The Cartagena Protocol on Biosafety

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Abstract

From the moment that it was possible to modify organisms using recombinant DNA technologies there was concern that although they had an incredible potential for good, they might also potentially be dangerous. As early as the late 1970s some countries instituted regulatory regimes (including guidelines) to ensure their safe use. This fear of harm led first to national regulatory regimes, then OECD, UNIDO and UNEP Guidelines on their safe use, and eventually to a protocol to the Convention on Biological Diversity. Those countries that embraced the technology commercially were not sure that a legally binding treaty that assumes adverse effects on biological diversity or human health was appropriate, but more than 140 countries have joined the Cartagena Protocol on Biosafety. There are many issues as to its interpretation and implementation, some of which are discussed in this article.

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Riassunto

Dal momento in cui è stato possibile modificare degli organismi usando la tecnica del DNA ricombinante, c'è stato il dubbio che, nonostante l'incredibile potenziale positivo, potessero essere anche potenzialmente pericolosi. Già alla fine degli anni 70 numerosi Paesi hanno istituito delle regolamentazioni (comprese delle linee guida) per assicurare l'uso sicuro di questi organismi. La paura dei potenziali rischi ha portato inizialmente a regolamentazioni nazionali, poi sono nate le linee guida di OECD, UNIDO e UNEP e alla fine è nato un protocollo alla Convenzione sulla Diversità Biologica. Per i Paesi più interessati al lato commerciale di queste tecnologie un trattato legale che ammetta un effetto negativo sulla diversità biologica o sulla salute non è sembrato appropriato, ma più di 140 Paesi hanno firmato il Protocollo di Cartagena sulla Biosicurezza. Vi sono molte controversie sia sulla sua interpretazione che sull'implementazione; alcune di esse sono trattate in questo articolo.

1. GENETICALLY MODIFIED ORGANISMS

It is now more than 10 years since the first genetically modified organisms (GMOs)[1] became commercially available, with the first GM crops appearing in 1996. Genetic techniques for the improvement of commercially-grown plants have been used for generations, but initially involved techniques which are now considered 'traditional' – chemical mutation, radiation mutation or embryo rescue followed by selection. These techniques modify the genetic material within an organism, but do not introduce genetic information from other organisms in a way that many consider to be unnatural. During the 1980's, new scientific tools from molecular biology began to be used to introduce new characteristics into plants (and animals) for use in commercial agriculture. Many scientists saw little difference between this new technology, where genes were isolated from unrelated organisms (often micro-organisms) and introduced into crop varieties, and traditional methods of plant breeding (natural selection, cross breeding, conjugation, chemical- or radiation-induced mutation).

Commodity crop plants have been the primary focus for modification where recombinant DNA (rDNA) has been introduced into an organism in order that the expressed gene product (e.g. enzymes or other proteins) changes some characteristic of the organism. Those stakeholders involved in the early days of GMO regulation, i.e. during the 1980s, expected that micro-organisms would be used commercially for applications such as bioremediation, but this has not yet happened. Surprisingly, relatively few products with relatively few traits have been introduced into the market; it is often argued that the products are designed for markets where technology is important, and therefore they are primarily those crops for which the seeds have a commercial value. Oilseed rape, cotton, maize and soya bean constitute the main GM crops available, and almost all of the modifications that have been made involve either or both herbicide tolerance or pesticidal traits.

In most countries, products of the new technology are subject to legal restrictions different from those that apply to traditionally-bred varieties. The initial step in transforming traditional varieties employs modern

[1] The terms "genetically modified" (GM), "transgenic", "genetically engineered" (GE) and "living modified" (LM) are used in different legal instruments around the world. It is useful (and deliberate) in this document, to essentially use them interchangeably.

biotechnological techniques, but thereafter all subsequent steps involve the use of traditional plant breeding methods to produce commercial (GM) varieties suitable for particular farming cultures. The technologies have aimed at improving or modifying plants (primarily) in order to improve yields, through reducing competition with weeds or decreasing the range and extent of pests that cause loss of yield. It is argued that the new techniques allow much more precise alterations of the traits and permit the targeting of single desired characteristics (Fernandez-Cornejo, 2006).

In the USA, the Department of Agriculture (USDA) argues that the strengthening of intellectual property rights protection during the 1970s and 1980s offered incentives to invest in new varieties of crop plants and seed development, which facilitated the first 10 years of commercially available transgenic plants (Fernandez-Cornejo & Caswell, 2006). By 2006, the USDA's Animal and Plant Health Inspection Service (APHIS) had received more than 11600 applications for the field-testing of new varieties, 92 % of which involved major crops, with nearly half of those for maize (Fernandez-Cornejo & Caswell, 2006). A significant number of the field tests involved traits such as viral resistance, improved product quality, drought or fungal resistance. There are a vast number of unique transformation events that are being used commercially around the globe. Some products may involve more than one of these events. These have been approved on a case-by-case basis in a variety of countries, for example the European Union (EU) has granted permits to more than 50 GM crop plant varieties (all are insect-resistant [*Bt*] maize) (GMO Compass, 2008), with a GM potato (BASF's Amflora®) set to become the first authorisation for the commercial growing of a GM crop in Europe since 1998 (UK GM Inspectorate, 2007). A disparity therefore exists regarding the number of events approved in each country, and has resulted in GMOs being exported from countries in which they have undergone some form of approval procedure to countries where approval has not (yet) been gained or even where no application has been made. These numbers represent the vast majority of approvals world-wide for GM foods or feeds. In the USA, once the field trial process is completed, companies may apply to the authorities for de-regulation. *"If, after extensive review, APHIS determines that the new variety poses no significant risk to agriculture or the environment, permission is granted. [By] April 2005, APHIS had received 103 petitions for deregulation and had granted 63"* (Fernandez-Cornejo & Caswell, 2006), the latter of which comprise the GM products available on the market in the USA. It should be noted that once

approved for deregulation there is no mechanism for monitoring any use, including as the basis for traditional breeding to produce new varieties of GM crop plants. *"Once an article has been deregulated, APHIS cannot place any restrictions or requirements on its use, short of re-regulating the article. Restrictions and requirements have not been deemed necessary in the past because [Biotechnology Regulatory Services] risk assessments have concluded that the GE plants APHIS has deregulated pose no greater risks than conventionally-bred plants"* (USDA, 2007). The products have been taken up enthusiastically by a few countries, especially Argentina, Brazil, Canada and the USA (Table 1), and have been rejected by many, including the EU and most of Africa. These 'first generation' GMOs have major advantages for farmers, either enabling the use of 'environmentally benign' weedkillers or providing resistance to plant pests and enabling a significant increase in yield. In Argentina, the use of herbicide tolerant soya bean has been accompanied by a no-till practice, resulting in significant reductions in soil erosion.

Table 1. Countries in which more than 50,000 hectares are planted with transgenic crops. Data combined from CIA (2008) and James (2008) sources. [a] arable land - land cultivated for crops such as wheat, maize and rice that are replanted after each harvest.

Country	Total land area (M sq km)	Arable land (%)[a]	Arable land (M sq km)	Arable land under GM cultivation (%)	GM cultivation (M sq km)	GM cultivation (M hectare)
USA	9.16	18.01	1.65	34.98	0.580	57.7
Argentina	2.74	10.03	0.27	69.60	0.191	19.1
Brazil	8.46	6.93	0.59	25.59	0.150	15.0
Canada	9.09	4.57	0.42	16.85	0.070	7.0
India	2.97	48.80	1.45	4.28	0.062	6.2
China	9.33	14.86	1.39	2.74	0.038	3.8
Paraguay	0.40	7.47	0.03	87.67	0.026	2.6
South Africa	1.22	12.10	0.15	12.19	0.018	1.8
Uruguay	0.17	7.70	0.01	37.32	0.005	0.5
The Philippines	0.30	19.00	0.06	5.30	0.003	0.3
Australia	7.62	6.15	0.47	0.21	0.001	0.1
Spain	0.50	27.18	0.14	0.74	0.001	0.1

There is some evidence that consumers in the USA do have concerns over the new varieties of foods (Hallman *et al*., 2004; Hossain & Onyango, 2004; Peters *et al*., 2007), but not enough for action to be taken, and labelling of these new foods is not required. In Europe, the wholesale and retail sector has rejected the use of these new commodities for food on the basis of real consumer concern for human health and the environment. The regulatory regime that has been imposed in Europe attempts to ensure that consumers have the right to know if their food is derived from, or contains, GMOs, and if so, it has to be labelled. The impact of the regulatory regimes is argued about constantly. The rejection by the majority of Europe is seen as influencing many countries around the world. Although Europe figured prominently in the development of many of the technological breakthroughs that have enabled the commercial use of GMOs, their commercialisation has occurred almost exclusively in North America. Most of the modified crop plants grown elsewhere were produced (or designed) in North America. Some of the major commodity foods or feeds have been genetically modified and are being cultivated by the major producer countries (Tables 1 & 2; with the exception of Spain, Europe is notably absent from the list).

