



UNIVERSITY OF STELLENBOSCH

**THE INTERNATIONAL POLITICAL ECONOMY OF THE
CARTAGENA PROTOCOL ON BIOSAFETY**

Marthinus Johannes du Plessis

Thesis presented in partial fulfillment of the requirements for the degree of Master of
Arts at the University of Stellenbosch

SUPERVISOR: PROF PHILIP NEL

MARCH 2001

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DECLARATION

I, the undersigned, hereby declare that the work contained in this thesis is my own original work and that I have not previously in its entirety or in part submitted it at any university for a degree.

ABSTRACT

The development of the global biotechnology industry largely coincided with the development of the US biotechnology industry. This resulted in this industry's oligopolistic and centralised nature where only a few multinational chemical and pharmaceutical companies control most biotechnology processes and production of commodities emanating from these processes. The governance of biotechnology has, until recently, been dominated by state actors who have endeavoured to secure national interests, including those of large multinational corporations (MNCs) based within their boundaries.

The technological ability of developed states to exploit and use unevenly distributed resources to their advantage means that an uneven relationship exists between these and poor developing countries. This has been highlighted by differences in public opinion about the role and application of biotechnology in society. While some opinions favour the use and application of biotechnology to enhance food supplies and boost production levels and trade, other opinions caution against the possible hazards that genetically manipulated organisms (GMOs) hold for the environment and human existence.

The commercialisation of biotechnology has resulted in the exponential growth of genetically manipulated crops in especially the United States and countries like Argentina and Canada. These countries produce large surpluses of staple grains such as corn and soya and try to sell these to countries with food supply problems. The clash in commercial interests stemming from developed countries' insistence on the protection of intellectual property rights (IPR) on genetically manipulated (GM) seeds has caused considerable conflict with poor farmers who will not be able to sustain their livelihoods if they cannot save seeds for future harvests.

This is one aspect of the problems surrounding the protection of knowledge products that is exacerbated by the scientific uncertainty pertaining to the risk involved with biotechnology. While some observers agitate for precaution with the use of GMOs, others feel that a lack of scientific proof of harm is sufficient grounds for proceeding with developments in biotechnology. Conversely, there are some that feel that

biotechnology is market driven instead of human needs driven, ultimately resulting in developing countries receiving very little benefit from it.

The Cartagena Protocol on biosafety was drafted to address some of the difficulties involved with the transboundary movement of GMOs. Although it holds very specific advantages for developing countries, as a regulatory framework it is limited in its scope and application. Developing countries are limited in their policy options to address their need to protect biodiversity and secure their food supply. This means that considerable challenges and constraints await these countries in utilising global governance of public goods and building their human and technological capacities.

OPSOMMING

Die ontwikkeling van die globale biotegnologie-industrie het grootliks saamgeval met die ontwikkeling van die Verenigde State se biotegnologie-industrie. Dit het aanleiding gegee tot hierdie industrie se oligopolistiese en gesentraliseerde aard waar slegs enkele multinasionale chemiese en farmaseutiese maatskappye die meeste biotegnologie prosesse en die vervaardiging van kommoditeite uit daardie prosesse beheer. Die regering van biotegnologie was tot onlangs oorheers deur staatsakteurs wie gepoog het om nasionale belange te beskerm, insluitend die belange van multinasionale korporasies (MNK) wat vanuit hulle grondgebied funksioneer.

Die tegnologiese vermoë van ontwikkelde state om oneweredig verspreide hulpbronne tot eie gewin te benut beteken dat 'n ongelyke verhouding bestaan tussen hierdie en arm ontwikkelende state. Dit word beklemtoon deur verskille in openbare mening oor die rol en aanwending van biotegnologie in die samelewing. Terwyl sekere opinies ten gunste van die aanwending van biotegnologie vir die verbetering van voedselbronne en produksievlakke en handel is, dui ander opinies op die moontlike gevare wat geneties gemanipuleerde organismes (GMOs) vir die omgewing en menslike voortbestaan inhou.

Die kommersialisering van biotegnologie het gelei tot die eksponensiële groei van geneties gemanipuleerde gewasse in veral die Verenigde State en state soos Argentinië en Kanada. Hierdie state produseer groot hoeveelhede stapelgrane soos mielies en soja en poog om dit te verkoop aan state met voedselvoorsieningsprobleme. Die botsing in kommersiële belange wat spruit uit ontwikkelde state se aandrang op die beskerming van intellektuele eiendomsreg op geneties gemanipuleerde saad veroorsaak beduidende konflik met arm landbouers wie nie hulle lewensonderhoud kan verseker as hulle nie saad kan berg vir toekomstige saaiseisoene nie.

Dit is een aspek van die problematiek rondom die beskerming van kennisprodukte wat vererger word deur die wetenskaplike onsekerheid wat gepaard gaan met die risiko's van biotegnologie. Terwyl sekere waarnemers vir waaksaamheid pleit in die

gebruik van GMOs, is daar ander wat voel dat 'n gebrek aan wetenskaplike bewyse van skade genoegsame gronde is vir die voortsetting van ontwikkelings in biotegnologie. Insgelyks is daar diegene wat meen dat biotegnologie markgedrewe in plaas van menslike behoefte gedrewe is, wat uiteindelik daartoe lei dat ontwikkelende state baie min voordeel daaruit trek.

Die Kartagena Protokol oor bioveiligheid is opgestel om van die probleme betrokke by die oorgrens verskuiwing van GMOs aan te spreek. Hoewel dit spesifieke voordele vir ontwikkelende state inhou is dit as reguleringsraamwerk beperk in omvang en aanwending. Ontwikkelende state het beperkte beleidsopsies om hulle behoefte om biodiversiteit te beskerm en voedselvoorsiening te verseker, aan te spreek. Dit beteken dat beduidende uitdagings en beperkings hierdie state in die benutting van globale regering van openbare goedere vir die bou van menslike en tegnologiese kapasiteite in die gesig staar.

DEDICATION

In loving memory of my father, Marthinus Johannes du Plessis, who was a humble man with a deep love and respect for Africa's veld, its sun, its rain, and all its creatures.

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- My son, Martin, who was born when I started this project and is a constant source of inspiration and laughter.

LIST OF ACRONYMS

| | |
|-------|--|
| AIA | Advance Informed Agreement |
| BSWG | Biosafety Working Group |
| CBA | Cocoa Butter Alternatives |
| CBD | Convention on Biological Diversity |
| CEE | Central East European Countries |
| CPGR | Commission on Plant Genetic Resources |
| ECLA | United Nations Commission for Latin America |
| ExCOP | Extraordinary Conference of the Parties |
| FAO | Food and Agricultural Organisation |
| FCCC | Framework Convention on Climate Change |
| GATT | General Agreement on Tariffs and Trade |
| GEF | Global Environment Facility |
| GM | Genetically Modified |
| GMO | Genetically Manipulated Organism |
| GRAIN | Genetic Resources Action Network |
| HFCS | High Fructose Corn Syrups |
| ICJ | International Court of Justice |
| IP | Intellectual Property |
| IPRs | Intellectual Property Rights |
| IUCN | World Conservation Union |
| LDC | Less Developed Countries |
| LMOs | Living Modified Organisms |
| MAFF | (Japanese) Ministry of Agriculture, Forestry and Fisheries |
| MNCs | Multinational Corporations |
| NARS | National Agricultural Research System |
| NGOs | Non-governmental Organisations |
| OECD | Organisations for Economic Cooperation and Development |
| PVP | Plant Variety Protection |
| RAFI | Rural Advancement Fund International |
| SIRC | Social Issues Research Centre |
| TRIPs | Trade Related Aspects of Intellectual Property Rights |
| TWN | Third World Network |

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|--------|---|
| UNCCD | United Nations Convention to Combat Desertification |
| UNCED | United Nations Conference on Environment and Development |
| UNCTAD | United Nations Conference on Trade and Development |
| UNDP | United Nations Development Programme |
| UNFCCC | United Nations Framework Convention on Climate Change |
| UPOV | International Union for the Protection of New Varieties of Plants |
| WEF | World Economic Forum |
| WHO | World Health Organisation |
| WIPO | World Intellectual Property Organisation |
| WTO | World Trade Organisation |
| WWF | World Wide Fund for Nature |

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THE INTERNATIONAL POLITICAL ECONOMY OF THE CARTAGENA PROTOCOL ON BIOSAFETY

CHAPTER 1

INTRODUCTION

"Half of politics today is conducted in science and technology, half of what we regard as nature is a technical artifact sealing a social bond" (Allen, referring to Latour, 1998:169).

1. **Background**

Biotechnology can be defined as "the use of BIOLOGICAL processes for industrial or other purposes, e.g. in producing ANTIBIOTIC drugs" (Crowther, 1995:107). The Greek word "bios" means life and the English "bio" is often used to denote that which has to do with life or living organisms. For its part, the word "technology" has a much more varied range of meanings, from the study of the way humans change and manage their environment, to any set or collection of human-made tools. Here technology is conceived of as a "set of methods, know-how, tools, instruments and machines, as well as...organizational and managerial principles, designed to increase the efficiency of productive activities" (Bifani, 1989:136). Thus, technology can also be understood to involve tools or mechanisms to solve problems or make useful products [<http://www.bio.org/aboutbio/guide2000/whatis.html>], or "the scientific study and use of applied sciences" (Crowther, 1995:1226). But these definitions shed very little light on the controversy and politics surrounding biotechnology.

During the 1960s and 1970s biotechnology advanced to a point where scientists were able to manipulate some of the smallest known parts of organisms, their cells and molecules (e.g. DNA and proteins), in addition to the use of whole organisms. This "new" biotechnology means that cellular and molecular processes in live organisms

are used to solve problems or make new products through various new technologies¹ [<http://www.bio.org/aboutbio/guide2000/whatis.html>]. These new technologies have introduced a problematic dimension into international relations which, up to now, has been characterised by a lack of an overall regime or protocol on the handling of biotechnology on various levels such as international trade and intellectual property rights. At the same time consumers and activists have objected to some of the uses of biotechnology, especially where genetic engineering is involved. This has sparked a debate on the ethics and social values surrounding some of the biotechnology developments and practices. This is a debate that has various levels of interest and where the dividing lines are still being explored, making the issue of biotechnology in international politics an interesting one as it unfolds at the beginning of this new millennium. The following words by Krinsky and Wrubel (1996:230) indicate some of the dynamics and complexity that biotechnology has generated:

“Modern biotechnology has brought biology from a predominantly analytical phase to a new synthetic phase in its historical development. The possibilities for rearranging species are, for all practical purposes, unlimited. Various interests are involved in a struggle over the power images of modern biology. Power is central to the mythmaking that is taking place.. The grand techno-myth is that with genetic engineering we can fine-tune nature, preserve its diversity while reaping its bounty”.

Biotechnology does not, however, only challenge the worlds of policy-makers, biologists and geneticists. Biotechnology's influence on society and nature and the way mankind thinks about these phenomena is so widespread that it can be called profound.

2. Problem Statement

The twentieth century was an era characterised by tremendous growth in man's capacity to interact with his fellow man and the environment. It saw two wars that were great in the magnitude of their destruction and devastation combined with loss

¹ Examples of these new technologies include cell culture technology, biosensor technology, genetic modification technology, antisense technology, protein engineering technology [<http://www.bio.org/aboutbio/guide2000/whatis.html>], recombinant DNA, gene transfer, embryo manipulation, embryo transfer, plant regeneration, cell culture, monoclonal antibodies, and bioprocess engineering (Board on Agriculture in Hueth, Kung and Colwell, 1992:355).

of human life. It saw the invention and manufacturing of artifacts hitherto thought not possible, such as the aeroplane, the motorised vehicle, flights to the moon, television, microwave ovens, regular space flights, cellular communication, and the internet, to name but a few. These inventions have left most of the human race awe-struck with the wonders of technology and the expectation that it could solve almost any problem. Unfortunately, the wonders of technology have not meant universal benevolence to mankind. Harmful waste products, pollution, and environmental degradation, the effects of which were already patently manifest during the height of the industrial revolution more than a century earlier, accompany many new technologies. The spoils of new technology also do not fall on all people equally, creating new challenges of equity and justice. This became especially clear after the Second World War.

Powers of production and destruction were developed simultaneously after 1945 (Sakamoto, 1995:132). During the Cold War industrialised countries created immense wealth for certain sectors of its populations while at the same time developing military hardware and nuclear capacities that could wipe out the entire human race in a few hours. The extent of this affluence was of such a nature that the environmental destruction and its impact on marginalised societies faded into obscurity. As one author put it, "the very structural condition which generated the catastrophic danger made it possible for them (North) to forget about the real danger of catastrophe" (Sakamoto, 1995:132). This process has been exacerbated by what has come to be known as the unstoppable force of globalisation.

One of the consequences of globalisation is destruction of the environment (Cox, 1995:41). This is facilitated by what Cox identifies as new forms of hegemony, imperialism and dominance when he states, "The aggressive search for resources by economically dominant interests and the off-loading of polluting and energy-intensive processes to newly industrializing countries has resulted in a kind of environmental neo-colonialism – the dominant societies clean up and move to more knowledge-intensive production while those following in their tracks become sites of environmental degradation" (Cox, 1995:41-42). Biotechnology is one of the developments that are part of the process of knowledge-intensive production that can lead to the unequal distribution of power and resources. Yet, it seems that there is

not enough control in the form of rules and mechanisms of governance to control these forces of technology. Biotechnology seems to be a part of “a more general acceleration of scientific discovery and technological innovation” that is expanding at a rate that existing regulatory mechanisms can not handle (Pirages, 1990:106).

Developments in biotechnology do not only have a fundamental influence on our understanding of technology and life in general, but also hold profound implications for food, pharmaceutical, chemical and agro-chemical industries. Its use in biological weapons and warfare can also affect military and national security in the battlefield of the future in very dramatic ways (Munson, 1993:497). Yet, despite the importance of biotechnology in the fields mentioned, and despite its potential misuse, no consolidated and clear set of rules that is geared specifically towards the management, use and control of biotechnology have yet been introduced into the international political framework. Many conventions and protocols exist to safeguard national interests and protect the environment, but they are not coordinated or unified in purpose, scope or application. In January 2000, the Cartagena Protocol on Biosafety was adopted in Montreal, Canada. But its scope and focus is limited to the regulation of the transboundary movement of genetically manipulated organisms (GMOs).

Multilateral negotiations with the aim of creating a Convention on Biological Diversity had already begun in 1990. The purpose at the time was to provide governments with a guide to achieve sustainable development (Munson, 1993:498). Recognition by governments of the importance of biotechnology was demonstrated during the United Nations Conference on Environment and Development (UNCED) in June 1992, when biotechnology was placed on the agenda, both within the negotiations for a Biodiversity Convention, and in the so-called *Agenda 21*, UNCED’s programme of action. The result of these negotiations was a split between the USA, favouring a looser regime with regards to the handling of genetically manipulated organisms (GMOs), and the European Community, which saw the necessity for an International Code of Conduct on biotechnology to regulate biotechnology at all levels (Munson, 1993:500). Many developing countries supported Europe in asking for more control over the development and use of biotechnology.

The outcome of the UNCED process is what Munson (1993:501) calls a compromise package, summarised firstly in Article 19 of the Biodiversity Convention, which obliges contracting parties firstly to “consider the need for and modalities of a protocol setting out the safe transfer, handling and use of any living modified organism resulting from biotechnology”. Secondly, Chapter 16 of *Agenda 21*, on the “Environmentally Sound Management of Biotechnology”, requires governments to “consider the need for and feasibility of internationally agreed guidelines on safety in biotechnology releases”. Despite the USA’s full participation in the formulation of the final draft of the biosafety “compromise”, President Bush was the only OECD leader who did not sign the Convention on Biological Diversity at the Rio Earth Summit. His explanation was that it would adversely affect US economic interests, the competitiveness of the US biotechnology industry, American jobs, and their intellectual property rights. He said “(I)t is our science, our technology that helps the world the most...in this instance, not signing is the best for the rest of the world” (Munson, 1993:501-2).

Scientists have not yet been able to provide conclusive evidence that biotechnology, and especially GMOs, will *not* adversely affect the environment and biodiversity as we know it, and it is doubted that they will ever be able to. It is therefore imperative that developments in biotechnology proceed with the necessary caution and vigilance associated with a posture of long-term responsibility and consequences in mind. The scientific community is anxious to see how the development of a set of rules or protocol on biotechnology develops, as this will determine in which direction/s their work can proceed. At the same time strategists and national security planners, international traders and economists, bio-technicians and bio-industrialists, environmentalists and lobbyists, and various informed communities are all awaiting the establishment of a more secure regime in which biotechnology will develop. This thesis will explore and examine the problems surrounding the development of such a regime.

3. **Questions that need to be answered**

From the problem statement it is evident that biotechnology influences many dimensions and levels of the globalising world. It is a technology that challenges

more than the biologists, geneticists and other scientists in the natural sciences. It has been responsible for stimulating the thoughts of economists and social scientists because of its impact on trade and development as well as on power and structural relations. Biotechnology not only poses new questions of moral responsibility and ethics where genetic manipulation is concerned. It has sparked a renewed groundswell by environmentalists and anti-globalisation activists who view the role of technology and free markets as threats to the future existence of human society. These dynamics have presented countless new questions that need to be answered if any understanding of the future role of biotechnology is to be understood. Only some of these questions will be addressed in this thesis. They are:

- What is the nature and direction of genetic governance?
- Who determines the allocation of values in biotechnology?
- What is the role of biotechnology in international trade?
- Why has biotechnology become a part of knowledge protection?
- How should the debate about risk and safety of biotechnology be understood?
- How have environmental issues been regulated in the past?
- What is the content, nature and role of the Cartagena Protocol?
- What are the issues that the Cartagena Protocol does not resolve?
- How do biotechnology and regulatory issues affect developing countries?
- Why is biodiversity and food security important to developing countries?
- Which are the obstacles developing countries face in building capacity?

Before attempting to answer these questions, a common understanding of the meaning of biotechnology is necessary.

4. Conceptualisation of Biotechnology

Biotechnology is defined by Persley and Doyle (1999:2) as "...any technique that uses living organisms or substances from those organisms to make or modify a product, improve plants or animals, or develop microorganisms for specific uses. The U.S. Office of Technology Assessment states that "biotechnology includes any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop micro-organisms for specific

uses" (U.S. Congress in Wiegele, 1991:21). Thus, biotechnology involves the manipulation of genes or DNA sequences. When biologists remove genes from cells and manipulate them in a laboratory to reinsert them into the organism from which it was removed, or another organism, it is called recombinant DNA or rDNA technology. This technology is deemed revolutionary because it enables scientists to create 'new' products, or organisms, by "merely" joining together pieces of DNA from different organisms (Wiegele, 1991:25). One typology of the essential components of modern biotechnology focuses on the following: Genomics: the molecular characterisation of all species. Bioinformatics: the assembly of data from genomic analysis into accessible forms. Transformation: the introduction of single genes conferring potentially useful traits into plant, livestock, fish, and tree species. Molecular breeding: the identification and evaluation of desirable traits in breeding programs with the use of market-assisted selection. Diagnostics: the use of molecular characterisation to provide more accurate and quicker identification of pathogens. Vaccine technology: use of modern immunology to develop recombinant DNA vaccines for improving control of lethal diseases (Persley and Doyle, 1999:2).

An alternative range of technologies² denoted by biotechnology is sited by Wiegele (1991:22), who indicates that these can be used in various industrial and other applications. This can place the definitional emphasis on the *processes* involved to produce products. However, some definitions specifically highlight the *products* that emanate from the processes of biotechnology. This stems from the perceived impact that these products have or can have in society, whether it is political, social or environmental. These aspects are dealt with in more depth in later chapters. How the study is conducted needs also to be considered.

5. Theory, Methodology and Research Design

5.1. A Conceptualisation of Theory

Social theory can be defined as "a system of interconnected abstractions or ideas that condenses and organizes knowledge about the social world" (Neuman,

² Examples of these technologies include molecular and cellular manipulation, separation and purification technologies, biomolecular instrumentation, cell culturing, enzymology, and X-ray crystallography (Wiegele, 1991:22).

2000:40). There is certainly no consensus among scientists about the most suitable way to proceed upon the path of discovery or how to acquire knowledge. Thus, social theory, or theories are embedded in different schools of thought, different approaches, different worldviews, or different paradigms that each have specific criteria about the nature of reality (ontology) and how knowledge can best be acquired (epistemology).

5.2. Theoretical Alternatives

In the social sciences in general, a distinction can be made between positivist, interpretive and critical approaches (Neuman, 2000:63). The advent of the behavioural revolution in the social sciences has meant that positivism has become the dominant approach, with the other approaches regarded by most as secondary or not taken seriously at all. The same tendency is true for International Relations and International Political Economy, where the theoretical framework of Realism, and in its updated guise, neo-Realism, has been predominant. Some scholars call this predominance orthodoxy, with the alternative approaches labeled heterodoxy (see George, 1995). The heterodoxy approaches have also been called reflectivist, including the theories of Post-modernism, Critical Theory and Constructivism (Woods, 1996:24).

The political-economic framework of *critical structuralism* informs the theoretical framework that underlies this thesis. A brief explanation for electing to use critical theory rather than any of the other frameworks is in order. Although Critical Theory has much in common with the other reflectivist theories, the specific differences in approach as they relate to a study of an international regime need to be highlighted. The Post-modernist approach is similar to Critical Theory for its criticism of materialism and rationalism. It was also the first theory to point to the way social constructions of reality have taken place, thereby acting in opposition to the often preferred theory and method of neo-Realism (Wendt, 1999:32). Yet, despite its strong critical voice and “rebellion against hegemonic ways of thinking”, post-modernists do not offer much beyond this rebellion (Woods, 1996:25). A third reflectivist theory is that of Constructivism, which looks at the international system as a construction that can be reconstructed (Kennedy-Pipe, 2000:752). Constructivism’s main proponent, Alexander Wendt, follows an approach he calls

“moderate”, one “that draws especially on structurationist and symbolic interactionist sociology” (Wendt, 1999:1). Although Constructivism manages to direct attention to the rules and norms that make up the boundaries of interest articulation and formulation, it offers very little resistance to the orthodoxy in International Relations theory (Woods, 1996:26). Wendt, by his own admittance, uses the dialogue of Realism as found in concepts such as the state, national interest, anarchy, and science (Wendt, 1999:33). Thus, Constructivism, for its lack of an emancipatory capacity, is rejected in favour of a critical theory approach.

There are many variants of structuralist theorising, which makes a brief explanation for choosing the critical theory variant appropriate. In its common usage, structure refers to the way something is organised, built or put together, while structuralism refers to the relations between elements of a system rather than to the elements themselves (Crowther, 1998:1186). The latter usage was the result of the work done by the Swiss linguist, Ferdinand de Saussure, whose epistemology was applied by the French social anthropologist, Claude Lévi-Strauss, to social science in his effort to encourage the development of models to reveal the underlying structural mechanisms which guide the surface phenomena of social life. This usage later found fruition in structuralist Marxism of which the basic idea was that structure conditions outcome, where Marx contended that the economic substructure in capitalist societies determine the political and ideological superstructure that results in class divisions. Vladimir I. Lenin took this view to the international level. He called the exploitative relationship of industrial countries with their colonial possessions imperialist and unjust (Balaam & Veseth, 1996:59-60).

More recent examples of structuralism that highlights imperialism, or the unequal relationship between developed and developing countries, include the writing of André Gunder Frank, Raul Prebisch and Immanuel Wallerstein. Frank was a neo-Marxist who fathered the basic ideas of *dependencia* theorising, which found popularity in Latin America during the middle of the twentieth century. Prebisch gave rise to a related but different form of Latin American structuralism developed in collaboration with the UN Economic Commission for Latin America (ECLA). The main plight in this instance was for national strategies of import-substituting industrialisation and regional integration coupled to international cooperation, policies

later adopted by the United Nations Conference on Trade and Development (UNCTAD) established by Prebisch in 1964 (McLean, 1996:481). Wallerstein developed the so-called modern world system theory that sees interstate relationship according to a *core-periphery model*, where developed and industrialised states are able to secure and advance their interests while poor and developing countries serve as suppliers to these stronger economies' functioning. Emphasis is not exclusively on the state level but also on class relations that exist at all levels of society within and between states and other actors (Balaam & Veseth, 1996:71-2). Although these theories are useful in highlighting the position of the underprivileged, they have been discredited for their oversimplified typologies; because the so-called underdeveloped have not managed to successfully speak with a united voice; and because the economic and sometimes political successes of a number of the South-East Asian states have shown that underdevelopment can be overcome without specific privileging from the rich North.

These and other forms of structuralism each emphasise specific elements of society and how these elements are interrelated. What they all have in common is the fundamental difference in approach to international political economy when compared to that of liberals and mercantilists. Where liberals and mercantilists focus on the individual and the state respectively, structuralists focus on class divisions and the global political economy. This structuralist viewpoint is taken as a broad frame of departure in this study. More specifically, critical structuralism takes structure to denote "persistent social practices, made by collective human activity and transformed through collective human activity" (Vico cited by Cox, 1987:4). The power relations that emerge from these structures are determined mostly by production relations, each with its own power dynamic, which fall within a range of being dominant and oppressive to being equitable and just. Production is shaped by power relationships and also creates resources that can be "transformed" into other forms of power such as financial power, ideological power, military power, and power over products emanating from the access to and use of knowledge (Cox, 1987:5). The difference between historical structuralist theory and critical structuralism lies in the interaction of human behaviour with these structures. The historical approach takes structures as given entities that can not be altered by human action – they need to be accepted and actions have to be directed to adapt to structure. The

critical structuralist approach takes structures as man-made entities that can be altered by collective effort; i.e. they are “transformable”. These differences are explored further in the next section.

5.3. The neo-Realist/Critical Theory Divide

Theorists from different schools of thought have examined structures emanating from different power relationships with different, sometimes opposing results. One of the most prominent examples of this in International Political Economy is the theoretical divide between the neo-Realist work of Kenneth Waltz and the Critical Theory work of Robert Cox. This divide is explored further in this section with said theorists as the protagonists.

