THE REGULATION OF GENETICALLY MODIFIED ORGANISMS*

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It has long been possible for scientists to ignore the social sciences, humanities and law. Indeed, many scientists still protest that legal or societal curbs should not affect their work; that it is the technological application of pure science that needs regulation rather than that which is done in the science laboratory. A famous physicist once said (when asked about the practical application of his work) that if he became aware of any practical application he would immediately change that which he was doing.

The need to obtain money to facilitate research has directed that which is being done in the laboratory. It is perhaps true that science has always been achieved at the whim of a patron, and that the patron has often dictated that which can or cannot be researched. Innovation depends both of the quality of scientific research and the realisation of practicality that follows discovery. Much of the disquiet (in some countries) that is associated with genetic modification is related to the manner of its exploitation, particularly in agriculture. Advances in medical science that have used the same technology as that used for agriculture have occasioned much less opprobrium. It may be that the regulatory system that controls the introduction of pharmaceuticals into a market has a greater degree of trust than that which is perceived to impact on agriculture and chemicals used therein.

Science (and its exploitation) has to be regulated by society which decides on the norms that should apply. This regulation needs to ensure that basic science is not inhibited and that innovation can still occur. Some countries have permitted research on embryos; others have applied

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the brakes. Some have permitted embryonic stem cell research; others control or even ban the research. Legislators in some jurisdictions have indicated that germ line gene therapy is morally wrong. Hence the impact on pure research and development of social ideas and law is significant, and scientists and social scientists are beginning to recognise the importance of working with and for one another.

Science is about pushing frontiers, discovering how things work and why. Often the experiments themselves or the apparatus designed for and used to increase knowledge are dangerous to the workers in the facility if for no other reason than the results may be unpredictable. This is different from development of known science, where prediction of danger can be made. Towards the end of the 20th century attempts were made to ensure the safety of those engaging in the science - insofar as it is practical when the unknown is being probed. Basic rules that address the safety of those who might be working on a topic, those who are working in the same facility, or those who are casually within the facility have been instituted. In reality, safety laws only work if scientists are aware of them, understand their logic and the reasoning behind them, and accept that they are sensible. Where blanket laws are applied that seem to lack credence or sense to those working in a laboratory, they will not obey the law. Law is brought into disrepute if applied excessively and without an understanding of the difficulties research scientists face in pursuing new knowledge.

It is possible to separate the generation of new knowledge in research laboratories from the exploitation of that knowledge in commercial endeavour. The regulatory systems are different, for in the first instance it is primarily those with access to the research facilities that need protection, whilst there are many other areas of major concern when a product is released into a commercial environment. Consumers expect protection; systems of liability and redress in case of harm need to be addressed; and the environment needs protection in a sustainable manner. The commercial exploitation of research is subject to many legal restraints. In medicine, drugs have to be shown to work and not to have excessive side-effects that may challenge those already ill in unexpected ways. Food has to be wholesome and as safe as those already on the market. Consumer protection law enacted in most countries ensures that products that have the potential to harm those using them are either not permitted to enter the market place or are withdrawn rapidly. Litigation has re-

sulted in companies being careful about that which is introduced into commerce. Protection of the environment where effects may be indirect and even delayed for many years is much more difficult.

While all pharmaceutical products and most industrial products have been subject to regulation, specific regulation of modern biotechnology has been introduced in many countries throughout the world. The acceptability of these products in a particular market is governed by many factors which appear to relate to the culture (and even legal culture) of the society. The United States has accepted GM products (in particular foods) with little opposition although public opinion surveys suggest people are wary. GM derived medical products and drugs seem to be acceptable in most societies, but GM foods (and to some extent feed) are deemed unacceptable in many, including most of the European Union.

The exploitation of scientific endeavour for the financial gain of the scientist and the institution is also important. The property that is inherent in knowledge, discovery, innovation and invention needs to be protected but also disclosed to other scientists in order for knowledge to progress. Scientists do not necessarily have the experience or understanding to fully exploit that which they discover and invent without the involvement of non-scientists in the exploitation of discovery.

Ethical and legal oversight is part of the story. Indeed it is crucial to allow effective research to be done. To ensure that the discovery, inventive and innovative work is properly rewarded, systems for assuring that the intellectual property arising from scientific research are also crucial and that society is not harmed by the work done by scientists. Technologists are used to ensuring intellectual property protection, scientists are not. For many scientists private gain from their research is abhorrent. They work night and day to further knowledge, not to obtain money. Publication of their findings so that further research is enabled is their aim, and they view any system that stops publication (or delays it) as inimical to science. On the other hand, finance is needed to permit science to proceed. A number of funding authorities are beginning to require that all funded science meet strict legal and ethical requirements. This means that in order to obtain funding, scientists need to work with social scientists, ethicists and lawyers to pursue their projects. Collaboration is crucial. It also requires lawyers, ethicists and social scientists to work with scientists and pursue and observe research directly at the time it is done rather than commentate from afar.