Table 2. Transgenic crops commercially grown around the world (James, 2008)

Country	Crops
Argentina	Soya bean, maize, cotton
Australia	Cotton
Brazil	Soya bean, cotton
Canada	Oilseed rape, maize, soya bean
China	Cotton, tomato, poplar, petunia, papaya, sweet pepper
India	Cotton
Paraguay	Soya bean
The Philippines	Maize
South Africa	Maize, soya bean, cotton
Spain	Maize
Uruguay	Soya bean, maize
USA	Soya bean, maize, cotton, canola, squash, papaya, alfalfa

As shown, the vast majority of commodity maize and soya bean is genetically modified, even though it is only a relatively small number of countries that have chosen to grow these crops. Other than the USA, where most of the experimentation and most of the commercialisation has been carried out, the range of crops grown in most of the countries that have accepted the products with alacrity is small. For example, Argentina has almost 100 % transgenic soya bean production, but hardly grows any other transgenic crop. The USA has over 50 % of the area devoted to GM crops. The range of crops grown in these countries is influenced by what is available, as well as by what can be grown given the agricultural conditions; nevertheless, the range remains small (Tables 2 and 3).

Table 3. Percentage of the 'Global Biotechnology Crop Area' (James, 2007)

Crop	Global Area Cultivated with GM Crops (%)
Soya bean	57
Maize	25
Cotton	13
Oilseed	5

Although agricultural production is important in most countries in the world, its contribution to GDP varies widely (Table 4), with that of the United Kingdom at less than 1 % of GDP, Argentina and Brazil close to 10 % and many African countries more than 30 %. The number of people involved in agriculture is also significant, with European countries involving very few people in agricultural production. The data in Table 4 are (arguably) more important, as the vast majority of crops introduced to the market have greater value for farmers than they do for consumers. If the farmers' lobby is weak, due either to the small contribution of agriculture to GDP or the relatively small number of individuals working the land, governments may be less amenable to arguments for these new crops.

Table 4. Selection of countries to demonstrate the range of dependence of GDP on agriculture (World Resources Institute, 2008)

Country	Proportion of GDP as Agriculture (%) in 2005
Germany	0.9
Belgium	1.0
United Kingdom	1.0
Austria	1.5
Denmark	1.8
France	2.2
South Africa	2.5
Mexico	3.8
Russian Federation	5.6
Brazil	8.1
Argentina	9.4
China	12.6
Egypt	14.9
Philippines	14.3
Lesotho	17.3
India	18.3
Bangladesh	20.1
Paraguay	22.1
Kenya	27.0
Malawi	34.7
Ghana	37.5
Cameroon	41.1
Laos	44.8
Democratic Republic of the Congo	46.0
Ethiopia	47.7
Central Africa Federation	53.5

Genetic modification of food crops and their derived foods has been extremely controversial. In the USA and Argentina, in particular, the new products have been welcomed by the farming community and have not met with significant rejection by the consumer. In both of these countries the introduction of the new variants has proceeded apace and farmers have benefited from the agronomic traits that have been introduced. In

Argentina in particular, the adoption of no-till approaches when using the new variants has had a dramatic effect on conservation.

The picture in Europe has been very different. There were differences in the manner in which governments reacted to this new technology; whilst it was strongly supported in the United Kingdom, it was rejected by Austria, Denmark, Greece and Norway. Communities in much of Europe made their feelings clear to Governments and a strong movement for rejection of these products began in the late 1990s which still continues today. Many regions have declared themselves GM-free areas. In much of Europe, consumers have chosen to shun GMO-containing products and retailers have chosen to use this as a marketing ploy to attract customers. In 1998 the EU introduced a *de facto* moratorium on the introduction of GM products into both the environment and as new foods – although not restricting GM feed for animal use to quite the same extent. This resulted in a dispute between the EU and Argentina, Canada and the United States, starting in 2003. The disputes panel produced one of the longest reports (WTO, 2006) in WTO history. Although some of the decisions were controversial, the EU did not appeal. It found that there was a case for the EU to address under the Sanitary and Phytosanitary (SPS) Agreement (WTO, 1995a). The Panel decided that there had been a general *de facto* EC moratorium in effect from June 1999 until 29 August 2003 in that the European Union had failed to make decisions on applications. It found, contrary to the arguments of complainants, that the general and product-specific moratoria were not themselves SPS regulatory measures under the SPS Agreement subject, among other requirements, to the risk assessment requirements in Art. 5.1. Article 5.7 addresses the question related to the insufficiency of scientific evidence in relation to phytosanitary or sanitary risks. Measures may be adopted to minimise or avoid the risks, but there is a presumption that further scientific analysis will eventually provide the additional evidence required on which decisions can be based:

> *"7. 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."* (Article 5.7; WTO, 1995a)

The panel found that there was sufficient evidence for a risk assessment, based on the fact that scientific committees within the EU had done precisely that. Hence member states could not use this article, and should either withdraw their objections or show cause for invoking the Article's provisions.

Developing countries have been wary of introducing the new varieties as the impact on their income if they fail to sell the commodities in Europe would be substantial, even though the improvement in agricultural production could have been substantial if the transgenic varieties had been effective in their agricultural conditions.

2. GMO REGULATION – AN HISTORICAL PERSPECTIVE

The impact of rejection of the products, and the requirement for regulation that distinguishes transgenic products from those produced using conventional methods has been profound. There appears to be a polarisation – with many countries fearful of EU rejection of their products as well as of accepting products that some consider harmful, and others accepting that there are likely to be significant gains from adopting the new technology. Whether modern biotechnology will have the impact on agriculture that the USA Government believe important is uncertain (Larson, 2002). As seen above, commercial applications have resulted in only a small number of crops that have had genes inserted to provide herbicide tolerance or pest resistance. These have captured a large market share but have also faced significant criticism concerning whether this technology will actually be used: *"Proponents of biotechnology and many agri-food policy makers around the world project a positive future in which technology overcomes food shortages, improves the environment, heals or eliminates disease and leads to a prosperous and healthy society. A smaller but still significant array of policy makers, citizens and consumers fear that the technology will exacerbate food insecurity, threaten the environment, endanger human health and ultimately impoverish some parts of society"* (Phillips, 2004). It would seem that there is a conflict between those who see technology as all good and those who see the technology as an example of globalisation and of the take-over of people's lives by anonymous multi-national conglomerates.

As soon as it was possible to modify organisms through the insertion of DNA

extracted from other totally unrelated organisms, the potential advantages of moving DNA within and between organisms was recognised. Whilst it was clear that there were enormous benefits that could be harnessed using this technology, recognition of the harm that could be done was almost immediate. Back in early 1975, the UK's Ashby committee reported 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"*, therefore the benefits of the new technology were perceived to far outweighed the risks *if suitable precautions were put in place* (UK Government, 1975). In 1974, a group of scientists wrote a widely-read letter to two respectable scientific journals, 'Science' (Berg *et al.*, 1974) and 'Proceedings of the National Academy of Sciences USA' (Committee on Recombinant DNA Molecules, 1974), calling for a self-imposed moratorium on the use of the technology until a meeting had been held to discuss the 'potential biohazards' amongst the scientific issues. There were concerns of the potential of the newly available techniques to create new forms of life; the technology was understood, but the underlying biological mechanisms were not. It was at least theoretically possible to introduce a gene or set of genes into an organism that would change the organism into something dangerous. The purpose of the meeting was therefore *"to review the progress, opportunities, potential dangers and possible remedies associated with the construction and introduction of new recombinant DNA molecules into living cells"* (Wright, 1994). The meeting of scientists, lawyers and journalists that took place in Asilomar CA, USA 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"* (Wright, 1994). At the time it was only micro-organisms that could be modified, and it was primarily the workplace – the laboratory – that needed to be considered. The guidelines introduced in the USA after the 'Asilomar meeting', and the regulatory structures introduced in the UK and other European Countries at about the same time, were all biased towards assuring the safe use of transgenic organisms in the laboratory – primarily the protection of those who might come into contact with the organisms. It was only in the late 1980's and early 1990's that the likely release of transgenic organisms into the environment and hence a potential threat to the environment or to the health of consumers became a reality.