Realism, as the dominant school of thought in IR and IPE “came to be framed by a Westphalian legacy which placed sovereignty, the state and the anarchical interstate system at the core of the discipline” (Jabri, 2000:307). For Realists, change in anarchical systems is only possible “when it comes from the top, when it is in the interests of the major powers, and when it does not unbalance the systemic order based on the “self-help” principle” (George, 1994:117).

Traditionalist/Realist theorising for people like Descartes, Locke, Hume, Comte, Popper and Keohane takes the form of a “*cognitive reaction to reality*”. Seen thus, theory is not part of the construction of reality, but always follows reality so that it becomes a mere tool to place reality into different categories (George, 1994:132). In criticism of this approach, Susan Strange states that neo-Realism focuses on the status quo to the exclusion of hidden agendas. It gives no voice to the voiceless such as the underprivileged, the disenfranchised or the unborn about the functioning of the system, let alone changing it (George, 1994:134). This exclusionary principle is also mentioned by Cox, when he says that “(p)roblem-solving theories can be represented, in the broader perspective of critical theory, as serving particular national, sectional, or class interests, which are comfortable within the given order.” (Cox, 1981:446)

George explains the inevitable outcome of realist/neo-realist reasoning in his reaction to Gilpin’s *Political Economy of International Relations* (1987). Using a Traditional

rational-actor model, Gilpin reduces behaviour in the state system to a “symplistic utilitarian calculus”, the inevitable end-result of which is denotes anarchism which is overcome by the order created by institutional mechanisms (e.g. World Bank/IMF/WTO). A further inevitable implication is that states’ interests are best served when they support these institutional mechanisms and play by the rules laid down through the hegemonic leadership of the United States. This Gramscian view is evident in the word of Cox: “Neo-realism puts the accent on states reduced to their dimension of material force and similarly reduces the structure of world order to the balance of power as a configuration of material forces”. (Cox, 1981:453). This so-called “knowledge/power nexus” used by Gilpin, Waltz and other exponents of neo-Realism has a one-sided view of international affairs, namely that of large capitalist states, and seek a structural stability and political order maintaining the interests of these states in a conservative manner (George, 1994:128). Waltz sees instability and war as the results of changing power distribution across states in an anarchical international system (McLean, 1996:481) that is threatening and conflictual (Jabri, 2000:305). The neo-Realist view thus differs very little in this respect from its predecessor, orthodox Realism, i.e. that states should prepare for the inevitability of conflict and war.

Yet, Buzan (1995:212) warns that we should not regard Waltz as a “structural determinist”. Waltz recognised that “structural causes could never offer more than a partial explanation of international outcomes”, and that unit-level and system-level outcomes needed always to be considered simultaneously (Buzan, 1995:212). Despite Buzan’s cautionary remarks, Strange’s earlier comment still seems relevant. When Buzan refers to unit- and system-level outcomes the frame of reference is still that of states and state interest. The state-centered bias does not make provision for the specific treatment of the problems of the “underclass” or those aggregates of people excluded from political agendas by hegemons whose main aim is favourable trade balances and national security. Thus, the reaction to any challenge to the said stable order involves questions such as: “How will this influence trade?”, or, “Is it in the interest of the American economy?”, or, “Will we (America) still have the comparative advantage?”. The sentiments underlying these questions are reflected in the reaction of George to the work of Krasner when he states, “Exposed also at the core of neo-Realist structuralism, again, is a modernist ontology that is paradoxically

reductionist and reliant upon positivist premises concerning the anarchic structure that *just exists* (beyond explanation) “out there” (George, 1994:130). This brings the discussion to the reflectivist school of thought, and more precisely, to Critical Theory.

The Critical Theorists of the Frankfurt School tried to avoid the scientific orthodoxy of the time that led to reductionist theorising. This was an attempt to recapture the philosophical essence of Marxism in the evaluation of society and culture. They argued that social progress did not depend “on concrete social practice associated with critical reflection on dominant knowledge/power relations”. George (1994:151) explains further that positivism was used to transform a particular knowledge form, namely scientific empiricism, into a sociopolitical force with universal application, thus reducing critical reason to instrumentalist ends and relinquishing social power to the knowledge of the scientist or expert. In this instance the saying, ‘Knowledge is power’, becomes very real, where the positivist language of the natural science is applied uncritically to social life (George, 1994:151).

In their edited book, *The New International Political Economy*, Murphy and Tooze (1991:17) criticise the orthodoxy of IPE methodologies on three basic fronts, stating that its positivism and empiricism makes it restrictive; that its methodological individualism results in the locus of explanation being restricted either to “economic man” or the “state as individual”; and that orthodox IPE theory lies in totality within three opposing and mutually exclusive “ideologies” and their respective constructs. When the issue agenda of orthodox IPE is examined critically, it becomes evident that certain issues are privileged “within a universe that is constructed so as to exclude a number of other important questions and issues” (Murphy and Tooze, 1991:24). This privileging of issues is centered around the interests of the United States government to maintain its role as singular superpower in a post-Cold War globalised world where privileged trade and comparative advantage have taken the place of ideological rivalry as the number one foreign policy priority. In such a structural dispensation, even national security, the mainstay of traditional realism, is measured in terms of economic superiority and trade surpluses as opposed to recession and deficits. This results in the neglect of crucial issues such as technological change, population dynamics, and resource depletion on international

security forums and IPE analysis. Furthermore, questions of the exact nature of the ethical life, dependency, insecurity, powerlessness, and opportunities to change these, do not feature at all on the orthodox IPE list of concerns, probably because “it has few organic links to those who would raise them” (Murphy and Tooze, 1991:27).

It was Robert Cox who “confronted” neo-Realism with an emancipatory perspective during the 1980s. In turn, his approach was influenced by the work of Habermas, Gramsci and antistrukturalist Marxism (George, 1994:176). Cox drew attention to the way Morgenthau objectified Realism and supported American hegemony for its supposed role in maintaining order. Cox drew attention to some of the important philosophical principles ignored by neo-Realist orthodoxy. Firstly, Cox rejected the idea of an independent reality “out there” that could be grasped by means of empirical observation. Instead he maintains that “knowledge of reality is always intrinsically connected to social practice (forces) and to the ways human affairs are organised in particular times and places” (George, 1994:177). This historical view is explicitly stated when Cox says that “Critical theory is theory of history in the sense of being concerned not just with the past but with a continuing process of historical change” (Cox, 1981:446).

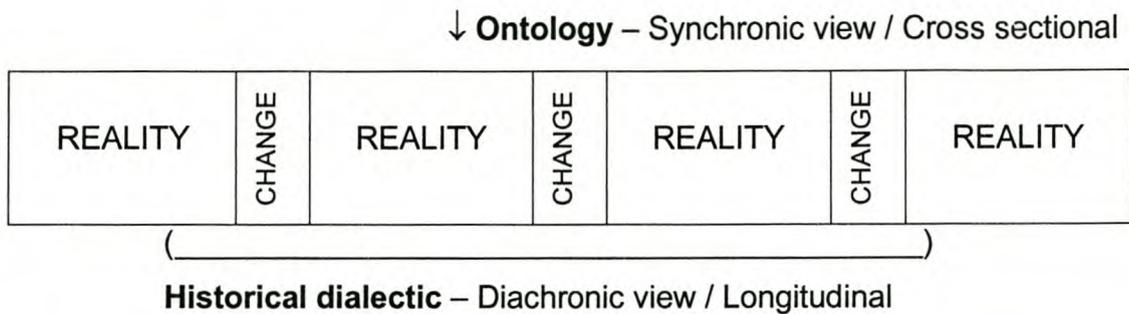
By focusing on social forces, Cox manages to reach beyond the conventional Marxist notion of social relations of production, thereby laying bare three dimensions of power: the power involved in the productive process; the power inherent in class relationship, or social power; and political power or state control (George, 1994:178). By moving away from a neo-Realist state centric approach and adopting a critical approach that views power as a multi-faceted phenomenon that shapes the lives of people in societies at different levels of a globalised world, it becomes possible to recognise the predicaments of the underclasses, the poor, the marginalised, the exploited, and the underdeveloped. It follows that these individuals and communities should want to change their circumstances. Critical theory makes it possible to look for avenues and possibilities of change.; of questioning status quo belief systems and orthodoxies; of questioning long-standing power relationships that have theorised itself beyond rapproach. Ultimately, Critical Theory makes it possible to emancipate and discover; to see reality and how it has changed; and finally, to discover where and how reality on its part can be changed.

Social scientists use theory to try and understand the reality around them – to get “a grip” on reality. In this sense theory is developed in reaction to events that have already occurred. This chronology may also be reversed when theory prompts behaviour to take place in a certain manner or alters the way certain actions are executed. Thus, theory may precede reality. This is why Cox maintains that theory is not an entity with its own inherent driving force separate from historical context. Rather, “(t)heory is the way the mind works to understand the reality it confronts” (Cox, 1995:31). This link means that theory “is always *for* someone and *for* some purpose”. Cox makes a distinction between theories employed to maintain existing social orders and theories used to change social realities. The first is labeled as ‘problem-solving theory’, which accepts the existing social order as a given except for certain problems that need to be corrected from time to time. The latter is labeled ‘critical theory’, which questions the origins of existing social order/s and seeks methods to change that order (Cox, 1995:31-32). In an earlier work, Cox states the same principle as follows: “Critical theory allows for a normative choice in favor a social and political order different from the prevailing order, but it limits the range of choice to alternative orders which are feasible transformations of the existing world”. (Cox, 1981:447). Cox is confident that Critical Theory is a viable alternative to the orthodoxy of neo-Realism when he posits that “(I)n this way critical theory can be a guide to strategic action for bringing about an alternative order, whereas problem-solving theory is a guide to tactical actions which, intended or unintended, sustain the existing order.” (Cox, 1981:447). A brief examination of the capabilities inherent to Critical Theory in effecting change, as opposed to the static approach of neo-Realism, follows.

As a means of inquiry, political economy is more critical than merely problem-solving. As Cox denotes:

Political economy by contrast (to political science and economics), is concerned with the historically constituted frameworks or structures within which political and economic activity takes place. It stands back from the apparent fixity of the present to ask how the existing structures came into being and how they may be changing, or how they may be induced to change. In this sense, political economy is critical theory.” (Cox, 1995:32)

To understand the nature of our existence (ontology) at a particular point in time, social scientists take a synchronic view of reality. But reality changes over time leading to structural change. To grasp the nature and extent of change over time, a diachronic/longitudinal or historical dialectical approach is necessary (Cox, 1995:34-5). This can be diagrammatically illustrated as follows:



Another author that has drawn attention to the uneven power relations in IPE is Stephen Gill (1995). He talks of “varied and complex efforts... by the forces of the political right and those of neoclassical economists and financial capital, to develop a politico-legal framework for the reconstruction of capital on a world scale, and thus for the intensification of market forms of discipline” (Gill, 1995:78). This is another way of illustrating in practical terms the results of perpetuating neo-realist orthodoxy in theory, i.e. those with power and wealth employ not only academics and scientists to maintain the status quo. Nor do they rely solely on ideology to direct others’ action to desired outcomes. Hegemons and self-appointed custodians of “economic sensibility” have been the architects of what Gill calls a “new constitutionalism”, designed to keep privileging the rich and to prevent intervention by poor countries, or any nonactor that tries to become a ‘player’ (Gill, 1995:78). Cox (1987:395) identifies such frameworks or structures at three levels of inquiry: social relations of production, forms of state, and structures of world order. A study of the Cartagena Protocol on Biosafety, as a norm-based international policy and action document, falls within the latter of these structures.

5.4. **Critical Theory and International Regimes**

The main reasons for relying on this theoretical point of departure are, firstly, to highlight the position of developing countries in the unfolding of international relations

as it impacts on science and technology and the politics of biotechnology; and secondly, to explore whether a regime such as the Cartagena Protocol together with the Convention on Biodiversity has the capacity to facilitate a change in this precarious position the farmers and communities of developing countries find themselves in. The hope is to balance some of the views expressed by developed countries where the focus is mostly on economic advantage, industrial growth, and technological competitiveness, often resulting in the exclusion from the international agenda of what is needed for developing countries to advance their people, infrastructure and economies. It needs to be said at this point that the concept 'developing countries' is a very arbitrary classification tool that does not make provision for the divergent nature of the societies, economies, culture and politics of those countries belonging to the so-called South. Even the classification of developed, developing, and least developed does not account for the unique situation of each nation-state, and even less so for specific communities and indigenous peoples that are so often the focus of development and social studies. Nevertheless, from a structuralist perspective a distinction needs to be made between the rich and the poor, the dependent and the self-sufficient, and the powerful and the powerless. In this thesis the relationship portrayed is that between developed countries (also called the rich North), and developing countries (called the poor South). The former is characterised by industrialisation, market economies and long-term prospects of stable economic growth, while the latter shows characteristics of lesser industrialisation and agrarian-based command economies that are often hostile to open markets with mostly bleak prospects of economic development and growth.

5.5. Methodology and Research Design

The purpose of the study is mainly to explore and describe, with only some explanation. Biotechnology is a rapidly developing field where changes take place in a revolutionary fashion. These developments need constantly to be explored just as do the effects thereof on mankind's ethical and social value responses to those developments. The international politics of biotechnology has a relatively short history with certain developments that need to be described in order to highlight the main issues of contention and the progression that has been made in establishing a set of rules or controlling regime. For a clear understanding of these dynamics, it is

necessary to describe certain relationships, and where possible, to explain why they have come about and how they could affect the future of biotechnology.

The unit of analysis is a transnational institution, namely the emerging regime that determines the rules, values and decision-making practices that govern the production, legitimisation and dissemination of technologies that involve the manipulation of living organisms, i.e. biotechnology. Transnational institutions, like states, are abstractions that become more tangible when viewed as a set of rules, as examples of human or social artifacts. Coupled to this, the contributions of certain states and corporations that influence the biotechnology debate will be analysed as examples of groups and organisations. The level of analysis is mainly macro, with elements of the meso- and micro-levels entering the study. International regime dynamic lies mainly on the macro level as it deals with the relationships between large aggregates or groups over a wide range of issues on a global level. Where individuals and organisations interact on the macro level and bring personal and state-views to the different debates, the meso-level is introduced. Where the focus is on the family or household level the micro-level becomes evident.

This is a qualitative study. Certain research guidelines are stated which are pursued by means of conceptualisation of key concepts and argumentation of pertinent questions, which are informed by theory. As many aspects surrounding the biotechnology debate have to do with people's values and certain ethical issues, there are no quantitative answers to be arrived at or empirical answers to be found. Rather, the normative aspects that underlie the different actors' approach to biotechnology provide the backdrop for the study. Furthermore, the thesis will be ideographic to the extent that it examines a very specific aspect of international relations and the dynamic that is peculiar to biotechnology. It is also a cross-sectional study because it examines a specific phenomenon at a given point in time and will not be repeated.

6. Limits to the Research

Apart from being of acute interest to the student, biotechnology in international relations is already affecting people's lives on various levels. Ethically and morally,

developments in biotechnology have opened up a Pandora's box. In terms of international trade, it has introduced a new dimension to comparative advantage. In terms of sustainable food production and supply, it is promising dramatic increases in agricultural production, which at the same time is disputed. To environmentalists and green lobbyists, it has brought new issues to add to the debate on better interaction with the environment. And to big industry who are intent on establishing and protecting intellectual property rights on their knowledge products, it has brought new challenges. There are more examples, but what is important is that biotechnology, whether seen as a benevolent or malevolent development, is not going to go away. Rather, it is going to change societies profoundly in the future in ways that have not been contemplated. What is needed is better understanding of what these changes will entail and how to manage them. A first step in that direction is not to overstate one's intentions and, at the same time, to set limits to what is to be accomplished.

This study will seek mainly to explore possible answers to the list of questions already stated. The section on biotechnology is thus limited to genetic governance and does not seek to elaborate on international relations in general. The following section deals with trade and agriculture, but does not attempt to address agriculture in its entirety. Similarly, the section on the Cartagena Protocol is limited to a review of the Convention on Biological Diversity, the contents of the Cartagena Protocol and the issue of safety as embodied in the precautionary principle. It is not intended to explore the significance of the protocol at other levels other than its role as a regulatory framework. The implications of the Cartagena Protocol for developing countries are limited to global public goods issues, biodiversity, and food security. The author recognises that this is a very limited selection when considering the dynamics and breadth of biotechnology issues. However, the reasoning is that these three issues are at the core of what biotechnology's significance to developing countries is and will be in the near future. Under the section on capacity building a *capita selecta* of challenges and constraints was necessary to keep the length of the document within prescribed limits. Here, again, it is recognised that there are many other challenges and constraints that might be of equal significance to developing countries.

This study highlights some of the pertinent problems facing developing countries when dealing with biotechnology. It does not endeavour to provide tentative answers to all of these challenges. Nor is it the intention to prescribe to policy-makers what their most suitable options are. Rather, the approach is one of stating alternatives and exploring the viability of certain orthodox attitudes. Furthermore, the study provides established typologies and explores certain new modes of classification. It does not presume to construct any models or theories. Rather, as the preceding section indicates, an existing theoretical framework (critical structuralism) is used to guide the inquiry. The study remains, therefore, largely exploratory and descriptive, with only certain aspects of biotechnology and its role in international political economy explained.

CHAPTER 2

BIOTECHNOLOGY AND INTERNATIONAL RELATIONS

"Contemporary world politics is a matter of wealth and poverty, life and death"
(Robert O. Keohane, 1988:289).

This chapter deals with the role biotechnology plays in the international and global arenas. It starts with an overview of the biotechnology industry to indicate the structural inequalities that have given rise to this oligopolistic regime. This is followed by a discussion of genetic governance, where, firstly, the focus is on regimes and international legal instruments, next, on international and supranational organisations, and, lastly, on non-state actors in general. The aim of this section is to indicate the role and position of different actors and to get an understanding of how they influence the governance of biotechnology. Looking at the structural features of the biotechnology regime follows this. Identifying the main points of international public opinion on biotechnology concludes the chapter, which indicate that it is highly divided and often unnecessarily emotional.

1. The Evolution of the Biotechnology Industry

The roots of science in genetics can be traced back to 1865 with the discovery by Mendel of the law of genetics. Mendel's work on the inheritance patterns of peas was published in that year, but it was only until 1900 that the significance thereof was better appreciated. The discovery in 1953 by James Watson and Francis Crick of the double helical structure of DNA was the starting point of a tremendous amount of research in the field of genetics. This also resulted in biotechnology being defined more narrowly, i.e. focusing on the manipulation of genes to the exclusion of fermentation techniques and animal breeding. Techniques for splicing genes and recombination have been used since the early 1970s. But the biotechnology industry's proper establishment and growth coincided with the growth of the U.S. biotechnology industry.

The U.S. biotechnology industry was founded in the early 1980s when reforms were made to the institutional environment for technological innovation (Daemmrich and Sagar, 2000:1). In 1980, the U.S. Supreme Court ruled that microorganisms could be patented. The protection of intellectual property rights created an incentive for private companies to invest substantial amounts of capital in the development of commercially attractive transgenic crops. This made it possible for the first time to protect, by means of patents, new types of plants and parts of plants such as seeds, tissue cultures, and genes (Paarlberg, 2000:25). By the early 1990s, a significant number of new companies had formed in the medicine, agriculture, human identification and other sectors and areas of technology. Between 1996 and 1998 U.S. sales of biotechnology products rose from \$9.2 billion to \$13.4 billion, while market capitalisation rose from \$83 billion to \$97 billion over the same period (Daemmrich and Sagar, 2000:1). A brief explanation of the nature of biotechnology *vis a vis* other sciences accounts for some of the reasons why this sector has shown such phenomenal growth.

Biotechnology is described by some not as 'Big' science (manipulation of very high energies), but as "high intensity" science, because it is concerned with the manipulation of information (Russell, 1990:10). Russell states that information and knowledge "form the heart of modern biotechnology". Biotechnology is characterised by transnational movements of information through a variety of formal and informal communication channels. The industry is also characterised by openness in the tradition of scientific exchange and publication, and at the same time by secrecy resulting from the sensitivity of certain types of basic research (military research included). Thus, the advent of globalisation, with its emphasis on the rapid dissemination for information, created an ideal breeding ground for a technology such as biotechnology to flourish. Government officials in the United States, Europe and Japan were soon convinced that aggressive development of a biotechnology sector would be integral to economic growth and industrial competitiveness (Sharp in Daemmrich and Sagar, 2000:1) indicates that. Thus, especially in the US, new relationships between academic scientists and the private sector were formed with funds readily available from venture capitalists, stock offerings and federal budgets.

The development of the biotechnology industry in Europe during the 1980s was somewhat different. Large chemical and pharmaceutical firms established in-house research laboratories and invested in North American start-up firms. Because of the concern that European countries and some multinational firms were falling behind the U.S. in competitive terms and economic progress, collaborative research agreements were entered into and purchases of U.S. biotechnology firms took place. What exacerbated the competitive position of nations in Europe, Africa and Latin America further was the combination of stricter environmental and safety regulations together with risk-averse investment practices. Because of what Henzler (in Daemmrich and Sagar, 2000:2) calls an “anti-business” culture in these regions, research personnel and investments were shifted to the United States, spawning the growth of its biotechnology industry even further.

By the mid-1990s the US had established a biotechnology industry with large, multinational “life science” firms. European chemical companies soon redefined themselves as life science firms. The result is that only a few global firms hold the intellectual property rights to DNA sequences useful in food and pharmaceutical research and production (Thomas in Daemmrich and Sagar, 2000:2). During this same period there was loosening of regulatory controls over research with genetically modified organisms that led to the establishment of a number of new biotechnology firms in Europe, Asia and to a lesser degree in Africa and Latin America. According to Daemmrich and Sagar (2000:2) the growth in the biotechnology industry in the mid-1990s is evidence that governments and the public in these regions recognised the value of this sector for national competitiveness. For nations to be able to compete, they need to be able to harness their innovative capacities.

Barriers to innovation were overcome by decreased regulatory oversight, changes in public opinion, and the harmonisation of investment policies. This trend, however, was short lived. Since the late 1990s to the present, environmental lobbyists and public interest groups have protested anew the efforts by especially the United States biotechnology companies to export their products. This has led to Europe taking a position of caution on the possible risks involved in the release of biotechnology products into the environment. On 25 June 1999, the European Union’s environment ministers adopted a decision imposing a de facto moratorium on the export of

biotechnology products to new markets – something which would bring them, together with various groups from the developing world, at loggerheads with the United States when it came to efforts to draw up a biosafety protocol. Two days earlier, the Japanese Ministry of Agriculture, Forestry and Fisheries (MAFF) indicated that it was to tighten safety regulations on genetically modified crops. In addition, on 23 June 1999, the Brazilian State of Rio Grande do Sul declared itself a genetically modified free zone.

The 1999 G-8 summit's call for an international inquiry into the safety of genetically modified (GM) foods indicates the importance of biotechnology in international politics (Brodnig, 1999 (a):1). Russell (1990:5) sites three reasons why biotechnology is of significance to international relations. In the first place, biotechnology has the capacity to be used as weapons of mass destruction. Here it is necessary to establish (or at least attempt to establish) which actors are undertaking military-oriented biotechnology research. This is problematic, since biotechnology research can be done in small laboratories on small scale. Furthermore, the development of biotechnology for purposes of warfare can closely resemble the development of this technology for benevolent purposes. Pirages (1990:106) uses the term "dual-use" when referring to the application of biotechnology for both peaceful and aggressive measures. The same laboratories, techniques, and equipment used for benevolent research can be used for the manufacturing of biological weapons.

Secondly, the practice of biotechnology has resulted in international agreements that need to be studied and scrutinised by international relations scholars. Specific attention needs to be paid to how comprehensive and adequate these agreements, protocols and treaties are in terms of the interests of different role players (the South versus the North), and changes that take place due to new developments in science and technology. Such international agreements also have significance for states that battle with food supply, especially those who have not managed to establish economic growth and sustainable development.

Thirdly, international relations scholars need to be aware of the implications of biotechnology warfare and of how such a war can be prevented. This should not be

restricted to traditional conceptualisations of warfare. Russell (1990:5) indicates the necessity to think of biological warfare not only in terms of its applications or threat of its use by state and non-state actors, but to be cognisant of political power that can be derived from the control of knowledge in the modern international political economy. The acquisition of structural political power from gaining control over knowledge products has shaped the biotechnology industry and determines which actors are in the best position to determine and uphold “the rules of the game”. This matter is dealt with in more detail in subsequent sections and chapters. Here, it is necessary to identify the influence of biotechnology on the international political system.

A broader view of biotechnology is evident in the three sets of circumstances identified by Caldwell (in Wiegele, 1991:13) that have influenced the way in which biotechnology has influenced the international system:

1. The first circumstance relates to the amount of willingness with which a nation accepts scientific innovation. It seems that nations with established scientific infrastructures are more accepting of biotechnology – European nations being the exception.
2. A second set of circumstances relates to how knowledge of biotechnology is communicated to policy decision-makers and the public at large. Information abundance may in one case cause feelings of lack of control, while in other cases it might cause a sense of empowerment.
3. The third set of circumstances relates to the level of control that a nation is able to exert over its use of biotechnology. Many developing countries lack scientific infrastructure, knowledge of testing and capacity of evaluation of risk, as well as means of establishing possible societal effects of the use of biotechnology. These countries might find it extremely difficult to develop the broad range of skills and educational infrastructure that is required by the nature of biotechnology (Wiegele, 1991:23). In contrast to those countries struggling to establish biotechnology industries, a handful of countries have managed to dominate this industry.

The United States leadership in scientific research extends to biotechnology in general and GM crops in particular. Other countries that have advanced their biotechnology research capacities and production of GM products include Argentina,

Canada, Australia, Mexico, certain EU countries, South Africa and China. Most developing countries have not made any significant advances in biotechnology research or development. Their focus has been more on the risks of this technology than the benefits (Brodnig, 1999 (a):3). From the above the oligopolistic nature of the biotechnology industry is evident when the dominant position of the US and Europe is considered. It is also interesting to note that despite the rise in regionalism and the use of supranational structures for the governance of global affairs, in the case of biotechnology, the state seems to remain the primary unit of regulation. The structural imbalance in states' biotechnology capacity is reflected in the way that this sector is being governed.

