Agricultural Biotechnology, Politics, Ethics, and Policy

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Summary

The implementation of agricultural biotechnology for food and feed production is an area of considerable controversy and concern to many people across the world. It is an area of strongly conflicting views and opinions, not only in the science but also the ethical and moral issues surrounding the use of the technology. The science is often uncertain and open to interpretation, while ethical and moral debates frequently polarise opinions both within countries and between countries. However, food security is one of the major challenges facing the world and perhaps the largest challenge facing Southern Africa, exemplified by the current famine in the region. Agricultural biotechnology has the potential to help alleviate the current situation by providing crops that are targeted for a particular environment.

It may be argued that governments and the scientific community have a duty to ensure the technology is made available in a responsible way. Some would argue that the current situation requires the technology to be introduced immediately to alleviate the suffering, while others would take a more pragmatic approach and only introduce the technology once the appropriate legislation and regulatory frameworks are in place and risk - benefit assessments carried out.

This paper has attempted to highlight many of the key ethical and moral issues that may need to be addressed before the implementation of agricultural biotechnology, set against an historical background of the development of the legal and regulatory frameworks in the EU and the US. The paper seeks to flag the arguments and issues, while it is solely up to each country to decide for themselves if, how and when to implement agricultural biotechnology.

1. INTRODUCTION

The aim of this discussion paper is to raise the policy, regulatory and ethical issues surrounding agricultural biotechnology. The paper provides a background into the shaping of policy and regulatory frameworks within the EU and the United States amongst others, as well as outlining the global framework in which all countries have to operate. In addition the paper summarises the UN lead initiative to assist developing countries to implement biosafety frameworks devised by that country for that country. The paper also highlights the ongoing debate in the areas of environmental protection, public perception and acceptance and intellectual property rights.

The most important reason for addressing the European Union's and the United States policy on genetically modified organisms, rather than others is that they are very different in concept – although in practice once the regulatory system has been triggered the formal treatment is very much the same.

As in many other areas of technology, the introduction of a new technology such as agricultural biotechnology may depend on the perceived balance between the benefits of the technology and the potential risks to the environment and human health. This paper aims to put forward the arguments and issues for the potential benefits of agricultural biotechnology, against the background of perceived risks, but does not in itself seek to provide the answers.

2. POLICY

Biology has been used for millennia to provide food and other products for use by humans. It is used to make food palatable or safe, and many mechanisms have been 'discovered' that enable foods to be 'modified' using organisms (usually micro-organisms). Bread, beer, wine, cheese, tofu and yoghourt are amongst the modified food products we use all the time. We choose to use micro-organisms to modify starting ingredients to form the food we eat. Less obvious is the modification of all our food crops. The wild, undomesticated relatives of all food crops are almost unrecognizable in comparison to that which we grow in fields today. Genetic modification of crop plants has been practised since the crops were first identified. The first human to choose to keep the best seeds for growing in the following season rather than eating them was practising biotechnology.

Modern biotechnology[1] is seen as different to traditional selection, for it permits the transfer of characteristics that could not be achieved naturally. Scientists often argue that the new techniques are simply an extension of the continuum of selection and genetic modification that has been used 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.

There are many scientists who believe that the transfer of genes between non-compatible organisms is truly different from traditional techniques and

[1] **Modern biotechnology** is defined in the Cartagena Protocol (Article 3) to be "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;"

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

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.

Different uses of modern biotechnology to produce transgenic organisms elicit varying reactions in most countries. Genetic modification to provide medicines is not as controversial as the genetic modification of crops for human consumption. Often the genetic modification of animals (especially reproductive cloning) is considered as less acceptable than modification of plants. Modification of the germ line in humans, for example, is usually considered as immoral[2].

Many opinion polls indicate that the public discriminates markedly between uses of biotechnology. Medicine and horticulture/floriculture are often found to be acceptable whereas the genetic modification of crops for food use, or the modification of animals and humans are less acceptable. "While most Americans say they would be in favour of at least some genetically modified food products, and nearly two-thirds believe that genetically modified foods will benefit many people, more than half (56 percent) say that the issue of genetic modification causes them great concern[3]

[2] European Directive 98/44 on *Directive on the Legal Protection of Biotechnological Inventions*
Article 6.2: The following inventions include those that are unpatentable where their exploitation would be contrary to *ordre public* or morality:

- processes for cloning human beings;
- processes for modifying the germ-line genetic identity of human beings;
- uses of human embryos for industrial or commercial purposes;
- processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.'

[3] William K Hallman *et al* (2002) Public Perceptions of Genetically Modified Foods *Americans Know Not What They Eat* Food Policy Institute, Rutgers, The State University of New Jersey, RR-0302-001, page 26
http://www.foodpolicyinstitute.org

a. History

It may be useful to provide some historical background to the many issues that arise from the use of modern biotechnology. Policy on the safe use of biotechnology set precedents. It is often the case that safety legislation is brought in because an accident has occurred and systems need to be put into place in order to ensure that it does not reoccur. The possible risks of modern biotechnology were recognized at the very beginning of its use, and steps were taken to ensure that it was used safely.

It is 50 years since the paper identifying the double helical structure of deoxy-ribonucleic acid was published by Watson and Crick in *Nature*[4]. They recognized that the complimentary relationships between Adenosine and Thymidine and between Guanosine and Cytidine[5] could be important as a mechanism for transferring information between generations and between organisms. With the discovery (during the 1960s) of enzymes that could cut the DNA sequences at specific points in the sequence mechanisms became available for transferring information between organisms in a precise and controlled manner. If two molecules are cut using the same enzyme, they will be cut at identical sequences, and can therefore be wrongly re-assembled. It is thus possible to cut a piece of DNA and insert a desired sequence precisely at that point. This technique was only initially effective in micro-organisms, as the insertion of specific molecules into the whole genome of plants is much more complicated. It only became possible when a bacterium was discovered capable of inserting a sequence of DNA into a random position in the plant genome. The ability to regenerate a complete plant from a single cell (impossible in other higher organisms) made it possible to easily modify many plant species. It was later discovered that if ballistics was used to literally fire DNA into cells a small

[4] Watson, J. D. & Crick, F. H. C (1953) Molecular structure of Nucleic Acids *Nature* **171,** 737-738

[5] The nucleotides that when joined together in an extremely long linear chain constitute DNA –. DNA consists of two strands coiled round one another in a double helix. A stable interaction between Adenosine (A) and Thymidine (T) and between Guanosine (G) and Cytidine (C) means that the two strands are complementary: wherever A occurs in one strand, T occurs in the other and vice-versa.

proportion would have sequences stably integrated into their genome. Selection techniques involving (usually) choosing to have one of the inserted sequences express antibiotic tolerance mean that the tiny proportion of cells modified using the technique can be identified relative to the rest.

The potential uses of genetic modification[6] were obvious from the moment that the techniques that enabled the transfer of genes from one organism to another unrelated organism were first identified. A United Kingdom government initiated committee reported in 1975 that genetic manipulation techniques would provide "substantial though unpredictable benefits" … "application of the techniques might enable agricultural scientists to extend the climatic range of crops and to equip plants to secure their nitrogen supply from the air"[7] A meeting of scientists using the very new recombinant DNA technology in Asilomar in California in February 1975 produced a set of guidelines for the use of biotechnology: The formal goals of the meeting included the need to identify the "possible risks involved for the investigator and or others" and "the measures that can be employed to test for and minimize the biohazards so that the work can go on"[8] The benefits of the new technology far outweighed the risks *if suitable precautions were put in place* in the view of the Ashby committee in 1975.[9]

The use of modern biotechnology, however, extends far beyond arable agriculture, and it is heavily used in the industrial manufacture of high value chemicals and pharmaceuticals. In addition animals are being modified; higher animals acting as factories or to use them more efficiently for food; insects for research purposes and to attempt to eliminate disease, etc. For safety reasons the contained or confined use of genetically modified organisms is likely to be

[6] Variously and at various times called genetic modification, genetic manipulation or genetic engineering

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

[8] Wright, Susan (1994) "Molecular Politics: Developing American and British Regulatory Policy for Genetic Engineering 1972-1982" The University of Chicago Press, Chicago, USA ISBN 0-226-91066-0, page 145.

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

favoured over crop plant modifications particularly where they are used as factories for the manufacture of toxic chemicals and pharmaceuticals.

- Transgenic organisms may be used for human and animal medicine that are then purified for chemicals rather than sold as organisms.
- Transgenic viruses may be used as vaccines through to vectors for inserting needed gene sequences into other organisms.
- Bacteria and fungi are likely to be used industrially for making chemicals. It is likely that these modified microorganisms will be traded to be used industrially, or used in factories to produce wanted chemicals. Modified micro-organisms are already being used for all sorts of purposes, and are likely to be used directly as bio-control agents in the future.
- Small 'animals' (insects for example) may be manufactured either because they are the only organisms identified for a particular use, or because they are a perfect *vector* for a particular reason – e.g. mosquitoes incapable of carrying the malaria parasite. In most instances these will be released into the environment and will impact on the ecology into which they are released.
- Large animals are being used as factories for the production of high value chemicals. Animals that express pharmacologically active compounds in their milk, for example, are contained and effective factories – but care has to be taken to ensure that the animals are treated humanely and are not seriously affected because of the nature of the chemical they are being used to fabricate.

Although the public in many countries has been fearful of the introduction of the "products of this technology, Parliaments have not been as reticent, and have recognised both benefits that may arise from its use and the risks that it theoretically poses. In 1993 the Parliamentary Assembly of the Council of Europe passed recommendation 1213 (13th May 1993) on developments in

biotechnology, for which there were many wonderful prospects, but also for which there were many concerns[10]. The Council of Europe includes many countries in Central and Eastern Europe as well as those of the affluent European Union[11]. The resolution 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[12]. Many of the benefits have been effected, although many do not realise that vaccines, pharmaceuticals and food additives (such as chymosin[13] and ascorbic acid) are often the products of modern biotechnology.