The Asilomar Meeting was an early example of precaution where scientists, conscious of the potential of their work, met with others to consider how the new technology could be safely carried out. *"Asilomar remains a scientific landmark, a rare if not unique instance of scientists independently questioning and successfully regulating their own cutting-edge work"* (Russo, 2000). The meeting at Asilomar was ground-breaking, for it not only indicates the manner in which precaution was properly undertaken, but its ramifications have resulted in the strict regulatory systems that are now in place, possibly providing the basis for much of the current concern about GMOs, primarily in Europe. A further concern is that most regulatory systems are instituted as reactions to disaster. It is not often that they are put into place for precautionary reasons. While still not fully understanding the biological mechanisms inherent in the organisms into which the genes are inserted, there is greater certainty as to the low probability of harm being caused to either human health or to the environment due to the insertion of genes into a plant. The insertion process (transformation) can still harm the plant, and indeed, many if not most of transformed plants are not viable as commercial products because of changes to their characteristics derived from the process of insertion rather than due to the expression of the inserted genes. The use of traditional plant breeding techniques following the initial genetic modification phase ensures that (for most purposes) only those candidate lines that show the expected characteristic change (and no, or few, others) are developed further with the ultimate goal of meeting the requirements of a new plant variety – distinct, stable and uniform.

In 1986 the Organisation for Economic Cooperation and Development (OECD) addressed some of these concerns for their member states (OECD, 1986). The document produced at the time, called 'the Blue Book', identified that the *"specific aims of rDNA techniques in agriculture are, for example, to reduce vulnerability to environmental stresses; to detect and control infectious agents in animals and in the field and post-harvest; to reduce dependence on and modify use patterns of chemical pesticides; to decrease dependence on chemical fertilizers and irrigation; and to increase the nutritional qualities of seeds, fruits, grains, and vegetables."* The conclusion of the OECD report was that *"[s]afety concerns focus on whether environmental and agricultural applications of organisms modified by rDNA techniques pose an 'incremental' risk. While rDNA techniques may result in the production of organisms expressing a combination of traits that are not observed in nature, genetic changes from rDNA techniques will often have inherently greater predictability compared to traditional*

techniques, because of the greater precision that the rDNA technique affords to particular modifications."

> *"Recombinant DNA techniques represent a development of conventional procedures. They permit precise alteration, construction, recombination, deletion and translocation of genes that may give the recipient cells a desirable phenotype. Moreover, rDNA techniques allow genetic material to be transferred into, and to express in, another organism which may be quite unrelated to the source of the transferred DNA."* (OECD, 1986)

Twenty years later, these assertions remain controversial in much of the world. Many states remain concerned that living modified organisms pose significant threats to human health and the environment (and/or to the conservation of biological diversity). At the time of drafting the Blue Book, most of the applications of modern biotechnology (which they defined as solely the use of rDNA) were laboratory-based. They argued that different issues arise when the technology results in organisms being deliberately introduced into the environment. The assessment of potential risks, even of micro-organisms used in environmental or agricultural applications, was less developed than the methods used for assuring safety within industry. The OECD Blue Book presumed a *"provisional approach … to confer sufficient flexibility to suit individual countries" but hoped that "international safety criteria would eventually be agreed."*

The regulatory systems that countries introduce depend on existing legislation, their legal systems and the administrative systems that are in place. Immediately after the Asilomar meeting, many countries introduced some form of regulation intended to assure the safe use of the technology. In the USA, the National Institutes of Health produced guidelines that applied to all organisations that received funding from the USA Government (NIH, 2002a). These NIH Guidelines remain the primary regulatory system for assuring safety in the USA where transgenic organisms are used in containment (or confinement) (NIH, 2002b). For the agricultural use of commercially-released GMOs, the USA Government deliberately chose to use existing agencies and not to change any law (US Office of Science and Technology Policy, 1986). The USDA works with the Environment Protection Agency and the Food and Drug Administration to regulate the use of GMOs. The USDA first implemented regulations

for GEOs in 1987 (USDA, 1987). Under these regulations, plants, micro-organisms, fungi, insects, and mollusks were subject to regulation if they have the potential to pose a plant-pest risk as defined in the regulations. The regulations established a permitting system to authorise importation, interstate movements, and environmental release of GEOs. The regulations have since been modified several times (e.g. USDA, 1997; 2005; 2007). The EU chose to make major changes to law and instituted new pan-European agencies whose role is the assurance of safety of the products of modern biotechnology, including novel food and feed. The regulatory systems of the USA and EU can be considered as opposite extremes, and many countries have instituted systems that lie between them. Other countries were quick to introduce guidelines for research involving rDNA technology, and then, where appropriate, regulations. For example, there have been strict safety regulations controlling all contained use work with GMOs in the UK since 1978. The legislation has developed over the years, partly due to changing technology.

Modern biotechnology, therefore, has positive and negative implications for human health, the environment and trade. The assurance of safety (biosafety) has led to regulatory regimes that examine the implications of its use. Biosafety regimes tend to stress risk rather than benefit. This may be due to a presumption that a decision to market a product implies that there are perceived benefits. However, comparative risk analysis might suggest that although the risk of using the new technology is not minimal, neither are current methods for achieving similar aims, and the less-risky process should replace current technology (FAO, 2003). Risks to human health and to biological diversity (impact on the environment) were foreseen when the Convention on Biological Diversity (CBD; United Nations, 1992a) was negotiated in the early 1990s. These were considered to be different from the risks posed to human health and the environment by plants bred using traditional methods, even though the modifications are more closely defined than those introduced through chemical and radiation mutation, for example.

> *"By itself, biotechnology cannot resolve all the fundamental problems of environment and development, so expectations need to be tempered by realism. Nevertheless, it promises to make a significant contribution in enabling the development of, for example, better health care, enhanced food security through sustainable agricultural*

> *practices, improved supplies of potable water, more efficient industrial development processes for transforming raw materials, support for sustainable methods of afforestation and reforestation, and detoxification of hazardous wastes. Biotechnology also offers new opportunities for global partnerships, especially between the countries rich in biological resources (which include genetic resources) but lacking the expertise and investments needed to apply such resources through biotechnology and the countries that have developed the technological expertise to transform biological resources so that they serve the needs of sustainable development"* (Chapter 16, Agenda 21; United Nations, 1992b).

The CBD came into effect after the World Summit in Rio de Janeiro in 1992. Article 8 of the convention deals with *in situ* conservation and 8(g) requires that *"each contracting party shall, as far as possible and as appropriate: …*

> *(g) Establish 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;"* (United Nations, 1992a)

In this context, Article 19 of the CBD is important. It deals with the handling of biotechnology and the distribution of its benefits between rich and poor nations – and effectively, globalisation of the distribution of products of the new technology. It envisages that the benefits arising from modern biotechnology should be shared between developing and developed countries. It is the safe use of the technology that was thought to be paramount. In 2000, after protracted negotiation, the Cartagena Protocol on Biosafety (CPB; Secretariat of the CBD, 2000) was agreed that addressed, in particular, the transfer of the products of modern biotechnology and ensured that these products are as safe as possible. This international treaty entered into force on 11 September 2003, ninety days after receipt of the 50th instrument of ratification, and currently has 143 Member States (Box 1; Secretariat of the CBD, 2008) although many of the countries that currently produce commercial transgenic crops are not members (Table 5).