2. Genetic governance

Biotechnology research is very difficult to monitor and verify and the production of toxins and other biological agents using new techniques can be carried out in complete secrecy in a small laboratory (Russell, 1990:8). This has prompted authorities, some of who also have an economic incentive, to attempt the regulation of the products of genetic manipulation. Like other knowledge-intensive areas of international relations, the affairs of biotechnology are represented by governmental officials, which still dominate international forums. Yet, the governance of genetic material has been greatly influenced by a variety of actors and mechanisms not necessarily directly representing nation-states, although it needs to be acknowledged that the influence of states and their representatives in these mechanisms cannot be discounted. These actors and mechanisms are discussed briefly.

2.1. Regimes and International Legal Instruments

The concept 'regime', has been defined in various, and often overlapping manners: "networks of rules, norms, and procedures that regularize behavior and control effects" (Keohane and Nye in Lang, 1990:38); "...principles, norms, rules, and decision-making procedures around which actor expectations converge in a given issue area³" (Krasner in Russell, 1990:110); "sets of implicit or explicit principles, norms, rules and decision-making procedures around which actors' expectations

³ Issue areas here, include trade regimes, monetary regimes, oceans, and nuclear energy (Russell, 1990:110).

converge in a given area of international relations” (Hurrell and Kingsbury, in Brodnig, 1999 (a):2); and “the norms, rules, and decision-making procedures that states (and sometimes other powerful actors) have created to govern international life within specific realms” (Murphy, 2000:793). The benefit of analysing regimes is found in the exposition of the origin of the principles and norms of the issue area that are highlighted. This enables the researcher to better understand and scrutinise the rules and decision-making procedure as the mechanisms by which the regime maintains or manages order (Russell, 1990:110).

Prior to the Cartagena Protocol on Biosafety, a number of international legal instruments existed to regulate, implicitly or explicitly, the governance of biotechnology at different levels. These instruments and what they were designed to govern are discussed briefly, mainly from the work of Wiegele (1991, Chapter 3).

2.1.1. The Trail-Smelter Decision: During the early 1920s, the Canadian Consolidated Mining and Smelting Company Limited operated a zinc and lead smelter along the Columbia River at Trail in British Columbia, approximately 16 kilometres north of the international boundary with the State of Washington. During the period 1925-1935, the US Government objected to the Canadian Government that sulfur dioxide emissions from the mine was damaging land and trees in the Columbia River valley, causing harm to logging, farming and cattle grazing industries. After seeking legal arbitration twice, it was ruled in both instances that Canada pay damages to the State of Washington and that the mine adjust its operation to a set of guidelines to prevent damage for a year and a half (TED, 2000). Writers in international law accept the Trail-Smelter case as establishing the principle of national responsibility for transboundary environmental damage – a principle upheld by international legal cases involving nuclear tests and river pollution (Wiegele, 1991:50). It is further indicated how this case resulted in an actual regime being established for the monitoring of sulphur dioxide emissions as well as for the principle that international legal bodies may initiate transboundary regimes to regulate the effects of environmental damage (Wiegele, 1991:51).

2.1.2. The Corfu Channel case: On 22 October 1946, two British Navy destroyers struck sea mines in Albanian waters in the Corfu Channel that had been swept

recently and considered safe. The British Navy lost 45 lives and 42 men were injured in the incident. The United Kingdom presented a case to the United Nations Security Council, which made a resolution on 9 April 1947 recommending that both governments take the dispute to the International Court of Justice (ICJ). The ICJ ruled on 25 March 1948 that Albania was responsible for both the explosions because it had had the responsibility to inform all ships of the minefield; that the United Kingdom did not violate Albanian sovereignty by its presence in the Corfu Channel; and that Albania was responsible to pay compensation. This case illustrates that nations are responsible for actions within their jurisdictions (specifically in their territorial waters) that might cause harm to other states and persons. This case is applied in instances where there is a question pertaining to national responsibility for damages resulting from the unauthorised release of genetically manipulated organisms (Wiegele, 1991:52-3).

2.1.3. Biological weapons: Several legal instruments have been created to govern and contain the production of biological weapons, e.g. the 1925 Geneva Protocol, signed by 118 nations (a “no first use” pledge of biological weapons”. The central legal instrument for the governance of biological warfare is the Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on their Destruction, which was signed in 1972 (Wiegele, 1991:54). Other instruments that were created as efforts to control chemical and biological weapons include the Chemical Weapons Convention, the Biological and Toxin Weapons Convention, the Trilateral Agreement on Biological Weapons (Russia, United Kingdom, and United States), the Australia Group, the Bilateral Memorandum of Understanding (US-USSR), the Bilateral Destruction Agreement (US-USSR), the Mendoza Accord (Latin America), and the India-Pakistan Agreement on Chemical Weapons (Stimson Centre, 2000:1).

2.1.4. International commerce: From the perspective of firms, the issue of intellectual property rights is of primary importance. These rights include trade secrets and patents and related enforcement and protection. The international legal regime that exists to manage the patent process includes the Paris Convention, the International Union for the Protection of New Varieties of Plants, the Patent Cooperation Treaty, the European Patent Convention, the Budapest Treaty on the International

Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, and the World Intellectual Property Organisation (Wiegele, 1991:56). A number of international agencies have attempted to stimulate biotechnology activities in less-developed countries (LDC). They include the World Health Organisation, the United Nations Industrial Development Organisation, the Food and Agricultural Organisation, the United Nations Education, Scientific, and Cultural Organisation, and the International Council of Scientific Unions. The international legal community has focused its attention especially on two aspects in this regard. Firstly, the dwindling resource of native plant germ plasm, most of which is found in LDCs, and secondly, the export of field tests for genetically engineered organisms from one nation to another. Both of these issues involve relationships between developed and developing nations (Wiegele, 1991:57).

2.1.5. Harmonisation: The first trend towards harmonisation emanated from the spring of 1988 at the First International Conference on the Release of Genetically Engineered Microorganisms held in Cardiff, Wales (Wiegele, 1991:61).

2.1.6. International environmental regulation: Supranational legal instruments that can be used to protect the environment include the UN Conference on the Human Environment (Stockholm, 1972); the multilateral Long-Range Transboundary Air Pollution Convention (which entered force 1983); the Nuclear Test Ban Treaty of 1963; the Convention on the Prohibition of Military and Other Hostile Use of Environmental Modification Techniques (Wiegele, 1991:62-3).

2.1.7. Biotechnology and the sea: The 1957 *Lake Lanoux Arbitration* stipulates regulations for the governance of biotechnology emanating from marine resources (Wiegele, 1991:64).

A number of other regimes regulating the release into the environment of toxic substances include the following: the Convention on Long Range Transboundary Air Pollution (1979) and its additional protocols related to sulphur emissions (1985) and to nitrogenoxide emissions (1988); the Vienna Convention on the protection of the Ozone Layer (1985), the Montreal Protocol on Substances that Deplete the Ozone Layer (1987); and the Basil Convention on the Control of Transboundary Movements

of Hazardous Wastes and Their Disposal (1989) (Lang, 1990:42). These protocols were put in place during the 1970s and 1980s when it became clear that certain developments in technology had adverse effects on the environment that could affect not only national populations, but also the whole of human existence.

From the preceding discussion it is evident that the multitude of conventions, cases and protocols can be considered an emerging regime on the transboundary movement of the products of technology, specifically biotechnology. Such a *regime* becomes more recognisable when it is understood as “a set of basic understandings, rules and expectations shared by actors involved, and covering a specific area of policy” (Nel & McGowan, 1999:328). The different rules discussed point to the shared norms by state and non-state actors of conserving the environment, protecting individual and group rights, and safeguarding commercial, national, and other interests. This dimension of emerging regimes has inspired certain supranational institutions to become involved with the governance of biotechnology and its products.

2.2. International and Supranational Organisations

International organisations that have been involved in the governance of biotechnology since its appearance in the international arena include the World Health Organisation, the International Council of Scientific Unions, the United Nations Education, Scientific and Cultural Organisation, the Food and Agricultural Organisation, the United Nations Industrial Development Organisation, and the United Nations Development Programme (Wiegele, 1991:17). Most of these organisations are UN subsidiaries, which might account for the weakened position of developing countries *vis a vis* their biotechnology capacities at the advent of the 21st century when viewed from a structuralist perspective. One of the problems with international institutions is that they have a legacy of being weak structures in terms of enforcing their provisions (Pirages, 1990:108). Where biotechnology is concerned, this could become a serious problem for developing countries that are trying to maintain sovereignty over their domestic biodiversity resources.

During the 1990s, a number of supranational institutions were established to regulate international ‘environmental interests’ as well as the transboundary flows of natural

resources such as genetic information and knowledge about nature. These structures of governance, which McAfee (1999:133) calls “eco-economic governance” include environmental treaties, such as the Framework Convention on Climate Change (FCCC), the Convention on Biological Diversity (CBD), and the Global Environment Facility (GEF). There is close collaboration between these regimes and the World Bank, United Nations agencies concerned with green environmental issues, and mainstream conservationist organisations (McAfee, 1999:133).

2.3. Other Non-state Actors

This group of non-state actors influencing the governance of biotechnology is comprised of Multinational Corporations (MNCs), Non-governmental Organisations (NGOs) and interest groups, and certain individuals such as scientists and academics, which have brought new issues to the biotechnology debate.

The consolidation of the agrobiotechnology industry has meant that a number of powerful multinational enterprises with significant influence share this arena with a small group of issue-oriented NGOs such as Rural Advancement Fund International (RAFI), Genetic Resources Action Network (GRAIN), WWF (World Wide Fund for Nature), IUCN (World Conservation Union), Indigenous Peoples' Biodiversity Network, International Alliance of Indigenous Tribal Peoples of the Tropical Forests, and Cultural Survival, and Third World Network (TWN).

Rights-oriented interest groups include the Kari-Oca Declaration and the Indigenous Peoples' Earth Charter (1992, Kari-Oca); Recommendation from the Voices of the Earth Conference (1993, Amsterdam); the Charter of the Indigenous-Tribal Peoples of the Tropical Forests (1992, Penang); and the Julyinbul Statement of principles and Declaration Reaffirming the Self Determination and Intellectual Property Rights of Indigenous Nations and Peoples of the West tropics Rainforest Area (1993, Jingarrba) (Sutherland, 1998: 296); as well as advocacy organisations such as Greenpeace (Brodnig, 1999 (a):2).

The large number of scientists involved in pure and applied biotechnology research contributes significantly to the biotechnology agenda. These different actors convene at various international forums that range from United Nations agencies and international conventions to regional economic organisations and other political forums such as the G-8.

The governance of biotechnology has created a number of new issues to confront diplomats, policy-makers and representatives of the governing bodies and interest groups mentioned. Brodnig (1999 (a):3) indicates that the more globalisation and new technologies lead to an internationalisation of formerly domestic issues, the more decision-making structures will be assessed against broader notions of legitimacy and democratic rule. This should present unique challenges to especially those countries that have experienced little economic liberalisation and democratic governance.

The amount and variety of actors involved in the governance of biotechnology means that a multitude of interests and values need to be balanced. This has resulted in conflict between the global trade system and environmental safeguards. Efforts during 1999 to adopt a Biosafety Protocol failed because of these conflicts. Brodnig (1999 (a):2) indicates that the development and adoption of an effective global regime for transgenic crops has also been hampered by disagreements and even controversy in the scientific community as to the health and ecological impacts of genetically modified organisms. Juma (1999:4) points out that the issue of the governance of biotechnology is mostly the underlying theme in these conflicts over control, equity, and choice. He proposes that the following set of activities can be used to deal with these technical and governance issues: promoting consultative processes; undertaking scientific and technical assessments; conducting research and training; reforming national policies and institutions; harmonising standards and sharing experiences; and facilitating technological cooperation (Juma, 1999:4-5). This will not only require a significant reorientation of "current patterns of technological development", but also a serious appraisal of the nature and direction of the processes and patterns of biotechnology governance. In this regard, biotechnology and the trade resulting from the exchange of products of this technology have given rise to very specific international structural relationships.

3. **Structural Features of the Emerging Biotechnology Regime**

For an understanding of the structural relations in biotechnology, an appreciation of the structure of international affairs and the changes in technology in general is necessary. Strange (1995:62) highlights certain fundamental structural changes that have shaped the international relations of the late twentieth century. Among these are the liberation of Central Europe, the demise of the Soviet Union, U.S. payment deficits juxtaposed against Japanese surpluses, the rapid rise of the so-called Asian tigers or newly industrialised countries, democratisation in a number of former authoritarian developing countries, and a move from protectionism and import substitution to a more borderless economy that favours exports. In the time since Strange wrote this chapter, it could be argued that some of these trends have shifted or even shown a complete turnaround in certain case specific instances. But where the influence of technology is concerned, the wisdom of Strange should be heeded.

Strange (1995:62) argues that the most articulated of the structural changes can be seen in the way that technology (of industrial and agricultural production) has acted as a “driving force” on the behaviour of governments and firms. Technology has enabled producers to increase their production to supply markets with new and innovative products. This was and is made possible through more advanced processes of research, design and manufacturing. It has inevitably increased quite dramatically the investment and cost involved in the research and development of new technologies – something which is especially true of the biotechnology sector which is characterised by actors possessing vastly different resources and capacities.

Many of the problems that underlie technology transfer can be addressed within the globalist image of North-South relations (Russell, 1990:16). This approach cautions against the possibility of exploitation and economic imperialism. He says that biotechnology is a “prime candidate” to strengthen the North’s already dominant position of political and economic influence in the developing world. When looking at biotechnology in its international political context it is evident that resources are very unevenly distributed among different nations (Wiegele, 1991:12). The talks at the UNCED Rio Summit were aimed at the question of North-South inequality and what was needed for social justice in a system where the so-called South had been left

behind. Purdue (1995:101) calls this a "liberal, technicist tendency (that) allows environmental problems to be defined as a lack of technology rather than a surfeit thereof". In the same way, development is defined as the South trying to catch up with the North, rather than as a social justice issue of the distribution of finite resources. This portrays the South as an "area of deficit of liberal capitalism" instead of seeing it as a group of separate countries with different cultures and interests to those of the North (Purdue, 1995:101). Pirages (1990:107) argues that it could be technology, rather than capitalism, that is creating and perpetuating inequalities in today's societies. Biotechnology, in particular, is promoting deeper interdependence and creating inequalities that would not have existed otherwise.

Purdue (1995:101-102) illustrates how the US biotechnology companies pressurised their politicians into ensuring that Southern states buy into the idea of equitable technology transfer as an effort to maintain 'sovereign rights'. Initially the biotechnology industry in the US convinced the Bush administration to subordinate the Biodiversity Convention to the rules of GATT. After Bush's refusal to sign the treaty, *Article 16* was inserted, stating that "(i)n the case of technology subject to patents and other intellectual property rights, such access and transfer shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights". This effectively meant that the TRIPs and bilateral arrangements would govern the Biodiversity treaty. The hegemonic status of biotechnology is thus derived from the linkage of biodiversity and environmentalism with established cultural patterns, such as free trade and new scientific languages (Purdue, 1995:102). Instead of encouraging technology transfer, TRIPs enables industrialised countries, and the biotechnology industry in particular, the ability to "collect the rent" on their technological dominance. These factors of inequality in biotechnology together with factors such as environmental safety and human health where biotechnology is harnessed have created a new dimension in international public opinion.

4. International Public Opinion and Biotechnology

Since its infancy, biotechnology has promised to transform economic systems and the way humans think about health and nutrition. The fact that biotechnology

involves the altering of the genetic material of living organisms has inspired some people to believing that it holds the answer to many health and nutrition problems facing mankind, while others are fearing that the use of biotechnology holds potential risk if introduced into the environment. Between these extremes are parties that aim to maximise the benefits of the technology while minimising the risk (Juma, 1999:2).

The use of biotechnology in the manufacturing of pharmaceuticals and in agriculture is directly linked with concerns of human health (Daemmrich, 1999:1). When biotechnology was first introduced to the wider arena of science and research, there were many hopes of it enabling scientists to develop drugs with less side effects and food products that would greatly increase production. This largely benevolent view of biotechnology has subsequently been replaced by a great measure of caution exercised by certain individuals, states, interest groups and consumers as to the health and environmental risks that could emanate from the release of GMOs into the environment.

The ethics and moral use of biotechnology have been placed in the forefront of public debate and opinion with the cloning of the sheep "Dolly", in Great Britain. This is despite the fact that biotechnology had been in the public mind at a lesser level of consciousness since the mid-1970s. Recently, public attention has also shifted to food purity and safety and the issue of labeling genetically modified food substances (Daemmrich and Brodnig, 1999:1). There is, however, vehement disagreement amongst scientists, policymakers, consumers and the public as to which specific social issues and ethic agendas should be investigated and exactly which values should predominate. Policy-making on biotechnology issues is no longer the exclusive domain of government officials and diplomats. International interest groups in biotechnology have tended to highlight a set of traditional issues such as environmental affairs, safety in the workplace, legal proscriptions, the poor, economics, agriculture, the military, and animal rights (Wiegele, 1991: 38). In addition, the voices of industry, NGOs, academics and consumers have all contributed to biotechnology issue debates, say Daemmrich and Brodnig (1999:2), who explain why this debate has broadened so much.

The broadening of the biotechnology debate can be attributed to suspicions that technological change was driving public policy, causing ethical and social assessments to become post-hoc activities. The major shift in this regard occurred first in Europe and later in the developing world during the 1980s and 1990s. The United States and Europe followed different policies where the release of GMOs into the environment, public acceptance of GMOs, and patent protection for biological inventions were concerned. Negative public reaction to the use of GM agricultural products has led to the requirement by countries in Europe and recently Japan, that some or all biotechnology-based products be clearly marked with labels to indicate this status. This is in keeping with the precautionary principle (see Chapter 4), which holds that until there is certainty about the safety of GM products for human use and environmental release, precautions should be taken and the public informed (Juma and Gupta, 1999:1).

The differences in public opinion mentioned are indicative of different societal perceptions of the role of individuals, tolerance for risk, and approaches to the construction of value systems. In the light of these differences, it is important not to view contrasts in policies merely in terms of economic interests. It is precisely ethical and social values that often “determine the boundaries of disputes, mechanisms of resolving conflict, and shape the very discourse, the style and contents of interactions about biotechnology around the globe” (Daemmrich and Brodnig, 1999:2). This is why room should be made for national divergence, even if for some it is a priority to strive towards international harmonisation of rules, procedures and practices. Wiegele (1991: 40-41) is of the opinion that neither the public nor political decision-makers are adequately informed regarding biotechnology issues. He arrives at this conclusion after scrutinising a public opinion survey done by the U.S. Office of Technology Assessment in 1986. If Wiegele is correct, a reason for the ignorance could be that developments in the areas of the trade and especially the agriculture of biotechnology have been neglected. This is where the discussion moves to in the next chapter.

CHAPTER 3

BIOTECHNOLOGY AND INTERNATIONAL TRADE AND AGRICULTURE

"Knowledge, in the form of technology and market information, is the principle resource in the world economy, especially knowledge in its dynamic form as the capacity to generate new technologies and to market new products" (Robert W. Cox, 1987:244).

The previous chapter indicated that significant power relations could result from the planned governance of biotechnology and its related resources. This chapter deals with the effects that such relationships have on international trade and agriculture. A structuralist viewpoint is proposed to ensure that the politico-economic position of developing countries of the South are balanced against the often-hegemonic position of the developed nations of the North. The premise of this viewpoint is that a structural imbalance results from the inability of developing countries to compete on international markets. This weakness is a result more of the insensitive actions of developed countries towards poorer countries than from the incapacity of the latter. Trade rules and restrictions are designed to favour the rich and to marginalise the poor. In an economic system that was designed to be 'liberal', rich northern countries use methods of protection and bilateral leverage to safeguard their own economies while struggling countries from the south are not able to escape so-called economic backwardness and economic stagnation/stagflation. This is also true for the biotechnology sector, especially when agricultural biotechnology, or agrobiotechnology, is examined.

Compared with other technology sectors, perhaps with the exclusion of computer and communication technology, advances in agricultural technology during the past two decades have been dramatic. Agricultural production has changed from being decentralised and labour intensive to being characterised by industrial mass production where the use of electricity, mechanisation, chemicals, and management sciences have become integrated⁴ (Krimsky and Wrubel, 1996:3). Where it was once a mode of life, agriculture has become an international mode of production,

⁴ This 'modern' picture of agriculture is relevant to developed nations with a broad base of industrialisation. Some developing countries and most LDCs (least developed countries) still rely on labour intensive agricultural sectors that are characterised by subsistence farming.

shifting from being the hallmark of local and regional economies to being a fully integrated sector of the global economy (Krimsky and Wrubel, 1996:213). According to Goodman, Sorj, and Wilkinson (in Krimsky and Wrubel, 1996:19), the transformation of agriculture can be conceptualised as processes of *appropriationism* and *substitutionism*. This means that agriculture is changing from a rural based sector to one that is urban or industrial based. This paradigm has the inherent quality of promoting agricultural innovation before consideration of factors such as economic efficiency, markets and safety. Yet, developments in agricultural technology have not received much public attention until recently. A possible explanation for this is the lack of debate in the public arena on technological innovations coupled with industrial societies' trust of technological change (Krimsky and Wrubel, 1996:2).

Siting the work of Fliegel and van Es, Krimsky and Wrubel (1996:18) indicate that a distinction needs to be made between agricultural improvements and agricultural innovations. The former refers to changes or enhancements to existing technologies, while the latter refers to departures from existing technology. The innovative nature of most of the biotechnology advances of the past two decades have been responsible for changes, not only in agriculture, but also in the way that the products of biotechnology are introduced and traded on international markets.

The introduction of GM foods in the world market has been accompanied by efforts to facilitate trade liberalisation (Brodnig, 1999 (b):1). Apart from the moral and ethical row that GM foods have sparked because of its potential impact on human health and environmental safety, the international trade framework of biotechnology products has come under severe scrutiny. It is here where the World Trade Organisation's role in promoting globalisation and free trade is being assessed against principles such as environmental conservation and risks in the trade and transportation of GM foods. These would have been non-issues, were it not that biotechnology experienced such rapid commercialisation over a relatively short period of time.

1. The Commercialisation of Biotechnology

The US's efforts to promote the early commercialisation of biotechnology products has meant that these products, especially genetically-modified (GM) foods, have entered international trade at a rapid rate. The global area of GM crop production (mainly soybean, maize, canola, corn, cotton and rapeseed) has shown an estimated growth from 1.7 million hectares in 1996 to 39.9 million hectares in 1999. This includes an increase of 44 per cent growth between 1998 and 1999 alone. Developing countries held 15 per cent of the area planted with transgenic varieties. The sales volume of GM crops has increased approximately 30-fold in the period 1995 to 1999, and the global market for GM crops is projected to reach \$8 billion in 2005, and \$25 billion in 2010 (Falkner, 2000:301; Persley and Doyle, 1999:1). In 1999, Brodnig (1999 (b):2) stated that around 80 biotechnology-based products were on the market or were awaiting commercialisation. The market value of these drugs was estimated at \$12 billion and is projected to rise to \$25 billion in 2005.

GM agricultural products have also increased substantially. Brodnig (1999 (b):2) indicates that the reported global coverage of transgenic crops had risen from 11.0 million hectares in 1997 to 27.8 million hectares in 1998. These crops originated from nine countries, of which the United States accounted for 74% of the coverage, with the rest distributed over Argentina (15%), Canada, (10%), Australia, Mexico, Spain France, South Africa and China (1%). These crops were mostly limited to soybean (52%), corn (30%), cotton (9%) and canola (9%) (James in Brodnig, 1999 (b):2). According to Paarlberg (2000:26), the figures for international transgenic crops had changed to the following by 1999: United States 72%, Argentina 17%, Canada 10%, and the remaining one percent divided among Australia, China, France, Mexico, Portugal, Romania, South Africa, and Spain. Paarlberg (2000:26-27) sites as reason for the absence of Western European farmers from these figures the consumer scare for GM foods that followed the "mad cow disease" in 1996. Although this disease was in no way related to genetic food manipulation, it coincided with the first attempts to import U.S. grown GM soybeans into the European Union.

However, commercialisation of biotechnology is not such a smooth process in all countries. Environmental lobbyists, concerned consumers, the mass media and

other social and pressure groups in Europe have forced their governments to review their regulatory systems (Brodnig, 1999 (b):2). These groups' concerns are causing them to conflict with the international trading and intellectual property rules that are being promoted through organisations such as the WTO and the World Intellectual Property Organisation (WIPO).

The "global environmental discourse" with which international environmental institutions occupy themselves has been dominated by what McAfee (1999:133) calls "a post-neoliberal version of environmental economics" applied globally. In its simplest form this means that post-neoliberals have a market solution for all economic problems. As far as the environment is concerned, every aspect of nature can be privatised and commodified – from molecules to mountains, from human tissue to the earth's atmosphere. This "global environmental-economic paradigm" reduces all living entities to their constitutive components to which a monetary value is assigned, calculated with reference to actual or hypothetical markets. By thus measuring the worth of living things a framework⁵ for the implementation of the triple mandate of the CBD is established. McAfee (1999:134) says this approach to the pricing of life "offers to nature the opportunity to earn its own right to survive in a world market economy". "By promoting commodisation as the key both to conservation and to the 'equitable sharing' of the benefits of nature, the global environmental-economic paradigm enlists environmentalism in the service of the worldwide expansion of capitalism" (134).