The Cartagena Protocol was agreed in 2000 after years of negotiation and argument, with many misgivings, but in an atmosphere which had changed from

[10] "Biotechnology can be used to promote contrasting aims:
i. to raise agricultural outputs or reduce inputs;
ii. to make luxury products or basic necessities;
iii. to replace chemical herbicides and insecticides or target them more efficiently;
iv. to upgrade pedigree flocks and herds or expand indigenous stock in developed countries;
v. to upgrade plants for industrial use;
vi. to convert grain into biodegradable plastics or into methanol for fuel;
vii. to hasten maturity in livestock or prevent sexual maturation in locusts or in farmed salmon;
viii. to produce more nutritious and better flavoured foods or diagnose tests for bacterial contamination;
ix. to engineer crops for fertile temperature zones or for semi-arid regions;
x. to fight viral epizootic or build up populations of endangered species;
xi. to reduce production of "greenhouse gases" or utilise them in food production;
xii. to clone meat animals for particular markets or form embryo banks to maintain genetic diversity.

[11] 44 countries in Europe are members of the Council of Europe.

[12] 'transgenic organism' is used in this paper as synonymous with 'living modified organism' or 'genetically modified organism'

[13] for example, http://www.ncbe.reading.ac.uk/NCBE/GMFOOD/chymosin.html

that which pertained at the time the negotiations started. Article 19(3) of the Convention on Biological Diversity (June 1992) had required parties to consider the possibility of a Protocol to the convention that addressed the use (and primarily transboundary movement) of living modified organisms that might have an adverse impact on biological diversity[14]. Eight years later Europeans were no longer accepting modern biotechnology; products had disappeared from the shops, and there was a gloom and distrust in many countries not observed elsewhere. Few if any products derived using modern biotechnology are now available in Europe[15]. In North America, farmers adopted transgenic organisms with little opposition, and products derived from them have been in the shops for over 5 years.

The Developing Countries had wanted far more in the Protocol than they were able to get, with many more safeguards. The producer countries fought hard to ensure that, insofar as it was possible, few if any controls were applied particularly to commodity goods. The size of the commodity market alone, they argued, made it difficult to contemplate a regime which required what amounted to 'visas' at country entry points.

The Protocol requires 50 ratifications to come into force. To date[16] it has received 45 ratifications, one of which is by the European Union, which does not count as part of the 50 required (not all the European Union countries have ratified – when they do, the number will exceed the threshold). More than 100 countries have signed. Southern African countries that have signed but not yet ratified are Malawi, Namibia, Uganda and Zimbabwe. Amongst those which have ratified or acceded to the protocol are Mozambique, Botswana, Mauritius, Kenya, Uganda

[14] "The Parties shall consider the need for and modalities of a protocol setting out appropriate procedures, including, in particular, advance informed agreement, in the field of the safe transfer, handling and use of any living modified organism resulting from biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity."
[15] The Royal Society (February 2002) Genetically Modified Plants for Food Use and human helath – an update, Policy Document 4/02 ISBN 0 85403 576 1 paragraph 2.
[16] March 2003

and Lesotho. Most of these countries do not yet have the legal systems in place to implement the requirements of the Protocol. The major user of transgenic organisms in southern Africa, South Africa, was involved in the discussions during its adoption but has not (yet) signed or ratified.

The need for specific legislation in regard to the use of genetically modified organisms was never a presumption even though it was recognized that regulation was needed from the earliest days of the use of this technology. 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, on the other hand, had 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[17] 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 genetically 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

[17] Office of Science and Technology Policy, Coordinated Framework for Biotechnology, Federal Register 51, Pages 23302 – 23350, June 26 1986.

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". [18]

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.

Coordinated Framework – Approval of Commercial Biotechnology Products[19]

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

[18] Ibid, page 23302.
[19] Ibid Page 23304

b. Regulatory systems

Guidelines or regulations were quickly introduced in some countries, particularly to protect those who might come into contact with the modified organisms. In the UK the first regulations were introduced in 1978; the NIH[20] guidelines were implemented in the United States soon after Asilomar and applied to work funded through grants received from the NIH. Initially the 'regulations' applied primarily to work in laboratories because that was the only place in which the work could progress. They were aimed at the protection of those individuals who had access to the laboratories or facilities and attempted to assure that the work was contained and that workers were protected from the hazards posed by the modified organisms. It was only in the late 1980s that the introduction of modified organisms into the environment became really feasible. At first it was expected that these releases would mainly be of micro-organisms, but as methods capable of modifying plants became available and efficient it was clear that most environmental releases would be of plants. Very few modified microorganisms have been released. Many countries have decided to implement different systems of regulation for organisms intended for use in containment (or confined) and those that are released into the environment. Contained use included organisms used in industrial plant and processes for manufacturing where the organisms themselves are not intended to be marketed or exposed to the 'open' environment.

Most countries in the Southern African Region are considering the frameworks necessary for a regulatory system to ensure the safe use of modern biotechnology or have already enacted legislation. South Africa initially regulated transgenic organisms[21] through a voluntary system but since 1997 have had legislation in place to ensure that the use of modified organisms in South Africa is done safely. It is the only country in the region that has, so far, permitted the

[20] National Institutes of Health, United States of America.
[21] In this overview document, transgenic, genetically modified and even living modified organisms are used synonymously.

commercial use of any transgenic plants[22]. "Zimbabwe was the second country after South Africa to come up with bio-safety regulations; was the first to come up with an institutional framework and is one of the few countries to have post-graduate training in biotechnology"[23]. Namibia was part of a UNEP/GEF financed Pilot project which permitted 18 countries to start the process of regulating Biotechnology and is now one of 12 countries financed by the GEF[24] to implement the biosafety frameworks that have been devised for the country. Zambia, Uganda and Kenya were also among the countries that participated in the Pilot project and Uganda and Kenya are among the twelve now implementing their frameworks with significant funding from the GEF. Botswana, Lesotho, Mozambique, Rwanda, Zimbabwe and others in the region are currently being funded through a follow up project to the Pilot which assists countries to design frameworks to assure safety of biotechnology[25]

Countries have chosen to use a variety of triggers for regulation of biotechnology. In Europe it is the fact of using modern biotechnology as defined in the Directives [26]that triggers the regulatory process. In the United States, because current law is used, the trigger tends to be the use of organisms that are pests – plant pests

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[22] South African Genetically modified Organisms Act, 1997, No. 15 of 1997, Government Gazette, Vol. 383, No. 18029, 23 May 1997

[23] Nqobile Nyathi (2002), **"**Biotech offers new horizons and problems", The Financial Gazette, Zimbabwe: http://www.fingaz.co.zw/fingaz/2002/May/May9/1309.shtml

[24] Global Environment Facility

[25] UNEP/GEF Project on the Development of National Biosafety Frameworks, http://www.unep.ch/biosafety and specifically http://www.unep.ch/biosafety/countries.htm

[26] "Genetically modified organism (GMO) means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination …..genetic modification occurs at least through the use of the techniques listed in Annex I A, part 1;…." and Annex 1A states

> "(1) recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules produced by whatever means outside an organism, into any virus, bacterial plasmid or other vector system and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation;
> (2) techniques involving the direct introduction into an organism of heritable material prepared outside the organism including micro-injection, macro-injection and micro-encapsulation;
> (3) cell fusion (including protoplast fusion) or hybridisation techniques where live cells with new combinations of heritable genetic material are formed through the fusion of two or more cells by means of methods that do not occur naturally."

for example - in the manufacture of the organism if the Department of Agriculture is to be involved. Canada has chosen to use a concept of novelty to trigger the regulatory process. Many analyses have suggested that once the process is started, the risk assessment and management processes are very similar.

c. Environmental Policy in relation to GMOs

All the countries that are participating in GEF funded projects have signed the Cartagena Protocol on Biosafety that specifically requires regulation in relation to the trans-boundary transfer of living modified organisms[27] that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health. Those participating in the 'implementation' projects have also ratified or acceded to the Protocol or have agreed to do so. They are also all party to the Convention on Biological Diversity which requires, through Article 8(g), that they 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 impacts that could affect the conservation and sustainable use of biological diversity, taking also into account the risks to human health;" 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

[27] "Article 1, Objective, of the Cartagena Protocol on Biosafety (http://www.biodiv.org/biosafety/protocol.asp#) states "In accordance with the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development, the objective of this 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."

to link the protection of human health to legislation that primarily addresses biodiversity would not be acceptable to most legislatures.

Countries have understood that biosafety in this instance means primarily protection of the environment, and that the release of living modified organisms needs be regulated in order to protect the environment[28]. Safety concerns are not, however, limited to the impact on the environment and regulatory systems that attempt to assure human and animal health are often different from that set in place for environmental protection. The European Novel Food Regulation[29] provides extensive risk assessment and management for the use of genetically modified organisms or products derived from them in foods. Amongst other foodstuffs, it applies to

"(a) foods and food ingredients containing or consisting of genetically modified organisms within the meaning of Directive 90/220/EEC;

(b) foods and food ingredients produced from, but not containing, genetically modified organisms;"

d. Precaution

Scientific data is able to be collected at many sites around the world which can provide an insight into the manner in which the product may interact with its environment when released into a particular environment. Where data is not available or where a country believes that its environment is different from that in which the organism was tested it may require field testing before an organisms is released or placed on the market. Where data is 'knowable' further experimentation will provide data that may address concerns and provide

[28] "The environment is not an abstraction but represents the living space, the quality of life and the very health of human beings, including generations unborn" Advisory Opinion of the International Court of Justice on the Legality of the Threat or Use of Nuclear Weapons, 1996, paragraph 29.
[29] Regulation No 258/97 Of The European Parliament and of the Council of 27 January 1997 concerning novel foods and novel food ingredients; note that this Regulation is about to be substantially modified taking into account the greater public awareness of GM technology since 1997.

answers as to the likely behaviour of the organism in a particular environment. However, because of the inherent variability of biological systems information as to the behaviour may fall into the 'not-knowable' category where no amount of information collected can provide more than increased precision in determining the variability. Further experimentation will not provide any assurance that the organism will (or will not) impact on the environment in an unacceptable manner. The *precautionary approach* is invoked in order to address the absence of data. It is usually taken to refer to Principle 15 of Agenda 21 agreed in Rio de Janeiro in 1992:

> "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."[30]

There have been many cases of serious environmental degradation that have made governments change their perception of environmental protection. These have also affected the public's perception of the environment. Outbreaks of disease in animals and humans due to lack of care (as it is perceived) or to environmental pollution has had a significant effect on an appreciation of both known and potential risks to the environment and to human health and a public acceptance that these potential problems need to be addressed.[31]

"The use of precaution cannot be limited to approving an action or process, or prohibiting it, but implies managing various levels of risk and uncertainty, and taking the appropriate measures at each level"[32] A risk may vary significantly

[30] Rio Declaration on Environment and Development, The United Nations Conference on Environment and Development, Rio de Janeiro 3 to 14 June 1992, www.igc.apc.org/habitat/agenda21/rio-dec.htm
[31] Organisation for Economic Cooperation and Development (OECD) Joint Working Party on Trade and Environment, Uncertainty and Precaution: Implications for Trade and the Environment, 5 September 2002. COM/ENV/TD(2000)114/final
[32] ibid, page 7.

depending on the level of activity or the likelihood that an organism may persist and establish itself in the environment. The inter-relationship with other actins or processes or other organisms with which genetic material may be exchanged may also require caution in analysing the potential risk.