BOX 1. PARTIES TO THE CARTAGENA PROTOCOL ON BIOSAFETY

Africa: Algeria, Benin, Botswana, Burkina Faso, Cameroon, Cape Verde, Chad, Congo, Democratic Republic of the Congo, Djibouti, Egypt, Eritrea, Ethiopia, Gabon, Gambia, Ghana, Kenya, Lesotho, Liberia, Libyan Arab Jamahiriya, Madagascar, Mali, Mauritania, Mauritius, Mozambique, Namibia, Niger, Nigeria, Rwanda, Senegal, Seychelles, South Africa, Sudan, Swaziland, Togo, Tunisia, Uganda, United Republic of Tanzania, Zambia, Zimbabwe (40 Countries)

Asia and Pacific: Bangladesh, Bhutan, Cambodia, China, Cyprus, Democratic People's Republic of Korea, Fiji, India, Indonesia, Iran (Islamic Republic of), Japan, Jordan, Kiribati, Kyrgyzstan, Lao People's Democratic Republic, Malaysia, Maldives, Marshall Islands, Mongolia, Nauru, Niue, Oman, Palau, Papua New Guinea, Philippines, Qatar, Republic of Korea, Samoa, Solomon Islands, Saudi Arabia, Sri Lanka, Syrian Arab Republic, Tajikistan, Thailand, Tonga, Viet Nam, Yemen (37 Countries)

Central and Eastern Europe: Albania, Armenia, Azerbaijan, Belarus, Bulgaria, Croatia, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Montenegro, Poland, Republic of Moldova, Romania, Serbia, Slovakia, Slovenia, The former Yugoslav Republic of Macedonia, Ukraine (20 Countries)

Latin America and Caribbean: Antigua and Barbuda, Bahamas, Barbados, Belize, Bolivia, Brazil, Colombia, Costa Rica, Cuba, Dominica, Dominican Republic, Ecuador, El Salvador, Grenada, Guatemala, Mexico, Nicaragua, Panama, Paraguay, Peru, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, Trinidad and Tobago, Venezuela (25 Countries)

Western Europe and Other Groups: Austria, Belgium, Denmark, European Community, Finland, France, Germany, Greece, Ireland, Italy, Luxembourg, Malta, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, Turkey, United Kingdom of Great Britain and Northern Ireland (21 Countries)

Table 5. Main GMO producer countries membership of the Cartagena Protocol on Biosafety (CPB)

Country	Member of the CPB
USA	No (not a member of the CBD)
Argentina	No
Brazil	Yes
Canada	No
India	Yes
China	Yes
Paraguay	Yes
South Africa	Yes
Uruguay	No
Philippines	Yes
Australia	No
Spain	Yes

There were many who thought that the CPB would never come into force, for the major producing countries (in particular, the USA) were implacably opposed to its terms, with a concern that it could result in barriers to trade. It needed an unusually large number of ratifications before it would come into force, and now more than 75 % of the members of the Convention on Biological Diversity have become members of the CPB. The presence of regulatory regimes in most of the countries that had already been using the technology influenced the decision to introduce this important treaty. There are a number of other considerations necessary before proceeding to a discussion of the CPB and the manner in which it has been implemented. These include definitions and precaution.

3. DEFINITION OF GENETICALLY MODIFIED ORGANISMS

Historically there have been many definitions of genetic modification, genetic engineering, genetic manipulation or the vast array of pseudonyms regarding the introduction of genetic material into organisms in which that material cannot (or does not) occur normally. Two of the early definitions were:

1. "***'Genetic manipulation'*** *means the formation of new combinations*

> *of heritable material by the insertion of nucleic acid molecules, produced by whatever means outside the cell, into any virus, bacterial plasmid, or other vector system so as to allow their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation."* (UK Government, 1978)
>
> *2. "**Definition of Recombinant DNA Molecules**. In the context of these Guidelines, recombinant DNA molecules are defined as either (i) molecules which are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, or (ii) DNA molecules that result from the replication of those described in (i) above."* (NIH, 1983)

These definitions contrast markedly with those found in the European Directives that are currently in force. In Directive 98/81 (European Union, 1998) that deals only with the contained use of GM micro-organisms (GMMs), the definitions are designed for relatively simple modification. Article 2 provides the definitions. The first, and for this Directive, important definition is that of contained use, which is *"any activity in which micro-organisms are genetically modified or in which such GMMs are cultured, stored, transported, destroyed, disposed of or used in any other way, and for which specific containment measures are used to limit their contact with the general population and the environment."* Hence a modified organism designed for sale, even where its use is to be within containment, is marketed rather than 'contained'. In addition, a micro-organism can be cellular or non-cellular but must be capable of replication or of transferring genetic material. A GMM is a micro-organism in which the genetic material has been altered in a manner that does not occur naturally by mating and/or natural recombination. The Directive provides two lists, one indicating the organisms not considered GMMs due to their method of manufacture; the other lists techniques used in the manufacture of GMMs. The latter include *"recombinant nucleic acid techniques involving the formation of new combinations of genetic material by the insertion of nucleic acid molecules … … and their incorporation into a host organism in which they do not naturally occur but in which they are capable of continued propagation."* This would imply that self-cloning, which involves the insertion of genetic material into a place in the DNA different from that in which the DNA normally occurs does not result in a GMM for these

purposes. The definition further adds the direct introduction of heritable material (including techniques like micro or macro-injection) and cell-fusion or hybridisation techniques using methods that do not naturally occur.

Directive 2001/18 (European Union, 2001) is the European Directive addressing both release into the environment and marketing of GMOs. The definition used in this Directive is different from that in the Contained Use Directive. The definition is much more concise, although two lists are again provided:

> *"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"* (European Union, 2001)

The Annex listing those techniques included or excluded in the definition provides slight differences from that in Directive 98/81 (Contained Use). Firstly, those techniques that are considered to result in GMOs are:

> *"(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."* (European Union, 2001)

Whereas, the techniques that would not result in genetically modified organisms for the purpose of the Directive are (as long as they do not rDNA):

> *"(1) <u>in vitro</u> fertilisation,*

(2) natural processes such as: conjugation, transduction, transformation,

(3) polyploidy induction." (European Union, 2001)

A further problem with definitions is provided in the CPB, which again gives very slightly different definitions, but the differences are important when moving organisms between Parties. In this instance the term GMO is not used, instead 'Living Modified Organism' (LMO) is preferred. The definitions occur in Article 3 of the CPB as follows:

"(g) 'Living modified organism' means any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology;

(h) 'Living organism' means any biological entity capable of transferring or replicating genetic material, including sterile organisms, viruses and viroids;

(i) 'Modern biotechnology' means 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;" (Secretariat of the CBD, 2000)

In this definition, *"overcoming natural physiological reproductive or recombination barriers"* is significant. It applies to both a) and b) above. If there are no barriers (e.g. self-cloning) then the techniques are not modern biotechnology.

4. PRECAUTION

The concept of 'precaution' plays a primary role in determining the legislation relating to GMOs. Over the past few decades, the 'Precautionary Principle' has become an underlying rationale for a large and increasing number of

international treaties and declarations in the fields of sustainable development, environmental protection, health, trade and food safety (UNESCO, 2005). Both known and potential risks to the environment or to human health may need to be addressed where there is a real basis for concern and when a causal link with a certain action or process is not fully known. This concept is based on the responsibility of governments to demonstrate that their decisions (in general) are based on scientific evidence, but the scientific evidence is often characterised by uncertainty and even disagreement among the scientific community. Regulatory regimes have to be based on the assurance of minimum risk, which may be difficult when the risks cannot easily be determined. Precaution recognises that action cannot be postponed when there is an absence of scientific evidence and a possibility of serious or irreversible harm. This principle has been used widely in the regulation of drugs and pharmaceuticals, largely since the Second World War, but was not in place for foods or cosmetics until recently. Decisions have to be made, even in those circumstances where gaps in current scientific knowledge exist and even where further experimentation could not provide certainty.

Precaution is an integral part of risk analysis in the food safety area in all OECD countries (OECD, 2000; referred to in OECD, 2002). In addition, the preamble to the Agreement establishing the World Trade Organization (WTO; WTO, 1995b) provides that the WTO has the objective of *"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 them and for doing so in a manner consistent with their respective needs and concerns at different levels of economic development."* This has been interpreted by the WTO Appellate body as a statement incorporating precaution into the WTO's remit: *"….this preambular language … must add colour, texture and shading to our interpretation of the agreements annexed to the WTO Agreement, in this case, the GATT 1994… It is proper for us to take into account, as part of the context of the chapeau, the specific language of the preamble to the WTO Agreement…"* (WTO, 1998).