2. **Biotechnology and the global trading system**

Sutherland (1998:293), examining liberal cultural politics, points out that the General Agreement on Tariffs and Trade (GATT) was intended to promote international economic cooperation and prevent the "continuation of economic mercantilism" which was a problem in the *interbellum* period. While the GATT might not have resembled mercantilist values, it seems to have reinforced neo-realist values when one considers that negotiations were dominated by corporate interests of the G7 countries. A considerable amount of negotiations were centered around reinforcement of property rights and entry and exit options of transnational

corporations. Negotiations on agricultural matters were skillfully directed to protect the interests of large agricultural corporations in G7 countries (Gill, 1995:71). The GATT has subsequently been reformed to the World Trade Organisation (WTO), which has as its main function the liberalisation of international trade through the removal of protective measures and tariffs. Thus, the WTO represents liberal cultural values that favour open markets and the recognition of private property ownership and rights. The G77 opposed the inclusion of intellectual property rights (IPRs) into the GATT, but failed because of a lack of expertise and agenda setting. Multinational corporations involved in biopharmaceutical and agrobiotechnology were keen on a GATT that would guard against international trade in goods that were protected by IPRs. This was accompanied by efforts to allow patents for all biotechnology inventions, including microorganisms, parts of microorganisms, and plants. Corporate and government stakeholders also had a “cultural preference for rigorous and effective dispute resolution processes”, which were effectively met (Sutherland, 1998:294).

Krimsky and Wrubel (1996:28) rightly point out that “(i)nnovation is not a pure scientific ideal. It has its own political economy”. Citing Kloppenburg, McAfee (1999:144, footnote 12) indicates that international access to and exchange of biological resources had, until the 1980s, been governed by the implicit principle now referred to as ‘common heritage’, under which all interest groups treated genetic resources as “open-access resources, free for the taking”. Pressure from the states of the South, who are rich in biodiversity, led to the UN Food and Agricultural Organisation’s adoption of the International Undertaking on Plant and Genetic Resources, which established a ‘common heritage’ principle for all plant genetic resources. The implication for farmers and other users of plant material was that patents or other property claims on such material could not prevent them from still producing or selling hybrid or genetically modified varieties.

However, this interpretation has been vehemently opposed by developed countries and their multinational seed and agro-chemical companies. Under pressure from these companies, the governments of especially the USA, the United Kingdom, and

⁵ This framework includes: (1) The conservation of biological diversity, (2) the sustainable use of biological diversity, (3) the ‘equitable’ sharing of the benefits of genetic resources (McAfee, 1999:134).

Japan, insisted that any provision of new technology to developing countries would have to comply with “adequate and effective protection of intellectual property rights”, including patents (McAfee, 1999, citing CBD, 1994, Article 16). McAfee indicates how these same countries succeeded, through Article 15, to also exclude from the jurisdiction of the CBD the collections of germ plasm removed from source countries before the entry into effect of the CBD on 28 December 1993.

This is yet another indication that the emerging international ‘genetic resources’ market has been designed by developed countries to serve the short-term interests of pharmaceutical and agro-chemical corporations, based on their estimates of the potential profits to be made from them (McAfee, 1999:146-7). This resembles Russell’s (in Krinsky and Wrubel, 1996:21) contention that biotechnology businesses are “unorthodox” because they were not created to fulfill an existing need in society or in world markets. Brandon and Klevorick (in Purdue, 1995:94) have scrutinised the way global welfare arguments are projected and have found that global interests seem to concur with US interests. They indicate that the US always portrays itself as the fair player while those in opposition find themselves foul of the rules. This is used as legitimisation for using political power to reach economic objectives.

In this regard Krinsky and Wrubel (1996:107) talk of “bio-imperialism”, which is a term used to describe how biotechnology results in the economic subordination of farmers in the developing world. The fear is that traditional farmers and commodities in the South will be replaced by genetically engineered substitutes (Seabrook in Krinsky and Wrubel, 1996:107). Examples of this include artificial sweeteners that threaten sugar produced from cane plants, artificial vanilla that can cause the seventy thousand vanilla farmers in Madagascar to lose their income, and genetically enhanced oil palms and cocoa butter that threaten the livelihood of large numbers of small farmers in Africa and Latin America.

There are, however, certain analysts who contend that biotechnology could be beneficial to developing countries. Persley, Brenner and Walgate (all in Krinsky and Wrubel, 1996:108) have indicated how biotechnology, in the form of GM grains, could aid developing countries with their food supplies. What these authors did not anticipate, was that biotechnology companies’ use of intellectual property rights to

protect their products would make GM seeds expensive. Add to that the introduction of properties to seed that makes re-use impossible and the benefits to developing countries of biotechnology in agriculture become negligible.

The US has established a technological advantage in the area of biotechnology, and it is doing everything in its power to ensure that the rules of this game are of their making. The United States has an Intellectual Property Coalition, which consists of 13 companies such as Pfizer, Monsanto and Du Pont, who advise the US Administration on biotechnology and other matters pertaining to the production and marketing of their products. In the EU companies such as Unilever, Hoechst and Ciba Geigy play a similar role. These 'agro-chemical giants' are using their influence in political arenas to enforce patents for pharmaceuticals and biotechnology innovations. Laclau (in Purdue, 1995:89) says that no hegemonic project is ever completely successful; that hegemony "is contingent upon struggles and is therefore always socially constructed, never given and is always susceptible to subversion". The hegemon always tries to restrict alternatives to other players/actors. One of the most prominent tools in the hands of developed hegemons to restrict other actors is that of intellectual property.

3. Intellectual property rights and biotechnology

According to Krinsky and Wrubel (1996:240) there is a link between the "unique tools" of biotechnology (gene sequencing) and the legal support for the privatisation of genetic resources. This link results from patent protection being regarded as a necessity for transnational companies' commercial success together with a few crop varieties that are likely to dominate the seed market as a result of the protection of intellectual property. Before biodiversity can benefit any user it has to be commodified and traded, it has to be privatised or ownership has to be clarified. Intellectual property rights to genetic information is the 'conceptual cornerstone' of proposals for the allocation of biodiversity benefits under the Convention on Biological Diversity (CBD), which was adopted by ninety-eight countries during the United Nations Conference on Environment and Development, held in Brazil in 1992. The United States was not one of these signatories, the Bush administration opposing the convention because it was argued that it would undermine U.S. patent

protection for its biotechnology industry. The controversy over intellectual property rights resulted in the development of a schism between biotechnology and biodiversity (Krimsky and Wrubel, 1996:223-4). The assumption inherent to the Convention is that the technology that is developed by and for developing countries from the genetic resources in developing countries is the technology that the developing countries need (McAfee, 1999:144).

3.1. The How and What of Protecting Commodities

Purdue (1995: 90) proposes that biotechnology is part of a scientific social movement by biotechnology companies who are trying to persuade the world that their ownership of life forms is in the public interest. Referring to Haas, Purdue (1995:90) states that the epistemic community no longer defines the term 'biotechnology'. Because of the dynamics of globalisation, hegemonic projects are no longer easily attributed to state actions such as can be done with class or social movements within national politics. The same dynamic influences the changes in social and biological sciences. This means that when biotechnology companies attempt to establish universal intellectual ownership of genetic material, they have to do it on various fronts. These include scientific social movements, transnational corporations, strategic policy makers in countries such as the United States, and molecular biological researchers. This enables biotechnology firms to hegemonise "key scientific discourses, agricultural practice, legal definitions of knowledge, trade and international relations..." (Purdue, 1995:90).

According to Ashiya (1999:1) one of the most significant developments associated with the advent of biotechnology has been the strengthening of intellectual property protection for biological inventions. The Trade-Related Aspects of Intellectual Property Rights (TRIPs) agreement under the WTO stipulates a minimum level of protection for intellectual property rights (IPRs) to encourage the export of knowledge-intensive goods and services. Brodnig (1999 (b):3) says "(i)t is also intended to combat disguised or discriminatory trade restrictions resulting from insufficient enforcement of IPR regulations". TRIPs makes provision for seven types of intellectual property: copyright, trademarks, geographical indicators, industrial designs, patents, layout-designs of integrated circuits and undisclosed information.

Article 27 deals with patents where it states that “patents shall be available for any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application” (Purdue, 1995: 97). *Article 27* of TRIPs is particularly relevant to GM crops. It exempts plants and animals from patentability, provided that plant varieties receive some form of intellectual property protection. Some developing countries would like to use the exemption to adopt *sui generis* systems that enable them to “assert national control over plant genetic resources and the related traditional knowledge” (Brodnig, 1999 (b):3).

Disputes between states over the operation of TRIPs are dealt with in *Article 64*. Such disputes are referred to the WTO’s Integrated Dispute Settlement Understanding, which will give the US, the EU and Japan the ability to “retaliate” on perceived infringements through the use of their access to the markets for Southern goods. For this reason Southern countries have argued that these disputes should be settled by the World Intellectual Property Organisation (WIPO), but the North insisted that they be kept within the WTO precisely because “linking intellectual property rights to trade gives them more power” (Purdue, 1995:98). This illustrates what Murphy refers to in his article on global governance when he says that institutions such as the WTO (and the IMF and World Bank) “have contributed to the growing numbers of the destitute as well as to the growing privilege of the world’s rich” by promoting unregulated economic globalisation (Murphy, 2000:791). But attempts to patent biotechnology products have been shrouded in controversy from the start.

Regular granting of patent rights on plants started with the decision of the *Diamond versus Chakrabarty* case in 1980, starting in the United States and moving later to Europe. In 1998 alone, more than 400 patents mentioning rice and biotechnology were issued in the United States compared to 12 in 1988. The US grants patents on all plants of a particular species into which a new gene has been inserted using biotechnology. This means that the US grants patents to any isolated gene and DNA sequence, the genetic engineering tools that use those sequences, and over the plants that have been transformed using these tools. These rights do not extend to the original plant in which the gene occurs naturally (Barton, 1999:1).

Patents for microorganisms have come up against fierce criticism in Europe where it is seen by human rights organisations as “antithetical to morality” (Ashiya, 1999:2). The ethics of the ownership of living entities was foremost in the intellectual property rights debate with the submission of patent applications for animal-human hybrids. Barton (1999:1) states that nations have offered Plant Variety Protection (PVP, also called Plant Breeders’ Rights) since the beginning of the mid-1900s. The PVP made provision for protection of new varieties on the condition that it was novel, distinct, uniform, and stable. The PVP⁶ also gave the breeder the exclusive right to market the new variety. With treaty revisions brought about in 1991, nations could prohibit farmers from reusing harvested seeds. The example by Ashiya (1999:3) of germination control technology, where seeds become sterile after one planting, illustrates this point. Establishing harmonised practices between these regimes is certain to create a lot of frustration for both trade liberators and environmental protectionists. Multinational seed companies seek to maximise profits by protecting their intellectual property in an effort to regain the money spent on research and development. On the other hand, indigenous and local farming communities feel that their rights are being undermined where they have traditionally saved seed for future crops. It also enables breeders to protect material bred from already protected materials and gain even stronger rights over products grown with protected seeds (Barton, 1999:1).

Developing countries have been reluctant to introduce these forms of intellectual property protection, but the TRIPs agreement requires all of its members to make patents available in all fields of technology. The efforts by industrial countries to protect products resulting from biotechnology have encouraged developing countries to try and protect the genetic sources of those products by exercising their sovereign right over them. These actions by developing countries resulted in the negotiation of the 1992 Convention on Biological Diversity (CBD) (Barton, 1999:1-2).

The biotechnology sector has felt the effects of globalisation and market liberalisation through greater competition influenced by technological capacities and national policies to improve biotechnology abilities. Juma (1999:3) believes that there is room

for compromise and consensus in the arena of market liberalisation in solving the questions around biotechnology's potential influence on health, economies and the environment. However, the question needs to be asked who will benefit most from such 'compromise and consensus' in a system where market liberalisation has a built in bias favouring the richer developed countries (Juma, 1999:3).

3.2. The Main Benefactors of Protection

Biotechnology has advanced to the point where scientists are able to combine molecular biology with information technology; where institutional arrangements use knowledge and technologies to improve international competitiveness. New national systems of innovation have been created where the focus is on rapid commercialisation of biotechnology and on reforms in intellectual property protection systems. This has resulted in disputes over the ownership of bio-innovations in a world where different actors are not equal in terms of their legal resources and human capacities. Developing countries seek national control over genetic material and new regimes of resource rights. This is met with strong opposition from the developed world which claims that existing mechanisms are sufficient to deal with these matters (Juma, 1999:3).

As biotechnology develops, new structures emerge to govern and manage it. These institutions are shaped by the value systems of the communities in which they are found, but there are countries where regulatory mechanisms and government oversight is still lacking. Juma (1999:3) says that "institutional flux" has caused uncertainty about the regulation of biotechnology. Institutions such as the WTO are still developing mechanisms of analysis and response to technological risks. Juma (1999:3) is in favour of the transformation of existing regimes to build capacities that match regulatory tasks, rather than creating new regimes. As with the previous point, this statement seems to be biased in favour of the interests of developed countries who have been instrumental in creating existing regimes to suit their needs. The insistence of the United States of using WTO rules to regulate biotechnology, rather

⁶ The PVP system is governed by an international agreement and organisation called UPOV, a French acronym for International Union for the Protection of New varieties of Plants (Barton, 1999:1).

than create a new regime, is an example.

Sutherland (1998:295) demonstrates how the minimum requirements set out in the TRIP's do not guarantee the recognition of the value of indigenous and local communities' traditional knowledge, innovations and practices. Purdue (1995:93) argues that just as there is no non-interventionism in domestic economies, there is no such thing as free trade: "Political power is always intrinsic to the constitution of the terms of trade just as it is to the constitution of the market". This implies that industrialised countries have never subjected themselves to the rules of free trade they established in the first place. Purdue (1995:94) indicates that neo-mercantilists dispense with ethical niceties and readily accept the 'military metaphor' of strategic trade policy (which Purdue equates with protectionism). TRIPs form an 'agenda' for the globalisation of U.S. intellectual property rights. This is hegemonic because it is presented as being in the international public interest while serving specific industrial interests in the North, especially that of the biotechnology industry (Purdue, 1995:99).

Barton (1999:2) describes the structural consequences of the trend toward intellectual property protection by referring first to the radical increase in private-sector research. This increase is ascribed to the possibility of profits driven by intellectual property rights. A great deal of centralisation has also taken place to the extent where a "global oligopoly" is led by five firms, AgrEvo, DowElanco, DuPont, Monsanto, and Novartis. This oligopolisation is explained partly by intellectual property litigation, where many disputes arising from reciprocal infringement were resolved by merging companies, especially during the period between 1996 to 1999. Barton also expects that intellectual property rights will have a significant affect on international trade patterns. He states that the "competitive use of variety and intellectual property rights can be expected to increase in light of the large number of new markets and applications for genetically modified crops. It may even become a response to the lowering of more formal trade barriers" (Barton, 1999:2).

According to Purdue (1995:88) attempts to establish "uniform global intellectual property rights over living material" is a hegemonic effort by the biotechnology industry. He says "GATT has provided a fertile terrain for the hegemonic ambitions of the biotechnology industry" (Purdue, 1995:88). According to Persley and Doyle

(1999:1) most of the biotechnology-based solutions for agriculture will likely be in the form of new plant seeds or new strains of livestock.

3.3. Responses from Non-benefactors of Protection

According to Sutherland (1998:296) there is an “expanding academic literature on agro-biodiversity, agro-ecology, ethno-biology and ethno-botany, traditional ecological knowledge and sustainable development”. At the same time the application of biotechnology to agriculture has highlighted the “deep symbolism associated with contemporary agrarian culture” (Krimsky and Wrubel, 1996:214). Individuals and communities are confronted with appraisals of what the farm is and what it ought to be, of what food and livestock are and how it can and ought to be used by humans. Voices that are involved in the debate over the use of biotechnology include small advocacy organisations, start-up companies, international green organisations, traditional environmental groups, multinational corporations, natural food associations, and animal rights supporters. There is also a considerable amount of disagreement on biotechnology issues among organisations and the documents that result from their deliberations. Some declarations denounce all intellectual property rights over life forms. There are those that call for a moratorium on biotechnology research involving indigenous peoples. An organisation that is very active in its campaign against IPRs sought by those in biotechnology research and development is the Rural Advancement Fund International (RAFI). This organisation denounces bio-piracy by focusing on the unjust way that multinational corporations enrich themselves when IPRs are claimed over products or processes to which indigenous people have added value through their own innovation, knowledge and customs⁷ (Sutherland, 1998:297). Other concerns G77 governments and NGOs have about the application of TRIPs rules are:

- Most countries with abundant biodiversity lack the capacity in the biotechnology sector to maximise that comparative advantage.

⁷ Other NGOs opposed to IPRs include the Genetic Resources Action International (GRAIN), Searice, the Third World Network, the Research Foundation for Science, Technology and Natural Resource Policy, the Institute for Agriculture and Trade Policy, Friends of the Earth International (FoE), the Dag Hammarskjold Foundation (Sutherland, 1998: 297).

- IPR laws in TRIPs recognise only novelty and private invention without providing for collective or accumulated knowledge often found in developing countries.
- Traditional farmers will not be able to meet many of the requirements stipulated in TRIPs rules.
- IPRs over biological material will lead to a further decline in biodiversity and the cultural practices that helped maintain that diversity.
- Commercialisation of the seed industry will mean that farmers in developing countries will not be able to pay for expensive genetically engineered seeds.
- IPR protection will result in aggressive marketing of protected varieties, mono-crop practices, industrial production, and exacerbated declining levels of biological and cultural diversity (Sutherland, 1998:297).

Recognising the plight of developing countries, McAfee (1999:150) states that "(j)ust as development in any meaningful sense will require increased democracy and greater equality, so does environmental sustainability depend upon environmental justice". The strongest opposition to IPRs and other forms of privatising and commodification of life forms comes from locally and regionally based peasant movements from especially South and South East Asia and Latin America (McAfee, 1999:148). Multinational NGOs that have actively highlighted the position of the developing world include the Third World Network, Rural Advancement Foundation International, Genetic Resources Action International, the US Institute on Agriculture and Trade Policy, the multinational Pesticide Action Network, and others based in Western Europe, Latin America, Ethiopia, India, and Japan. At the individual level there are countless conservationists, scientists, and intellectuals who oppose the patenting of organisms, human cloning, human gene collection, genetic screening and surveillance and other biotechnological intrusions.

McAfee (1999: 149) indicates that although it does not have a united voice, this "broad coalition" has, through its interventions, challenged green developmentalism in the CBD on a range of important issues, including biosafety, agrobiodiversity, and intellectual property rights. Some of the actions taken by these protesters include: pressure for internationally recognised rights of states and indigenous nations to refuse to allow the patenting of organisms and private monopolisation of genetic resources and knowledge; endorsement of an international moratorium on

bioprospecting; and rejection of any specific rights of subnational groups to local sovereignty over resource regimes (McAfee, 1999:149-150). There are, however, many Southern states that are not living up to their commitments to respect “indigenous territorial boundaries and other rights”. This means that affected people turn for help to the “transnational level” where legal and public relations campaigns are already established to protest against ‘bio-piracy’ and the environmental damage caused by MNCs (McAfee, 1999:150).

4. **The Risk and Safety of Biotechnology**

In the biotechnology debate over risk, there is very little consensus, if any at all. The problem is described by Krimsky and Wrubel (1996:246) as follows: “Controversy over the environmental risks from the applications of biotechnology to agriculture rests on differences of opinion regarding the level of uncertainty in assessing the probability and consequences of an adverse impact”. The current understanding of the long-term interaction between GMOs and the environment means that risks cannot yet be quantified. Krimsky and Wrubel (1996:219) state that empirical research cannot determine perceptions about whether biotechnology is natural or unnatural. In the absence of such empirical information, scientists and analysts have turned to historical, theoretical, or analogical reasoning in the search for plausible answers (Krimsky and Wrubel, 1996:247). This has meant that the debate has been polarised between the proponents and opponents of biotechnology. Proponents of biotechnology seem to view nature as something that humans should control and manipulate. According to Krimsky and Wrubel (1996:221) this largely dominant view of nature is rooted in the texts of Judeo-Christianity and was later reinforced by the “post-Baconian scientific Enlightenment”. It implies that control over nature is not only necessary, but also aesthetically, morally and religiously justifiable. Krimsky and Wrubel (1996:221) explain this notion further by saying that “when nature is rationalized it looks more pleasing, it better serves people’s interests, and, according to Western religious doctrine, it rewards the Creator, who has implored humans to harness nature’s secrets and subdue its irrational impulses”. Opposing this view of nature are those who see “an organic and dynamic ecosystem that cannot function under the type of mechanistic control found in industrial manufacture” (Krimsky and Wrubel, 1996:221). The place of humans in such a system is not one of master over

nature, but rather one where humans are a species together with other species – a part of nature - that need to live in balance with its environment. This view holds that misuse of power and scientific capacity by humans ultimately results in destruction of the environment with detrimental effects to humans, animals and plants.

Falkner (2000:300) says one of the reasons for the lack of popular support for bio-agriculture in certain parts of the world is the uncertainty pertaining to environmental and health risks that GMOs pose. Together with this, there seems to be a general public distrust of scientific and corporate self-regulation. The slow pace at which government authorities have moved to implement regulation of the biotechnology industry, with some developing countries having no regulatory frameworks at all, has not done the public image of the industry any good either. Falkner (2000:301) says that the “fragmented framework” of biotechnology regulation can in no way keep up with the rapid expansion of the agribiotech sector around the world.

One of the problems in determining the risks of biotechnology has been inadequate long-term research, partly because budgets allocated for such research have been neglected. Butler and Reichhardt (in Sagar and Ashiya (1999 (b):2) indicate that the U.S. Department Of Agriculture spends only one per cent of its biotechnology budget on biosafety. Suspicion of risk has also meant that there have been different responses to the way safety standards should be applied. Krimsky and Wrubel (1996:20) indicate that new chemical products are subjected to rigorous toxicological testing, whereas biological products are not tested as thoroughly, especially those modified by genetic techniques. Separate processes were launched in the early 1990s to harmonise standards for biotechnology-based foods and drugs. In 1990 the Food and Agricultural Organisation (FAO) and the World Health Organisation (WHO) convened “an expert consultation” that recommended the development of “improved toxicological testing methods and safety assessments with consideration of molecular and biological characteristics of food”. This move towards comparative safety assessments was followed by a call for the implementation of the “substantial equivalence⁸” principle by the Organisation for Economic Cooperation and Development (OECD) in 1991 (Daemmrich, 1999:1).

⁸ A substantial equivalent plant is a particular plant species with a novel trait, which is the same with respect to its use and safety to the environment and human health as types of the same species without the novel trait (AGCare, 1999:1).

The principle of substantial equivalence between GMOs and traditional selectively bred varieties has been fiercely criticised by organic food advocates, including the Campaign for Food Safety and NGOs such as Greenpeace. The criticism stems mostly from the concern about the inability to predict the long-term impact that GMOs might have on humans, e.g. allergic reactions (Butler in Daemmrich, 1999:2). Other associated risks to health include potential harm to economic, societal, and individual wellness (Daemmrich, 1999:2). Where these risks are played down or where biotechnology products are considered not to hold any risks, accusations of protectionist trade policies have highlighted the public's mistrust in regulatory institutions and procedures for scientific risk assessment. On this point, Wiegele (1991:65) points out that there is a difference between the dangers inherent to some product of biotechnology or research endeavor and biotechnology as a whole. The latter, he says, is not inherently dangerous and caution should be taken to condemn it outright.

Jasanoff (in Daemmrich, 1999:3) states that "regulatory styles are integral to the shaping of a technology and regulations themselves serve as social constructs to limit uncertainty and provide assurances that risks can be contained". This means that risk perception and methods of responding to human health concerns across the world are intertwined with cultural traditions, economic systems and structures of governance that are difficult to harmonise based on technical standards alone. If biotechnology companies want to assuage public fears about their products, they need to produce safety data that is consistent and considers national differences. Juma (1999:20) argues that the biotechnology debate will not be solved by simply providing more information to reduce uncertainty. The debate requires a deeper understanding of the structural benefits and risks posed by the use of biotechnology. The development of new technologies also requires "product testing, impact assessments, and information dissemination," processes that often take years to refine. Juma (1999:4) indicates that pragmatic countries opt for shorter time frames in the process of product commercialisation, which in turn sparks criticism from those countries, consumers and lobbyists that precautionary approaches are more prudent when the risk of releasing altered organisms into the environment are not known. These conflicts are often confined to narrow assessments of economic losses

incurred from not being able to market products on the one hand, and an emphasis only on potential dangers to the exclusion of benefits on the other.

Sagar and Ashiya (1999 (b):1) indicate that “(c)oncerns over the environmental implications of genetically-modified (GM) crops are largely based on the assumption that new products may have harmful effects and need to be introduced in a precautionary manner”. One of the main concerns is the possible movement of genes from GM crops to their wild relatives. The results would be serious in cases where genes have been coded for traits such as herbicide resistance. Insect resistant crops may reduce the need for the use of pesticides, but there is also the risk that natural selection could lead to the breeding of pests resistant to the “natural” insecticide. There is also the concern that the use of GM crops may lead to an increase in chemicals such as herbicides.

Krimsky and Wrubel (1996:108) state that the “strongest argument for regulating transgenic food as food additives concerns the spread of allergenicity throughout the food supply”. In the case of allergens it is especially important that products are labeled to enable consumers to protect themselves against substances which they know can harm them.

A differentiation should also be made between risks that emanate from accidental escape from a laboratory or production facility as opposed to the risk associated with large-scale deliberate release of an organism into the environment. Similarly there is a difference between short-term and long-term risks, and between suspected effects for which monitoring may be implemented versus unexpected effects (Funke, 1988: 64).

Leisinger (1999:1) distinguishes between risks that are inherent to a technology and risks that transcend it. He argues that the debate about technology-inherent risk has been clouded because biologists, legal experts, and “ethicists” have all expressed opinions, sometimes on areas where they are not experts. What is needed is for decision making and quality management issues to be kept distinct. The scientific project level should be separate from the national policy level, which in turn should be distinct from the international level. Technology transcending risk emanates from the

socio-political context in which the technology is used. In developing countries these risks arise from both the course the global economy takes and country-specific political and social circumstances. The most critical risks have to do with the aggravation of the prosperity gap between North and South, growth in the income disparities and wealth distribution within societies, and the loss of biodiversity (Leisinger, 1999:1-2).