Biological scientists are now able to modify living beings, including human beings, in ways that were not even dreamt of by science fiction writers 50 years ago. We have a great deal of knowledge about biological systems, but as yet little understanding. Experiments are able to be done which may modify organisms (including ourselves) in unpredictable ways; this may affect the germplasm and be irreversible for future generations. Whilst not understanding fully what has been done or the manner in which the change has affected the properties of the organism it is possible to produce effective and "safe" products that enhance the economic or social well-being of consumers. As early as 1975 the probable benefits of the new technologies were recognised if suitable precautions were put in place (Ashby committee, 1975).[1]

In 1986 a working group set up by the OECD[2] considered the implications of the commercial use of modern biotechnology. Twenty years later that which they asserted remains controversial in much of the world.

> Recombinant DNA techniques represent a development of conventional procedures. They permit precise alteration, construction, recombination, deletion and translocation of genes that may give the recipient cells a desirable phenotype. Moreover, rDNA techniques allow genetic material to be transferred into, and to express in, another organism which may be quite unrelated to the source of the transferred DNA.[3]

At that time most of the applications of modern biotechnology (which they defined as solely the use of recombinant DNA) was primarily laboratory based. They argued that different issues arise when the technology results in organisms being deliberately introduced into the environment. The assessment of potential risks even of micro-organisms used in environmental or agricultural applications was less developed than the methods used for assuring safety within industry. The OECD blue book presumed a "provisional approach... to confer sufficient flexibility to suit individual countries" but hoped that internationally safety criteria would eventually be agreed.

1 United Kingdom (1975) "Report of the Working Party on the Experimental Manipulation of the Genetic Composition of Micro-organisms". Cmnd 5880 (January 1975).

2 The Organisation for Economic Cooperation and Development.

3 Recombinant DNA Safety Considerations: Safety considerations for industrial, agricultural and environmental applications of organisms derived by recombinant DNA techniques ("The Blue Book"), OECD, 1986.

In 1992 Agenda 21 was agreed at a meeting of almost all the countries in the world in Rio de Janeiro. Chapter 16 addressed the issues raised by modern biotechnology and the countries agreed

> …that the technology cannot resolve all the fundamental problems of environment and development, so expectations need to be tempered by realism. Nevertheless, it promises to make a significant contribution in enabling the development of, for example, better health care, enhanced food security through sustainable agricultural practices, improved supplies of potable water, more efficient industrial development processes for transforming raw materials, support for sustainable methods of afforestation and reforestation, and detoxification of hazardous wastes.

There was a tangible excitement that modern biotechnology could provide for the needs of the 21st century. Where the 20th Century had been seen as the century for electronics, it was believed that the technological drive of the 21st century would be biotechnology. Perhaps most importantly (and this has been largely forgotten) the governments proclaimed that:

> Governments at the appropriate level, with the assistance of international and regional organizations and with the support of non-governmental organizations, the private sector and academic and scientific institutions, should improve both plant and animal breeding and micro-organisms through the use of traditional and modern biotechnologies, to enhance sustainable agricultural output to achieve food security, particularly in developing countries, with due regard to the prior identification of desired characteristics before modification, taking into account the needs of farmers, the socioeconomic, cultural and environmental impacts of modifications and the need to promote sustainable social and economic development, paying particular attention to how the use of biotechnology will impact on the maintenance of environmental integrity.[4]

Even in Europe the inevitability of technological advance through modern biotechnology was recognised and welcomed in 1993 the Parliamentary Assembly of the Council of Europe passed recommendation 1213 (13th may 1993) on developments in biotechnology, for which

4 Agenda 21 paragraph 16.4.

there were many wonderful prospects, but also for which there were many concerns.[5] The Council of Europe includes many countries in Central and Eastern Europe as well as those of the affluent European Union.[6] The recommendation noted that the gene pool has been widened far beyond the limits of sexual compatibility to encompass the possibility of transferring genes from almost any organism to others. Amongst the many uses of biotechnology it identified were the raising of agricultural outputs (or reducing inputs), the replacement of chemical herbicides and insecticides or more efficient targeting, the use of plants in industry, changes in responses of crop plants to stress and even the cloning of meat animals "for particular markets or to form embryo banks to maintain genetic diversity". The resolution noted that there might be significant drawbacks resulting from the application of the new biotechnology. The possibility of new diseases was raised, as were the potential environmental effects of transgenic organisms.[7] Many of the benefits have been effected, although many do not realise that vaccines, pharmaceuticals and food additives (such as chymosin and ascorbic acid) are often the products of modern biotechnology.