The Precautionary Principle is central to environmental policy-making and is a key element of several multilateral environmental agreements (MEAs). Indeed the members of the CBD were clearly of the view that

precaution (the Precautionary Approach) was central to the thinking about modern biotechnology when negotiating the CPB. A problem with the debate on precaution is that the absence of consensus within the scientific community, especially where weight is attributed equally to all scientists, provides ammunition for those who for many reasons wish to argue against the development of modern biotechnology. There is an important public constituency that has irrational (from a scientific perspective) opinions on these matters (Shaw & Schwartz, 2005). Many see the Precautionary Principle as a *"culturally framed concept […] muddled in policy advice and subject to the whims of international diplomacy and the unpredictable public mood over the true cost of sustainable living."* (O'Riordan & Cameroon, 1994)

There are many statements of the precautionary approach adopted by Governments and in international treaties, with that enunciated in Principle 15 of the 1992 Rio Declaration on Environment and Development and then incorporated into the CPB being:

> *"In order to protect the environment, the precautionary approach shall be widely applied by States according to their capability. 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."* (United Nations, 1992c)

The EC Treaty (Treaty Establishing the European Community; EC, 2002 [consolidated version]), incorporating provisions already introduced by the Maastricht Treaty of 1992 (Treaty of the European Union; European Union, 1992), and more specifically Article 174 thereof, states:

> *"2. Community policy on the environment shall aim at a high level of protection taking into account the diversity of situations in the various regions of the Community. It shall be based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should as a priority be rectified at source and that the polluter should pay ...*
>
> *3. In preparing its policy on the environment, the Community shall take account of:*

- *available scientific and technical data, ...*
- *the potential benefits and costs of action or lack of action ..."*

There are other examples of the use by the EU of precaution. In its Green Paper on the General Principles of Food Law in the European Union, the Commission reiterates this point:

> *"The Treaty requires the Community to contribute to the maintenance of a high level of protection of public health, the environment and consumers. In order to ensure a high level of protection and coherence, protective measures should be based on risk assessment, taking into account all relevant risk factors, including technological aspects, the best available scientific evidence and the availability of inspection sampling and testing methods. Where a full risk assessment is not possible, measures should be based on the precautionary principle."* (European Commission, 1997)

The EU Food Regulation 178/2002 identifies precaution as a major element in its strategy to assure safety in food and feed. Recital 20 states:

> *"The precautionary principle has been invoked to ensure health protection in the Community, thereby giving rise to barriers to the free movement of food or feed. Therefore it is necessary to adopt a uniform basis throughout the Community for the use of this principle."* (European Union, 2002)

The legal instruments incorporating precaution are primarily MEAs, amongst them the Convention on Biological Diversity and the Cartagena Protocol on Biosafety. They address the conservation and sustainable use of biodiversity, requiring that human health be also taken into account. There is no reference in these treaties to safety in relation to trade, but rather to the impact on biological diversity. In many ways, however the CPB is a trade treaty, although its objective is ensuring an adequate level of protection when transferring, using or handling living modified organisms that may impact on the sustainable use and conservation of biological diversity. The CPB represents *"a significant development in the field of environmental law, and its sometimes tense relationship with international trade. As an environmental protection treaty, it is noteworthy as one of the first international agreements enjoying widespread*

support to operationalise the precautionary principle. In fact, the precautionary principle is a central precept to the Protocol's regulation of the transboundary movement of genetically modified organisms (GMO) for intentional release into the environment, and as food and related products." (Hutchinson, 2001)

UNESCO suggested a working definition of the Precautionary Principle in 2005 (Box 2; UNESCO, 2005). It is important to clarify what the Precautionary Approach or Principle is not. It is not based on assuring zero risk, but aims to minimise risk. It is a rational decision tool that aims to *"use the best of the 'systems sciences' of complex processes to make wiser decisions"* (UNESCO, 2005).

The European Commission tried to meet this statement by identifying the major steps in applying the Precautionary Principle:

> *"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."* (European Commission, 2000a)

BOX 2. PRECAUTIONARY PRINCIPLE, A WORKING DEFINITION

When human activities may lead to morally unacceptable harm that is scientifically plausible but uncertain, actions shall be taken to avoid or diminish that harm.

Morally unacceptable harm refers to harm to humans or the environment that is

- threatening to human life or health, or
- serious and effectively irreversible, or
- inequitable to present or future generations, or
- imposed without adequate consideration of the human rights of those affected.

The judgement of *plausibility* should be grounded in scientific analysis. Analysis should be ongoing so that chosen actions are subject to review.

Uncertainty may apply to, but need not be limited to, causality or the bounds of the possible harm.

Actions are interventions that are undertaken before harm occurs that seek to avoid or diminish the harm. Actions should be chosen that are proportional to the seriousness of the potential harm, with consideration of their positive and negative consequences, and with an assessment of the moral implications of both action and inaction. The choice of action should be the result of a participatory process.

5. THE CARTAGENA PROTOCOL ON BIOSAFETY

The Cartagena Protocol on Biosafety (CPB; Secretariat of the CBD, 2000) is a hybrid instrument. It arises from the Convention on Biological Diversity, which is an MEA, yet the primary objective of the CPB is to ensure that when traded, LMOs are safe for the environment and for human health. During the negotiations for the CPB there was much concern as to its likely impact on the WTO treaties, as most of those involved in the negotiations were members of that group of treaties. In order for the latter treaty not to (necessarily) take precedence, a statement was inserted into the preamble to the CPB:

> *"Emphasizing that this Protocol shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements*

> *Understanding that the above recital is not intended to subordinate this Protocol to other international agreements," (Secretariat of the CBD, 2000)*

Article 30(2) of the Vienna Convention on the Law of Treaties (United Nations, 1969) provides that *"When a treaty specifies that it is subject to, or that it is not to be considered as incompatible with, an earlier or later treaty, the provisions of that other treaty prevail."* The wording in the CPB may mean that where two parties in dispute are both members of the WTO treaties and the CPB, attempts should be made so as to interpret the treaties to try to make both applicable.

The objective of the CPB is:

> *"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."* (Secretariat of the CBD, 2000)

The assurance of safety when transgenic organisms are used lies with government, in accordance with a number of international treaties and guidelines. A growing number of governments are instituting systems that permit an assessment of risk and the institution of management practices that minimise the risk. There are many problems within a country as different ministries (Table 6) with radically different priorities are required to regulate and, where appropriate, to encourage the use of modern technologies to improve yield, to maximise output, ensure safety for human health and reduce environmental degradation.

Table 6. Government Responsibilities for Genetically Modified Organisms

Ministry	Responsibility/ies
Agriculture	Responsibility for effective production of food and non-food products –both animal and arable. Possibly responsible for food and feed quality and safety; possibly animal health and welfare
Customs	Enforcing controls at borders for import and export
Environment	Protection of the environment
Fisheries	Similar responsibilities as Agriculture
Foreign Affairs	Coordination of all interaction between government and participation in relevant international agreements and conventions
Forestry	Similar responsibilities as Agriculture
Health	Protection of human health; possibly animal health and welfare
Industry	Encouraging industrial and commercial innovation
Justice / Legal Affairs	Enforcement of rules and regulations
Labour	Occupational health and safety
Local Government	Possibly responsible for food and feed safety; environmental protection may be devolved to Local Government
Police / Inspection Services	Responsible for aspects of enforcement
Trade	Regulation of import and export, and issue of trade permits
Transport	Safe transportation and storage

The CPB permits great freedom in choosing the manner in which countries choose to regulate the use of LMOs, whilst requiring risk assessment procedures in line with principles enunciated in Annex III. The safety assessments required are divided based on the intended use of the LMOs that are to be exported. If they are purely intended for food, feed or processing (LMO-FFP) then the country in which they are being used has to place information on a 'Biosafety Clearing House' as to the method for making safety assessments within that country. Other countries do not have to be informed directly, although there are provisions in the Protocol for informing adjacent countries. Unless a Party of import already has its own domestic regulatory framework that is consistent with the CPB, the procedure described under Article 11 applies and requires that the Party

that makes a *"final decision … shall, within fifteen days of making that decision, inform the Parties through the Biosafety Clearing-House"* (BCH; Secretariat of the CBD, 2000). There is no requirement to inform importing countries, as the products are not intended for introduction into the environment as viable organisms. The BCH is a mechanism established under the CPB to assist countries in its implementation (Article 20). It is intended to *"facilitate the exchange of scientific, technical, environmental and legal information on, and experience with LMOs"* (Secretariat of the CBD, 2000), and is also an important mechanism for implementing the Protocol, as seen in the LMO-FFP procedure. It is only through the information found in the BCH concerning domestic measures and/or final decisions for LMO-FFPs that one may learn about the presence of LMO-FFP imports in the country, and what procedure the exporter needs to undertake.