A problem with risk that has been pointed out previously is that scientists and technologists involved in biotechnology do not agree on what risks are, or might be, or how they should be measured once identified. Rather, what happens is that scientists together with non-scientists have been involved since the advent of biotechnology in voicing a number of concerns over a variety of biotechnology related issues such as ethics, lifestyle, social impacts, environment, and policy. Funke (1988:64) is of the opinion that this diversity of concerns over biotechnology could create new social inequalities and problems. One of these problems is agreement on how to respond to the so-called risks of biotechnology.

5. Institutional Responses to Risk Issues

Different countries and regions have made varied responses to the effects and possible risks of biotechnology. Juma and Gupta (1999:1) mention the measures taken to conduct biotechnology in a safe manner. These include scientifically based, case-by-case hazard identification and risk assessment; regulation of the end product rather than the production process; developing a regulatory framework that builds on existing institutions rather than establishing new ones; and building flexibility into biosafety systems to reduce regulation of products perceived to be low-risk. These are measures used especially in the United States. Biosafety risk assessment involves scrutiny of the organism being assessed, intended use of the organism, and features of the recipient environment.

Juma and Gupta (1999:1) admit that familiarity cannot be equated with safety, but it is used as the basis for applying existing management practices to new products. The Organisation for Economic Cooperation and Development (OECD) "recommends this approach to biosafety and the U.S. regulatory system relies on it".

The US is making decisions based on evolving science informed by a risk-benefit analysis, where it seems that financial benefit receives precedence over possible risk. This is why Krimsky and Wrubel (1996:111) state that the “use of genetic engineering for creating plant foods and other plant products is an example of innovation that has largely been science-driven rather than need-driven”. These authors indicate further that many of the “proposed new uses of transgenic plants, such as the production of biopolymers and pharmaceuticals, are attempts at increasing efficiency of production rather than filling a product need” in the market (Krimsky and Wrubel, 1996:112). Elsewhere the same authors say that the United States’ biotechnology policy “was designed to stimulate the innovative potential of American science and industry, to foster technology transfer, and to enable the U.S. biotechnology industry to achieve hegemony in global markets” (Krimsky and Wrubel, 1996:251). This is somewhat different to the process decided on in Europe and most other regions.

Europe is applying the precautionary principle where biotechnology will not be used until more certainty about possible environmental risks become clear. Thus, in the absence of certainty, caution is heeded. Developing countries favour the precautionary principle, but with the emphasis more on the socio-economic aspects related to environmental risk. Developing countries are also concerned that their biodiversity might be exploited without them receiving any benefit from it (Sagar and Ashiya, 1999 (b):2). Another policy used to lure developing countries into Northern-style development projects is the so-called ‘green developmentalism’.

The attraction of green developmentalism to international policymakers is that it obscures the identity of those who gain from environmentally destructive policies and practices. Instead, the destruction of biodiversity is blamed on abstractions such as ‘market failures’ and ‘policy failures’ (Perrings, 1995). But the direct threats to local culture and biodiversity are not so easily abstracted away. As McAfee (1999:151) points out:

“(g)reen developmentalism fosters the fantasy that we can ‘green the planet’ while continuing to grow along demonstrably unsustainable economic trajectories... It purports to provide an objective metric for estimating the values of all components

of nature worldwide, but actually offers values determined by the powers and desires of international elites”.

Prominent actors involved in the promotion of a global green developmentalist agenda include the World Bank’s Environment Department, OECD patent offices and representatives to international environmental negotiations, the quasi-governmental World Intellectual Property Organisation and World Conservation Union, and corporate lobbying bodies such as the US Biotechnology Industry Organisation. Citing various authors, McAfee shows that green developmentalism also enjoys growing support among large conservationist movements such as the World Resources Institute and the Worldwide Fund of Nature, and among academic scientists and environmental policymakers. Green developmentalism reinforces environmental injustice on a world scale. Green developmentalist theory already contains a bias with regard to the distribution of natural wealth and access to nature and its benefits (McAfee, 1999: 138). By interpreting the value of nature in relation to international markets, i.e. by denominating diversity in dollar or Euro, this paradigm justifies the claims of those with the greatest purchasing power worldwide to the greatest share of the earth’s biomass and all it contains. McAfee states:

“Green developmentalism attempts to maintain a separation between environmental problems and broader political-economic issues. It promotes a bias towards technological solutions and away from socio-cultural change. It provides justification for the continued conceptualisation of environmental goals in isolation from development aims and without changes in existing political institutions, distributions of economic power, and patterns of resource flows” (McAfee, 1999: 135)

Contrary to the premise of the global economic paradigm, there can be no universal metric for comparing and exchanging the ‘real values’ of nature among different groups of people from different cultures and with vastly different degrees of political and economic power. Nor is there any way to place a price on any element of biological diversity torn out of its social and ecological context (McAfee, 1999:139). The development of different regimes with different principles should in future be one of the major challenges facing international trade as well as intellectual property rights. What further complicates the issue is that these regimes are all sovereign in that they derive their authority from separate national jurisdictions. A regime such as

the Cartagena Protocol uses the precautionary principle, which is not applied in the WTO regime. This is the topic of the next chapter.

CHAPTER 4

THE CARTAGENA PROTOCOL ON BIOSAFETY

“In the unlikely event that an international regulatory regime is established in the near future, it will probably be far from effective” (Wiegele, 1991:69).

This chapter deals with international regulatory frameworks that regulate the environment and genetically manipulated organisms. The nature of the international regulatory environment is discussed briefly, followed by a look at the historical process that led to the establishment of the Convention on Biological Diversity. This is followed by a discussion of the developments and dynamics that led to the adoption of the Cartagena Protocol on Biosafety (see Appendix A). The main elements of the Cartagena Protocol are described, including the meaning and role of the precautionary principle. This is followed by a critical examination of some of the issues not resolved by the Protocol. The chapter is concluded by a brief look at the worth of the CBD and the Cartagena Protocol as international regulatory frameworks.

1. **The Nature of the Biosafety Regulatory Environment**

International discussions on the need for a global biosafety standard initially focused on the need for developing countries to strengthen their regulatory frameworks with regard to GMOs. Most countries in Asia, Africa and Latin America did not have sufficient scientific or regulatory capacities to institute satisfactorily such frameworks on a state-to-state basis, and relied, therefore, on international legal, financial and technological support in an international biosafety agreement. Thus, the need for a global biosafety standard started out as a North-South issue. This was soon changed with the growth of commercial GM applications.

Trade in GM crops in the second half of the 1990s brought the EU into direct conflict with the US. This meant that the initial North-South issue of biotechnology was reshaped into a conflict among northern countries over the implications of trade in biotechnology products and the rules that should regulate such trade. The conflict had its origins in the EU's insistence that the precautionary principle be applied to the regulation of GMO releases into the environment; a principle which focuses on the

potential threats of GMOs to the environment and human health. This principle conflicted directly with the United States' adoption of the so-called science-based method of risk assessment used in that country; an approach which accepts that a GM crop release is safe until there is evidence that it can cause harm (Falkner, 2000:301).

Falkner (2000:301-2) indicates how the EU approach to GMO releases resulted in the requirement for environmental evaluation and the recognition of the rights of states to participate in evaluation procedures. This was contrasted by the United States' more "streamlined and depoliticized" evaluation procedure that has enabled its biotechnology industry to rapidly commercialise biotechnology research. The United States, with its emphasis on the trade aspects of biotechnology, have maintained that the EU is in violation of WTO rules with its precautionary approach. It is with this transatlantic dispute over how GMO products and its release should be regulated, that the parties to the Convention on Biological Diversity initiated international talks to consider the safety aspects of trade in GMOs in the mid-1990s (Falkner, 2000:302).

2. **The Convention on Biological Diversity**

Discussions about an international biosafety standard were started in the 1980s on a diplomatic level (Falkner, 2000:302). Multilateral negotiations aimed at establishing a regulatory framework to deal with biological diversity started in 1990, two years before the Rio Earth Summit. These negotiations were aimed at establishing legal frameworks that would be environmentally sensitive and that would enable governments of poor countries to work towards sustainable development (Munson, 1993:498).

The Convention on Biological Diversity (CBD) was launched at the 1992 UN Conference on Environment and Development⁹ (UNCED) in Rio de Janeiro, colloquially known as the 'Rio Earth Summit'. During the early 1990s, developments in the biotechnology industry had given rise to concerns about the effects that GMO releases into the environment would have on biosafety. This led the Commission on

⁹ By 1998 the treaty had been ratified by 172 states, excluding the USA.

Plant Genetic Resources (CPGR), which is a commission of the Food and Agricultural Organisation (FAO), to prepare a Draft Code of Conduct on Biotechnology. According to Article 1.1. of this code, it was intended to promote the conservation and sustainable and safe use of plant genetic resources (Falkner, 2000:302).

The disputes that developed within the CBD are indicative of the persistence of North-South conflicts over the control of financial and natural resources, issues that are now excluded from other forums because of hegemonic neoliberalism. The CBD is a UN institution and therefore most of its funds come from industrialised countries of the north. The Global Environment Facility (GEF) and the World Bank have been designated the interim funding mechanisms for the CBD. In addition to their economic power, the OECD states and the World Bank exercise substantial institutional power by employing their own environmental experts, lawyers and academic consultants (McAfee, 1999:140). The main goals, according to McAfee (1999:140-1) of the northern states for signing the CBD were to limit the expansion of polluting industrialisation in the global South, to preserve some tropical forests as “carbon sinks”, to slow the rate of species extinctions, and to guarantee Northern access to Southern ecosystems and resources as sources of primary commodities and of ‘genetic resources’ for their own agrochemical, pharmaceutical, and other biotechnology industries.

The GEF’s four official programmes are biodiversity conservation, global warming, ozone depletion, and international waters. Southern states have argued that these programmes only reflect northern interests to the neglect of more pressing Southern environmental concerns, such as land desertification, which was subsequently added by the GEF, but only as a subcategory to one of the main programmes (McAfee, 1999:142).

Southern states joined the CBD after being promised new eco-development money, the recognition that states have the sovereign right to determine access to genetic resources in their territories, and the ‘vague’ promise that Northern biotechnology might be provided to developing countries on concessional terms, and that all parties to the treaty would receive their fair and equitable share of the benefits of biodiversity

(McAfee, 1999:141). Southern states signed the treaty with the following goals in mind: to attain additional foreign aid in the context of shrinking overall assistance, to please domestic conservationists and rural social movements that made environmentalist demands, and many of the diversity rich countries are hoping to boost their revenue earnings by exporting their genetic 'green gold' (McAfee, 1999:141).

In the CBD there are four problematic concepts together with that of biodiversity that have become instrumental in how the treaty is interpreted: global environmental problems, genetic resources, biodiversity benefits, and intellectual property rights. According to McAfee (1999:143) this set of interrelated concepts has been constructed in such a way as to link any gains to developing countries of the South from their participation in the CBD to their acceptance of the further privatisation and commercialisation of organisms, ecosystems, and knowledge about nature. This is further illustrated by the following words of McAfee:

"(The) equation of 'biodiversity benefits' with genetic resources, enshrined in the CBD text, represents a discursive conquest by the shortsighted instrumentalism of the environmental-economic paradigm. It reduces biological diversity to its purported essence as a commodity, presumably separable from its complex relationships with other 'units' of nature, and valuable only to the extent that it is consumed" (McAfee, 1999:144).

McAfee calls this a "reductionism" that gives only scant recognition to the complex ecological and social relationship in which biological diversity finds itself. He warns against viewing ecosystems as "warehouses of potential commodities" that are utilised by consumers in distant countries rather than as the foundations of indigenous communities: "sources of material necessity and meaning, and biophysical context and culture" (McAfee, 1999:144). In the same vein, Munson (1993:515) criticises the CBD for "failing to establish a vehicle for compensating the centuries of traditional knowledge and inventions of indigenous peoples and rural communities". This is despite the fact that the CBD is a reaffirmation of the sovereign right of states to govern their own biological resources (Munson, 1993:504).

Brodnig (1999 (b):2) indicates that the general principles of the global trading system as set out under the WTO cover most aspects of biotechnology. There are however issues of safety, such as the potential flow of genes from GM crops to the environment, which fall under the jurisdiction of other treaties and national regimes such as the Cartagena Protocol on Biosafety.

3. The Cartagena Protocol on Biosafety

International regulatory frameworks dealing with environmental issues that existed before the Cartagena Protocol on Biosafety include the following: the Convention on Long Range Transboundary Air Pollution (1979) and its additional protocols related to sulphur emissions (1985) and to nitrogenoxide emissions (1988); the Vienna Convention on the protection of the Ozone Layer (1985), the Montreal Protocol on Substances that Deplete the Ozone Layer (1987); the Basel Convention on the Control of Transboundary Movements of Hazardous Wastes and Their Disposal (1989) (Lang, 1990:42); The United Nations Framework Convention on Climate Change (1992)(UNFCCC, 2000); and the Convention to Combat Desertification (1996) (UNCCD, 2000).

Efforts to establish a Biosafety Protocol began in July 1996, a year after a group of experts met to define the issue area to be covered by such a protocol to the CBD (Falkner, 2000:303; Winfield, 2000:1). A Biosafety Working Group (BSWG) was established to facilitate negotiations and it was instructed to have a final draft treaty ready by 1998. The BSWG assembled five times between 1996 and 1998, but could not establish sufficient agreement for a draft treaty before the scheduled date. This led to the meeting of the BSWG for the sixth time in Cartagena, Colombia, in February 1999, which was intended as the meeting at which a biosafety protocol was to be adopted. However, due to fundamental disagreements on the scope, purpose and nature of the protocol, talks were suspended at Cartagena without a protocol being adopted (Falkner, 2000:304).

Efforts at Cartagena in Colombia in February 1999 to adopt a new biosafety protocol under the Convention on Biological Diversity (CBD) failed because of serious differences about perceptions and interpretations of risk. The main component of the

draft protocol comprised of an advance informed agreement (AIA) procedure to be followed before the transboundary movement of GMOs took place. At the time of disagreement the categories of GMOs to be covered under the AIA procedure was not agreed. This was one of the points on which there was most disagreement, i.e. whether GMOs that are “intended for food, feed, or processing” rather than for deliberate release into the environment should be covered under the AIA. The so-called Miami group (a group of agricultural exporting countries comprising of Argentina, Australia, Canada, Chile, the United States, and Uruguay) were adamant that agricultural commodities be excluded from the AIA procedure because these countries did not (and still do not) see the threat to biodiversity. The other groups, and especially the developing countries, were in favor of all “first-time transfers” of GMOs, including commodities, to fall under the AIA procedure. Negotiators disagreed further on whether decisions taken under AIA should be science based or guided by the precautionary principle (Juma and Gupta, 1999:2).

An area of fierce debate at Cartagena involved the relationship between a country’s obligations under the protocol and its rights and obligations under the World Trade Organisation (WTO) agreements. The debate on this issue escalated to the point where a deadlock meant that a protocol was not agreed at Cartagena. Coupled to this issue were disagreements about the socio-economic effects of GMOs, liability and compensation, and the inclusion of pharmaceutical products in the protocol (Juma and Gupta, 1999:2).

Three rounds of informal consultations followed the Cartagena talks during the period of July 1999 to January 2000. These consultations took place within and among the five groupings that emerged in Cartagena, namely the Miami Group of GMO-exporting countries; the European Union, the Central East European countries (CEE); the Compromise Group (Japan, Mexico, Norway, South Korea and Switzerland); and the Like-Minded Group, consisting of the majority of the developing countries. After the talks at Cartagena, the Miami Group focused its negotiating efforts on two objectives: the exemption of transboundary movements of GMOs that are commodities for use in food, feed or processing from the rules of the Protocol, and the subordination of the Protocol to the rules of the World Trade Organisation (WTO) regarding international trade. The Miami Group’s views on these issues led to

the failure of efforts to hold a next round of informal negotiations in Vienna on 15-19 September 1999 (Winfield, 2000:1-2; South-North Development Monitor, 1999:2).

At a meeting of these groupings in Montreal (Canada) in January 2000, called the Extraordinary Conference of the Parties (ExCOP), the conflicting approaches of biodiversity protection of the CBD versus the trade liberalisation of the WTO were pushed to the point where negotiations were once again threatened with collapse. It is notable that non-governmental organisations played a prominent role in securing certain agenda points through their position statement. In this statement they declared that it was reasonable to expect the Biosafety Protocol to contain three essential obligations for countries intending to export GMOs: advance notification of intended export, full disclosure of information, and the explicit consent of the receiving country prior to any transboundary movement of the GMO (NGO Position Statement, 2000:2).

After initial successes on the procedures for informed consent, talks stalled on the basic issues of previous contention, namely the scope of the Protocol (the range of GMOs and products of biotechnology to be covered by the protocol), the application of the definition of the precautionary principle instead of the use of full scientific proof, and the status and position the protocol would have within the international trade regime (Falkner, 2000:305; Winfield, 2000:5). The second last day of the conference saw the Miami Group attempting to reopen some of the issues in the draft protocol. This was met with unanimous and fierce opposition from the other groups, especially the developing countries. Just when it seemed that talks would fail once again, delegates emerged from chambers on the morning of 29 January 2000 with an agreement that finalised the Cartagena Protocol on Biosafety (Falkner, 2000:306).

3.1. The Contents of the Cartagena Protocol

The Cartagena Protocol (CBD, 2000) consists of a declaration of the parties to the Protocol (a preamble), forty articles, and three annexes. The preamble stipulates the relationship of the Protocol with other international agreements and indicates that it "shall not be interpreted as implying a change in the rights and obligations of a Party under any existing international agreements" (CBD, 2000). The next sentence clearly states that "the above recital is not intended to subordinate this Protocol to

other international agreements" (CBD, 2000). This establishes the principle that countries should honour their trade obligations under the rules of the WTO, but that they have the right to protect their biodiversity and human safety where biotechnology and its products are concerned. From a mercantilist perspective this seems to leave room for protection measures. But from a structuralist perspective it allows countries to choose to put the welfare of their citizens and the environment ahead of issues such as trade and comparative advantage.

The objective of the Protocol is spelled out in Article 1 (CBD, 2000:1):

"...to contribute to ensuring an adequate level of protection in the field of the safe transfer, handling and use of living modified organisms resulting from modern biotechnology that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, and specifically focusing on transboundary movements".

The scope of the Protocol (Article 4) indicates that it applies to "the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health". The Draft Report of the ExCOP of February 1999 made provision for inclusion into the Protocol of all but a few specific living modified organisms (LMOs)¹⁰(The CBD opted to use the concept 'living modified organisms' instead of 'genetically modified organisms'). However, developing countries represented at Cartagena did not succeed in having all products derived from LMOs included. This was largely the result of pressure from the representatives of business and the industrial countries (Falkner, 2000:307).

Exclusion of LMOs that are pharmaceuticals intended for human use already addressed by other international agreements is provided for in Article 5. Provision is made for the transit and contained use of LMOs (Article 6), but the regulations pertaining to the Advance Informed Procedure do not apply to them. Application of the Advance Informed Agreement procedure is laid out in Article 7. Provision is also made for the transboundary movement of LMOs (Articles 8-10, 12); risk assessment

¹⁰ LMOs excluded were those that were to be listed by the parties as environmentally safe; the transit and use of LMOs; and pharmaceutical LMOs for humans (Falkner, 2000:307).

and management (Articles 15 & 16); emergency measures (Article 17); the establishment of a Biosafety Clearing-House (Article 20); handling transport, packing and identification; and a secretariat (Article 31).

The Advance Informed Agreement procedure, which Falkner (2000:307) calls the “regulatory heart of the Protocol”, is intended to protect the rights of importing nations to refuse the transboundary movement of LMOs when a threat to biodiversity and/or human health is suspected. Thus, the AIA procedure “effectively reinforces national autonomy in environmental and health regulation against the erosive forces of economic globalization” (Falkner, 2000:308). Supporting the challenge the Cartagena Protocol is making to the hegemonic trade regime (WTO) used by the United States to favour its own interests, Winfield (2000:6) states that the Protocol can be regarded as the third of three defeats for the WTO/globalisation agenda in less than a year. First was the abandonment of the Multilateral Agreement on Investment followed by the collapse of the Seattle WTO Ministerial meeting. Taking into account the number of environment Ministers that attended the Montreal meeting, the Cartagena Protocol seems more a matter of environmental protection than one of trade.

The potential for conflict between the trade regime of the WTO, which wants to liberalise trade as much as possible, and the environment and safety regime of the Cartagena Protocol, which can restrict trade of biotechnology products, seems obvious. Much of this conflict arises from differences in the perceptions about the character of GM crops. Brodnig (1999 (b):3) indicates that in addition to procedural issues, “the main fault lines in this case concerned the viability of the precautionary principle, the scope and nature of risk assessments and the role of science, as well as the legitimacy of consumer preferences as a trade restricting factor”. Falkner (2000:307) also refers to the “role and definition of the precautionary principle within risk assessment” which was an aspect of the AIA procedure that was responsible for fierce debate during the final negotiation of the Protocol. The prominence of the precautionary principle in any analysis of the Cartagena Protocol necessitates a specific look at this concept.

3.2. The Precautionary Principle

The precautionary principle is not a new principle. The term originated in Germany in the 1960s as *Vorsorgeprinzip*, literally meaning foresight planning (SIRC, 2000:1). It has been in use in Europe since the 1980s and was the basis of a treaty enacted in 1987 that banned the dumping of toxic substances in the North Sea (HEC, 2000:3). The precautionary principle has been one of the most contentious aspects of the efforts to create a biosafety protocol. It has divided most of the participants and commentators on the issue of biosafety into two broad camps: those in favour of the principle of precaution, and those, notably countries intending to trade in GMOs, against it. This division is the result not only of different interests regarding biosafety and international trade, but also because of a misunderstanding and misinterpretation of the exact meaning of the precautionary principle. During a meeting of scientists, lawyers, policy makers and environmentalists at Wingspread¹¹, Wisconsin, in January 1998, a definition of the precautionary principle was formulated that can be of use here: "When an activity raises threats of harm to the environment or human health, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically. Together with this definition, certain key elements of the principle were also highlighted: precaution is to be taken where scientific uncertainty prevails; alternatives to possible harmful actions should be explored; the burden of proof lies with the proponents of an activity and not with the recipients (victims) of the activity; democratic processes should be used to carry out the principle and the public has the right to informed consent" (HEC, 2000:1; Montague, 1998:2).

Taken as a whole, the spirit behind the precautionary principle supports the common sense principles of being careful rather than brash, of saying, "better safe than sorry"; of trying to avoid doing harm rather than doing first and finding out the consequences later on. The relationship of the principle with science is also an important one. Those against the principle indicate that where there is no scientific proof of harm, no caution is needed. Supporters of the precautionary principle state that scientific certainty is not always possible and that where this is lacking, precaution is needed. The principle further has the intention of changing people's attitudes towards their

interrelationship with the environment. Rather than regulating the amounts of waste and pollutants put into the environment, it would serve future generations better to prevent harm to the environment instead of applying post hoc cleaning up strategies and policies (HEC, 2000:1-2).

The precautionary principle is also a mechanism of addressing certain inadequacies in existing environmental regulations. The first has already been mentioned – “scientific certainty”. The lack of certainty is used to justify the continued use of potentially harmful substances or technology. A second issue is that of narrowly defined ranges of “risk assessment”. In the past risk usually referred to death (mostly from cancer). Coupled to this narrow view of risk is the lack of information and consultation. Captains of industry need to be responsible in the way that they develop and distribute new technologies and products. The last issue is the so-called problem of “cost-benefit analysis”. More consideration is given to the cost of short-term regulation, while the long-term costs of harm and environmental damage is often forsaken. Taken together, these loopholes favour the development and marketing of new products, especially in a market driven economy (HEC, 2000:3). This brings the discussion back to the crux of the debate at Cartagena and Montreal, namely conflict between an environmentally sensitive precautionary approach versus an open market profit-driven approach. In its opposition of the precautionary principle, the Social Issues Research Centre (SIRC, 2000:1) of Oxford in the United Kingdom go so far as to say that it “generates a quasi-religious bigotry which history should have taught us to fear. Its inherent irrationality renders it unsustainable”. The insistence on scientific proof is evident from this reasoning.

Blanchfield (2000:1) indicates that science will never allow us to know everything there is to know about a phenomenon, i.e. science “cannot determine a ‘truth’ that is valid for all future time”; science cannot prove that anything is ‘safe’ (i.e. absence of harm) because “absence of evidence” is not “evidence of absence”. He comes to the conclusion that any policy purportedly based on requiring science to prove safety is unrealistic. Barrett (1999:2) shares these views when she states, “Central to the Precautionary Principle is recognition of the limits of scientific knowledge”. She

¹¹ Countries represented by participants at Wingspread were Britain, Canada, Germany, Sweden, and the United States ((Montague, 1998:2).

states that the Precautionary Principle “need not cause paralysis”. Rather, it is action oriented in that it calls for MORE, not less, research, discussion, organising and education” (emphasis in the original).

The European Union insisted that the precautionary principle guide the AIA procedure, to which the Miami Group objected. Whereas these two groupings took strong positions on these issues, and later made concessions both ways, it is ironic that the final text of the Protocol does not contain the term ‘precautionary principle’ in the main document (Falkner, 2000:309). The words “precautionary approach” do appear in the preamble, though, and seem to be stated as a matter of principle rather than of fact. Winfield (2000:6) indicates that this establishes the precautionary principle as a basis for decision-making and that it should be understood as including commodities.

The United States, having the world’s largest biotechnology industry, has raised sharp criticism against the European Commission for defending the precautionary principle where the regulation of GMOs is concerned. The US sees this as being in direct conflict with the rules of the WTO, which are founded on science-based risk-assessment methods (Falkner, 2000:299). Only the future will tell how the principle of precaution will be interpreted and applied. And it is not the only unresolved issue emanating from the Cartagena Protocol.