5 "Biotechnology can be used to promote contrasting aims:
to raise agricultural outputs or reduce inputs;
to make luxury products or basic necessities;
to replace chemical herbicides and insecticides or target them more efficiently;
to upgrade pedigree flocks and herds or expand indigenous stock in developed countries;
to upgrade plants for industrial use;
to convert grain into biodegradable plastics or into methanol for fuel;
to hasten maturity in livestock or prevent sexual maturation in locusts or in farmed salmon;
to produce more nutritious and better flavoured foods or diagnose tests for bacterial contamination;
to engineer crops for fertile temperature zones or for semi-arid regions;
to fight viral epizootic or build up populations of endangered species;
to reduce production of "greenhouse gases" or utilise them in food production;

6 Fourty four countries in Europe are members of the Council of Europe.

7 "Transgenic organism" is used in this paper as synonymous with "living modified organism" (LMO) or "genetically modified organism" (GMO). "Other terms have also been used. «Genetically engineered organism» is used in the United States and has earlier been noted, definitions are not quite the same. In the United Kingdom initially «genetically manipulated organism» was used, but this was later changed to «genetically modified organism» because of the negative connotations of «manipulated»".

The sense of euphoria about biotechnology that the quoted documents provide began to be forgotten as the end of the 20th century arrived. In Europe, in particular, suspicion as to the use of these technologies, plus concern at globalisation and the control that a small group of companies had over agricultural supply has meant that products derived using modern biotechnology have not been able to enter the market. Environmental concerns (possibly exaggerated) and disgust at industrialised agriculture have resulted in a backlash that has meant that in much of Europe products do not sell and that the main distributors of food have decided not to stock products containing or often even derived from GMOs. The move towards organic agriculture and assertions of the need to respect "terroir" is seen as important in affluent Europe.

The assertion that recombinant DNA procedures were simply a development of conventional procedures has not generally been accepted except by biological scientists. There have been many scientists who believe that the transfer of genes between non-compatible organisms is truly different from traditional techniques and constitutes something that is really new. Modern biotechnology that permits modifications that cannot happen naturally has elicited excitement, fear and concern for many reasons, and has been regulated from almost the initial experiments that allowed genetic material to be transferred among unrelated organisms. Even as the technologies were being invented there was controversy over the best manner in which regulatory systems should be adopted. Modern biotechnology is seen as different to traditional selection, for it permits the transfer of characteristics that could not be achieved naturally and from very different organisms. Scientists often argue that the new techniques are simply an extension of the continuum of selection and genetic modification that has been used and continuously modified over hundreds of years. These 'traditional' techniques have changed markedly during the 20th century as our understanding of the biological processes has improved. Deliberate mutation and many other artificial techniques have allowed selection of characteristics between weakly compatible organisms.

From the very beginning of the use of modern biotechnology regulations (or guidance) were introduced in those countries in which experimentation was most advanced. The first definitions used in legal instruments were those of the United Kingdom and the United States:

> 1. "Genetic manipulation" means the formation of new combinations of heritable material by the insertion of nucleic acid molecules, produced by whatever means outside the cell, into any virus, bacterial plasmid, or other vector system so as to allow their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation.[8]
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> 2. "Definition of Recombinant DNA Molecules". In the context of these Guidelines, recombinant DNA molecules are defined as either (i) molecules which are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) DNA molecules that result from the replication of those described in (i) above.[9]

The definitions are similar, but not quite the same. For example, self-cloning (in which recombinant DNA is introduced, but it is DNA which has been extracted from the same organism (family, species?) that is re-inserted in a different place) is not included in the UK definition as genetic manipulation, but falls within that of the NIH Guidelines.

The UK had regulated the genetic "manipulation" of micro-organisms starting in 1978, and by 1983 had a full set of legally binding regulations in place. The United States chose not to put new specific regulations in place, but specified guidelines (the NIH Guidelines) which identified the manner in which such organisms should be used by those funded by the National Institutes of Health. In 1986 the US government published its Coordinated Framework for the Regulation of Biotechnology[10] which described the

> …comprehensive federal regulatory policy for ensuring the safety of biotechnology research and products. Existing statutes provide a basic network of agency jurisdiction over both research and products; this network forms the basis of this coordinated framework and helps assure reasonable safeguards for the public. This framework is expected to evolve in accord with the experiences of the industry and the agencies.

The laws that already existed in the United States regulated specific product uses, such as foods or pesticides. It was considered that geneti-

8 United Kingdom-Health and Safety (Genetic Manipulation) Regulations, 1978.

9 United States-Guidelines for Research Involving Recombinant DNA Molecules, June 1983.

10 Office of Science and Technology Policy, Coordinated Framework for Biotechnology, Federal Register 51, June 26 1986, pp. 23302–23350.

cally modified organisms posed no new risks that could not be covered using the existing system."This approach provides the opportunity for similar products to be treated similarly by particular regulatory agencies".