Developing country Parties that do not have the specific domestic regulatory framework in place could inform the Biosafety Clearing House that it intends to make its decision according to a risk assessment. The required information is defined in Annex II of the CPB (Box 3). Most importantly, it requires a risk assessment identical in form to that required for other LMOs.

If intended for any other use (primarily release into the environment), then a much more complicated system in invoked. If it is a first transfer between two countries, then there is a requirement on the exporting country to notify the country importing the product of the intention to export; it must also assure the accuracy of all information provided (Article 8; Secretariat of the CBD, 2000). The importing country should respond, acknowledging receipt and asking for any information that is not contained in the notification. There are many details in Articles 9, 10, and 12 that identify the actions that may or should be taken by the importing country and requiring (expecting) that action will be taken within 270 days of receipt of the notification. The importing Party 'must' make one of the following decisions:

> *"(a) Approving the import, with or without conditions, including how the decision will apply to subsequent imports of the same living modified organism;*
> *(b) Prohibiting the import;*

BOX 3. INFORMATION REQUIRED CONCERNING LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING UNDER ARTICLE 11 (Annex II, CPB)

(a) The name and contact details of the applicant for a decision for domestic use.

(b) The name and contact details of the authority responsible for the decision.

(c) Name and identity of the living modified organism.

(d) Description of the gene modification, the technique used, and the resulting characteristics of the living modified organism.

(e) Any unique identification of the living modified organism.

(f) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.

(g) Centres of origin and centres of genetic diversity, if known, of the recipient organism and/or the parental organisms and a description of the habitats where the organisms may persist or proliferate.

(h) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.

(i) Approved uses of the living modified organism.

(j) A risk assessment report consistent with Annex III.

(k) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.

(c) Requesting additional relevant information in accordance with its domestic regulatory framework or Annex I; in calculating the time within which the Party of import is to respond, the number of days it has to wait for additional relevant information shall not be taken into account; or

(d) Informing the notifier that the period specified in this paragraph is extended by a defined period of time." (Article 10; Secretariat of the CBD, 2000)

A failure of the importing Party to inform the exporting Party of its decisions within the time limit does not imply that it has consented to the import.

There are many countries that produce LMOs that are not Party to the CPB, and the USA is not even Party to the CBD. Nevertheless, most of the important countries (in terms of their production of LMOs) have agreed to follow these requirements as fully as possible. The USA, for example, has agreed to ensure that its data are available on the Biosafety Clearing House and has made its databases inter-operable with those of the BCH.

Anticipating unintended transfers of LMOs, the CPB deals with them as follows:

"In order to minimize any significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party, under whose jurisdiction the release of the living modified organism referred to in paragraph 1 above, occurs, shall immediately consult the affected or potentially affected States to enable them to determine appropriate responses and initiate necessary action, including emergency measures." (Article 17; Secretariat of the CBD, 2000)

Articles 15 and 16 provide the basis for the risk assessment and risk management process, respectively, whilst article 23 identifies the needs for communication. The Biosafety Clearing House (BCH) is an important part of implementing the Protocol. The major purpose of the BCH is *"facilitating the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms"* (Article 20; Secretariat of the CBD, 2000). In addition the information placed on the BCH should assist Parties to implement the Protocol. The special needs of least developing countries and small island states have to be taken into account. Amongst other requirements, Member States need to provide the following to the BCH:

"(a) Any existing laws, regulations and guidelines for implementation of the Protocol, as well as information required by the Parties for the advance informed agreement procedure;

(b) Any bilateral, regional and multilateral agreements and arrangements;

(c) Summaries of its risk assessments or environmental reviews of living modified organisms generated by its regulatory process, and carried out in accordance with Article 15, including, where appropriate, relevant information regarding products thereof, namely, processed materials that are of living modified organism origin, containing detectable novel combinations of replicable genetic material obtained through the use of modern biotechnology;

(d) Its final decisions regarding the importation or release of living modified organisms;

and

(e) Reports submitted by it pursuant to Article 33, including those on implementation of the advance informed agreement procedure." (Article 20(3); Secretariat of the CBD, 2000)

In addition, the BCH is used as a means of informing Member States, non-Members and the Public on many of the actions taken under the CPB. Parties are required to provide contact information to the Secretariat, which then has the responsibility to place this information on the BCH. This includes Competent National Authorities and National Focal Points (Article 19; Secretariat of the CBD, 2000). There is also an obligation on all Parties to inform their public about their decision-making process and about the decisions taken in relation to any LMOs that are released or imported into their country that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health:

"1. The Parties shall:

(a) 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;

(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.

3. Each Party shall endeavour to inform its public about the means of public access to the Biosafety Clearing-House." (Article 23; Secretariat of the CBD, 2000)

Decision BS-I/3 of the Meeting of the Parties (CPB COP-MOP 1, 2004) provided an Annex that identifies the modalities of operation of the Biosafety Clearing House; it provides detailed references for that summarised above.

One of the most contentious issues that is still being negotiated is liability and redress in the event of transgenic organisms causing harm. The CPB specifies that:

"The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of the ongoing processes in international law on these matters, and shall endeavour to complete this process within four years." (Article 27; Secretariat of the CBD, 2000)

6. LIABILITY

Liability is a major issue which is being addressed by the Open Ended Ad Hoc Working Group of Legal and Technical Experts on Liability and Redress in the context of the Cartagena Protocol on Biosafety (see http://www.cbd.int/biosafety/issues/liability.shtml) which will be reporting to the Conference of the Parties to the Convention on Biological Diversity meeting as the Parties

to the Protocol in May 2008 (see http://www.cbd.int/mop4/).

Harm to human health can be easily defined, although the harm may be delayed for many years and identifying causality may be difficult. Harm to the environment, which can be indirect and delayed, is difficult to determine and needs to be carefully defined so as to ensure that when harm occurs it can be corrected as soon as practicable. Damage may be personal injury possibly resulting in death or serious injury, loss or harm to property or harm to economic interests, and harm to the general environment (Box 4).

BOX 4. TYPES OF LIABILITY (Croplife International, 2004)

State liability means holding a country responsible for damage to another country under the applicable rules of international law. It is also referred to as 'state responsibility.'

Civil liability means liability (as defined above), of a person under civil law, i.e. the law governing relations between one private party and another private party. It is also referred to as 'private liability'.

General environmental liability is liability that attaches not to a specific activity that is potentially hazardous to the environment, but to each activity that is found to have resulted in damage to the environment, without distinguishing between specific types of activities. Under this approach, any actual damage to the environment may be covered, regardless of which activity has caused it.

Product liability is liability placed on the producer, brander, distributor, importer, retailer or other supplier of products for personal injury or property damage (traditional damage) resulting from the use of the product.

Economic harm, where a product supplants a product already on the market, is an extremely contentious issue, particularly for GMOs where organic and traditional producers are concerned at the impact of transgenic products on their livelihood. If a new product is introduced that is preferred by consumers, the manufacturer and other stakeholders in the original product will suffer economic harm – they are no longer able to sell their product – but this is a normal consequence of technological advance and any legal system would not normally consider this to be a cause for litigation and compensation. If, however,

an individual produces organic seed and normal pollen flow from 'adjacent' farms contaminates the seed to the extent that the seed can no longer be classified as organic, then harm could have been done, as it is not simply a different, replacement product that has been placed on the market. In general, in common law systems it has been generally accepted that economic loss not causally consequent on physical harm to a person or property could not be compensated. There has been some change to this position in recent years.

All legal systems have a basic system whereby an individual may claim to have been damaged by the actions of another, and the courts are then involved in deciding both on the justice of the claim and on any compensation that might be paid. This system, however, differs widely in different countries or for different types of harm.

The issues that need to be considered in this context are:

1. What constitutes damage?
   a. To other individuals (economic damage)
   b. To the agricultural environment
   c. To the food or supply chain
   d. To health including loss of life
   e. To the natural environment

2. What, if any, threshold should be defined before damage is considered to be great enough to require redress or compensation?

3. Is there a need to identify an individual responsible for the damage, or could there be multiple individuals involved. Is it the operator, the importer or exporter, any person in the supply chain, the manufacturer or the person that designed and made the original product from which other products with the same characteristics have been derived?