Annex III of the Cartagena Protocol identifies the principles for scientific risk assessment that need to be addressed by member countries when considering living modified organisms that might have adverse effects on biological diversity also taking into account the impact on human health. It provides, *inter alia*, that "[l]ack 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".

This *precautionary principle* (or approach) has attracted many and various interpretations; for many it means that if the science is unknown and there is a risk of environmental damage, do not proceed. Caution dictates that it implies that where there is doubt over the safety of an action, that action should not be taken until evidence is available that the steps to be taken will not have disastrous consequences for the environment. The concern in relation to transgenic organisms is due to the possibility that once an organism is in the environment it is virtually impossible to recall and because of its property of replication, it does not decay over time; indeed numbers may increase disastrously. Others interpret this as an injunction to proceed with caution, considering each release into the environment on a case-by-case basis and probably also proceeding step-by-step, where small field trials precede larger ones and the results are analysed before proceeding to commercial unfettered release (if ever). Recourse to the approach "presupposes that potentially dangerous effects deriving from a phenomenon, product or process have been identified, and that scientific evaluation does not allow the risk to be determined

with sufficient certainty."[33] "Decision making about risks in the context of a precautionary approach is further complicated by the inherent dynamics of science. Even though scientific information may be inconclusive, decisions will still have to be made to meet society's expectations that risks be addressed and living standards maintained."[34] Scientists may be concerned that the 'principle' is used to stifle research, innovation and competition.

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

- *proportional* to the chosen level of protection,
- *non-discriminatory* in their application,
- *consistent* with similar measures already taken,
- *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),
- *subject to review,* in the light of new scientific data, and
- *capable of assigning responsibility for producing the scientific evidence* necessary for a more comprehensive risk assessment."[35]

The SPS Agreement[36] reflects precaution in Article 5.7 by allowing Members to adopt SPS measures where relevant scientific evidence is insufficient. There are four specific conditions applied if members are to use precaution[37]:

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[33] Commission of the European Communities, Brussels, 02.02.2000, COM(2000) 1, Communication from the Commission on the Precautionary Principle.
[34] A Canadian Perspective on the Precautionary Approach/Principle— Discussion Document
[35] Commission of the European Communities, Brussels, 02.02.2000, COM(2000) 1, Communication from the Commission on the Precautionary Principle, Paragraph 6 on page 4.
[36] The World Trade Organisation Agreement on the Application of Sanitary and Phytosanitary Measures http://www.wto.org/english/tratop_e/sps_e/sps_e.htm
[37] Article 5.7 reads "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."

- the measure must be provisional although it does not set a time-limit;
- it must be adopted on the basis of "available pertinent information";
- there must be an attempt "to obtain the additional information necessary for a more objective assessment of risk"; and
- the measure must be reviewed within a reasonable period of time.

The use of precaution requires a number of major considerations to be taken into account. The Canadian Principles[38] provide a starting point for defining policy in relation to precaution.

1. "The decision-making process for managing risks always requires sound and rigorous judgment" where "[J]udgment means determining what is a *sufficiently* sound or credible scientific basis, what *follow-up* activities may be warranted, and *who* should produce a credible scientific basis."[39]

2. "To reduce significant scientific uncertainty and improve decision making, the precautionary approach usually includes follow-up activities such as research and scientific monitoring." However, it has to be noted that in many instances the collection of data may increase the precision of determination of variation, rather than provide data which permits the reduction of uncertainty. Monitoring can only provide assurance that expected events occur, and events predicted not to occur are not observed. Unexpected, unpredictable, indirect and delayed effects on the environment are by their nature difficult if not impossible to monitor."

The arguments that have ranged around precaution are serious, for they have directly impacted on the policy decisions of many countries. In Europe precaution in relation to transgenic organisms is taken to require case-by-case and step-by step approaches to risk. This way of interpreting precaution is built into the

[38] ibid page 4
[39] ibid

Protocol, which also requires a case-by-case process in assessing risk (Annex III.6).

e. Public Opinion

The controversy over the use of modern biotechnology has centered primarily on commercial release into the environment, rather than use in laboratories for research, contained use in industry, use in the production of pharmaceuticals and veterinary products or even field trials. Protesters have, however, chosen to attack and destroy fields in which organisms are being tested. It is the industrial use of genetically modified organisms that may be the major use of modern biotechnology now and in the future. The Eurobarometer surveys show that there is considerable discrimination amongst the public (at least in Europe) in relation to the various uses that modern biotechnology can be put.[40] "Europeans continue to distinguish between different types of applications, particularly medical in contrast to agri-food applications."[41] For GM crops and GM foods support declined and opposition increased over the period 1996-1999, from 1999-2002 there is almost no change in levels of support or opposition[40]. European attitudes to six applications of biotechnology (from the Eurobarometer survey, 2002) indicate the discrimination that has been observed._The results displayed below indicate how discriminating the public is. Food, for example is considered risky, morally unacceptable and not to be encouraged yet crops (much to the surprise of the researchers) are considered useful but risky, morally acceptable and there is a slight majority in favour of their use! In a different survey "A total of 47.7% of Canadians consider the presence of GMOs in foods to be dangerous for human health while 20.7% feel they are not dangerous." (31.6% did not express an opinion)[42].

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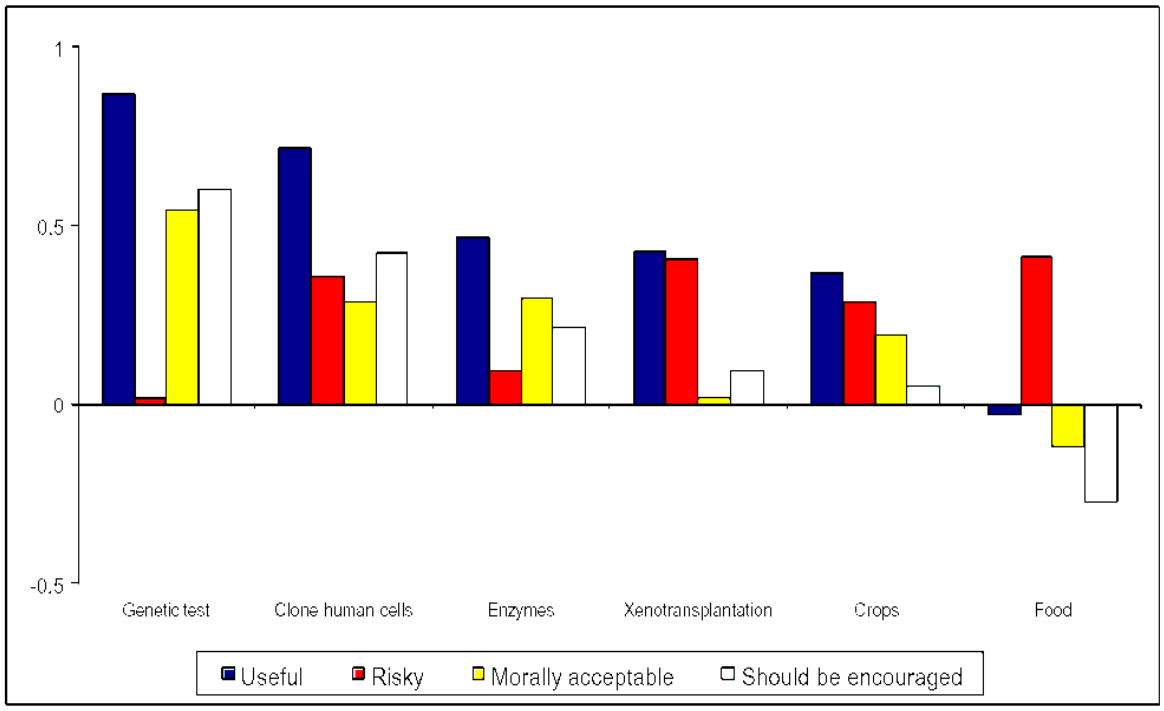
[40] Eurobarometer 52.1 (2000) "Europeans and Biotechnology", fourth in a series of opinion polls throughout the European Union. http://europa.eu.int/comm/research/pdf/eurobarometer-en.pdf

[41] Europeans and Biotechnology in 2002, Eurobarometer 58.0 http://www.europa.eu.int/comm/public_opinion/archives/eb/ebs_177_en.pdf