> The underlying policy question was whether the regulatory framework that pertained to products developed by traditional genetic manipulation techniques was adequate for products obtained with the new techniques. A similar question arose regarding the sufficiency of the review process for research conducted for agricultural and environmental applications. Upon examination of the existing laws available for the regulation of products developed by traditional genetic manipulation techniques, the working group concluded that, for the most part, these laws as currently implemented would address regulatory needs adequately. For certain microbial products, however, additional regulatory requirements, available under existing statutory authority, needed to be established.[11]

COORDINATED FRAMEWORK–APPROVAL OF COMMERCIAL BIOTECHNOLOGY PRODUCTS 1986[12]

Foods/Food Additives	FDA
Human Drugs, Medical Devices and Biologics	FDA
Animal Drugs	FDA
Animal Biologics	APHIS
Other Contained Uses	EPA
Plants and Animals	APHIS, FSIS, FDA
Pesticide Microorganisms released in the environment	EPA, APHIS
Other Uses (microorganisms), Inter-generic Combination	EPA, APHIS
Intra-generic Combination: Pathogenic Source Organism:	
1. Agricultural Use	APHIS
2. Non-Agricultural use	EPA, APHIS
No pathogenic Source organisms	EPA Report
Non-engineered Pathogens	

11 *Ibidem*, p. 23302.
12 *Ibidem*, p. 23304.

1. Agricultural Use	APHIS
2. Non-Agricultural Use	EPA, APHIS
Non Engineered Pathogens	EPA Report

> The US Administration decided to identify the various tasks needed to regulate biotechnology and clearly indicate the Agency and even the law which would be used to ensure that these technologies were used safely. Other countries did not (at the time) have the range of environmental, food, drug and safety legislation in place that permitted effective use of existing legislation. In the US it was decided that jurisdiction over the many different biotechnology products would be determined by their use rather than the manner of their products, just as was the case for traditional products.

This strategy is still in place, although each of the agencies has tried to institute rules or procedures that maintain public confidence in the new products. The United States decided that labelling of products produced using GMOs would be superfluous as it provides no useful information.

Countries have chosen to use a variety of triggers for regulation of biotechnology. The three main strategies for regulation of modern biotechnology are exemplified in the regulatory systems introduced by the United States (which has already been discussed), Europe and Canada.

In Europe it is the using of modern biotechnology as defined in the Directives that triggers the regulatory process, and a package of Directives and Regulations have been introduced to cover a vast range of activities:

- *Directive 90/219/EEC*, as amended by Directive 98/81/EC, on the contained use of genetically modified micro-organisms (GMMs), regulates research and industrial work activities involving GMMs under conditions of containment. This includes work activities in laboratories. Marketing of GMMs is addressed in Directive 2001/18.
- *Directive 2001/18 on the deliberate release into the environment of genetically modified organisms* is a "horizontal" Directive, which regulates experimental releases and the placing on the market of genetically modified organisms. Where appropriate legislation exists for particular products which provides for a specific environmental

risk assessment and for requirements as regards risk management, labelling, monitoring as appropriate, and information to the public etc at least equivalent as that required in the Directive, the major part of the Directive relating to marketing of these products is superseded.

- *Regulation 1829/2003 on GM food and feed* regulates the placing on the market of food and feed products containing or consisting of GMOs and also provides for the labelling of such products to the final consumer.
- *Regulation 1830/2003 on traceability and labelling of GMOs* and the traceability of food and feed products from GMOs introduces a harmonised EU system to trace and label GMOs and to trace food and feed products produced from GMOs.
- *Regulation 641/2004* on the detailed rules for the implementation of Regulation 1829/2003.
- *Regulation 1946/2003* on transboundary movement of GMOs (giving effect to obligations under the Cartagena Protocol)
- *Directive 2004/35* on environmental liability with regard to the prevention and remedying of environmental damage (to be implemented in Member State legislation by 30 April 2007).[13] Amongst many activities considered to have major environmental implications the Directive includes both any contained use, including transport, involving genetically modified micro-organisms (as defined by Council Directive 90/219/EEC) and any deliberate release into the environment, transport and placing on the market of genetically modified organisms (as defined by Directive 2001/18/EC).
- Commission Recommendation of 23 July 2003 on *guidelines* for the development of national strategies and best practices *to ensure the co-existence of genetically modified crops with conventional and organic farming*. This recommendation provides for national governments to make decisions in relation to coexistence, but

[13] The Commission is required to report by 30 April 2014 to the Council and European Parliament on "the application of this Directive to environmental damage caused by genetically modified organisms (GMOs), particularly in the light of experience gained within relevant international fora and Conventions, such as the Convention on Biological Diversity and the Cartagena Protocol on Biosafety, as well as the results of any incidents of environmental damage caused by GMOs".

> "Since only authorised GMOs can be cultivated in the EU, and the environmental and health aspects are already covered by Directive 2001/18/EC, the pending issues still to be addressed in the context of co-existence concern the economic aspects associated with the admixture of GM and non-GM crops".[14] The Guidelines recognise the difficulties that are likely to arise and state that "Measures for co-existence should be efficient and cost-effective, and proportionate. They shall not go beyond what is necessary in order to ensure that adventitious traces of GMOs stay below the tolerance thresholds set out in Community legislation. They should avoid any unnecessary burden for farmers, seed producers, cooperatives and other actors associated with any production type.

Contained use, whether industrial or laboratory based has hardly been affected by the controversy that rages in Europe about the use of the technologies; this means that the manufacture of pharmaceuticals, chemicals and even food and feed additives or enhancers continues relatively unabated. The new Regulation on labelling foods derived from GMOs may impact on the last of these.