4. Does the state have any liability, having through regulation approved the use of the product and assured itself through risk analysis (including assessment and management) that the risks of use are minimised? The wording of national biosafety law or regulation may need to assure that it is the 'user' that carries the responsibility even where all the requirements specified in the regulatory system have been met, and the risk to either human

health or the environment has been minimised.

5. Should a system of compulsory insurance be instigated, and if so, who is responsible for its administration, and who pays the premiums – all farmers, only GM farmers, designer of the original transformation?

6. Should there be any limitations on liability?

7. If the action that has resulted in harm occurred in countries distant from the actual harm, which jurisdiction applies? Where is any judgement to be enforced if it is a trans border issue?

All of these questions need to be answered for a claim of damage to succeed. Some are issues of national private law, others of international private law, and others depend on international treaties which attempt to obtain international agreement on these sorts of questions for particular (and closely defined) harm.

In addition, *"not all forms of environmental damage can be remedied through liability. For the latter to be effective:*

- *There need to be one (or more) identifiable actors (polluters)*
- *The damage needs to be concrete and quantifiable, and*
- *A causal link needs to be established between the damage and the identified polluter(s).*

Therefore, liability can be applied, for instance, in cases where damage results from industrial accidents or from gradual pollution caused by hazardous substances or waste coming into the environment from identifiable sources. However, liability is not a suitable instrument for dealing with pollution of a widespread, diffuse character, where it is impossible to link the negative environmental effects with the activities of certain individual actors. Examples are effects of climate change brought about by CO_2 and other emissions, forests dying as a result of acid rain and air pollution caused by traffic." (European Commission, 2000b)

The Lugano Convention (Council of Europe, 1993) was agreed within the

Council of Europe in 1993 to address civil liability resulting from activities dangerous to the environment. This treaty required 3 ratifications to come into force. Signed by 9 countries, none have ratified it. It is nevertheless important as it addresses two issues:

1. Liability for harm due to dangerous activities should be strict, and the basis of liability should be based on the principle of the 'polluter pays'.

2. It defines a range of dangerous activities, including *"the production, culturing, handling, storage, use, destruction, disposal, release or any other operation dealing with one or more:*
   - *Genetically modified organisms which as a result of the properties of the organism, the genetic modification and the conditions under which the operation is exercised, pose a significant risk for man, the environment or property;*
   - *Micro-organisms which as a result of their properties and the conditions under which the operation is exercised pose a significant risk for man, the environment or property, such as those micro-organisms which are pathogenic or which produce toxins;"* (Article 2; Council of Europe, 1993)

The definition of damage includes loss of life or personal injury, loss of or damage to property and loss or damage due to the impairment of the environment.

The objective of this convention is to ensure adequate compensation for damage resulting from activities dangerous to the environment, to provide for means of prevention and for re-instatement. Liability is strict and imposed on the operator, defined as the person who has operational control of the dangerous activity. The operator is not, however, liable if it can be shown that the damage resulted necessarily from compliance with a specific order or compulsory measure of a public authority; was caused by pollution at tolerable levels under relevant local circumstances or was caused by a dangerous activity taken lawfully in the interests of the 'person' who suffered the damage.

Under the fault-based liability standard, a person is held liable for environmental damage if he or she is proven to be at fault. Strict liability,

where fault is not required, imposes an additional burden on persons who may be held liable. This is considered justified only in particular circumstances. Most legal systems, as well as existing civil liability treaties, impose strict liability only for hazardous activities, acknowledged to be capable of causing severe and long-lasting environmental damage (Kummer Peiry, 2005).

Strict liability is usually understood to mean that once cause has been established there is no need to question whether the person responsible for something that results in damage has acted in a negligent manner. If an act results in damage, the 'operator' is responsible, but the liability may be limited in both financial terms - how much should be paid in compensation, and in temporal terms – how long does the complainant have to institute proceedings before the claim is not longer able to be considered. Often strict liability systems rely on setting up a fund to which all those who might be introducing a product subject to strict liability are 'required' to contribute. *"The main difference between the two standards of liability is that fault-based liability requires that the damage be caused through a wilful or negligent act (fault) of the liable person. Fault is determined on the basis of whether or not the person to whom the damage is attributed observed the prescribed duty of care in carrying out the activity.* [The person bringing a claim must normally prove this.] *Strict liability, on the other hand, applies regardless of whether or not the person to whom the damage is attributed is at fault, i.e. whether or not he or she observed the duty of care. The claimant is only required to prove the damage and the causal link, but not a failure to observe the duty of care. Strict liability is generally advantageous for the claimant, as fault can be difficult to establish"* (Kummer Peiry, 2005). Fault-based liability is much more difficult. Here the person damaged has to show that the act (for example, of introducing a product) that resulted in damage was due to the negligence in some way of the operator. The damaged individual bears the burden of proving all the elements of negligence on the balance of probabilities.

One of the few cases that have come to higher courts in relation to the use of genetically modified organisms and organic farmers (coexistence) is one that was argued in the Appeal Court of Saskatchewan in Canada (Court of Appeal for Saskatchewan, 2007). The action was between Larry Hoffman, LB Hoffman Farms Inc. and Dale Beaudoin as plaintiffs and Monsanto Canada Inc. and Bayer Cropscience Inc. The action was ostensibly taken on behalf of numerous organic grain farmers for the recovery of damages alleged to

have been suffered by them as a result of the introduction by the appellants of strains of GM canola (oilseed rape) for use by farmers generally. The court decided that a class action suit was not appropriate, and the organic farmers therefore lost the case but some of the arguments made in the case are fascinating. Importantly, the organisations certifying organic farmers in Saskatchewan did not have any standards in place regarding the presence of GMOs until well after Roundup Ready® canola (OECD Unique Identifier MON-ØØØ73-7; transformation event RT73 [GT73]) canola and LibertyLink® Innovator canola (OECD Unique Identifier ACS-BNØØ7-1; transformation event Topas 19/2 [HCN92]) had been made available and become widely used. Only then did these organisations amend their standards to preclude the presence of GMOs in grain marked as 'organically grown'.

The plaintiffs alleged that the appellants and other organic grain farmers suffered financial losses as a result of the introduction and commercial use of Roundup Ready® and LibertyLink® canola. They alleged that these strains of genetically modified canola, which are open-pollinating, inevitably would find their way onto their fields, thus preventing them from producing and marketing organically grown canola, and putting them to extra expense in producing other organically grown crops. They further alleged that the companies were liable for these losses on the bases of negligence, nuisance, and trespass. In the lower court the judge held that it was conceivable that the release of these products constituted a 'discharge' into the environment. It was also conceivable that the introduction of the GM canola had not received prior ministerial approval and therefore was contrary to the Environmental Management and Protection Act (2002). Their complaint was that the adventitious presence of GM canola in the fields of organic farmers has made it impossible to guarantee the organic status of the canola.

In the original decision by the lower court, the judge made the following observation:

> *"[35] It is clear that the principal challenge faced by the plaintiffs in relation to this criterion is to persuade the Court that there is a plausible basis for imposing on them defendants' liability for losses the plaintiffs may have suffered as a result of the adventitious presence of GM canola in crops or fields of organic grain farmers, and for losses related to the fact that the standards imposed by third parties (organic certifiers or organic markets) might prohibit*

the use or presence of GMOs in relation to commodities marketed as organic.

[36] The magnitude of this challenge is evident. In virtually every case, the plaintiffs conceded in argument that the cause of action asserted was in at least some respects novel, and relied heavily on the position that, given the novelty of the claim, it should be left for the trial judge to consider whether this is an appropriate case to expand the legal category at issue." (Court of Appeal for Saskatchewan, 2007)

The Canadian Supreme Court decided to dismiss without costs the application for leave to appeal from the judgment of the Court of Appeal for Saskatchewan in December 2007 (Supreme Court of Canada, 2007). For further information regarding liability, the reader is directed to ECTIL/ESRETL (2007).