3.3. Issues that the Cartagena Protocol has not Resolved

Assessment of the Cartagena Protocol and the protection of biodiversity in a globalising world where trade in free markets have become the order of the day, reveal a number of issues which are not resolved by the Protocol. The lack of a proper definition of the precautionary principle has already been discussed. Provisions for trade and the environment are only dealt with in the preamble and are vague and open to interpretation (Falkner, 2000:300). Conflict between the Protocol and the rules of the WTO can be expected in the future.

A further unresolved point is the concern of environmentalists that biotechnology advances at such a pace that some of the exemptions of the Protocol will soon be

questioned (Falkner, 2000:300). This is another of those aspects that will only be satisfactorily answered when the Protocol is tested through time and its application. The effectiveness of the Protocol in the protection of biodiversity and human health will depend on its ability to adapt to the rate of innovation and change in the biotechnology industry (Falkner, 2000:300).

The issue of dispute resolution remains unresolved because the Protocol contains no mechanism for this on its own. Parties may still have to take disputes to the WTO. Problems are also foreseen concerning the practicality of the mechanism for notice of potential exports of LMOs, particularly by developing countries. Export of commodities may be too complex and confusing in future under the AIA system. The Protocol's provision for trade with non-parties is very weak and leaves room for abuse. No provision was made for "direct social or cultural impact assessment regarding the introduction of LMOs". The Protocol only states that Parties are "permitted" to take socio-economic effects into account, but that this authority is subject to other international obligations, such as that of the WTO (Winfield, 2000:6).

The Cartagena Protocol also seems to have a number of inadequacies regarding labeling. The shipment of bulk commodities, such as seed and animal feeds, will not require labeling for at least two years. No labels are required for processed food containing GMOs. The only wording required on labels for commodities is "may contain genetically modified organisms". This is a shift brokered by the U.S. representatives away from the initial wording of "contains genetically modified organisms" (Mittal and Rosset, 2000:1). Informed consumers and environmentalists can be expected to voice their concerns on these matters in the future.

4. The Worth of the CBD and the Cartagena Protocol as International Regulatory Frameworks

Lang (1990) compiled a useful framework of five criteria, which can be used to test new treaties concerned with protection of the environment. The first is that regimes do not consist of only one single instrument that covers all aspects of the problem it addresses. Environmental treaties usually start with a framework convention with general obligations, which organise international cooperation and provide

mechanisms for more refined rules and regulations. The CBD fits this criterion well. More important than the framework agreement is the so-called “protocols”, which are “additional instruments that deal with specific types of substances or activities to be prohibited or controlled”. The Cartagena Protocol is specific in that it deals only with the transboundary movement of certain GMOs, thus meeting the criterion set by Lang.

The second criterion has to do with flexibility. Where scientific uncertainty and considerations of economic feasibility prevail, instruments should be drafted so that they can be amended or updated more easily than ordinary agreements. While the CBD is a document of principle with broad aims, the Cartagena Protocol is very specific in its scope and focus. There should thus be room for other protocols under the CBD to deal with biosafety matters, but that fall outside the specific issue of transboundary movement of GMOs. Those areas of the Cartagena Protocol that leave room for interpretation give it a measure of flexibility, but as has been indicated, this should be seen as a criticism of the Protocol rather than a praise. The reason for this is that too much flexibility in the protocol itself might render it useless to those that need it for the protection of their own human and biosafety – the reason why it was drafted in the first place.

The third criterion addresses the issue of definitions and scope of the agreement. A list of substances or activities to be controlled with their exact scientific identification is preferable to a more general definition that leaves too much room for interpretation and ambiguity, and might become redundant with the developments in science and technology. On this point, the Cartagena Protocol does not address specific substances. In Article 3.g. it refers to LMOs as “any living organism that possesses a novel combination of genetic material obtained through the use of modern biotechnology” (Cartagena Protocol, 2000:2). The article dealing with the scope of the Protocol shows that it applies to all living modified organisms (Article 4) with the exclusion of LMOs that are pharmaceuticals for human use (Article 5). The Cartagena Protocol may thus be criticised on this point for not being specific enough, but when the nature of genetic manipulation is considered, this is understandable.

The sensitive issue areas of compliance control and verification requires some form of minimum guarantees against the occurrence of violations to be reliable. Although the Cartagena Protocol's AIA procedure requires notification from states intending to move GMOs across national borders, this criterion is not sufficiently met by the Protocol. In Article 27 the Protocol states that the Parties responsible for the Protocol shall 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" at a next meeting (Cartagena Protocol, 2000:13). Article 34 on compliance indicates that the Protocol does not prescribe any procedures in this regard and that procedures and institutional mechanisms to this effect need to be created. These aspects of the Protocol, together with some of those issues that the Protocol does not resolve, leaves room for interpretation and possible abuse or violation.

The above four lessons will be meaningless unless there is some form of institutional machinery that can oversee issues of administration and operationalisation of plans. With the trade and protection disputes that have frequented the international arena in the past decades, such institutional machines are essential for the establishment of non-partisan frameworks that can ensure that all parties with an interest in the regime/treaty are called to the table and are able to place matters on the agenda. The Biosafety Clearing-House that is created by the Protocol is designed to play this role. The roles, functions, and procedures of the Biosafety Clearing-House are clearly laid out in a number of the articles in the Protocol. It still needs to be tested for efficiency and a judgement as to its expected functioning is premature at this early stage. The greatest test of the Biosafety Clearing-house is likely to be its ability to streamline administrative procedures and to enable developing countries with limited capacities to make full use of the Protocol's regulations.

While the Cartagena Protocol does create a framework to deal with the transboundary movement of GMOs, it should not be seen as the last word on biosafety matters relating to GMOs. Future protocols or regulatory frameworks under the CBD may be negotiated to address the issues not resolved by the Cartagena Protocol. Falkner (2000:299) sees the adoption of the Cartagena Protocol on Biosafety in January 2000 as a "significant achievement in trying to reconcile the

respective needs of trade and the environment". In that sense the Protocol can be seen as a victory for developing countries. The impact that the Cartagena Protocol is likely to have on developing countries is the topic of the next chapter.

CHAPTER 5

IMPLICATIONS OF BIOTECHNOLOGY AND THE CARTAGENA PROTOCOL FOR DEVELOPING COUNTRIES

“Biotechnology and its future impact on all aspects of human society is fraught with many uncertainties” (Russell, 1990:11).

An examination of biotechnology and international relations, the implications of biotechnology for trade and agriculture, and the Cartagena Protocol on Biosafety seem to pose more questions than answers. The only thing that can be said with a fair amount of certainty about the use of biotechnology is that the effects thereof on politics, trade and agriculture have already shown both benevolent and malevolent features in terms of the effects thereof on trade and the environment to both the developed and developing worlds. This chapter examines this double-edged sword characteristic of biotechnology from a developing country perspective. Subsequently the relationship between the Cartagena Protocol and developing country needs is examined with a focus on the need for the establishment and provision of certain global public goods, the protection of biodiversity, and the establishment of enduring food security. The policy options available to developing countries are included in this section.

1. The Likely Consequences of the Introduction of Agricultural Biotechnology into Developing Countries

There is certainly no short supply of advice to developing countries on how to make use of the proposed benefits of biotechnology. It is argued by some that although most biotechnology research and development is still situated in developed countries, developing countries stand to benefit most from plant technologies as they are experiencing the greatest losses incurred by insects, weeds and diseases (Hueth, Kung and Colwell, 1992:362). This will, however, only become true if and when biotechnology research is changed in focus to accompany the nutritional needs of the populations in developing countries, i.e. when research is not primarily focused on crops used in the developed North. Others direct their advice to small farmers and consumers on policies to guide research for the poor, protect against health and

ecological risks, and to regulate the private sector (Pinstrup-Anderson, 1999:1). Some of the benefits that can be derived from the use of GMOs include financial savings for farmers by the reduction of pesticides and fertiliser, and the reduction of pressure on agricultural land through more productive methods (Middleton, 1999:54), improvement in states' economies, reducing hunger and malnourishment and the development of pharmaceutical products (Sagar and Ashiya, 1999 (a):1). However, the introduction of biotechnology into national agricultural systems will not automatically lead to these benefits. Factors that need to be addressed simultaneously to improve the performance and productivity of the agricultural sector are the development of and access to agricultural input, rural extension, rural credit and markets.

Biotechnology may benefit agricultural sectors in poor countries where a specific sector has proven benefits derived from this technology, such as linking small flower farms to "high-quality high-value growth markets" (Galhardi, 1995:650). The use of biotechnology in the production of tubers in Central America is another agricultural area that could benefit. Here the use of biotechnology could lead to foreign exchange savings, an increase in productivity per employee, and even improvement of the livelihood of the small producer in this area (Galhardi, 1995:651-2).

In situations where big business and multinationals become involved in local communities through the introduction of GMOs, it is important that those local communities' development needs are considered. In May 2000, Fred Pierce of the *New Scientist* reported that Monsanto had donated the intellectual property rights (IPR) to work done in collaboration with Florence Wambugu on the sweet potato in Kenya to the local community where she grew up. She indicates that the Kenya Agricultural Research Institute now holds the intellectual property rights "on behalf of the whole of Africa" for the sweet potato genetically manipulated to resist a specific virus (Wambugu, 2000:42).

In her criticism of the anti-GMO stance in Europe, Wambugu (2000:43) states that there are no food shortages on that continent, and she reiterates that "there is a real need and a real hunger here (in Africa)". She also says "GM may be better for Africa than older technologies, like those of the Green Revolution" (Wambugu, 2000:40).

She is concerned with the plight of women in African agriculture who spend more than half of their working time doing weeding. She feels that a reduction of weeding through the introduction of suitable GM food would save women a large amount of labour that could be used more productively on other activities (Wambugu, 2000:41). It is essential to highlight some of the main differences between the Green Revolution¹² and the biotechnology revolution.

A result of the Green Revolution has been the maintenance of a rate of global food production above that of the population growth rate. However, the Green Revolution was the result of public good research through the use of public funds and improved seed was made freely available for distribution and multiplication. The biotechnology revolution, on the other hand, is driven by proprietary science and is already showing characteristics of monopolisation by private firms, which protect IPR with patents that extend beyond the first release (Swaminathan, 2000:38; Pinstруп-Anderson & Cohen, 2000:159).

A second difference between the Green Revolution and the biotechnology revolution is the patenting of processes as well as products. The Green Revolution was characterised by a conventional plant breeding process in the public domain funded by public institutions. In biotechnology, there is an increase in the use of IPR protection for both process and products emanating from that process. This may result in public institutions being denied access to basic knowledge and processes needed for research through the use of IPR (Pinstруп-Anderson & Cohen, 2000:163).

A third difference between the Green and the Gene Revolutions can be found in the application of the different technologies. The technology of the Green Revolution involved the adaptation of industrial country agricultural research to the conditions, requirements and needs found in the developing countries. This stands in contrast to biotechnology, which is developed predominantly for developed country agricultural needs and consumer preferences (Pinstруп-Anderson & Cohen, 2000:163).

¹² The Green Revolution refers to the increases in agricultural production in Third World/Developing countries during the 1960s resulting from international funding of the development and use of hybrid seeds, mechanisation, and pest control (McLean, 1996:211).

There are four particular areas where biotechnology can influence agriculture, namely production levels, industry structure, income distribution, and environmental equality (Hueth, Kung and Colwell, 1992:358). These authors state that patents, proprietary information, trade secrets, and the necessity to price products high enough to recover research and development input costs will impede exchange of information and technology between developed and developing countries. This means that biotechnology, as an emerging technology will not have the desired impact. However, these authors emphasise that agricultural biotechnologies can be “directed to increase the efficiency of small-scale agriculture relative to large-scale agriculture if society so chooses” (Hueth, Kung and Colwell, 1992:360). Suggestions of how this can be done are discussed later in this chapter.

When developed countries adopt new biotechnology processes for crops produced as export commodities in developing countries, it will lead to increases in crop yields and an increase in supply. This, in turn, will lead to a drop in the international price of the crop and will mean a loss in revenue to already poor countries. This should result in job losses in the agricultural sector and could ultimately lead to decreases in foreign exchange earnings and depreciation of currency. Worsening terms of trade will follow and in the worst case, poverty and malnutrition will increase (Galhardi, 1995:642). Examples of the trade impact that the introduction of biotechnology products can have on specific crops include the following (Galhardi, 1995:643-645):

- **Sugar:** Researchers in the North have developed an enzymatic process whereby cereal starch is transformed into high fructose corn syrups (HFCS). This has resulted in a decline of sugar imports by the US. The resultant effect in Latin America has been a reduction of 343 000 tonnes in sugar production and a loss in foreign exchange earnings of US\$ 130 million between 1983 and 1984. The employment and income stability of approximately 2.5 million people directly involved in sugar farming in the continent are attributed to this loss. Estimated reductions in sugar production per country are 50% in the Dominican Republic, 72% in El Salvador, 46% in Nicaragua, 35% in Brazil, and 34% in Argentina.
- **Coffee:** This crop has been an important foreign exchange earner in Latin America and other tropical regions for decades. Importers of coffee from the colder North have developed coffee varieties with frost tolerance, flavour substitution, and lower levels of caffeine. These developments reflect changes in

consumer preferences and effect changes in the demand for traditional coffee varieties. The adverse effect for Latin American agriculture lies in the fact that in all the countries in the region, except for Brazil, Colombia and Costa Rica, coffee production takes place mostly on small farms using family labour. This means that a reduction in imports of traditional coffee varieties impacts directly on thousands of families' income and livelihood.

- **Cocoa:** Cocoa is also largely produced in tropical regions and predominantly on small holdings. The threat from biotechnology to cocoa producing countries lies in the development of cocoa butter alternatives (CBA) from cheaper edible oils such as palm oil. Other biotechnology techniques that threaten the use of coconut are microbial processes, plant micropropagation and enzyme technologies that open the possibilities of producing high value oils from cheap crops such as palms. The Swiss food company, Nestlé, in a joint research venture with the American biotechnology company, Calgene, are attempting the development of cocoa butter substitutes and are trying to alter the composition of cocoa butter. Biotechnology is also used by other researchers to transfer genes from the cocoa plant to soya, which, if successful, could lead to cocoa being produced in consuming countries. The resultant shifts in trade patterns between the North and South and the effects thereof on agricultural jobs in developing countries is not hard to see.

From these three examples it seems that the introduction of biotechnology into agricultural systems in the developed countries of the North has already, and will in future, result in import substitution and job losses in the developing countries of the South. A precise estimate of the effect of declines in demand for developing country export crops on employment "is a speculative exercise beset with difficulties and shortcomings" (Galhardi, 1995:654). As long as the development of biotechnology and its introduction into agricultural systems remains a gradual process, there is opportunity for developing countries with a minimum level of technological capability to improve their production levels and even to migrate to other crops or production methods (Galhardi, 1995:655). However, as will be demonstrated later on, few developing countries will be able to do this without assistance. The needs of developing countries are subsequently discussed in relation to the Cartagena Protocol and the policy options available to developing countries.

2. **Developing Country Needs and the Cartagena Protocol – Policy Options**

Although the Cartagena Protocol provides developing countries with a regime that will enable the management and governing of the transboundary movement of GMOs as well as other mechanism already discussed in Chapter 4, there are pertinent issues it does not resolve, a selection of which are mentioned briefly. Firstly, the precautionary principle may allow some countries to use protectionist measures under the smoke screen that they fear damage to the environment or their own biodiversity, when such fears may not be warranted. Another problem is dealing with trade restrictions resulting from environmental concerns versus the obligations of nations to trade without discrimination under the WTO. Lastly, food security might be used as an excuse to restrict market access. In such an instance a set of rules that guarantees access to available food should be created. In all of these cases multinational corporations and developed countries who advocate free markets need to act in a way that builds the confidence of developing countries in these markets (Runge and Senauer, 2000:50).

Certain articles of the Cartagena Protocol make specific reference to the needs of developing countries. Special provisions are made under Article 11 on procedures for GMOs intended for direct use as food, feed or processing in the absence of a domestic regulatory framework. Least developed and developing countries should be assisted with the implementation of the Protocol through information sharing and the work of the Biosafety Clearing-House. Capacity building of least developed countries, developing countries and small island developing states should take place through the development and/or strengthening of human resources and industrial capacities, and with financial resources and access to and transfer of technology and knowledge through inter-state cooperation (Article 22). Developed country parties to the protocol may provide financial and technological resources for the implementation of the Protocol through bilateral, regional and multilateral channels (Article 28).

As far as structural inequality is concerned, it would be too idealistic to expect a protocol with such a limited scope as the Cartagena Protocol to change much of the socio-economic and political challenges developing countries experience. The

Protocol, however, does provide an indication of technological and agricultural inequalities and what both developed and developing countries can do in practical terms to alleviate some of these. This issue is explored further in Chapter 6.

The need of developing countries to conserve biodiversity and establish food security is approached from a global public good perspective. Before addressing these needs, the concept “global public good” is discussed.

2.1. Developing Countries and Global Public Goods

A “public good” is an economic term referring to goods that, once produced, benefit all of mankind. Global public goods can be understood as “goods that are unlikely to be provided by unregulated markets” (Kaul, Grunberg and Stern in Murphy, 2000:790). Examples of such public goods include national justice systems, norms and standards, a clean environment, and broad-based education. On the supra-national level social scientists talk of global public goods, which include benefits that accrue to all nations, generations, and population groups, such as financial stability, health, peace, and environmental sustainability. The inverse of global public goods can be termed global public bads, which equally affect people across boundaries, such as disease, pollution, and international crime (UNDP, 2000:2).

Public goods have the characteristic that they can be enjoyed by all once they have been established. It will be very difficult for a single person or party to claim ownership of public goods such as education, street names or the use of clean air. Another characteristic of public goods, whether at the local, national, or global level, is that they tend to be limited in their availability and underprovided when established. In other words, goods such as education and a clean environment are not infinite resources that can be treated as products of waste (Kaul, Grunberg & Stern, 2000).

For all nations to contribute to global public goods and to benefit from them, an approach of international cooperation is an essential ingredient of countries’ national policies (UNDP, 2000:2). At the same time, international cooperation must take place within the requirements of equity and justice if it is hoped that representative participation will take place and that the results will be acceptable to all parties. On

the national level it is important for governments to take full responsibility for the cross-border effects (such as the transboundary movement of GMOs) that their citizens and other interest groups (such as MNCs) generate. (Kaul, Grunberg & Stern, 2000). These authors refer to this as the principle of “internalizing externalities”, which is needed to deal effectively with global public goods.

For developing countries and poor communities, the challenge of participation in global public goods becomes a concern. When access is costly, public goods only benefit the rich and equity is not reached. Kaul, Grunberg and Stern (2000) suggest four measures that can be taken to work towards equity in determining global public goods and their utilisation. The first is to introduce better North-South representation in international organisations such as the G-8 and the UN Security Council. The negotiations to secure the Cartagena Protocol is an example of the use of skillful negotiation by developed countries in an attempt to advance only the interests of a handful of states in the face of opposition by all other representatives.

Secondly, globalisation necessitates the inclusion of business and civil society with government in searching for solutions to global problems. The riots that have become synonymous with World Trade Organisation (WTO) and World Economic Forum (WEF) meetings should by now have sent a clear message to government and business that bilateral decision-making to the exclusion of civil society will not secure a lasting solution to the trade and other problems these organisations try to address.

Thirdly, the interests of the voiceless future generations need to be protected by paying specific attention to the long-term effects of policy-decisions. In this instance the use of the precautionary principle in policy decisions about the use of biotechnology and the application of its products seems reasonable until there is more certainty about the long-term effects this technology will have on humanity and the environment.

Lastly, more interdisciplinarity is required to ensure that the costs and benefits of decision-making across political, social, financial, environmental and other boundaries are balanced. In the case of biotechnology, economists and MNCs need

to consult with biologists and interest groups from all parts of the globe before implementing new techniques or introducing new products onto the market. This is not only a responsible way of dealing with new policies, but will also go a long way in building trust between different interest groups, which up to now have dealt with each other mostly in a confrontational manner.

Developing countries not only have difficulty in meeting some of their international obligations, but they are often reluctant to enter new obligations precisely because they lack the confidence of living up to these requirements. I agree with Kaul Grunberg and Stern (2000) who state that "it would often be more efficient for the international community to support poor countries in meeting their commitments than to shoulder the costs of overproduction of global public bads". Thus, it would be cheaper in the long run to assist developing countries with the establishment of knowledge-protection capacities than to continue fighting piracy. This is what these authors call cooperation that is "incentive-compatible", where there are clear net benefits to all participating parties who perceive the benefits as fair. Environmental protection has recently been the cause of conflict rather than cooperation at the global level. One aspect of environmental protection that is a primary need of developing countries is now discussed.

2.2. The Maintenance of Biodiversity

The justification to preserve biodiversity emanates from the fact that "the genetic information it contains is a global public good" (Perrings & Lovett, 1999:301). The preservation of biodiversity is, however, a complicated and formidable challenge in the light of the demands that industrialisation, consumer preferences and new technologies place on the environment. Such conservation efforts have to be conducted on an international and even global level to be effective because ecosystems are rarely contained within the boundaries of single nation-states. Where conservation effectiveness is a concern, it is also necessary to adopt a 'habitat' rather than a 'species' approach in conservation strategies (Perrings & Lovett, 1999:305). This is to ensure that not only so-called valuable species are saved, but that entire food chains remain intact, which is necessary for biodiversity to be maintained. The goal of biodiversity conservation "should not be to safeguard all

wild resources in a limited set of wildlife reserves". The goal should rather be to safeguard "critical biodiversity thresholds" (Perrings & Lovett, 1999:305).

Preserving and maintaining the biodiversity of developing countries is not the explicit objective of the Cartagena Protocol, and there are fears that the use of GMOs will lead to single crop practices, thus contributing to loss of biodiversity. However, like with all technologies, biodiversity loss should not be attributed to the technology itself, but to how it is used. All participants in technology, agriculture and government, therefore, need to take responsibility for the maintenance of biodiversity. Environmentalists also need to be responsible in the way they criticise technological developments, because not all of it has adverse effects on the environment.

The potential for loss of biodiversity caused by the use of biotechnology becomes evident by looking at the effects that agricultural intensification had in Europe. During the last 30 years there have been declines in farmland plants, insects, and birds caused by agricultural intensification on the continent. Contributing factors include less use of crop rotation techniques, increased pesticide efficiency and drift, the use of artificial fertilizers, drainage, and intensification of soil cultivation (McLaughlin and Mineau in Johnson, 2000:135). Britain has documented a list of 200 arable plant species of which 25 are indexed as "Nationally Scarce" and 24 others that are of "conservation concern". Other declines can be seen in the shift towards less diverse, grass-dominated flora and a dramatic decline in British farmland birds with 13 species being red-listed by 1998 (various authors¹³ in Johnson, 2000:135).

One of the criticisms against biotechnology firms and developed countries is the small percentage of research funds spent on testing for biosafety. It seems fair to expect that if a specific technology supports a particular public good criterion, states and international institutions should become involved with its financing. Therefore, the beneficiaries of the profits of agricultural biotechnology are obliged to contribute to the financing of research for assessing biosafety. Similarly, if a private company stands to profit from the sale of new seeds, it should provide sufficient funding for research of the "environmental externalities of its product" (Van Dusen, 2000:2), not

¹³ Authors cited are McLaughlin & Mineau, Kleijn & Snoeing, Siriwardena & others (no date given).

only in the country of origin, but in all ecosystems where it intends selling or releasing its product.

The responsibility of governments and other authorities in maintaining biodiversity should also not be forgotten. The loss of biodiversity does not result merely from the use of biotechnology, but starts with a lack of political will to conserve diversity (Leisinger, 1999:3). There is much that governments can do to contain, stop or prevent the destruction of rainforests, the conversion of native land to agriculture, the replacement of wild lands with monocultures, and overfishing and other practices that have a far greater impact on biodiversity than the use of GM crops (Leisinger, 1999:3). There are four elements that could guide national policy for biodiversity conservation. The first is a regulatory regime to protect key species, habitats and ecological services (including protected areas). The Cartagena Protocol provides states with useful guidelines for the establishment of regulatory mechanisms. Second, is the establishment of an appropriate set of property rights in natural resources (Perrings and Lovett do not define "appropriate"). Third, is a compensation mechanism, and lastly, a supporting structure of incentives and disincentives to induce the desired response (Perrings & Lovett, 1999:305). It is not difficult to see how a strong political will should enable most governments to put at least some of these policies into effect, even in the face of limited resources.

There are other issues of concern that public officials involved with national biosafety policy in developing countries should be aware of. The first is that proprietary science and the shrinking of "public good" research supported from public funds may result in a situation where future technologies are controlled by a small group of privately owned companies. The second is guarding against monocrop practices dominated by monopolies over seed manufacturing and distribution. This could lead to large agricultural areas being covered by only a few crop varieties (genetic strains or hybrids). Genetic homogeneity enhances genetic vulnerability to biotic and abiotic stresses. It can also result in "genetic enslavement", especially if terminator seeds are introduced to developing countries by large agrochemical firms of the North. The third is the impact of GM foods on biodiversity. It is expected to result in genetic erosion through the replacement of a variety of indigenous plants with one or two new varieties. Lastly, policy-makers should strive for equity and justice when the

benefits of biotechnology are distributed amongst interest groups. In the past, conservers of biotechnology and those possessing traditional knowledge have remained poor, while those who exploit this knowledge through biotechnology have become materially rich, resulting in accusations of biopiracy (Swaminathan, 2000:39).

It is important to recognise that current levels of production in intensive agriculture may be sustained for decades to come, but the same may not be true for the consequences that this process will have on social, economic and environmental systems. Caution with the protection of biodiversity is especially important where the long-term consequences of the use of herbicide-tolerant and insect-resistant crops are not yet known with certainty (Johnson, 2000:132) (see Chapter 4 for a discussion of the Precautionary Principle). The importance of maintaining biodiversity and ecological integrity in developing countries is articulated proficiently by Johnson (2000:136):

Environmental damage resulting from the unwise use of biotechnology in agriculture would be a serious issue in developing countries where biodiversity and environmental factors such as unpolluted ground and surface water are fundamental resources used by large numbers of people. Intact and rich ecosystems are important not only for their intrinsic values but also as sources of revenue, whether from sustainable harvesting or from tourism.