In the United States, because current law is used, the trigger tends to be the use of organisms that are pests —plant pests for example— in the manufacture of the organism if the US Department of Agriculture is to be involved. There is a different trigger for each of the agencies, although all transgenic organisms that have been introduced so far have been required to meet some regulatory system that effectively takes their transgenic origin into account.

Canada uses a concept of novelty to trigger the regulatory process. "Health Canada defines novel foods as:

- products that have never been used as a food;
- foods which result from a process that has not previously been used for food; or
- foods that have been modified by genetic manipulation. This last category of foods have been described as genetically modified foods.

14 European Commission Recommendation of 23 July 2003 on guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming. Brussels, 23 July 2003 C(2003).

It is Health Canada's responsibility to assess the safety of novel foods".[15] This means that although the trigger is novelty, all genetically modified products are considered novel and "should be subject to rigorous scientific assessment".[16] A major criticism of the process developed in Canada has been the lack of transparency in the assessment process for novel products. There is, however, a new commitment by the Government of Canada to "Smart Regulation" regulation across all areas of Government. It is the intention, amongst others, to protect the public interest – "Smart Regulation strives to find the right blend of policy instruments to achieve the greatest overall benefit to Canadians, recognizing that social, environmental, and economic objectives are mutually supporting". Transparency is recognised as important, and the new policy has, as one of its objectives "Improved transparency, efficiency, timeliness and predictability of regulatory and decision-making processes, and reduced administrative burden for businesses and citizens".[17]

> The regulation of biotechnology presents many challenges, including the fast pace of scientific change that crosses conventional lines of regulatory authority. The Canadian Biotechnology Strategy will include a policy framework and action plan aimed at improving the regulation of biotechnology and enhancing the capacity of regulators to more quickly respond to biotechnology innovations, for example in health and agriculture, that can benefit Canadians. While progress has been made in some areas, such as aquatic biotechnology, the complexity of biotechnology and the involvement of multiple regulators in the process of designing a strengthened regulatory framework has led to a delay in delivering on March 2005 commitments. The priority for fall 2005 is developing a policy framework for novel biotechnology products.

The reason for quoting this Canadian information in full is that many of those observing the systems for regulation of biotechnology have considered the Canadian system to be one of those worth emulating in other countries were the transparency to be improved.

15 *http://www.fodsafetynetwork.ca/en/link-details.php?a=2&c=5&sc=29&id=42*.

16 Action Plan of the Government of Canada in response to the Royal Society of Canada Expert Panel Report Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada, Government of Canada, 23 November 2001.

17 Canada (2005) Smart Regulation: Report on Actions and Plans Fall 2005 update ISBN 0-662-41931-6 (PDF) Cat. no.: CP22-80/2005-1E-PDF.

Many analyses have suggested that once the process is started, the risk assessment and management processes are very similar. "For example, all modified organisms that would require regulation under the European system have been assessed in both the Canadian and United States".

The Cartagena Protocol requires that Safety Assessment should be carried out in a *scientifically sound manner*.[18] This has many interpretations. In the United States it is argued that it is only science that should be taken into account. In much of Europe, however, social, ethical and economic issues are addressed. "The risk assessment is science based, but the decision may take other factors into account".

The Protocol is very specific on what socio-economic considerations could be taken into account.

> The Parties, in reaching a decision on import under this Protocol or under its domestic measures implementing the Protocol, may take into account, consistent with their international obligations, socio-economic considerations arising from the impact of living modified organisms on the conservation and sustainable use of biological diversity, especially with regard to the value of biological diversity to indigenous and local communities.[19]

The concept of sound science "applied to both risk assessment procedures and to the decision process" would seem to be worth pursuing, for it means that decisions are distanced from political considerations and are based purely on fact determined experimentally. However, on many occasions the scientific evidence is neutral or equivocal. Worse, further experimentation may not provide any resolution as to risk or acceptability, for biological systems are open systems which are not necessarily predictable. How then may decisions be made?

Article 5(7) of the Agreement on the Application of Sanitary and Phytosanitary Measures (WTO) fails to address this problem effectively as there is a presumption that where the science does not provide the answer further experimentation will enable a rational decision to be taken:[20]

[18] Cartagena Protocol Article 15(1) includes "Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques".

[19] Cartagena Protocol article 26(1).

[20] Furthermore, while the SPS agreement applies to human health, sanitary and phytosanitary issues, it only applies to a fraction of the relevant environmental issues, where uncertainties can be more difficult to address.

> In cases where relevant scientific evidence is insufficient, a Member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other Members. In such circumstances, Members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.
>
> Where science does (or cannot) provide an unequivocal answer to the introduction to the environment of GMOs the benefit of using the technology may point to accepting risk, but monitoring the introduction and ensuring (so far as is possible) that the organism can be recalled in the event of harm to humans or the environment. This would appear to be the main contention of organisations such as GreenPeace and Friends of the Earth, who argue that the risks are too great and that such organisms should not be released into the environment at all. A counter argument is that the products of modern biotechnology are being used in huge amounts in agriculture and in food, have been used for over 10 years, and there is little if any evidence of harm to either the environment or to human health. Indeed, there is significant evidence of benefit.