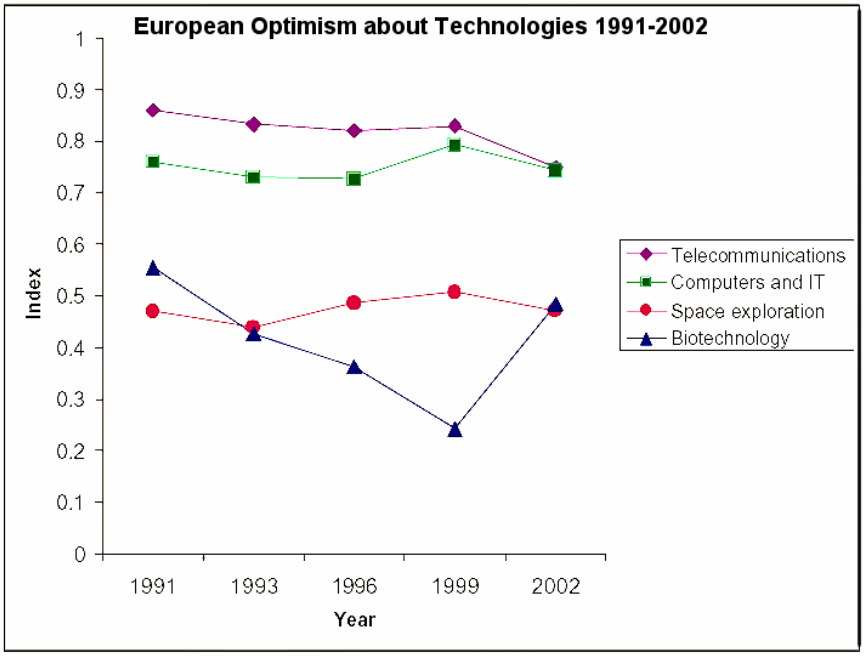
[42] Leger Marketing (2001) "How Canadians Perceive Genetically Modified Organisms" , 507 Place d'Armes, suite 700, Montreal, Quebec H2Y 2W8 _ Phone: 514-982-2464 _ Fax: 514-987-1960 _ www.legermarketing.com



The European public debate resulted in rejection of modern biotechnology which in 1998 had the effect of influencing the main distribution companies to remove these products from European shelves. In the United States, there appeared to be little rejection, attributed by the US government to the openness of the American system. "In 1994 approximately 7,000 acres were planted under 593 USDA field-test authorizations, compared to 57,000 acres under 1,117 authorizations in 2001. The first biotechnology-derived crops were commercialized in 1996 and, in 2001, approximately 88 million acres were planted in the United States and 130 million acres were planted world-wide"[43]. Canada, Argentina and Mexico are the only other countries in which there has been significant use of modern agricultural biotechnology, although many other countries including South Africa and Australia are starting to increase their use of living modified organisms in agriculture. China has approved a small number of

[43] Office of Science and Technology Policy (2002) - Proposed Federal Actions To Update Field Test Requirements for Biotechnology Derived Plants and To Establish Early Food Safety Assessments for New Proteins Produced by Such Plants; Notice, **Federal Register** / Vol. 67, No. 149 / Friday, August 2, 2002, p 50578 – 50580.

transgenic varieties of cotton and expects to proceed to the commercial production of modified rice in the next two years. The latest Eurobarometer survey of European attitudes to biotechnology has indicated a recovery of faith in technology, but this may simply be that the *de facto* moratorium on the commercialization of plants manufactured using GM techniques has taken the subject out of the public consciousness[44]:



In the United States the "American public's position on the acceptability of genetic modification of food is decidedly . . . undecided."[45] 58% of Americans either strongly approve or somewhat approve of creating hybrid plants using genetic modification, while 37% disapprove.

Many developing countries are fearful of the impact of agricultural biotechnology. Zimbabwe and Zambia, for example, have been wary of permitting food-aid

[44] Europeans and Biotechnology in 2002, Eurobarometer 58.0 http://www.europa.eu.int/comm/public_opinion/archives/eb/ebs_177_en.pdf

[45] William K Hallman *et al* (2002) Public Perceptions of Genetically Modified Foods *Americans Know Not What They Eat* Food Policy Institute, Rutgers, The State University of New Jersey, RR-0302-001, page 20 http://www.foodpolicyinstitute.org

which contains transgenic maize into the country, even though many of its people are starving. This reluctance relates to concerns at the safety of the food where it forms a very high percentage of intake and the possible disappearance of major markets if crops are 'contaminated' with transgenic material – Zimbabwe has accepted the maize when it has been milled.

That which is happening in Europe is significant as it has a direct bearing on that which can be done in developing countries. In the first instance the concerns being expressed by Greenpeace[46], Friends of the Earth[47], Christian Aid[48] or even the British Medical Association[49] create a groundswell against the use of this new technology. Can it be right to introduce these 'untested' technologies in developing countries when public 'informed' opinion is so virulently opposed to their use in Europe? When even statutory bodies like the Nature Conservation Organisations in Britain and France reject modern biotechnology because of a predicted negative effect on the environment, are developing countries to embrace them? The UNEP International Guidelines[50] and the Cartagena Protocol require the public to be informed and educated about biosafety, but the virulent reaction against the technology in Europe impacts directly on any public image more easily than a reasoned argument for the safe use of the technology. During the first nine months of 1999 in Britain there were a continual series of press reports "implying that eating GM food would lead to all sorts of serious diseases"[51].

The attention paid by the media to foods produced using modern biotechnology has been sustained over a long period and is almost totally hostile. The coverage

[46] For example http://archive.greenpeace.org/~geneng/ or http://ge.greenpeace.org/campaigns/intro?campaign%5fid=3942
[47] for example http://www.foe.org/foodaid/
[48] for example http://www.christian-aid.org.uk/indepth/0003bios/biosafet.htm
[49] for example http://www.foeeurope.org/GMOs/bma.doc or http://www.saynotogmos.org/bma_statement.htm
[50] UNEP International Technical Guidelines for Safety in Biotechnology, http://www.bmu.de/download/dateien/unep.pdf
[51] House of Commons Science & Technology Committee (1999) Scientific Advisory System: Genetically Modified Foods First Report HC 286-I ISBN 0 10 231499 3. paragraph 29.

has stressed the technology, rather than the products. The rejection of genetically modified foods by many European Supermarkets and food producers has impacted on production and growing of genetically modified crops that have to be exported to one of the largest food markets in the world[52]. To grow rice modified so that it produces vitamin A is a wonderful prospect for nutrition in the many countries that depend on rice as a primary food. If, however, the produce cannot be exported as well, producers will be reluctant to grow it! Concern over the impact on the environment has been the primary concern but fears about the long-term safety of eating modified foods and about the speed of entering the unknown have been powerful messages to the public[53] Christian Aid's paper asks

"[A]re GM crops the next in a long line of inappropriate products to be dumped on poor countries?" They state that "GM crops are irrelevant to ending hunger; the new technology puts too much power over food into too few hands; and too little is done to help small farmers grow food in sustainable and organic ways". "It is tempting to see biotechnology in agriculture as a clean neutral science, simply transferring progress from the laboratory to the field, improving the lot of everyone. This is illusory. All technologies are embedded in specific economic and social systems and have different costs and benefits."[54]

This response in Western Europe to the new technology cannot easily be dismissed through assertions by scientists that there is negligible risk, or that permits to market transgenic foods and crops (in particular) should be based solely on risk assessments that are science based. If all the scientific information had been available and a consensus amongst scientists could be achieved that

[52] The following is a report from 1999 in the July 1999 Issue of Natural Foods Merchandiser "The world's two largest food production companies have decided they no longer will accept genetically modified ingredients for products sold in Europe. Within hours of one another, both Unilever UK and Nestle UK announced a policy change in response to continued demonstrations by European consumers worried about potential consequences of GMO crops."

[53] Christian Aid (1999) "Selling Suicide" edited by Angela Burton, Christian Aid, PO Box 100, London, SE1 7RT. (http://www.christian-aid.org.uk/reports/suicide/index.html)

[54] Christian Aid (1999) "Selling Suicide" edited by Angela Burton, Christian Aid, PO Box 100, London, SE1 7RT. (http://www.christian-aid.org.uk/reports/suicide/biotechnology.html .)

the impact on the environment is minimal, it would be possible to argue for a totally science based risk assessment process. In an Irish Consultation Paper[55] the concerns about potential environmental and human health effects were thought to arise because of an absence of familiarity with the regulatory systems; the technology was thought to be complex and developing rapidly; "there is little experience on the interaction of GMOs with their surrounding environment"; the information being provided to the public is probably inadequate, particularly in relation to labeling to allow choice; the use of antibiotic resistance marker genes is thought to inimical to their use in human and veterinary medicine and the use of herbicide tolerant crops might increase the use and build-up of herbicides in the environment.

In 2000 The Council of Europe Parliamentary Assembly once again looked at the use of modern biotechnology (and, in particular, the patenting of genes and gene fragments). They resolved[56] that "[p]ublic opinion should be more strongly involved in political decision-making as regards scientific and technological choices and scientists should be encouraged to engage more in public debate."

There are many different ways in which policy on involving the public has evolved. The Cartagena Protocol requires that countries engage their public in decision making both at the policy level and when considering individual applications for use of modern biotechnology. For countries with a history of involving their public in the decision making process this is not easy; for those not used to direct public involvement it may be much more difficult.[57]

"1. The Parties shall:

(a) Promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of

[55] Government of Ireland (1999) Department of the Environment and Local Government Consultation paper on a national policy position on the deliberate release of genetically modified organisms to the environment.
[56] Council of Europe Parliamentary Assembly (2000), Recommendation 1468 on Biotechnologies
[57] Cartagena Protocol Article 23

living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies;

(b) Endeavour to ensure that public awareness and education encompass access to information on living modified organisms identified in accordance with this Protocol that may be imported.

2. The Parties shall, in accordance with their respective laws and regulations, consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21."

f. Science based decisions

There have been many arguments that decisions on the use of these living modified organisms must be based on science; Policy may be defined when designing the system that is applied to individual applications, but that the applications should only be considered in the light of this policy.

Decisions are usually made by Government based on advice received from a number of sources. The risk assessment procedure, at the very least, should be science based. This is made very clear in the Cartagena Protocol. Article 15 states that "Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner". A Royal Society Report in 2002 asserts that "scientific assessments must inform policy decisions but cannot pre-empt them, and that public opinion must be taken into account throughout. We believe that the public debate about GM food must take account of wider issues than the science alone. We also wish to stress the importance of informing

debate with sound science"[58] Article 23 of the Cartagena Protocol requires public involvement in the decision making process and article 26 allows for specific socio-economic issues to be taken into account in the process:

> "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."