A need of developing countries that is closely associated with the protection of biodiversity is that of food security.

2.3. Establishing and Maintaining Food Security

Food security can be defined as the “acquirement of both sufficient and nutritious quantities of food” (Sen in Van Rooyen, 2000:8). This simple definition makes the attainment of food security seem equally simple, yet millions of people are malnourished or starving in the developing and underdeveloped world. One fifth of the global population (an estimated 1.2 billion people) live in absolute poverty, which the World Bank defines as the equivalent or less of US\$1 per day (Pinstrup-Anderson & Cohen, 2000:159). Even more people suffer from micronutrient deficiencies such as iron and vitamin A. An estimated 2 billion people (one in every three) are

anaemic, mostly as a result of iron deficiency. This is why so many authors are of the opinion that poverty causes famine and food insecurity at the individual level (Swaminathan, 2000:40; Altieri & Rossett, 2000; Pinstrup-Anderson & Cohen, 2000).

One of the primary causes of poverty and food insecurity in underdeveloped countries in both urban and rural communities is low productivity levels in agriculture. There are other global problems that contribute to food insecurity. One is increasing populations coupled with a reduction in arable land and water supplies (Swaminathan, 2000:37). In these countries it is precisely agriculture that is expected to be the motor behind economic growth and poverty alleviation. In countries such as Indonesia, South Korea, India, and China, increases in agricultural production through agricultural research, also called the Green Revolution, was the driving force behind the broad-based economic growth and declines in poverty in recent decades (Pinstrup-Anderson & Cohen, 2000:160). Another problem has to do with changes in consumer and spending patterns. Improvements in purchasing power and urbanisation lead to increased demands for animal products, which places an increased burden on food grain requirements. Additionally, marine fish stocks are becoming stagnant or depleted and the ecological foundations of agriculture (land, water, forests, biodiversity, and atmosphere) are damaged at increasing rates. There is also evidence of climate changes and a rise in the sea level.

New technologies, such as biotechnology, cause high levels of excitement in economic and commercial spheres, but its potential impact on societies and the environment are not yet understood or appreciated (Swaminathan, 2000:37). There are a number of developing countries, such as Argentina, Mexico and South Africa, that have demonstrated an interest in the role biotechnology can play in improving the alleviation of hunger and establishing sustainable nutrition. This can best be achieved with a focus on research on more tropical staples that are cheap, labour intensive, give high yields, and are suitable for local soil and climate conditions (Sagar and Ashiya, 1999 (a):2). Unfortunately most of the developments in biotechnology R&D are driven by the trends in markets in the developed world. This research typically focuses on crops that are animal staples and on attributes that minimise labour, thus doing very little to bridge the gap between the rich and the

poor. The question arises what contribution the Cartagena Protocol can make in the improvement of poor countries' food supply.

The Cartagena Protocol has the objective of establishing protection and safety when genetically modified organisms resulting from biotechnology are transferred, handled and used. It is not intended to create mechanisms that will help poor countries increase their food supply. However, this does not mean that it cannot or will not benefit poor countries in this regard. If appropriate biotechnology transfer¹⁴ can take place to developing countries in a timely fashion, it is expected that food supplies can become sustainable if other conditions already mentioned are favourable.

One of the problems with food security is that many states and politicians still regard food self-reliance as a form of national strength that should be sought and guarded jealously. From this nationalist perspective, foreign competition is seen as a threat and leads to protection measures such as that of the United States' sugar, wool and mohair programmes (Runge and Senauer, 2000:42). This phenomenon becomes more pronounced among nations that have a history of food shortages, hunger and malnutrition, such as is commonly found among many developing countries. In India, for example, every five-year plan since its independence in 1947 has been dominated by plans to raise food production and reduce reliance on imports. These efforts were focused on the production of mainly wheat and rice to the exclusion of other crops. This resulted in self-sufficiency in wheat and rice to the extent that by 1995 some of its production could be exported. However, the neglect of other crops and foodstuffs has meant that more than half of India's population is short of energy requirements and 75 percent are protein undernourished (Runge and Senauer, 2000:44).

Such efforts to become food self-sufficient has meant that many developing countries shun international trade as a source of cheaper food, reasoning that international markets are too insecure. Runge and Senauer (2000:41-2) make the point that this attitude has less to do with the stability of markets than with these governments' "aversion" to free markets. Since the inception of the General Agreement on Tariffs

¹⁴ There are a number of issues of which developing countries should be aware when getting involved in the transfer of technology to ensure that it is appropriate. These are discussed in Chapter 6.

and Trade (GATT), agriculture has been a point of contention. However under pressure from the United States and Europe, it was kept off the agenda for the first seven rounds of negotiations. At the Uruguay Round of 1986-93 European and American interests in agriculture were brought to the table when it was argued that freer trade would be adverse to farmers in both these regions. This same period saw the emergence of conflict between environmentalists and agricultural trade liberalisation. It was only when the debates around GMOs emerged that environmentalists and free trade advocates started dealing directly with the effects that trade would have on food security (Runge and Senauer, 2000:45-6). These debates have connected agriculture, trade, the environment, and food security “to form a complex relationship that cries out for a global structure of rules and disciplines” (Runge and Senauer, 2000:47). In this instance the Cartagena Protocol, with its inclusion of the principle of precaution, is a step in that direction.

The role of the WTO in this regard could be to link food security and GM issues to a broader framework of trade regulation, intellectual property, and the environment. Food security as a global common good will have to be dealt with on the supra-national level through rules and mechanisms that are suitable to all role-players. It is a “problem of collective national action that can be pursued only through multilateral policies, just like international commerce or environmental issues” (Runge and Senauer, 2000:48). The provision of food security as a global public good is contingent upon concessions by and negotiated agreements between role-players in both the developed and developing worlds. It entails the improvement of developing countries’ access to cheaper food from exporting developed countries. It also means that developed countries should lower their tariffs on all goods from developing countries so that emerging markets can earn cash to import food. Lastly, the benefits of biotechnology should be accessible to developing countries to enable them to stabilise their food supplies and increase their agricultural production (Runge and Senauer, 2000:39).

Specific food security policies for developing countries can be divided into four broad categories. On the national level *development frameworks* need to be established. It would be ideal if governments could set up biosafety regulatory structures before the introduction of biotechnology into their agricultural systems. The major elements of

effective biosafety systems are written guidelines, structure, roles and responsibilities; well-trained regulatory authorities; an information system and response mechanisms (Cohen, Falconi and Komen, 1999:2-3). Such frameworks need to ensure the availability of food through the establishment of an environment that facilitates the safe use of biotechnology through investment regulation, intellectual property protection, and good governance (Van Rooyen, 2000:8; Persley & Doyle, 1999:3). These frameworks will be greatly enhanced by actively linking biotechnology and information technology. In this way new scientific discoveries worldwide can be assessed and applied to the problems of food insecurity and poverty in a timely manner (Persley and Doyle, 1999:3). Such frameworks are essential elements in securing social improvements through the use of biotechnology. This is the only way to ensure that this technology will reach the broad mass of the population of both genders. This is significant in terms of the benefits of biotechnology on small pieces of land, because of the technology's land-saving characteristics. As Leisinger (1999:2) points out, "(t)he economic and social impact of biotechnology can only be as good as the sociopolitical soil in which new varieties are planted".

On the micro-level *food security for households* needs to be secured through better access to and distribution of income. Attention also needs to be given to improved production capacity to acquire food at the household level. Specific plans need to be designed for the utilisation of nutritious foods on the individual level. Such an approach incorporates the strategies of reducing poverty at the household level and of economic growth and development at the national level (Van Rooyen, 2000:8). Poor communities are especially vulnerable where their diet is concerned. These communities mostly suffer from a lack of energy, protein, and micro-nutrients. Research should focus on those crops that best serve the needs of poor communities, e.g. bananas, cassava, yams, sweet potatoes, rice, maize, wheat, and millet. If biotechnology does not benefit developing countries the mistake will likely not be that of the technology, but because the technology was not given a chance. Where policymakers do decide to make use of biotechnology to the benefit of those at the household level they will need to allocate additional public resources to agricultural research, and to the conversion of social benefits to private benefits so that private sector research can be expanded. This implies that intellectual property

rights will need to be protected – something which is not always appropriate to especially poor farmers who could not afford seeds that become expensive because of protection rights on genetic manipulation (Pinstrup-Anderson, 1999:1).

Strategies for the *minimisation and management of risk* need to be implemented. Determining priorities and assessing relative risks and benefits need to be done in consultation with the poor. This needs to be followed by designing policies that minimise technology-transcending risks that adversely affect the poor (Persley and Doyle, 1999:3). Pinstrup-Anderson (1999:2) states that GM foods are not “intrinsically good or bad for human health”. How GM foods affect health depends on their specific content and the possibility of causing allergic reactions. In these cases, GM foods should be labeled clearly to indicate such risks. This also applies to foods of which the content or process of manufacturing may have cultural or religious significance. Policymakers need to be wary of herbicide resistance from GM plants to other plants that are not modified, and resistance to GM plants in insect populations when drafting policy to deal with ecological risks. Food security and biosafety regulations should heed international agreements and give an indication of a society’s acceptable risk levels, including “the risks associated with not using modern biotechnology to achieve desired goals” (Pinstrup-Anderson, 1999:3). The practical implication of implementing such policies means that developing countries will need a minimum amount of human and technical capacity to carry out biosafety tests, something which many poor countries lack (see Chapter 6 for suggestions on capacity building).

The *role of government and the private sector* in the use and management of biotechnology needs to be clear. A first policy objective could be to determine what investments governments and the international development community will have to make in human and financial resources in order to ensure that biosolutions to the problems of food security reach the poor. I agree with Pinstrup-Anderson and Cohen (2000:161) that it is of particular importance to developing countries to have public investment in agricultural research for them to achieve food security. Yet, low-income developing countries still spend only 0.5 percent of the value of their agricultural production on agricultural research, compared to 2 percent in more developed countries. In Sub-Saharan Africa there are only 42 agricultural

researchers per million economically active persons in agriculture, compared to 2458 in industrial countries (Pardy and Alston in Pinstруп-Anderson & Cohen, 2000:160). In many developing countries the availability of funds is not always the problem, but rather the way that funds are allocated to wasteful projects and resources that do not always benefit the poor. The obligation of private companies is to ensure that the results of research and development are not beyond the reach of the poor because of price difficulties and escalations. Leisinger (1999:2-3) suggests that this information be made available free or on favourable conditions. Effective antitrust legislation and institutions to enforce legislation are needed, especially in small developing countries where one or only a few seed distribution companies operate. Effective legislation means that intellectual property rights must be enforced in agreement with both the WTO rules and the CBD (Pinstруп-Anderson, 1999:3). However, the differences in the application of IPR between these two organisations need to be reconciled.

Officials involved in public policy making for agricultural research need to consider those areas of research that can compliment work done in the private sector. It is expected that the private sector will focus its attention on crops that will have commercial value in the developed world and in the process neglect those crops that are used by poor farmers and that are utilised by developing countries. Additionally, the private research sector can be expected to be less sensitive to environmental concerns than the public sector. It is thus a daunting task that faces the public sector in its efforts to ensure that poor farmers can still make a sustainable living (Barton, 1999:2). The final chapter examines some of these challenges and constraints developing countries face when dealing with capacity building in the introduction, use, and management of biotechnology in their agricultural systems.

CHAPTER 6

CONCLUSIONS - CHALLENGES AND CONTRAINTS FACING DEVELOPING COUNTRIES

“(T)he transfer of technology will be a dominant issue in international political economy for some time to come” (David Balaam & Michael Veseth, 1996:200).

In the previous chapter the likely effects of the use of biotechnology by developing countries in their agricultural systems were examined together with the specific needs and policy options of these countries. In this chapter, the challenges and constraints in capacity building facing developing countries when dealing with biotechnology, as well as some general conclusions are dealt with. This is done in three sections, starting with those capacities needed to govern the use of biotechnology and the institutional frameworks needed to do so. This is followed by a look at those capacities needed by developing countries to close the so-called knowledge gap that exists between them and the developed world. Developing countries lack human capacity when it comes to education in science, engineering and technology. If they intend to make use of biotechnology, there are very specific capacities that need to be developed. The chapter concludes with a brief examination of the challenges facing recipients of technology before, during and after the process of technology transfer and an opinion on the worth of the Cartagena Protocol.

1. Institutional Infrastructure and Governance Capacities

Developing countries could benefit from biotechnology if they can succeed in harnessing its potential as a mechanism to increase levels of agricultural production and to establish food security. Conversely, biotechnology could harm developing countries if they were to become the dumping grounds for untested genetically modified organisms and continue to be excluded from rule making in the international trade and production arenas. It is therefore imperative for these countries to establish and maintain minimum regulatory frameworks to deal with the transboundary movement of GMOs. On the international level, Barton (1999:3) expects significant political pressure on national governments to comply with TRIPs under the WTO. For those countries that do not have the competency to do this,

certain enabling measures can be taken. Appropriate legal training in the court structures, private firms and law schools should establish structures of competency as far as the rules of TRIPs are concerned, because the fundamental standards and compromises of TRIPs are unlikely to change. At the same time, it could lead to a more informed public opinion and meaningful debate on biotechnology issues. It is vital for poor nations to develop their legal and scientific human resources into systems with competence in dealing with these complex issues, because they will be faced with policy questions that “combine issues of science with issues of intellectual property, competition law, and international trade” (Barton, 1999:3). Failure in these arenas could seriously compromise developing country agricultural systems.

The Cartagena Protocol has removed a lot of the guesswork for countries lacking the expertise or finance to institute such mechanisms where biotechnology is concerned. The Cartagena Protocol was designed to strengthen the regulatory powers of developing countries (Krasner, 2000:310) by specifying certain procedures (e.g. the Advance Informed Agreement Procedure of Article 7 and the Decision Procedure of Article 10) and by indicating to countries how to handle documentation (Transport, Packaging and Identification in Article 18) and set up national focal points (Article 19). Article 22 states specifically that parties to the Protocol “shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology”. The subsequent paragraph makes it clear that the needs of developing countries with regard to financial resources and technology transfer “shall be taken fully into account for capacity-building in biosafety” (CBD, 2000:12). It remains to be seen how much assistance and consideration developing countries will receive from developed countries in the development of these capacities. On the national level there are also certain capacities that government and institutional frameworks dealing with biotechnology issues will have to contend with.

Firstly, policymakers, researchers and scientists involved with the introduction of biotechnology to developing countries need to determine the benefits and risks of biotechnology applications in their particular countries. Identifying essential productivity constraints and deciding to what extent a national research agenda should embrace technology can follow this. The important question national

agriculture research systems (NARS) face is how to integrate biotechnology into existing research programmes and priorities. This can only be done with adequate consideration of the high development costs, new demands on human, financial, and managerial resources, international collaboration, negative public perceptions, safety problems and intellectual property rights dilemmas that biotechnology brings (Cohen, Falconi and Komen, 1999:1).

Secondly, developing countries need to consider the four major elements of effective biosafety systems. They are (a) written guidelines that define the structure of the system and the roles and responsibility of all interest groups; (b) well-trained regulatory authorities; (c) an information system; and (d) response mechanisms. This can be followed by the definition of a clear research agenda by determining what the main constraints in agriculture are. Other issues in need of consideration are national capacity; cost of R&D and infrastructure; regulations for risk assessment of new products; managing IPRs; creating delivery systems; and establishing suitable institutional and legal frameworks for managing IP (Cohen, Falconi and Komen, 1999:2-3). It seems that developing countries have a difficult task ahead of them where policy choices will not be made any easier by the emotive nature of some of the debates surrounding these issues.

Developing countries need further to acquire managerial, analytical, and technical strengths in order to build a strong national capacity for understanding and analysing biotechnology problems, policies and issues (Cohen, Falconi and Komen, 1999:3). Unfortunately there are various funding constraints that prohibit this. Reasons for funding constraints that pose a challenge include the implementation of fiscal austerity policies, a lack of understanding of biotechnology among policymakers, insufficient research impact, dependence of funds from a single source, and a lack of political or financial support from agribusiness and farmers and their organisations (Cohen, Falconi and Komen, 1999:3). Agricultural problems facing small farmers in developing countries that policymakers dealing with biotechnology should be aware of include crop losses due to insects, diseases, weeds, and drought, which all affect income and food supply. Further problems include acid soils, low soil fertility and lack of access to cheaper fertilisers; poor infrastructures and dysfunctional markets

for inputs and outputs; and lack of access to credit and technical assistance (Pinstrup-Anderson, 1999:1).

An improvement in the regulatory environment through for example the adoption of biosafety procedures can provide a suitable environment for biotechnology research. Sagar and Ashiya (1999 (a):2) contend that “a redirection in research efforts will require new incentives for the private sector to support research efforts responsive to developing country needs”.. However, biosafety measures cannot be effectively implemented without adequate institutional and human capacity at the national level (Juma and Gupta, 1999:2). Capacity building as an essential area for international cooperation was already identified in the draft biosafety protocol. Together with this, it is important that the public is involved in risk assessment and decision making where GMOs are concerned. In this regard, it is not sufficient just to provide the public with information. What is needed is for a relationship of trust to be established between “science and society” (Juma and Gupta, 1999:3). Such a relationship will not develop if the risk assessment process lacks transparency and if data where ongoing field trials are held is not published (Van Dusen, 2000:2). This means that biotechnology will also have to be managed on the local level where indigenous and rural communities’ basic needs have to be addressed. It is here where the globalised nature of technology, development, knowledge rights and trade issues show clear signs of interconnectedness and cross-boundary influences.

Indigenous people need to conserve traditional medical and crop-cultivation knowledge and practices which are threatened by modernisation and shifting cultural values and patterns. The World Intellectual Property Organisation (WIPO) has decided to explore the intellectual property needs, rights, and expectations of holders of traditional knowledge, innovations, and culture. This is a necessary step in widening conceptualisations of intellectual property rights (IPR). From an ethical perspective it is vital that this component of IPR be included when the TRIPs (Trade Related Aspects of Intellectual property Rights) agreement of the World Trade Organisation (WTO) is reviewed. If policy-makers and high-level decision-makers are serious about the nature of public interest and want societies to have trust in the development of biotechnology, it is also crucial that they pay attention to complete

disclosure of information, decision-making in an open and transparent manner, and to involving all stakeholders in the process (Sagar and Ashiya, 1999 (a):3).

There seems to be a lack of objectivity in the discussion of policy issues associated with biotechnology. Discussions are often sidetracked by ideological positions that do not allow for plurality of viewpoints or policy options. Critics of biotechnology see only the disadvantages associated with the technology to the extent where it has been branded as an “evil” or “sinister” force (Wiegele, 1991:30). On the other hand, the proponents of especially commercial biotechnology often disregard (traditional) public concerns and conceptions of life and morality that conflict with new science and technology methods. These disputes are not made any easier by the hitherto lack of agreement on methods of assessing risks associated with the release of genetically manipulated organisms (Wiegele, 1991:36). One of the greatest challenges GMOs pose in terms of policy-making, is finding a way to give companies a fair return on their innovation, science, engineering and technology expenditures, while at the same time ensuring that poor farmers and indigenous communities develop and maintain sustainable livelihoods (Middleton, 1999:54). But these changes will not come easily. The difficulties of such changes are reflected in the following words of Robert Cox: “The reconstruction of society and political authority from the bottom up would require a different sense of the polity: one that put emphasis on arousing capacities for collective action inspired by common purposes” (Cox, 1995:45). To do this, human and technical capacities need to be established and expanded to aid better understanding of the nature and complexities of biotechnology.

2. Building Human Capacities

Biotechnology can only benefit developing countries if the necessary institutional and societal infrastructure is in place to handle its introduction and governance. A vital component of this infrastructure is a basic science capacity “to surround the biotechnology sector” and to allow for objective decision-making on risks and benefits (Van Dusen, 2000:1). There are four major constraints to the development of biotechnology infrastructure and application in developing countries cited by Hueth, Kung and Collwell (1992). They are:

- A lack of information exchange between scientists from developed and developing countries because of the treatment of such information as property.
- The development by multinational corporations of technologies inappropriate to developing countries.
- The lack of scientific skills and personnel in developing countries to develop appropriate technologies.
- Inadequate labour and management skills for the successful implementation and use of advanced technologies.

These constraints point to two factors. The first two constraints indicate that because developed countries, influenced by their powerful multinational industries, treat knowledge products emanating from biotechnology as economic resources with proprietary value, they are reluctant to share this resource with others unless they can be compensated for their research and development expenditure. It further indicates that biotechnology research and development in the North is focused solely on the needs of consumers in developed countries, a point that has been stated and explained before. Because private companies and MNCs dominate biotechnology in these countries, the only motive is profit in the short term with little attention given to the effects it has on maintaining biodiversity. Furthermore, these countries' comparative advantage in the biotechnology sector is likely to be enhanced in the future because they do most of the research and development (Hueth, Kung and Colwell, 1992:363). The second two constraints point to the lack of capacity in the developing world to enter into and make use of the benefits of biotechnology. This is evidence, once again, of the unequal distribution of power and capacity between developed and developing countries. The existence of regulatory mechanisms such as the Cartagena Protocol is important for the protection of at least some of the basic interests of developing countries. The Protocol provides a framework with practical measures that can be used to regulate the movement of GMOs. It also places a responsibility on developed countries not to turn a blind eye to the specific needs of the least developed and developing countries.

Developing countries might find it extremely difficult to develop the broad range of skills and educational infrastructure that is required by the nature of biotechnology (Wiegele, 1991:23). An inability or refusal to enter the commercial or political

relationships of the biotechnology arena could exacerbate this. There are various problems in developing countries for which biotechnology seems to provide some solutions. However, as Hueth, Kung and Colwell (1992:367) rightly point out, the success of the use of biotechnology by developing countries depends on the assistance by international organisations and “institution building”. They suggest that developing countries form “joint ventures” with the private sector or multinational firms in an effort to ensure that appropriate technologies are developed.

Issues of particular concern to developing countries are “the challenges to and opportunities for science and technology-led international development” (Hassan, 2000:1). Two critical challenges need to be met. First is the growing disparities in the “production and utilisation” of scientific and technological knowledge between developed and developing countries. The challenge here for developing countries is to close the knowledge gap and to respond to and benefit from globalisation by building capacity in science, technology and knowledge which will work towards sustainable economic growth (Hassan, 2000:3). Sagar and Ashiya (1999 (a):2) support this view when they say that the development of the “relevant national technological capabilities is crucial for any developing country to adapt, implement, diffuse and innovate in a new sector of technology”. One way of doing this is by means of appropriate and timely technology transfer, which is discussed in the following section. Second is the growing complexity of environmental problems impeding developing countries’ transition to environmentally and equitably sustainable development. This challenge is related to the depletion of biological resources, desertification, climate change, air and water pollution, and the negative impact thereof on poverty, health, food, and energy and water shortage. It is of the utmost importance to developing countries to maintain their biodiversity and to implement and use technologies that do not degrade their fragile environments in the long term. Unfortunately modern technology and development tend to have just the opposite effect if one considers the magnitude of environmental degradation in the industrialised North. This also holds true in certain instances of technology transfer, an aspect of capacity building which is often recognised but trivialised due to inadequate attention being paid to the specific needs and circumstances of local communities, especially in rural areas.

3. Technology Transfer as a Mode of Capacity Building

The origins of international technology transfer can be traced back to President Truman of the United States when he submitted a programme for development to Congress during his tenure of 1945-53. Point four of the programme presented the idea that the standard of living of non-industrialised people and countries could be improved by technology (Ogburn, 1957:4). During the 1940s and 1950s, American business leaders recognised the potential growth in their markets of exporting new technology to so-called backward people who had been eking out a living in agrarian simplicity up to then. This realisation was soon informed by the experience that knowledge of the use and repair of the transferred “machinery” that accompanied the technology was necessary (Ogburn, 1957:5). Thus, technology transfer from developed to developing countries was “born”.

Modern agriculture can be seen as “an industry which applies technology to the soil” (Miller, 1957:324). Advances in technology that have influenced agriculture were already recognised in the 1950s. The following technological improvements to agriculture mentioned by Miller (1957:324) illustrate this: mechanisation and electrification, improvement of plants and animals through breeding and selection (early forms of “genetic engineering”), the use of fertilisers and other additives to improve soil quality, and improvements in managerial and marketing techniques. These are all processes intended to improve agriculture in terms of higher production levels, pest and disease resistant crops and livestock, and reduction in labour intensive processes. However, innovations such as the processes involved in biotechnology have the potential to become a part of the problem instead of the solution. Ecological disruption caused by fertilisers, pesticides and herbicides, as well as the possibility that products of this technology may become “out of control” because of unforeseen results or circumstances, are a cause of concern (Wilson, 1992:321). It is here where receivers of technology transfer need to pay particular attention to the nature of the product or process being transferred.

Recipients of technology need to determine which specific technology is involved and in which form it will be transferred. Technology often involves proprietary systems and intellectual property rights of which the receiver should be aware. The transfer

costs involved with the new technology should also be stipulated. Particular attention should be paid to possible hidden costs involved with the future control of the technology or other rights that the originator of the technology might claim, such as with purchasing clauses, licensing, patents, legal expenses and copy rights. Developing countries also need to be aware of the stage of development and maturity of the technology they are to receive. MNCs and industrialised countries sometimes transfer their older technologies that might not comply with their home countries' health and safety regulations anymore. Lastly the mode of technology transfer is important as different originators of technology handle their products in different manners. The mode of inter-firm transfer will differ from the mode used between firms and states, NGOs and states, or MNCs and local communities. Developing countries need to be aware that private originators of technology have a financial profit interest that they will want to protect. MNCs and private firms tend to protect their ownership more vigorously in an effort to regain their investment in research and development and in keeping with the IPR they have established over their product (Fourie, 2000:89-91; Wilson, 1992:319).