The most important international treaty relating to modern biotechnology is the Convention on Biological Diversity (CBD). It was agreed in 1992 and has as its objectives the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding. The CBD has 188 members,[21] but the United States (which signed the treaty in 1993) is one of the few countries in the world that has chosen not to become a Party to the Convention. Mexico ratified the treaty in 1993. In order to ensure that biological diversity is protected, the CBD requires, through Article 8(g), that Member States institute national frameworks in order to "[E]stablish or maintain means to regulate, manage or control the risks associated with the use and release of living modified organisms resulting from biotechnology which are likely to have adverse environmental

[21] December 2005.

impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health". In the early part of this century few countries had instituted the internal systems to assure the safe use of the technology, even where the techniques termed modern biotechnology had already become basic tools within research institutes, universities and bio-industry.

Most countries today have adopted a consensus that assures that where modern biotechnology is used, it will be regulated. The Cartagena Protocol was agreed in 2000, came into force in 2003 and there are now 129 Parties to the Protocol.[22] This protocol provides for regulatory systems primarily where living modified organisms (LMOs) are transferred between countries. It is unfortunate that most of the countries that produce agricultural products that are LMOs have (so far) chosen not to become party to the treaty. The objective of the Protocol is "to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements". The objective also provides for a precautionary approach in its objective. This has been subject to extensive debate. The US insistence on "sound science" as the basis for decisions as to whether these products should be introduced into the environment is reflected in the manner in which risk assessment is identified (article 15 and annex III). It is argued that political decisions should not influence decisions on the acceptability of individual products.

The definition of modern biotechnology[23] in the Protocol is

> The application of:
>
> a. In vitro nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or
>
> b. Fusion of cells beyond the taxonomic family,
>
> that overcome natural physiological reproductive or recombination barriers and that are not techniques used in traditional breeding and selection.

22 1st December 2005.

23 Cartagena Protocol, article 3. There are more elaborate definitions in other texts, for example Directive 2001/18 of the European Union.

The provisions of the Cartagena Protocol extend only to those organisms resulting from modern biotechnology that might cause potential adverse effects to the conservation and sustainable use of biodiversity. Human health has "then" to be taken into account. However, when designing a regulatory system for biosafety, it is legitimate to assure safety of the environment and human health in general, with the needs for the Protocol forming a sub-set within the regulatory system. It seems likely that any attempt to link the protection of human health to legislation that primarily addresses biodiversity would not be acceptable to most legislatures.

A major issue raised in the Protocol is transparency and public involvement in the decision making process. This transparency (addressed in Article 23) requires in particular that (in accordance with their respective laws and regulations) Parties should consult the public in the decision-making process and make the results of any decisions public.

Although a protocol to the major multilateral environment agreement (CBD) it is primarily a trade agreement relating to the movement across national boundaries of organisms that have been modified using modern biotechnology as identified in the objective. Hence, once in place it became more important than before to ensure that the necessary legal instruments are in place to permit cross-border trade between Parties to the Protocol and other Parties or countries not party to the treaty.

The objective of the Cartagena Protocol is predicated on the "precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development". Interpretations of this differ significantly, and have led to major disagreements amongst those involved in the discussion before and since the Protocol was agreed. Principle 15 is "In order to protect the environment, the precautionary approach shall be widely applied by States according to their capabilities. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not be used as a reason for postponing cost-effective measures to prevent environmental degradation".

The European Union is the main protagonist of the Precautionary approach.

> The issue of when and how to use the precautionary principle, both within the European Union and internationally, is giving rise to much debate, and to mixed, and sometimes contradictory views. Thus, decision-makers are cons-

> tantly faced with the dilemma of balancing the freedom and rights of individuals, industry and organisations with the need to reduce the risk of adverse effects to the environment, human, animal or plant health. Therefore, finding the correct balance so that the proportionate, non-discriminatory, transparent and coherent actions can be taken, requires a structured decision-making process with detailed scientific and other objective information.[24]

In paragraph 6 of the summary of this document it states.

Where action is deemed necessary, measures based on the precautionary principle should be, *inter alia*:

- *proportional* to the chosen level of protection, requiring the tailoring of measures so as to achieve an agreed level of protection. "A total ban may not be a proportional response to a potential risk".
- *non-discriminatory* in their application, comparable situations should be treated in a similar manner.
- *consistent* with similar measures already taken – measures should be of comparable scope and nature to those taken in other areas where more information is available.
- *based on an examination of the potential benefits and costs* of action or lack of action (including, where appropriate and feasible, an economic cost/benefit analysis). Decisions as to whether to act or not would be based on the scientific data available
- *subject to review*, in the light of new scientific data and where new information is available decisions should be revised accordingly, and
- *capable of assigning responsibility for producing the scientific evidence* necessary for a more comprehensive risk assessment "Countries that impose a prior approval (marketing authorisation) requirement on products that they deem dangerous a priori reverse the burden of proving injury, by treating them as dangerous unless and until businesses do the scientific work necessary to demonstrate that they are safe".