7. WHAT HAVE COUNTRIES DONE TO IMPLEMENT THE CPB?

It was realised as soon as the CBP was signed that developing countries would have to be provided with help to bring their systems into line with the requirements of the Protocol. Even during the negotiations that led to the Protocol, a pilot project involving 18 countries was financed by the Global Environment Facility to assist countries in designing and putting into place a system for the regulation of modern biotechnology. The project aimed to set up National Biosafety Frameworks in 18 countries and develop systems for the cross boundary movement of LMOs (GEF, 1987). The countries involved were Bolivia, Bulgaria, Cameroon, China, Cuba, Egypt, Hungary, Kenya, Malawi, Mauritania, Mauritius, Namibia, Pakistan, Poland, the Russian Federation, Tunisia, Uganda and Zambia. It involved the preparation of National Biosafety Frameworks, including a survey of capacity for both biotechnology and for safety assessment; and the organisation of a series of eight workshops, in which all the countries participated, that explored risk analysis and management, and transboundary movement of LMOs.

Once the CPB was in place, the GEF financed a large project which has assisted well over 100 countries to institute 'National Biosafety Frameworks' that assure the safe use of the products of modern biotechnology as defined in the CPB. *"As of 8 March 2008, 99 countries have completed*

the majority of development of their National Biosafety Projects and their draft National Biosafety Frameworks are available online" (UNEP, 2008). The participating countries had, first, to identify the set of laws that already existed in the country that might have applied to biotechnology. Given this information, it is then possible to identify the differences between modern biotechnology that needs regulation of some sort (through the provisions of the CPB) and those that had proceeded for generations and should not be disturbed in implementing new regulatory structures. Examples might be the manufacture of wines and beer or even the sewage systems, which without care could have been caught by the new implementing structures. Secondly, Governments needed to survey and assess that which was being done in the country, and if any modern biotechnology was being done and where, and then, how the provisions of the CPB needed to be implemented to assure that the procedures were being done safely. With this information, Governments could then decide on whether specific new law was required, or whether current law could be implemented to cover the requirements as defined in the CPB.

Virtually all countries have decided to create new law, and are not using current law to implement the CPB; however, few as yet have brought these laws into effect. Only very few are analysed here, as the policy documents are available on the UNEP website.

Botswana define their National Biosafety Framework (NBF) as:

> *"…… a combination of policy, legal, administrative and technical instruments that are put in place to address safety for the environment and human health in the application of modern biotechnology. The key components of an NBF are the biosafety policy, regulatory regime, system to handle requests (administrative, risk assessment and management, decision making), follow-up activities (enforcement, monitoring); public awareness and participation."* (Republic of Botswana, 2006)

Similarly, Bangladesh asserts in its document that:

> *"The National Biosafety Framework (NBF) provides a basis for administrative system and regulatory regime to be developed for adequate level of protection in the environment and human health*

against uses of GMOs resulting from modern biotechnology.

The purposes of development of the NBF are:

- *To give an outline of the administrative system to deal with GMOs for adequate level of protection in the field of the safe transfer, handling and use of GMOs resulting from modern biotechnology.*

- *To give an overview of existing legislations relevant to biosafety and to give an outline of a proposed regulatory regime to be developed.*

- *To indicate what is the status of biotechnology and biosafety in the country and what should be done in order to strengthen biotechnological research and development capacity and to ensure biosafety aspects arising from modern biotechnology."* (Government of the People's Republic of Bangladesh, 2006)

Ghana has produced a very similar document. Once again there is a draft of a parliamentary bill to implement the work done within the project:

"***Biosafety Bill (2004)***

(i) Status: Draft

(ii) Scope: The draft law regulates all activities in biotechnology including contained use, releases into the environment and placements in the market, export and import and transit of GMOs. The only exemption is on genetically modified organisms that are pharmaceuticals for human use which are regulated by other international agreements……

……The Bill covers procedures for handling of requests including contained use, introduction to the environment, import and export, genetically modified organisms in transit, handling of confidential information and acknowledgment of applications. Additional information requirements on contained use, releases

and placement on the market are spelt out in the second and third schedules respectively. It also has procedures on risk assessment and risk management, an exemption clause, the key elements for a decision and communication of decision. It gives room for review of applications and a mechanism for appeal through the appeals board.

The bill makes provision for a technical advisory committee which shall provide technical advice to the Board of the National Biosafety Authority and other related agencies. It shall also be responsible for risk assessment. The existing regulatory agencies are given the function of enforcement after issue of a decision or a permit. Risk assessment procedures and the regulatory agencies targeted to assist in monitoring and enforcement are spelt out in fourth and fifth schedules respectively.

The bill also provides for a governing council, the board, which is tasked with decision making, whilst the Chief Executive Officer and the Staff of the National Biosafety Authority handles the day-to-day activities. The first schedule gives provisions on conduct of business and affairs of the authority. The bill makes room for appointment of inspectors with powers and the legal backing to undertake biosafety inspectorate activities for compliance and enforcement by the regulatory agencies (fifth schedule), individuals and companies.

Provisions for financial management and reporting have been catered for in the bill. Public awareness and participation issues are also captured in the bill. In all, the bill is planned to give legal backing to all the expected key components of the National Biosafety Framework for Ghana. The bill also provides for the issuance of further guidelines to facilitate better performance of the National Biosafety Authority." (Ghanaian Ministry of Environment and Science & Ghanaian Biotechnology & Nuclear Agriculture Research Institute, 2004)

In the case of Bangladesh, their analysis provides that there is no law *"that deals comprehensively with the adverse impacts that might arise from the use, handling, transfer and transboundary movements of GMOs as required by the Protocol"* (Government of the People's Republic of Bangladesh, 2006). The laws in place are considered to be old, and therefore do not

deal effectively with the threats of the new technology *"to biodiversity, environment and human health"* (Government of the People's Republic of Bangladesh, 2006). They therefore identify the need to amend existing law, or proceed to pass a new law through the parliament, taking care regarding overlaps with existing law. In their case, there is provision in existing law for making regulations under their Environment Conservation Act of 1995. This is effectively, new law.

> *"The title of the proposed regulatory regime can be the 'Bangladesh Biosafety Rules, 2007' or 'Bangladesh Biosafety Act, 2007'.*
>
> *"The objectives of the regulatory regime include the following:*
>
> *(i) To ensure, in accordance with the precautionary approach, an adequate level of protection against potential risks arising from any dealings with GMOs resulting from modern biotechnology.*
>
> *(ii) To establish a transparent and predictable decision making process relating to GMOs and related activities, including environmental risk assessment, social impact assessment, conditions of monitoring and enforcement, and provision for penalty and redress."* (Government of the People's Republic of Bangladesh, 2006)

Most of Eastern Europe has followed the regulatory structures that are defined by the EU, for many have aspirations towards joining or are reliant on exports to the EU. In Asia, similarities emerge. In Lao, they recommend that *"The Government of Lao PDR should make and translate National Policy on biotechnology and biosafety into national framework, law and regulation, technical guidelines, plans and detailed project for the management and monitoring of biotechnology and living modified organisms"* (Government of Lao PDR, 2004). The country has a draft law that, among other requirements, specifies:

> *"A. Objective: to regulate biotechnology and living modified organism, that may have adverse effects on the conservation and sustainable use of genetic resources at adequate level by insurance the safety of living organism and taking also into account risks to human health, socio - economic development and environment protection.*

B. Scope of the regulation:

- *Biotechnology Research and Development*
- *Risk Assessment and Management on Modern Biotechnology*
- *Notifications Movements and Management of Modern Biotechnology Product*
- *Public Education, Awareness and Participation and Human Resource Development*
- *Cooperation, Coordination and Information*
- *Biosafety Fund Management*
- *Awards and Sanctions*
- *Management and Monitoring Organization Inspection and Redress"* (Government of Lao PDR, 2004)

8. CONCLUSION

Although it is likely that most of the almost 200 countries that are members of the Convention on Biological Diversity are using modern biotechnology in their research institutions and universities, few are considering the commercialisation of products that are likely to be the subject of transboundary movement as defined in the Cartagena Protocol on Biosafety. There are few products on the market (as yet) and most have been developed in North America. Export of these products as food, feed or for processing is almost universal, as most soya bean and maize grown is now transgenic. Few countries, however, are growing the products and even fewer are exporting them to third countries.
Almost 8 years after the agreement on the CPB and 16 after the CBD, relatively few countries have laws in place to deal with GMOs, even though many still assert that risk of damage to human health or to the environment is palpable. The negotiations on liability and redress demonstrate that there are real concerns. It may be that the manner in which Europe has chosen to regulate these technologies influenced both the decision to adopt the CPB and increased the concern of many that the technology is intrinsically hazardous.

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