 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. The same principle is reflected in other developing countries' legislation.

For example, in the Mexican Law on Sustainable Rural Development the precautionary principle provisions apply in case of presumption of risks or adverse effects deriving from the use of GMOs when no scientific adequate evidence is available (art. 97). In Peru, the principle is reflected in art. 10 of the Law on the Prevention of Risks Derived from Biotechnology. Analysis of the negative impacts to human health, the environment and biodiversity, which may be caused by the release of LMOs, is to be carried out. The State can refuse authorization for the use and release of LMOs where threat of serious damage exists, and only if such denial has technical justification and does not constitute a technical barrier or restriction on trade.

In the finalization process of the Andean Community Biodiversity Regional Strategy, a series of principles have been identified in the context of the Biosafety Strategy. One of those is the precautionary principle.

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 harmonize 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" (sect. 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 (sect. 57).

As is the case with risk assessment, additional principles have been recognized 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 harmonize 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 minimize 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 minimized to acceptable levels. If risk cannot be minimized 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 (sect. 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). The various aspects of the release should match the potential risks. In other words, any scale-ups should be evaluated and authorized 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" (sect. 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.

4.2.2.1. 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 minimize the risks of modern biotechnology.

After receiving consent, the authorization 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 authorization 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 organizations 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 are 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 (sect. 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 (sect. 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 (sect. 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 authorization 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)).

The Official Mexican Standard NOM-056-FITO requires the issuance of a plant certificate for the release into the environment and/or import of GMOs. If the certificate is granted, the Secretariat of Agriculture, Livestock and Rural Development appoints officers to inspect and to monitor the transgenic product released. They are also to receive a periodical update.

In Brazil, pursuant to Law No. 8974, any organization using genetic engineering techniques and methods is to create an Internal Biosafety Commission/CIBio. A CIBio is responsible for, *inter alia*, (1) establishing prevention and monitoring programmes; (2) maintaining progress reports for each activity or project involving GMOs; (3) notifying the National Biosafety Commission (CTNBio), the Public Health Authority and employees' organizations of the results of risk assessment as well as of any accident that may be caused by the dissemination of biological agents; and (4) investigating accidents and pests possibly related to GMOs.

A Biosafety National Commission is to be created under the Tunisian draft Law on the Contained Use, Deliberate Release and Commercialization of GMOs. The Commission is tasked with, *inter alia*, monitoring any GMO imported or locally produced.

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 provides 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 authorization holders will have supervisory obligations to undertake post-market monitoring and report to the European Food Authority (art. 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 (art. 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 (sect. 112 of the 1990 Environmental Protection Act as amended by regulation 9 under the GMO Deliberate Release Regulations of 1992).

4.2.2.2. 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 3.2 (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 minimize 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. In the biosafety context, this latter role is being further examined under the Biosafety Protocol pursuant to article 18(2) in cooperation with other fora.

4.2.2.3. 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 (sect. 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 (sect. 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, art. 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, art. 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), authorization 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 Tunisian draft Law on the Contained Use, Deliberate Release and Commercialization of GMOs refers explicitly to traceability. A dossier containing all the information concerning the utilization of GMOs in public or private laboratories has to be made available to the public. The dossier is to include, with the exception of information protected by trade and industrial secrets, general information on traceability of GMOs.

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 realizing 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 commercialization. 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 Alimentarius Commission has been working to further elaborate "other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade" (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 ".....will have regard, where appropriate, to other legitimate factors ..." as it develops and adopts food standards.

The Codex Alimentarius Commission has adopted "Criteria for the Consideration of the Other Factors Referred to in the Second Statement of Principle" as a final Codex text (Codex, 2001c). Other Codex committees are feeding into the Commission'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 micro-organisms 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 recognizes 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 finalized 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 emphasized.

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 micro-organisms (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.

In Costa Rica, pursuant to the Plant Protection Law, in the risk analysis carried out to protect plants and to identify measures to achieve an adequate level of phytosanitary protection, the State Phytosanitary Service is to take also into consideration economic factors, such as the possible damage for lost of production or sale in case of entry and propagation of pests; the costs for the control or eradication within the national territory; the relation cost-efficacy of others possible methods to eliminate risks. In determining the adequate level of phytosanitary protection, the Service will have to consider the objective to reduce to the minimum the negative effects on the commerce and will not constitute a restriction to it.

The Biodiversity Regional Strategy for the Andean Tropic Countries contains provisions on biosafety. Reference is made to security measures that are to be designed to minimize the LMO-related risks for sustainability of the environment, biological diversity, human health and the socio-economic structure.

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 (art. 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 (art. 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 (art. 31(7)(d)). Finally, the Commission will report annually to the Council and the Parliament on ethical issues (art. 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 realize 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 not undermine traditional knowledge and technologies" (art. 6(8)).

Resolution 76/200 on Biological Safety for the Facilities where Biological Agents and their Products, Organisms and Fragments with Genetic Information are Used regulates in Cuba the granting of authorizations in the field of biosafety. The authorization of "safety in biodiversity" is necessary to: (1) construct, restructure, start up and closure of laboratories which use micro-organisms, their products and GMOs; (2) research, production and field trials of such organisms; (3) release into the environment; (4) import and export; and (5) transfer of dangerous waste (art. 3). The authority responsible for granting such authorization will proceed with an analysis of the documents presented by the applicant and with a risk analysis for each activity mentioned in the application.

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" (sect. 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 authorized by the license can be managed to protect human health and safety and the environment (sect. 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 (sect. 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 (sect. 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 (sect. 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 (sect. 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 (sect. 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 ('procedures and guidelines on the introduction, movement and field releases of regulated materials', sect. 1, para. 1.1.6).

V. 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 realize 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 recognized 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 organizations 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 harmonize standards. For food, harmonization 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 maximize 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 emphasizes 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 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.