Other countries have also embraced precaution in relation to genetically modified organisms. Canada has stated that "Principle 15 of the

24 European Commission (2000) Communication from the commission on the precautionary principle, Brussels, 02.02.2000 COM (2000) 1.

1992 Rio Declaration on Environment and Development, and the approach that it represents are consistent with today's regulatory practices in the field of environmental protection in Canada".[25] They indicate that guidance and assurance are required as to the conditions governing the actions that need to be taken.[26]

> The new law on genetically modified organisms adopted in Mexico in 2005[27] addresses the precautionary approach explicitly – primarily in Articles 9 and 63. The wording is very similar to that found in the Cartagena Protocol.
>
> Where there is a threat of serious or irreversible damage, the uncertainty regarding the level of the potential risk that the GMOs may pose to biological diversity or human health shall not be used as a reason for the Ministry to postpone the adoption of cost-effective measures to prevent the negative impact on biological diversity or human health. In adopting such measures the Ministry will take into account the existing scientific evidence, which serves as the basis or criteria for the establishment of the measure or measures; the administrative procedures set forth in this law, and the commercial regulation contained in international agreements and treaties of which Mexico is a Party.[28]
>
> Regulatory issues are a major concern of developing countries. They see the rapid adoption of the technology in the United States, Canada and Argentina, all of which have slightly different criteria for the acceptability of these organisms, and the almost total rejection of GMOs intended for

25 Action Plan of the Government of Canada in response to the Royal Society of Canada Expert Panel Report Elements of Precaution: Recommendations for the Regulation of Food Biotechnology in Canada, Government of Canada, 23 November 2001.

26 A Canadian Perspective on the Precautionary Approach/Principle —Proposed Guiding Principles.

27 Ley de Bioseguridad de Organismos Genéticamente Modificados, 18 March 2005, entered into force 17 April 2005.

28 Article 63 (second paragraph):

"En caso de peligro de daño grave o irreversible, la incertidumbre acerca del nivel de los posibles riesgos que los OGMs puedan causar a la diversidad biológica o a la salud humana, no deberá utilizarse como razón para que la Secretaría correspondiente postergue la adopción de medidas eficaces que impidan la afectación negativa de la diversidad biológica o de la salud humana. En la adopción de dichas medidas, la Secretaría correspondiente tomará en cuenta la evidencia científica existente que le sirva de fundamento o criterio para el establecimiento de la medida o medidas; los procedimientos administrativos establecidos en esta Ley, y la normatividad comercial contenida en tratados y acuerdos internacionales de los que los Estados Unidos Mexicanos sean parte".

> deliberate release into the environment in the European Union. There would be an enormous benefit if the new plants (in particular) could be used, but there are dangers both to the environment and to trade where a major marked is the European Union. The benefits of current crops are that significantly less chemical is needed to protect the crops (in theory). Trust is important.

In 2000 the main United Nations financial organisation for funding environmental projects, the Global Environment Facility (GEF) agreed an *Initial Strategy for Biosafety*.[29] The strategy was *developed* in response both to a resolution of its *own* governing Council and Article 28 of the Protocol that identified the GEF as the Financial Mechanism for the treaty. It was agreed that "[t]he mandate envisaged is consistent with the GEF's general approach of assisting action that is beneficial to the global environment, since national action on biosafety will yield global benefits in terms of conservation and sustainable use of biological resources". The plan that was devised for funding by the GEF was aimed at:

> (a) assisting countries to prepare for the entry into force of the Cartagena Protocol on Biosafety through the establishment of national biosafety frameworks, including strengthening capacity for risk assessment and management with a wide degree of stakeholder participation,
>
> (b) promoting information sharing and collaboration at the regional and sub-regional level and among countries that share the same biomes/ecosystems, and
>
> (c) promoting identification, collaboration and coordination among other bilateral and multilateral organizations to assist capacity-building for the Protocol and explore the optimization of partnerships with such organizations.

Each of these aims was laudable and a significant sum of money was provided to the implementing agencies (United Nations Environment Programme, United Nations Development Programme and the World Bank) to assure the development of appropriate biosafety systems in countries that were committed to membership of the Protocol. The GEF agreed to

29 GEF Council, November 1-3, 2000, Agenda Item 5(c) GEF/C.16/4/Rev.1.

(a) A project to assist interested signatories to the Cartagena Protocol in establishing national biosafety frameworks;

(b) individual, country-based demonstration projects, through any of the GEF Implementing Agencies, to assist in capacity-building to implement national biosafety frameworks;

(c) coordination with other multilateral and bilateral organizations providing assistance in the area of biosafety;

(d) support to enable countries to participate in the biosafety clearing-house, once the clearing-house terms of reference are agreed upon by the Parties; and

(e) enhancement of the scientific and technical advice to the GEF on biosafety issues.