Unlike the European Union, the US and Canada, the vast majority of developing countries may not have expertise directly employed by government in the vast array of disciplines needed to perform a complete risk assessment for transgenic organisms. The data needed to assess likely environmental degradation or impact may not be available in many countries. A different approach may be needed, where an applicant requesting a permit for the use of a transgenic organism must perform a detailed risk assessment – possibly even performing field tests in an appropriate environment – and submit this for audit to a government, rather than the government performing the risk assessment. Most scientists may feel more confident at auditing a detailed assessment than attempting the assessment themselves. Applicants could also be expected to design their own risk management, consultation and monitoring procedures, with input from government appointed assessors where appropriate. There is an obvious danger in this approach, however, for lack of trust in those applying to release organisms to provide all the necessary information may mitigate against the acceptance of the risk assessment. Can applicants be trusted to provide all the necessary information? Where a decision is made to use audit rather than direct risk assessment by government, it is important that the scientists involved in the

[58] Ibid, paragraph 3

audit are able to ask for further information and are able to identify gaps in the approach taken by the applicant.

Risk assessment of genetically modified organism is largely based on the concept of familiarity, or of 'substantial equivalence'. It is actually difficult to identify other ways of approaching the problem of identifying risk. It assumes that the characteristics of the modified organism except for the specific characteristics introduced are those of the host organism. It is not easy to see any other approach, but the Royal Society of Canada[59] and the Royal Society in the UK have both indicated dissatisfaction with 'substantial equivalence' which is arguably substantially equivalent to familiarity. Can the approach be justified when stress tolerance, modification of metabolism or production of pharmacologically active compounds really begins?

Crop varieties developed through conventional plant breeding techniques not involving modern biotechnologies are not generally tested for their safety. Rather they have to meet plant variety registration requirements that identify whether they are distinct from those currently on the market, uniform and stable. These traditional methods use (primarily) crossing selection and back-crossing processes to select a desired characteristic and remove inadvertently introduced extra characteristics that initially accompany the introduced trait. These mechanisms introduce new and numerous gene combinations. If there are toxins known to occur in these crops (e.g. glucosinolates in canola, glycol-alkaloid accumulation in potatoes), the new variety is normally tested to ensure that the level of toxin (or allergen) is no greater than the range that is normally observed for that substance. Interactions of traits introduced by traditional methods with other characteristics of the plant are normally ignored until they prove to make the variety unusable. "[T]he implicit assumption behind this methodology is that, even where a breeding-derived novel trait is involved, *new combinations of*

existing genes operating within highly selected germplasm are not expected to generate harmful outcomes."[59]

For transgenic crops, the concept of 'substantial equivalence' was introduced. This was first described in a 1993 report of the OECD which suggested that "If a new food or food component is found to be substantially equivalent to an existing food or food component, it can be treated in the same manner with respect to safety"[60]. The World Health Organization (1995) published a report in which the concept of "substantial equivalence" as a decision threshold was promoted as the basis for safety assessment decisions concerning GMOs.[61]

Substantial equivalence can be considered in three ways:[62]

- "the GM foodstuff might be regarded as substantially equivalent to its conventional counterpart both toxicologically and nutritionally…… When a product has been shown to be substantially equivalent, no further safety assessment is required.

- "it might be substantially equivalent apart from certain defined differences. Sometimes the GM food product includes the components deliberately introduced by genetic modification. In this case the GM food product might be regarded as 'substantially equivalent to its conventional counterpart except for a small number of clearly defined differences'. Assessment is then limited to examining the implications of the difference(s), perhaps by testing the novel components of the GM plant in isolation."

[59] Royal Society of Canada (2001) "An Expert Panel Report on the Future of Food Biotechnology prepared by The Royal Society of Canada at the request of Health Canada, Canadian Food Inspection Agency and Environment Canada" ISBN 0-920064-71-x

[60] OECD (1993). *Safety evaluation* of foods produced bymodern biotechnology – concepts and principles. Organisation for Economic and Cooperative Development: Paris

[61] Royal Society of Canada (2001) "An Expert Panel Report on the Future of Food Biotechnology prepared by The Royal Society of Canada at the request of Health Canada, Canadian Food Inspection Agency and Environment Canada" ISBN 0-920064-71-x - page 179

[62] Royal Society (2002) February 2002 Genetically modified plants for food use and human health—an update Policy document 4/02; ISBN 0 85403 576 1

- "the GM product might be regarded as not substantially equivalent to its conventional counterpart, or there might not be a suitable reference available for comparison. The product will then need a highly detailed safety assessment" taking all the properties of the modified foodstuff and determining by direct measurement where necessary the impact on human health and the environment.

Many countries are deciding that the use of the term 'substantial equivalence' is misleading. It suggests that if substantial equivalence is demonstrated, no further assessment need be done. There is a 'mistaken perception that the determination of substantial equivalence was the end point of a safety assessment rather than the starting point'.[63] The Royal Society recommended in 2002 that

> "Safety assessments should continue to consider potential effects of the transformation process. The phenotypic characteristics to be compared between foods derived from GM plants and their conventional counterparts should be defined. It may not be necessary or feasible to subject all GM foods to the full range of evaluations but those conditions that have to be satisfied should be defined."[64]

g. Intellectual Property Rights and Ethics

There are many arguments for and against the use of intellectual property rights in relation to modern biotechnology. "The patent system, as a system for the protection of intellectual property, is an integral part of the market economy and therefore can be a driving force for innovation in many technological questions"[65] The same resolution notes that "[L]iving organisms are able to reproduce

[63] FAO/WHO (2000). Safety aspects of genetically modified foods of plant origin. Report of a Joint Food and Agriculture Organisation/World Health Organisation Consultation. FAO/WHO: Rome

[64] Royal Society (2002) February 2002 Genetically modified plants for food use and human health—an update Policy document 4/02; ISBN 0 85403 576 1 page 10

[65] Parliamentary Assembly of the Council of Europe, Recommendation 1425 (1999) on biotechnology and intellectual property

themselves even if they are patented, and in view of this special quality of living organisms the scope of a patent is difficult to define, which makes it nearly impossible to find a balance between private and public interests". The resolution notes that there are ethical concerns related to the use of patents on living systems:

> "9. The Assembly considers that monopolies granted by patent authorities may undermine the value of regional and worldwide genetic resources and of traditional knowledge in those countries that provide access to these resources.
>
> 10. It considers that the aim of sharing the benefits from the utilisation of genetic resources within this broader view does not necessarily require patent-holding but requires a balanced system for protecting both intellectual property and the "common heritage of mankind".
>
> 11. It also considers that the many outstanding questions regarding the patentability and the scope of protection of patents on living organisms in the agro-food sector must be solved swiftly taking into account all interests concerned, not least those of farmers and developing countries."

Over the last few decades the global trading importance of biotechnology has been recognised and as a result there have been concerted and concentrated efforts to protect the results of research and development involving genetic material. The result of this has been the extension of intellectual property protection to most forms of biological material. The trade importance of biological information has been underlined the adoption of the Agreement on the Trade Related Aspects of Intellectual Property Rights (TRIPS) within the World Trade Organisation. This requires states party to the agreement to provide protection for all types of inventions irrespective of the field of technology. The aim of the Agreement is to ensure that all member states provide effective and appropriate

intellectual property protection and protect the intellectual property rights by the appropriate enforcement mechanisms. The Agreement sets down the minimum standards of protection[66]. The TRIPS agreement permits countries to exclude from patentability those inventions whose commercial exploitation may be contrary to *ordre public* or morality[67]. Countries may exclude from patentability "diagnostic, therapeutic and surgical methods for the treatment of humans or animals" and more importantly. Article 27(2) allows Members to exclude from patentability innovations in order to protect animal, plant life or health or to avoid serious damage to the environment and Article 27(3) provides for exclusion from patentability of

> "plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof…"

What constitutes *sui generis* protection for new plant varieties is not defined hence countries are free to adopt a system that ensures intellectual property protection for plants. One option is for countries to implement the International Convention for the Protection of New Varieties of Plants (UPOV) but "this form of protection has been criticized for focusing too much on the rights of plant breeders, and too little on the rights of those using the seeds – farmers."[68]

Whilst obliging member states to provide protection systems, those 'inventing' new products do not need to obtain that protection. The rights only apply in the

[66] Article 27(1) "… patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.5 Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

[67] TRIPS agreement Article 27(2)

[68] Walker, Simon. 2001. *The TRIPS Agreement, Sustainable Development and the Public Interest: Discussion Paper*. IUCN, Gland, Switzerland and Cambridge, UK and CIEL, Geneva, Switzerland. ISBN: 2-8317-0604-1

country in which the inventors have chosen to invoke protection. In most African countries many of the biotechnology inventions will not have been protected through patent rights and can legally be used as if in the public domain. It is only when products developed using patent protected materials or methods are exported into countries where protection exists that the rights of the inventor must be respected.

There is an underlying assumption that the introduction of an intellectual property system will result in a dramatic increase in the innovative capacity of the private sector, while allowing the public sector to become more self-financing. This may be true to an extent in countries with a substantial research capacity but is unlikely to be the case in developing countries where the research and development sector is not as strong. A 'Northern' intellectual property system may provide an incentive but there may be limited local capacity to exploit it. Even when technologies are developed, firms in developing countries can seldom bear the costs of acquisition and maintenance of rights and to an even greater extent, enforcement (especially in those countries where substantial earnings may be realisable).

The costs of establishing an infrastructure to support a intellectual property rights regime may be substantial, and mechanisms for the enforcement of IP rights is costly both to government and to private stakeholders.

If there is a policy commitment to the implementation of a rights system, then perhaps the best way to proceed would be to look at the systems in Europe and the United States and adapt them to local and cultural needs. The required patent system would need to balance the costs and benefits to local needs and requirements. The implementation of IP system should examine whether there might be a necessity for

- Raising the standard of the granting criteria of novelty, inventiveness and industrial application to ensure that the reward of the patent is consummate with the benefit to society
- Widen the subject matter that can be excluded from patentability
- Provide an effective compulsory license system.
- Include an exclusion of patentability on the grounds of 'morality' similar to article 53(a) of the European Patent Convention
- Consider the suitability of other forms of protection to encourage local innovation, such as utility models.