This decision resulted in a major series of projects designed to assist countries to implement National Biosafety Frameworks that would permit decisions to be made as to the mechanisms for the national implementation of the provisions of the Cartagena Protocol. There were two kinds of project envisaged. Those developing countries that had some framework in place would be funded to implement the Biosafety Framework so as to be fully compliant with the Cartagena Protocol. The GEF Council approved 12 proposals for demonstration projects. Two of those projects (India and Colombia) were coordinated by the World Bank, two (Malaysia and Mexico) by UNDP and eight by UNEP. The main project, coordinated by UNEP eventually involved over 120 countries and was designed to assist countries in developing a national biosafety framework. The initial phase of the project within countries addressed the need to assist countries to identify existing technological and legal capacity. It was expected that the process would help identify the talent, expertise and experience in the countries (or region) and the gaps that would need to be followed to ensure that risk could properly be assessed, managed and communicated. The process required the participating States to:

1. Conduct surveys to provide detailed knowledge of the use of biotechnology within the country, and was expected to include all organization that were involved in using modern biotechnology and thereby allow the efficient interaction between the public and private sectors.

2. Conduct surveys to identify all the existing legal instruments or guidelines that might impact on the use, import or export of LMOs
3. Identify the existing or available bilateral or multilateral support on biosafety to ensure the best use of resources in developing capacity.
4. Involve stakeholders' in the decision making process to provide a national biosafety framework that reflected the needs of the country and its international obligations– to include the public and private sector, consumers, consumer organisations and NGOs.
5. Once this work had been done, and in consultation, to draft legal instruments including regulatory frameworks and guidelines as appropriate, recognising that many of the requirements to implement the Protocol would already exist in national law.
6. Establish systems needed for risk assessment, audit of risk assessments and risk management in order to ensure adherence to the requirements of Articles 15 and 16 of the Protocol and ensure adequate risk communication. It was noted at the time of drafting of the projects that this could required sub-regional cooperation.
7. Assist harmonisation of guidelines, regulations or laws at the national level with those in neighbouring countries. The intentional and unintentional movement of transgenic organisms across national borders is recognised in the Protocol and needs recognition in national law and sub-regional cooperation. In addition the sharing of scientific assessments (and if necessary decisions at either regional or national level) was recognised as possibly important – particularly in developing countries where in some cases the sharing of scientific expertise would make risk assessment possible.

Almost all eligible countries have entered this project, and most are in the final stages of its implementation. The main result is that most countries have discovered that there is a large body of legislation that addresses the topics that relate to the use of LMOs, ranging from trade to environmental protection. Most countries have chosen not to simply utilise existing legislation and divide the duties and responsibilities amongst existing ministries and agencies. They have also not followed the Canadian approach and legislated for novelty, which would have included LMOs as a subset whilst still meeting the requirements and responsibilities placed on them by membership of the Cartagena Protocol.

New legislation is planned, or in the process of being designed which will either be put to Parliaments or implemented through decree and will specifically address the use and transboundary movement of LMOs.

The introduction of legislation to address the needs of countries to ensure that modern biotechnology is used in a safe manner is extremely important. That legislation must be consistent with international obligations and responsibilities but also take note of the national acceptance of its use. The introduction of transgenic organisms into particular environments may be fraught with difficulty. This is particularly true in centres of origin or centres of diversity. The Commission on Environmental Cooperation Report "Maize and Biodiversity: The Effects of Transgenic Maize in Mexico: Key Findings and Recommendations"[30] concluded that current varieties of genetically modified maize that had been deregulated in the United States were unlikely to have any major effect on the biodiversity of maize in Mexico; however, until the effects on the country (including socio-economic effects) have been properly ascertained, it was believed that the import of viable GM maize should cease. At stake is about 1.5 billion US dollars of exports to Mexico and confidence in the maize exported from the United States. It is, however, "sound policy to prevent planting of fertile GE corn in Mexico until Mexico has put a regulatory system in place. Doing so protects the environment, protects U. S. interests in expanding commodity markets, balances social and economic concerns, and respects Mexico's sovereignty".

Mexico is seen as very different from its partners in NAFTA. There are "high levels of poverty, dependence upon agriculture by large populations for income and food security, and a significant indigenous population". "The diversity of maize in Mexico is maintained primarily by local and indigenous farming communities. This system allows the conservation of the maize genetic resources that constitute the basis of food and agricultural production".

Modern biotechnology has the potential to change our world. For most biological scientists that potential is good. There will be an impact on the quantity and quality of food available to all. The technology has the potential to protect and conserve biodiversity whilst providing for

30 Commission for Environmental Cooperation (2004) Maize and Biodiversity: The Effects of Transgenic Maize in Mexico: Key Findings and Recommendations ISBN 2-923358-00-7.

man's needs. To environmental campaigners it also has the capacity to change our world – for the worse. It permits multi-national companies access to resources and markets. It has the capacity to pollute that which we hold dear without true sustainability.

Whichever view is taken, the need for regulatory regimes that address any risks and benefits that may accrue is important so as to assure safety and to involve the people in informed decision processes.