There is real concern about the use of intellectual property law in developing countries, particularly in relation to health care but also in relation to that which is emotively called biopiracy or bio-prospecting.

In May 2000 the revocation by the European Patent Office of a patent on a *neem*[69] product was undoubtedly a victory for India and developing countries. However, individual legal action is no substitute for a legally enforceable integrated approach to bio-prospecting.

Pharmaceutical companies worldwide are interested in finding new and alternative therapies and have widened their search to include traditional medicines and practices largely based on medicinal plants endemic to developing countries. There are many traditionally used herbal medicines which may have real therapeutic properties. If a company takes the knowledge as the starting

[69]The neem tree (Azadirachta indica) is a tropical evergreen related to mahogany. Native to east India and Burma, it grows in much of southeast Asia and west Africa. The people of India have long revered the neem tree. For centuries, millions have used parts of the neem tree for medicinal purposes, such as a general antiseptic against a variety of skin diseases including septic sores, boils, ulcers, and eczema. In particular, neem may be the harbinger of a new generation of "soft" pesticides that will allow people to protect crops in benign ways. The active ingredient isolated from neem, azadirachtin appears to cause some 90 percent of the effect on most pests. It does not kill insects, at least not immediately. Instead it both repels and disrupts their growth and reproduction.

point for a serch for new pharmaceuticals, extracts the active product it is entitled to a patent on the extracted product even though it cannot replace the traditional product itself. Developing countries are thus faced with the acute dilemma of their valuable indigenous wealth being taken away and exploited commercially by the resource and technology rich trans-national pharmaceutical companies.

Bio-prospecting is not just in the area of pharmaceuticals. In Northwest Mexico, yellow beans have been cultivated for centuries being the staple diet of many Mexicans. In 1994, John Proctor the owner of a small seed company POD-NERS, L.L.C., bought a bag of commercial bean seeds in Mexico and took them back to the United States. Proctor planted the yellow beans in Colorado and allowed them to self-pollinate. By selecting yellow beans in several generations, a segregating population resulted in which the colour of the beans is uniform, stable and changes little by season. In 1996 Proctor applied for a US patent which was granted in 1999[70]. With the patent granted, Proctor has an exclusive monopoly on yellow beans and can exclude the importation, sale, offer for sale, make, use for any purpose, including drying edible or propagation of any yellow bean exhibiting the yellow shade of the Enola beans.

Customs officials at the US-Mexico border are now inspecting beans, searching for any patent infringing beans being imported into the United States. Because of this bean alone and the threat of infringement, some export sales have dropped over 90%. This has also had an affect on the market for other non-yellow beans as often the beans are not separated and yellow infringing beans are mixed in the non-yellow beans. As agriculture is the primary source of employment and livelihood for Northwest Mexico this patent has had a serious effect on farmers in that area. Although farmers can still grow and sell the beans in Mexico, they can no longer export them to markets in the United States without paying royalties to the patent holder.

[70] US Patent No 5,894,079

The International Center for Tropical Agriculture (CIAT) is legally challenging the patent, arguing that the patent claims are invalid, failing to meet novelty and non-obviousness requirements and disregarding available prior art. The opposition proceedings have been slowed by POD-NERS, L.L.C. filing new claims and as yet no decision has been made.

One extremely important lesson can be learned from what many people feel is an example of bio-prospecting at its worse. In the US[71] under Section 35 U.S.C. §102(a) the invention cannot be "known or used in this country, or patented or described in a *print publication* (emphasis added) in this or a foreign country". Therefore, mere use in Mexico without printed publication is insufficient to show a lack of novelty. Hence the need to document genetic resources as discussed below.

Membership of the WTO requires countries to have in place an effective intellectual property regime. However the simple implementation of the Agreement into national law is insufficient to protect a country's genetic resources as Article 27(3b) is inadequate to meet their protection requirements. What is required is the enactment of legislation that incorporates the framework of current agreements and negotiations – TRIPS, the requirements of the Convention on Biological Diversity and the International Treaty for the Protection of Plant Genetic Resources.

In November 2001 at the WTO Ministerial Conference in Doha the concerns resulted in a statement and an agreement to find a solution to some of these pressing problems before the end of 2002[72]. No agreement has yet been reached. The Doha Statement recognised

[71] This is not the case with the European Patent Convention

[72] Declaration on the TRIPS Agreement and Public Health, Adopted on 14 November 2001, WTO Ministerial Conference - WT/MIN(01)/DEC/2

- "the gravity of the public health problems afflicting many developing and least developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics."

- "the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems."

- "that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."

The Ministers also recognised that compulsory licensing to produce drugs was not an option for many of the developing countries, and that other solutions would have to be found for many of these countries.

Hence Developing countries should consider the manner in which they implement the various agreements in order to protect their people and their resources, including

1. Enacting appropriate biodiversity protection legislation including benefit sharing consistent with Article 8j[73] of the CBD and access to genetic resources (Article 15)[74]

[73] Article 8j: "Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices;

[74] Article 15. Access to Genetic Resources

2. The TRIPS agreement does not require countries to institute a patent regime for plant material but replace it with a *sui generis* system for protection of the plant intellectual regime[75]. The replacement system could be designed to protect extant varieties that are in the public domain as well as new plant varieties and provide for the needs of the country taking into account, for example, the communitarian approach to property that are often part of the culture of developing countries as well as the needs for innovation.

3. Developing countries may need to document and catalogue their biological assets not only to ensure protection but also to assure future collaboration and exploitation. States have sovereign rights over their biodiversity and are responsible for conserving their biological diversity and for using their biological resources in a sustainable manner.[76] Article 3 of the Convention of Biological Diversity states that

> "States have, in accordance with the Charter of the United Nations and the principles of international law, the sovereign right to exploit their own resources pursuant to their own environmental policies, and the responsibility to ensure that activities within their jurisdiction or control do not cause damage to the environment of other States or of areas beyond the limits of national jurisdiction."

There are many who are concerned at the way in which IP protection has been used in many countries. "The balance in many IP systems seems to be shifting too far in favour of technology producers. Negotiations over IPRs have been powerfully influenced by industry lobby groups and are being driven by concerns of trade liberalization and international investment between developed countries.

[75] Walker, Simon. 2001. *The TRIPS Agreement, Sustainable Development and the Public Interest: Discussion Paper*. IUCN, Gland, Switzerland and Cambridge, UK and CIEL, Geneva, Switzerland. ISBN: 2-8317-0604-1
[76] Preamble to the Cartagena Protocol.

The legitimate technological and developmental objectives of developing countries – generally technology users – are not being given due consideration. This shift in the ownership and control of information, and the resulting boon to private investors, has been called an "information land grab"[77]

[77] [77] Walker, Simon. 2001. *The TRIPS Agreement, Sustainable Development and the Public Interest: Discussion Paper*. IUCN, Gland, Switzerland and Cambridge, UK and CIEL, Geneva, Switzerland. ISBN: 2-8317-0604-1 quoting Boyle, J., "Sold Out", *New York Times*, March 31, 1996. http://www.wcl.american.edu/pub/faculty/boyle/sold_out.htm>.

3. ETHICAL ISSUES RAISED BY MODERN BIOTECHNOLOGY[78]

In May 1999 the Nuffield Council on Bioethics, an independent organisation in the United Kingdom published a major report on 'Genetically modified crops: The ethical and social issues'[79]. In the executive summary of the report they state "The application of genetic modification to crops has the potential to bring about significant benefits, such as improved nutrition, enhanced pest resistance, increased yields and new products such as vaccines. **The moral imperative for making GM crops readily and economically available to developing countries who want them is compelling....**"

There have been many who have argued that transgenic crops will assist in the task of providing enough food in the right place and the right time in order to retain, as far as possible, the way of life of those who desperately need food. It is possible that the technology, used properly, will provide for these needs. It is essential, however, that in order to do so, the crops that are modified and the genes inserted are chosen with the needs of those who are hungry in mind. To suggest that the current range of modified crops is primarily anything other than products designed for industrialised farming is clearly wrong; however, the technology has been used where it was possible in the early stages of its development. New uses that really do benefit those who are needy are imperative if this really is to benefit the poor.

[78] Many of the points made in this section of the report arise from

- Linda Nielsen and Berit A Faber (2002) Ethical Principles in European regulation of Biotechnology – Possibilities and pitfalls, The Ministry of Economic and Business Affairs, Denmark ISBN 87 7408 663 4
- Nuffield Council on Bioethics (1999) Genetically modified crops: The Ethical and Social issues
- Food & Agriculture Organisation (2001) Ethical Issues in Food and Agriculture Rome, ISBN 92-5-104559-3

[79] Nuffield Council on Bioethics (1999) Genetically modified crops: The Ethical and Social issues. Nuffield Council on Bioethics, 28 Bedford Square, London WC1B 3EG, Telephone: 0171 681 9619, Fax: 0171 637 1712. http://www.nuffieldfoundation.org. ISBN 0 9522701 4 5

"It is increasingly important to include ethical considerations centred on humankind, society and the environment in deliberations regarding developments in biotechnologies, life sciences and technologies and their applications."[80]

h. Natural and Unnatural

There are many who perceive genetically modified organisms in the environment as equivalent to 'playing God': an unnatural act that should not be done. The industrialisation of nature, to many, is unacceptable. There is a deep rooted belief in many societies that tinkering with nature is unacceptable. This argument will at least be as strong in African societies as it is in Europe. There is a view that tampering with nature is inherently wrong. We have 'dominion' over nature[81], which implies responsibility to look after and protect rather than own.

The concept that genetic modification 'that could not happen naturally' is wrong is held by many people even though it is not often clearly enunciated. Many argue that the argument precludes any selective approach that results in improved crop plants, for by doing so, we are playing God. Others argue that it is only that which could not have happened without human intervention that is unacceptable. Even where the modification itself is acceptable there are religious objections that might mean that the resulting organism is unacceptable – possibly (for example) genes derived from the pig inserted into foods could arguably be unacceptable to those whose religion precludes the use of products derived from the 'unclean' animal.

Any discussion based on objections to playing God is generally not accessible to logical argument. Respect for such beliefs usually involves ensuring that there are mechanisms in place to permit believers to choose not to use such products. "[P]roponents of the technology citing practical benefits may have an intrinsic value system that views science and progress as good things in themselves, and

[80] Council of Europe Parliamentary Assembly (2000), Recommendation 1468.
[81] Genesis Chapter 1:26: "Let man have dominion over the fish of the sea, and over the fowl of the air, and over every living thing that moves upon the earth."

opponents may be analysing risks from a world-view that questions the rightness of technological progress."[82]

i. The principle of Justice[83]

One of the most important issues that we need to recognise is that many different groups within a society have competing rights and fears. There is a need to attempt to balance these needs. "For example, if protecting the rights of consumers by providing adequate labelling was very expensive and was generally agreed to do nothing to prevent harm, most people would say that upholding the right to know would not be worth the loss of value to producers, particularly if the producers were poor. Conversely, if informative but inexpensive labelling was desired by the majority of consumers, it would probably command wide public support."[84] The principles at stake are not complex but their implementation is. Securing a consensus is complicated by the fact that producers have an interest in exaggerating the difficulty of complying with new regulations and pressure groups have an opposite interest in exaggerating the public demand for them. Such questions about where the balance of burden and benefit is to be struck are the subject of everyday political debate.

This principle of justice poses many questions which need to be addressed. Is this new technology likely to increase the gap between the rich and the poor, both within countries (particularly in the developing countries) and between developed and developing countries? Are the products produced by the technology able to provide for those who really need it, the poor? Will it generate wealth for the society as a whole which can assist those who need it? If the technology is more efficient and it will provide more food but at the expense of

[82] Council on Bioethics (1999) Genetically modified crops: The Ethical and Social issues. Paragraph 6.7
[83] Ibid Paragraphs 1.20 – 1.31.
[84] ibid paragraph 1.20

some who farm traditionally, is it acceptable? "GM crops are currently vulnerable to questions about their real usefulness and to questions about who benefits."[85]

j. Economic and Social Benefits and Risks – Principle of general welfare

Of necessity biotechnology has to be applied for the benefit of human beings, society and the environment. These are not necessarily the same, for the benefit to 'living' human beings may be at the short or long term cost to the environment. There is a presumption that 'acceptability' of the risk must include an improved quality of life, perhaps as we develop better (or more) food, better health and an environment which is improved in a sustainable manner. Human usage of the environment in the 10000 years of our exploitation of nature has been relatively benign. In the last 100 years, however, we have made rapid and possibly irretrievable changes to the environment, including the excessive use of fossil fuels relative to their replacement, excessive use of water, production of greenhouse gases etc and even a huge increase in the human population. Humans are no longer in harmony with their environment, and we have to be aware of an impact on the environment. Where a primary goal was the pursuit of happiness (and the greatest good) we now have to pursue sustainability.

These concerns are human centred. Many of those that live in Southern Africa are suffering from severe malnutrition, and drought is causing havoc with and to the environment. If the application of modern biological techniques could result in food products that can better survive drought and heat, and also is able to provide more food in the right place and the right time, then there are clear benefits that result from its use. It is axiomatic that food is essential for our survival. "Both formal ethical systems and ethical practices in every society presume the necessity of providing those who are able-bodied with the means to

[85] ibid paragraph 1.23

obtain food and enabling those who are unable to feed themselves to receive food directly.[86]

> "We consider it intolerable that more than 800 million people throughout the world, and particularly in developing countries, do not have enough food to meet their basic nutritional needs. This situation is unacceptable. Food supplies have increased substantially, but constraints on access to food and continuing inadequacy of household and national incomes to purchase food, instability of supply and demand, as well as natural and man-made disasters, prevent basic food needs from being fulfilled. The problems of hunger and food insecurity have global dimensions and are likely to persist, and even increase dramatically in some regions, unless urgent, determined and concerted action is taken, given the anticipated increase in the world's population and the stress on natural resources."[87]

It is clear that we need to promote access to the genetic resources for food and agriculture for farmers, farming communities and the consumer.

Human health is important in this context. Health is improved where hunger and quality of food is eliminated. Healthy people are empowered in that they are able to participate in society and are more able to live meaningful lives. The FAO constitution identifies the need to raise levels of nutrition, secure improvements in the efficiency of production and distribution of all food and agricultural products, and better the conditions of those who live in rural areas.

For most consumers in developed countries the choice of whether to eat genetically modified foods or not is not an ethical issue. To eat genetically modified food would not be wicked, even if the individual was concerned as to its

[86] Food & Agriculture Organisation (2001) Ethical Issues in Food and Agriculture Rome, ISBN 92-5-104559-3, page 3
[87] Rome Declaration on World Food Security, 1996 : http://www.fao.org/docrep/003/w3613e/w3613e00.htm

safety. If however, that food was proscribed by the society as (for example) not being *halal* or *kosher*, then an inability to identify the food as proscribed would be unethical. Where there are people who are starving and where a technology can help to provide for more and nutritionally better food, and it is not made available is an ethical issue.

The industrialisation of agriculture is an issue in many African countries, for it takes away the traditional structures of society and substitutes a more individualist system that may cause harm. This industrialisation may arguably help in providing more and better food at the cost of disrupting traditional belief systems and modifying the way of life of many in rural areas which may result in less food available where and when necessary.

The agreement setting up the World Trade Organisation tries to balance the many conflicting issues that this principle requires - "relations in the field of trade and economic endeavour should be conducted with a view to raising standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand, and expanding the production of and trade in goods and services, while allowing for the optimal use of the world's resources in accordance with the objective of sustainable development, seeking both to protect and preserve the environment and to enhance the means for doing so in a manner consistent with their respective needs and concerns at different levels of economic development". The WTO and its disputes resolution system has placed the freedom to trade above environmental concerns, but there is recognition of the importance of environmental concerns.

"If one country believes another country's trade damages the environment, what can it do under the terms of the WTO agreements? Can it restrict the other country's trade? If it can, under what circumstances? At the moment, there are no definitive legal interpretations, largely because the questions have not yet

been tested in a legal dispute either inside or outside the WTO".[88] Where both countries are party to an international environment agreement their dispute may be able to be addressed through that agreement. If one of the countries is not a party to the agreement it is not yet possible to decide what the implications might be. It will depend on the obligations placed on the member country by the treaty and by the specifications identified in the agreement in regard to relations between Parties and non-Parties. If neither country involved in the dispute are party to an environmental agreement (or if there is no agreement relating to that issue) then WTO rules apply. They have been interpreted to mean that trade restrictions cannot be imposed on a product purely because of the way it has been produced and any one country cannot impose its standards on another.

k. Sustainable Development

In 1987 the Brundtland Report[89], also known as *Our Common Future*, considered the need for ensuring that economic development was achieved whilst natural resources were not depleted. It is, the report asserted necessary to provide for the future without harming the environment. Published by an international group of politicians, civil servants and experts on the environment and development, the report provided a key statement on sustainable development, defining it as:

> *"It is in the hands of humanity to make development sustainable, that is to say, seek to meet the needs and aspirations of the present without compromising the ability of future generations to meet their own. The concept of sustainable development implies limits -not absolute limits, but limitations that the present state of technology or social organisation and the capacity of the biosphere to absorb the effects of human activities impose on the resources of the*

[88] Trading into the Future – WTO - The World Trade Organization (2001) WTO Publications, World Trade Organization, Centre William Rappard, Rue de Lausanne 154, CH–(1211 Geneva, Switzerland. Tel (+41–22) 739 52 08 / 739 53 08. Fax: (+41-22) 739 57 92 e-mail: publications@wto.org Page 47.

[89] Our Common Future. The World Commission for the Environment and Development Alianza Publications 1988

environment-, but both technology and social organisation can be organised and improved so that they will open the way to a new era of economic growth. The Commission believes that poverty is no longer inevitable. Poverty is not only a malaise in itself. Sustainable development demands that the basic needs of all are satisfied and that the opportunity of fulfilling their expectations of a better life is extended to all. A world where poverty is endemic will always be susceptible to suffering an ecological or any other kind of catastrophe."

"The report highlighted three fundamental components to sustainable development: environmental protection, economic growth and social equity. The environment should be conserved and our resource base enhanced, by gradually changing the ways in which we develop and use technologies. Developing nations must be allowed to meet their basic needs of employment, food, energy, water and sanitation. If this is to be done in a sustainable manner, then there is a definite need for a sustainable level of population. Economic growth should be revived and developing nations should be allowed a growth of equal quality to the developed nations."[90]

This is an important policy statement; it provides for an approach to our environment which must inform the manner in which crops are produced and land is used.

I. Autonomy, Dignity, Integrity and Vulnerability

Human autonomy and dignity need to be respected. Article 2 of the UNESCO Universal Declaration on the Human Genome and Human Rights[91], 1997 states that

[90] Taken from http://www.doc.mmu.ac.uk/aric/eae/Sustainability/Older/Brundtland_Report.html
[91] see http://www.unesco.org/human_rights/hrbc.htm

(a) Everyone has a right to respect for their dignity and for their rights regardless of their genetic characteristics.

(b) That dignity makes it imperative not to reduce individuals to their genetic characteristics and to respect their uniqueness and diversity.

Article 6 requires that "[N]o one shall be subjected to discrimination based on genetic characteristics that is intended to infringe or has the effect of infringing human rights, fundamental freedoms and human dignity." Governments are expected to treat the deeply held convictions of their citizens with respect: they have to pursue policies that can command a general consensus even where some views cannot be accepted as they are in direct contradiction with others.[92]

Animals and the natural world are also entitled to respect for their integrity and vulnerability[93]

There are also concerns that the new technology will lead to exploitation of those living in the 'developing' countries:

- monopoly control of chemicals used in agriculture and of seeds which allow plants to resist these chemicals might be exploitative and place a strain on the economy of developing countries
- major changes in social structures which might sequentially affect the types of agriculture and needs for distribution of foods and food products.

m. Just Distribution of Benefits and Burdens

An ethical use of biotechnology would require a just distribution. This is particularly important in the context of developing countries, for it has been

[92] Nuffield Council on Bioethics (1999) Genetically modified crops: The Ethical and Social issues, section 1.09

[93] Linda Nielsen and Berit A Faber (2002) Ethical Principles in European regulation of Biotechnolgy – Possibilities and pitfalls, The Ministry of Economic and Business Affairs, Denmark ISBN 87 7408 663 4, page 12

argued that for obvious reasons most of the products derived from modern biotechnology are being introduced by private companies that have an obligation to maximize earnings for their shareholders, and therefore that the products are aimed at markets that can best pay for their use. If the technology simply increases the divide between rich and poor can it be ethical. This would have to be addressed through public and private funds that attempt to provide for those who cannot purchase the new products.

The most important means of providing aid to those living in countries which rely on subsistence agriculture is to ensure adequate food and clean water. There are very important benefits that may accrue from the provision of technological expertise.

It is argued that there should be equity in the manner in which agricultural resources are distributed. There have been many arguments about both the distribution of food and farmland between the rich and poor, both in developed and developing countries. The need to redistribute land to the people of Zimbabwe and to dispossess those who had taken the land during the colonial past was seen as part of a equitable redistribution within Zimbabwe.

`Most of the world's poor are small tenant farmers. In order to increase the standard of living of these farmers, the governments of many developing countries adopted in the 1970s the policy of `industrializing' agriculture; making their farmers over in the image of large successful farmers in more developed countries. During the green revolution of the 1960s and 70s, countries such as India, Costa Rica, and Nigeria increased the efficiency of farmers's yields by borrowing money from international lending agencies such as the World Bank. The funds were used to extend credit to farmers who in turn were taught to buy high yielding varieties of seeds (such as rice, wheat, and maize) and to use the necessary accompanying technologies: mechanical implements (tractors) and

synthetic chemicals (herbicides and pesticides). Many farmers flourished and nations that once were importing grain became self-sufficient in certain crops.'[94]

A majority of the world's resource-poor farmers are women. World-wide, women produce more than 50% of all the food that is grown. In many developing countries, this percentage can be much higher. For instance, it is estimated that women produce 80% of the food grown in sub-Saharan Africa, 50-60% in Asia, 46% in the Caribbean, 31% in North Africa and the Middle East and about 30% in Latin America. The advent of modern crops may release those working in the fields from much of the tedium of subsistence agriculture, but may lead to an increase in poverty and in migration into cities[95]

n. Openness

Decisions on whether the technology should be used in a particular context would have to be addressed through an open process where respect is given to all viewpoints and where the structure of the society to which the technology is made available is respected. The Cartagena Protocol requires that the Public is consulted. Consultation extends from the design of the regulatory system through to individual decisions concerning products.

There is an expectation that Parties to the Protocol will "promote and facilitate public awareness, education and participation concerning the safe transfer, handling and use of living modified organisms in relation to the conservation and sustainable use of biological diversity, taking also into account risks to human health. In doing so, the Parties shall cooperate, as appropriate, with other States and international bodies"[96].

[94] Gary Comstock (2000) Agricultural Bioethics, Routledge Encyclopedia of Philosophy, Edward Craig, ed. (Routledge, 2000).
[95] Background documentation prepared for the International Technical Conference on Plant Genetic Resources, Leipzig, Germany, 17-23 June 1996, Food & Agriculture Organisation, Rome, 1996
[96] Cartagena Protocol Article 23(1a)

In addition, the Parties are expected (insofar as their law permits) to "consult the public in the decision-making process regarding living modified organisms and shall make the results of such decisions available to the public, while respecting confidential information in accordance with Article 21".[97]

o. Consumer choice and rights

Perhaps the simplest way of ensuring that all views are respected is to provide real choice to the consumer. Those who do not wish to eat meat derived from pigs, for example, should be respected in that foods could be labeled to provide them with choice. Some seek simply to avoid GM food; could this be a reason for labeling or for ensuring that food is not provided which could offend these sensibilities? This is particularly important for those who cannot easily purchase food and are being provided with food aid. The inability to purchase should not strip them of their rights.

There needs be a balance struck between these consumer needs and the expectation of commercial firms that they will be able to operate in a predictable environment[98]

p. Exploitation

In terms of control over genetic resources or food resources, two quite different types of exploitation of a position of power may be distinguished :

- "blocking access" to products or to technology. Some fear that this will happen on a significant scale by the abuse of the IPR systems in place. Although this is theoretically conceivable, it does go against the primary interest that owners of IPR have, which is to make money out of their ownership by selling the product.

[97] Cartagena Protocol Article 23(2)
[98] Nuffield Council on Bioethics (1999) Genetically modified crops: The Ethical and Social issues paragraph 1.16.

- "dumping unwanted products" that have not been properly tested, or that are not approved in the industrialised countries.

"It is often stated that only 30 crops "feed the world". These are the crops which provide 95% of dietary energy (calories) or protein. Wheat, rice and maize alone provide more than half of the global plant-derived energy intake. These are the crops which have received the most investment in terms of conservation and improvement. A further six crops or commodities, sorghum, millet, potatoes, sweet potatoes, soybean, and sugar (cane/beet), bring the total to 75% of the energy intake. This information is based on data for national food energy supplies aggregated at the global level.[99] When food energy supplies are analysed at the sub-regional level, however, a greater number of crops emerge as significant. For example, cassava supplies over half of plant-derived energy in Central Africa, although at a global level, the figure is only 1.6%. Beans and plantain also emerge as very important staples in particular sub-regions. These major food crops, as well as others such as groundnut, pigeon pea, lentils, cowpea and yams are the dietary staples of millions of the world's poorer people, though they receive relatively little research and development attention.[99] Resource-poor farmers constitute over half the world's farmers and produce 15 - 20% of the world's food. These farmers have not benefited as much as others from modem high-yielding varieties. It is estimated that some 1,400 million people, approximately 100 million in Latin America, 300 million in Africa and 1,000 million in Asia are now dependent on resource-poor farming systems in marginal environments.

q. Bias Against the Poor

One of the issues that has been mentioned on a number of occasions in this paper is that the use of modern biotechnology could, if not used in a careful manner that respects the integrity and needs of all, be a strong driving force

[99] Background documentation prepared for the International Technical Conference on Plant Genetic Resources, Leipzig, Germany, 17-23 June 1996, Food & Agriculture Organisation, Rome, 1996

towards increasing inequity. "Most societies were once structured so that, even though many people were poor, most had access to sufficient food to ensure their survival. Social, economic and technological changes have since erode the traditional "safety nets", and ties to the land have been weakened or severed, making it difficult or impossible for the poor to grow their own food."[100]

r. Animals

There maybe intrinsic objections to the use of modern biotechnology when working with animals. It is recognised that particular kinds and degree of harm should not be inflicted on any animal. Where harm is permissible it needs to be justified and must be outweighed by the benefit either to animals in general or to human beings[101]. Such harm must be minimised.

It has been argued that genetic modification of animals is unethical in that it involves human playing God. For some whose religious convictions forbid the eating of certain animals care must be taken to permit them to be able to avoid modified plants and animals into which such animal genes have been placed. Human genes in animals or plants may be offensive to some.

"Traditionally, ethical and juridical systems in Western society are highly human orientated. Insofar as individual animals were valued, the value was derived from the importance of animals to man. …the sense of values with regard to animals is shifting. Especially the criticism of the use of animals as experimental animals and of livestock housing has resulted in the recognition that *animals have* [102]*a value of their own, or an intrinsic value to man . . .*Animals come to fall under the province of ethics, not in the sense that animals are thought to act morally, but in the sense of deserving moral care."

[100] Food & Agriculture Organisation (2001) Ethical Issues in Food and Agriculture Rome, ISBN 92-5-104559-3, page 12.
[101] Ethical Implications of Emerging Technologies in the Breeding of Farm Animals (1993) HMSO ISBN 0 11 242965 3.
[102] Advisory Committee Ethics and Biotechnology in Animals Netherlands (1990)

"Application of genetic modification technology to animals can be used in medical research to create models of human disease. Such models help identify disease pathways and allow assessment of new therapies. Analysing gene function is an area in which the use of GM animals is likely to rise significantly, because by modifying a gene, its various roles in different functional systems of the body can be identified."[103] The concept of stewardship is critical for animals, as we perceive them to have feelings but they are not able to fend for themselves.

The use of animals does pose risks. There may be new allergic reactions when humans come into contact with the animals or eat them. There are possible toxic effects on humans, animals and other organisms. Changes in behaviour may be important, and even the bonds between animals within the same family group may either be modified by the modification or the animal has to be taken out of its social context in order to maintain its freedom from disease. It is possible that transgenic animals may be able to transmit disease to humans and other animals where this was not possible before.

4. CONCLUSION

The policy choices made by countries that are members of the OECD have been different. The United States chose not to introduce new laws for the products o biotechnology, relying on its existing regulatory structure. The European Union has used the use of modern biotechnology as a trigger for regulation and Canada regulates all novel products. These choices and the resulting concern at the safety of transgenic organisms in the environment have been confusing to those in the least developed countries. Reasons for decisions need to be clear. There is a clear need to balance benefit to human health and the environment with risk. The risks are often unclear, speculative and impossible to test. The benefits of

[103] The Royal Society (2001) The use of Genetically Modified Animals, Science Advice Section, The Royal Society 6 Carlton House Terrace, London SW1Y 5AG

these new crops have not yet been fully demonstrated. People need to feel safe and assured that as far as possible their safety, their health and their beliefs have been taken into account before the introduction of new forms of food products. Although it is undoubtedly a useful exercise to observe the arguments and discussions other countries are having or have had when implementing agricultural biotechnology, it is in the end up to each country, whether developed or developing, to assess the benefits and risks as they may impact on their own culture and environment, when deciding the best way forward.