Other factors developing countries need to consider when taking part in technology transfer include the following:

- They need to ensure that they will be able to transfer capacity with the technology. The transfer of the technology on its own will not suffice. Receivers of technology will need to operate and maintain their new equipment and this requires new skills and competencies that need to be developed. This involves not only the ability to handle and use the technology, but also to develop local human and institutional capacities to deal with the technology in the long term.
- The transfer should also be seen as successful only when the technology can be indigenised with the recipient country's culture and social circumstances. It should be remembered that technology is not value free or value neutral. It is a reflection of the culture in which it originates (Anderson in Wilson, 1992) and carries the code of a society's genetics with it (Reddy in Wilson, 1992).
- Lastly, where appropriateness is concerned, recipient countries need to assess whether their physical environments are suited for the introduction of the technology intended for transfer. Climatic conditions, topography, and

ecosystems need to be considered for suitability (Fourie, 2000:95-98; Wilson, 1992:319).

The process of technology transfer will be greatly enhanced by disseminating any results of research done on the specific technology in a user-friendly manner to the recipient. Simultaneously and wherever possible, the farmers' needs and problems have to be communicated to the researchers, which, if done properly, will include an assessment of household systems and production constraints (Van Rooyen & Bembridge, 1998:84). Such feedback on farmers' problems is the only meaningful way of ensuring that technology transfer to rural communities is "adaptive, relevant and acceptable to farmers" (Van Rooyen and Bembridge, 1998:85). Thus, the complexity of the technology and its expected long term impacts on the environment need to be known for the recipient country to partake in the transfer with confidence. Put in another way, recipients should be able to control the technology, the technology should not control the recipient. The phenomenon where technology starts determining the nature of society is what Wilson (1992:322) calls technological determinism. In the countries of the developed world societies have accepted this phenomenon because their exposure to new technologies has been gradual compared to that of developing countries that have to make revolutionary adaptations to their habits and cultures in the face of rapid technology transfers. The following statement by Galbraith (in Wilson, 1992:322) made in 1972 illustrates how such economic determinism through technology transfer may end up being yet another form of neo-colonialism: "The imperatives of technology, not the images of ideology, are what determine the shape of economic society".

4. Biotechnology and Developing Country Prospects

This study set out to explore and describe some of the most pertinent issues about biotechnology in international political economy, specifically its role in international relations, trade, and agriculture. It seems that developing countries have held onto the wrong end of the stick where the governance, trade and regulation of biotechnology have been concerned. It was demonstrated that poor countries have, until the Cartagena Protocol, been kept at the periphery of decisions concerning their own and other natural resources that could be enhanced through biotechnology. The

Cartagena Protocol on biosafety, however, is a regulatory framework that seeks to correct some of these imbalances by addressing the specific needs of developing countries, especially where their interests in terms of safety during the transboundary movement of GMOs are concerned. This protocol also has broader implications for the way that global public goods, biosafety, and food supply will be handled in the future. Unfortunately the challenges and constraints facing developing countries when dealing with these biotechnology issues are extremely daunting and may at times seem insurmountable.

Modern biotechnology does not hold all the answers to food insecurity and poverty. Biotechnology does, however, hold significant advantages in certain areas for specific communities if it can be given a chance through well thought out policies. These policies should guide increased public investment in research and development in biotechnology and make provision for regulatory mechanisms that inform and protect the public from any risks arising from the release of GMOs. They should also make provision for intellectual property management to encourage greater private-sector investment; and have the capacity to regulate the private seed and agricultural research sector so that the interests of small farmers and poor consumers in developing countries are protected (Persley and Doyle, 1999:2).

The development challenges facing poor countries certainly seem very daunting. Without the building of relevant capacities, the challenges of dealing with new mechanisms such as the Cartagena Protocol on Biosafety seem almost insurmountable. These challenges are made even more difficult by the quagmire of opposing opinions and moral and ethic viewpoints on issues such as the introduction of genetically manipulated organisms. Leisinger (1999) aptly indicates that the controversies over biotechnology have a lot to do with the plurality of opinion that is expressed as well as the lack of balance with which many arguments are presented. He cautions that because we live in heterogeneous social systems with a plurality of value judgements and interests, we should expect different evaluations to exist. On the one side it is evident that biotechnology has a lot to offer in terms of alleviating food shortages and helping poor communities with their food supplies and environmental sustainability. On the other hand, it is also true that the use of biotechnology products does entail certain economic, social and ecological risks, but

that not all of these risks are necessarily the result of the technology itself. The question, thus, should not be: "Should we use biotechnology?". The use of this technology can and will not be stopped by treaties, protocols, environmental activists or any other grouping or mechanism. The question should rather be, "How can this technology be used in a safe manner to benefit all in society who want to make use of it?". In the final analysis it needs to be asked if the Cartagena Protocol will mean anything to developing countries. Phrased in Coxian/Gramscian terms: What prospects do developing countries and communities have of seeing this protocol change any of the agricultural predicaments they experience?

The theoretical orthodoxy (realism/neo-realism) that has reigned during the best part of the twentieth century no longer adequately accounts for the changes that have taken place during the last two decades. These changes have been cited repeatedly by various scholars, a comprehensive list of which would be nigh impossible to assemble. Suffice it to say that events such as the demise of the Soviet Union, the establishment of a European Community, the end of the so-called Cold War, the dramatic advances made in communications and service delivery together with renewed nationalist, ethnic and cultural sentiments (the combined effects of which are popularly referred to as globalisation), and a surge in environmental awareness and activism in the light of pollution, natural resource depletion, and changes in global climatic patterns have altered dramatically the way individuals and society experience reality. This "ontological shift", as Cox calls it, is evident in many aspects of political economy: the prospect of a post-Westphalian order; economic globalisation and societal restructuring; the intervention of the biosphere into world politics; and the "implications of a multicultural post-hegemonic world order (Cox, 1995:36).

It is with the role of the biosphere in international political economics, that this thesis is concerned. The Cartagena Protocol is one of the first supra-state institutionalised mechanisms that could effect marked changes in the way humans have organised their relationship with nature. It may be part of a "countermovement", as Cox (1995:40-1) calls it, to the disruption caused by the restructuring of production, the consequences of which include a shift from dominant subordinate relationships at the national economy level to the social relationship level; the marginalisation of the

majority of the world's population into obscurity and poverty; and a mass migration from South to North and from East to West. In other words, the significance of the Cartagena Protocol lies in its potential to be part of a real starting point of a change in our ontology of global power relationships.

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APPENDIX A

CARTAGENA PROTOCOL ON BIOSAFETY TO THE CONVENTION ON BIOLOGICAL DIVERSITY

The Parties to this Protocol,

Being Parties to the Convention on Biological Diversity, hereinafter referred to as "the Convention",

Recalling Article 19, paragraphs 3 and 4, and Articles 8 (g) and 17 of the Convention,

Recalling also decision II/5 of 17 November 1995 of the Conference of the Parties to the Convention to develop a Protocol on biosafety, specifically focusing on transboundary movement of any living modified organism resulting from modern biotechnology that may have adverse effect on the conservation and sustainable use of biological diversity, setting out for consideration, in particular, appropriate procedures for advance informed agreement,

Reaffirming the precautionary approach contained in Principle 15 of the Rio Declaration on Environment and Development,

Aware of the rapid expansion of modern biotechnology and the growing public concern over its potential adverse effects on biological diversity, taking also into account risks to human health,

Recognizing that modern biotechnology has great potential for human well-being if developed and used with adequate safety measures for the environment and human health,

Recognizing also the crucial importance to humankind of centres of origin and centres of genetic diversity,

Taking into account the limited capabilities of many countries, particularly developing countries, to cope with the nature and scale of known and potential risks associated with living modified organisms,

Recognizing that trade and environment agreements should be mutually supportive with a view to achieving sustainable development,

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,

Have agreed as follows:

Article 1

OBJECTIVE

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.

Article 2

GENERAL PROVISIONS

1. Each Party shall take necessary and appropriate legal, administrative and other measures to implement its obligations under this Protocol.
2. The Parties shall ensure that the development, handling, transport, use, transfer and release of any living modified organisms are undertaken in a manner that prevents or reduces the risks to biological diversity, taking also into account risks to human health.
3. Nothing in this Protocol shall affect in any way the sovereignty of States over their territorial sea established in accordance with international law, and the sovereign rights and the jurisdiction which States have in their exclusive economic zones and their continental shelves in accordance with international law, and the exercise by ships and aircraft of all States of navigational rights and freedoms as provided for in international law and as reflected in relevant international instruments.
4. Nothing in this Protocol shall be interpreted as restricting the right of a Party to take action that is more protective of the conservation and sustainable use of biological diversity than that called for in this Protocol, provided that such action is consistent with the objective and the provisions of this Protocol and is in accordance with that Party's other obligations under international law.
5. The Parties are encouraged to take into account, as appropriate, available expertise, instruments and work undertaken in international forums with competence in the area of risks to human health.

Article 3

USE OF TERMS

For the purposes of this Protocol:

- (a) "Conference of the Parties" means the Conference of the Parties to the Convention;
- (b) "Contained use" means any operation, undertaken within a facility, installation or other physical structure, which involves living modified organisms that are controlled by specific measures that effectively limit their contact with, and their impact on, the external environment;
- (c) "Export" means intentional transboundary movement from one Party to another Party;
- (d) "Exporter" means any legal or natural person, under the jurisdiction of the Party of export, who arranges for a living modified organism to be exported;
- (e) "Import" means intentional transboundary movement into one Party from another Party;
- (f) "Importer" means any legal or natural person, under the jurisdiction of the Party of import, who arranges for a living modified organism to be imported;
- (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;

(j) "Regional economic integration organization" means an organization constituted by sovereign States of a given region, to which its member States have transferred competence in respect of matters governed by this Protocol and which has been duly authorized, in accordance with its internal procedures, to sign, ratify, accept, approve or accede to it;

(k) "Transboundary movement" means the movement of a living modified organism from one Party to another Party, save that for the purposes of Articles 17 and 24 transboundary movement extends to movement between Parties and non-Parties.

Article 4

SCOPE

This Protocol shall apply to the transboundary movement, transit, handling and use of all living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Article 5

PHARMACEUTICALS

Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to the making of decisions on import, this Protocol shall not apply to the transboundary movement of living modified organisms which are pharmaceuticals for humans that are addressed by other relevant international agreements or organisations.

Article 6

TRANSIT AND CONTAINED USE

1. Notwithstanding Article 4 and without prejudice to any right of a Party of transit to regulate the transport of living modified organisms through its territory and make available to the Biosafety Clearing-House, any decision of that Party, subject to Article 2, paragraph 3, regarding the transit through its territory of a specific living modified organism, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to living modified organisms in transit.

2. Notwithstanding Article 4 and without prejudice to any right of a Party to subject all living modified organisms to risk assessment prior to decisions on import and to set standards for contained use within its jurisdiction, the provisions of this Protocol with respect to the advance informed agreement procedure shall not apply to the transboundary movement of living modified organisms destined for contained use undertaken in accordance with the standards of the Party of import.

Article 7

APPLICATION OF THE ADVANCE INFORMED AGREEMENT PROCEDURE

1. Subject to Articles 5 and 6, the advance informed agreement procedure in Articles 8 to 10 and 12 shall apply prior to the first intentional transboundary movement of living modified organisms for intentional introduction into the environment of the Party of import.
2. "Intentional introduction into the environment" in paragraph 1 above, does not refer to living modified organisms intended for direct use as food or feed, or for processing.
3. Article 11 shall apply prior to the first transboundary movement of living modified organisms intended for direct use as food or feed, or for processing.
4. The advance informed agreement procedure shall not apply to the intentional transboundary movement of living modified organisms identified in a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol as being not likely to have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health.

Article 8

NOTIFICATION

1. The Party of export shall notify, or require the exporter to ensure notification to, in writing, the competent national authority of the Party of import prior to the intentional transboundary movement of a living modified organism that falls within the scope of Article 7, paragraph 1. The notification shall contain, at a minimum, the information specified in Annex I.
2. The Party of export shall ensure that there is a legal requirement for the accuracy of information provided by the exporter.

Article 9

ACKNOWLEDGEMENT OF RECEIPT OF NOTIFICATION

1. The Party of import shall acknowledge receipt of the notification, in writing, to the notifier within ninety days of its receipt.
2. The acknowledgement shall state:
 - (a) The date of receipt of the notification;
 - (b) Whether the notification, prima facie, contains the information referred to in Article 8;
 - (c) Whether to proceed according to the domestic regulatory framework of the Party of import or according to the procedure specified in Article 10.
3. The domestic regulatory framework referred to in paragraph 2 (c) above, shall be consistent with this Protocol.
4. A failure by the Party of import to acknowledge receipt of a notification shall not imply its consent to an intentional transboundary movement.

Article 10

DECISION PROCEDURE

1. Decisions taken by the Party of import shall be in accordance with Article 15.
2. The Party of import shall, within the period of time referred to in Article 9, inform the notifier, in writing, whether the intentional transboundary movement may proceed:
 - (a) Only after the Party of import has given its written consent; or
 - (b) After no less than ninety days without a subsequent written consent.
3. Within two hundred and seventy days of the date of receipt of notification, the Party of import shall communicate, in writing, to the notifier and to the Biosafety Clearing-House the decision referred to in paragraph 2 (a) above:
 - (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;
 - (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.
4. Except in a case in which consent is unconditional, a decision under paragraph 3 above, shall set out the reasons on which it is based.
5. A failure by the Party of import to communicate its decision within two hundred and seventy days of the date of receipt of the notification shall not imply its consent to an intentional transboundary movement.
6. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of the living modified organism in question as referred to in paragraph 3 above, in order to avoid or minimize such potential adverse effects.
7. The Conference of the Parties serving as the meeting of the Parties shall, at its first meeting, decide upon appropriate procedures and mechanisms to facilitate decision-making by Parties of import.

Article 11

PROCEDURE FOR LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING

1. A Party that makes a final decision regarding domestic use, including placing on the market, of a living modified organism that may be subject to transboundary movement for direct use as food or feed, or for processing shall, within fifteen days of making that decision, inform the Parties through the Biosafety Clearing-House. This information shall contain, at a minimum, the information specified in Annex II. The

Party shall provide a copy of the information, in writing, to the national focal point of each Party that informs the Secretariat in advance that it does not have access to the Biosafety Clearing-House. This provision shall not apply to decisions regarding field trials.

2. The Party making a decision under paragraph 1 above, shall ensure that there is a legal requirement for the accuracy of information provided by the applicant.

3. Any Party may request additional information from the authority identified in paragraph (b) of Annex II.

4. A Party may take a decision on the import of living modified organisms intended for direct use as food or feed, or for processing, under its domestic regulatory framework that is consistent with the objective of this Protocol.

5. Each Party shall make available to the Biosafety Clearing-House copies of any national laws, regulations and guidelines applicable to the import of living modified organisms intended for direct use as food or feed, or for processing, if available.

6. A developing country Party or a Party with an economy in transition may, in the absence of the domestic regulatory framework referred to in paragraph 4 above, and in exercise of its domestic jurisdiction, declare through the Biosafety Clearing-House that its decision prior to the first import of a living modified organism intended for direct use as food or feed, or for processing, on which information has been provided under paragraph 1 above, will be taken according to the following:

(a) A risk assessment undertaken in accordance with Annex III; and

(b) A decision made within a predictable timeframe, not exceeding two hundred and seventy days.

7. Failure by a Party to communicate its decision according to paragraph 6 above, shall not imply its consent or refusal to the import of a living modified organism intended for direct use as food or feed, or for processing, unless otherwise specified by the Party.

8. Lack of scientific certainty due to insufficient relevant scientific information and knowledge regarding the extent of the potential adverse effects of a living modified organism on the conservation and sustainable use of biological diversity in the Party of import, taking also into account risks to human health, shall not prevent that Party from taking a decision, as appropriate, with regard to the import of that living modified organism intended for direct use as food or feed, or for processing, in order to avoid or minimize such potential adverse effects.

9. A Party may indicate its needs for financial and technical assistance and capacity-building with respect to living modified organisms intended for direct use as food or feed, or for processing. Parties shall cooperate to meet these needs in accordance with Articles 22 and 28.

Article 12

REVIEW OF DECISIONS

1. A Party of import may, at any time, in light of new scientific information on potential adverse effects on the conservation and sustainable use of biological diversity, taking also into account the risks to human health, review and change a decision regarding an intentional transboundary movement. In such case, the Party shall, within thirty days, inform any notifier that has previously notified movements of the living modified organism referred to in such decision, as well as the Biosafety Clearing-House, and shall set out the reasons for its decision.

2. A Party of export or a notifier may request the Party of import to review a decision it has made in respect of it under Article 10 where the Party of export or the notifier considers that:

(a) A change in circumstances has occurred that may influence the outcome of the risk assessment upon which the decision was based; or

(b) Additional relevant scientific or technical information has become available.

3. The Party of import shall respond in writing to such a request within ninety days and set out the reasons for its decision.

4. The Party of import may, at its discretion, require a risk assessment for subsequent imports.

Article 13

SIMPLIFIED PROCEDURE

1. A Party of import may, provided that adequate measures are applied to ensure the safe intentional transboundary movement of living modified organisms in accordance with the objective of this Protocol, specify in advance to the Biosafety Clearing-House:

(a) Cases in which intentional transboundary movement to it may take place at the same time as the movement is notified to the Party of import; and

(b) Imports of living modified organisms to it to be exempted from the advance informed agreement procedure.

Notifications under subparagraph (a) above, may apply to subsequent similar movements to the same Party.

2. The information relating to an intentional transboundary movement that is to be provided in the notifications referred to in paragraph 1 (a) above, shall be the information specified in Annex I.

Article 14

BILATERAL, REGIONAL AND MULTILATERAL AGREEMENTS AND ARRANGEMENTS

1. Parties may enter into bilateral, regional and multilateral agreements and arrangements regarding intentional transboundary movements of living modified organisms, consistent with the objective of this Protocol and provided that such agreements and arrangements do not result in a lower level of protection than that provided for by the Protocol.

2. The Parties shall inform each other, through the Biosafety Clearing-House, of any such bilateral, regional and multilateral agreements and arrangements that they have entered into before or after the date of entry into force of this Protocol.

3. The provisions of this Protocol shall not affect intentional transboundary movements that take place pursuant to such agreements and arrangements as between the parties to those agreements or arrangements.

4. Any Party may determine that its domestic regulations shall apply with respect to specific imports to it and shall notify the Biosafety Clearing-House of its decision.

Article 15

RISK ASSESSMENT

1. Risk assessments undertaken pursuant to this Protocol shall be carried out in a scientifically sound manner, in accordance with Annex III and taking into account recognized risk assessment techniques. Such risk assessments shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence in order to identify and evaluate the possible adverse effects of living modified organisms on the conservation and sustainable use of biological diversity, taking also into account risks to human health.
2. The Party of import shall ensure that risk assessments are carried out for decisions taken under Article 10. It may require the exporter to carry out the risk assessment.
3. The cost of risk assessment shall be borne by the notifier if the Party of import so requires.

Article 16

RISK MANAGEMENT

1. The Parties shall, taking into account Article 8 (g) of the Convention, establish and maintain appropriate mechanisms, measures and strategies to regulate, manage and control risks identified in the risk assessment provisions of this Protocol associated with the use, handling and transboundary movement of living modified organisms.
2. Measures based on risk assessment shall be imposed to the extent necessary to prevent adverse effects of the living modified organism on the conservation and sustainable use of biological diversity, taking also into account risks to human health, within the territory of the Party of import.
3. Each Party shall take appropriate measures to prevent unintentional transboundary movements of living modified organisms, including such measures as requiring a risk assessment to be carried out prior to the first release of a living modified organism.
4. Without prejudice to paragraph 2 above, each Party shall endeavour to ensure that any living modified organism, whether imported or locally developed, has undergone an appropriate period of observation that is commensurate with its life-cycle or generation time before it is put to its intended use.
5. Parties shall cooperate with a view to:
 - (a) Identifying living modified organisms or specific traits of living modified organisms that may have adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and
 - (b) Taking appropriate measures regarding the treatment of such living modified organisms or specific traits.

Article 17

UNINTENTIONAL TRANSBOUNDARY MOVEMENTS AND EMERGENCY MEASURES

1. Each Party shall take appropriate measures to notify affected or potentially affected States, the Biosafety Clearing-House and, where appropriate, relevant

international organizations, when it knows of an occurrence under its jurisdiction resulting in a release that leads, or may lead, to an unintentional transboundary movement of a living modified organism that is likely to have significant adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health in such States. The notification shall be provided as soon as the Party knows of the above situation.

2. Each Party shall, no later than the date of entry into force of this Protocol for it, make available to the Biosafety Clearing-House the relevant details setting out its point of contact for the purposes of receiving notifications under this Article.

3. Any notification arising from paragraph 1 above, should include:

(a) Available relevant information on the estimated quantities and relevant characteristics and/or traits of the living modified organism;

(b) Information on the circumstances and estimated date of the release, and on the use of the living modified organism in the originating Party;

(c) Any available information about the possible adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, as well as available information about possible risk management measures;

(d) Any other relevant information; and

(e) A point of contact for further information.

4. 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 18

HANDLING, TRANSPORT, PACKAGING AND IDENTIFICATION

1. In order to avoid adverse effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health, each Party shall take necessary measures to require that living modified organisms that are subject to intentional transboundary movement within the scope of this Protocol are handled, packaged and transported under conditions of safety, taking into consideration relevant international rules and standards.

2. Each Party shall take measures to require that documentation accompanying:

(a) Living modified organisms that are intended for direct use as food or feed, or for processing, clearly identifies that they "may contain" living modified organisms and are not intended for intentional introduction into the environment, as well as a contact point for further information. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall take a decision on the detailed requirements for this purpose, including specification of their identity and any unique identification, no later than two years after the date of entry into force of this Protocol;

(b) Living modified organisms that are destined for contained use clearly identifies them as living modified organisms; and specifies any requirements for the safe handling, storage, transport and use, the contact point for further information,

including the name and address of the individual and institution to whom the living modified organisms are consigned; and

(c) Living modified organisms that are intended for intentional introduction into the environment of the Party of import and any other living modified organisms within the scope of the Protocol, clearly identifies them as living modified organisms; specifies the identity and relevant traits and/or characteristics, any requirements for the safe handling, storage, transport and use, the contact point for further information and, as appropriate, the name and address of the importer and exporter; and contains a declaration that the movement is in conformity with the requirements of this Protocol applicable to the exporter.

3. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall consider the need for and modalities of developing standards with regard to identification, handling, packaging and transport practices, in consultation with other relevant international bodies.

Article 19

COMPETENT NATIONAL AUTHORITIES AND NATIONAL FOCAL POINTS

1. Each Party shall designate one national focal point to be responsible on its behalf for liaison with the Secretariat. Each Party shall also designate one or more competent national authorities, which shall be responsible for performing the administrative functions required by this Protocol and which shall be authorized to act on its behalf with respect to those functions. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.

2. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the names and addresses of its focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is responsible for which type of living modified organism. Each Party shall forthwith notify the Secretariat of any changes in the designation of its national focal point or in the name and address or responsibilities of its competent national authority or authorities.

3. The Secretariat shall forthwith inform the Parties of the notifications it receives under paragraph 2 above, and shall also make such information available through the Biosafety Clearing-House.

Article 20

INFORMATION SHARING AND THE BIOSAFETY CLEARING-HOUSE

1. A Biosafety Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention, in order to:

(a) Facilitate the exchange of scientific, technical, environmental and legal information on, and experience with, living modified organisms; and

(b) Assist Parties to implement the Protocol, taking into account the special needs of developing country Parties, in particular the least developed and small island developing States among them, and countries with economies in transition as well as countries that are centres of origin and centres of genetic diversity.

2. The Biosafety Clearing-House shall serve as a means through which information is made available for the purposes of paragraph 1 above. It shall provide

access to information made available by the Parties relevant to the implementation of the Protocol. It shall also provide access, where possible, to other international biosafety information exchange mechanisms.

3. Without prejudice to the protection of confidential information, each Party shall make available to the Biosafety Clearing-House any information required to be made available to the Biosafety Clearing-House under this Protocol, and:

(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.

4. The modalities of the operation of the Biosafety Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

Article 21

CONFIDENTIAL INFORMATION

1. The Party of import shall permit the notifier to identify information submitted under the procedures of this Protocol or required by the Party of import as part of the advance informed agreement procedure of the Protocol that is to be treated as confidential. Justification shall be given in such cases upon request.

2. The Party of import shall consult the notifier if it decides that information identified by the notifier as confidential does not qualify for such treatment and shall, prior to any disclosure, inform the notifier of its decision, providing reasons on request, as well as an opportunity for consultation and for an internal review of the decision prior to disclosure.

3. Each Party shall protect confidential information received under this Protocol, including any confidential information received in the context of the advance informed agreement procedure of the Protocol. Each Party shall ensure that it has procedures to protect such information and shall protect the confidentiality of such information in a manner no less favourable than its treatment of confidential information in connection with domestically produced living modified organisms.

4. The Party of import shall not use such information for a commercial purpose, except with the written consent of the notifier.

5. If a notifier withdraws or has withdrawn a notification, the Party of import shall respect the confidentiality of commercial and industrial information, including research

and development information as well as information on which the Party and the notifier disagree as to its confidentiality.

6. Without prejudice to paragraph 5 above, the following information shall not be considered confidential:

- (a) The name and address of the notifier;
- (b) A general description of the living modified organism or organisms;
- (c) A summary of the risk assessment of the effects on the conservation and sustainable use of biological diversity, taking also into account risks to human health; and
- (d) Any methods and plans for emergency response.

Article 22

CAPACITY-BUILDING

1. The Parties shall cooperate in the development and/or strengthening of human resources and institutional capacities in biosafety, including biotechnology to the extent that it is required for biosafety, for the purpose of the effective implementation of this Protocol, in developing country Parties, in particular the least developed and small island developing States among them, and in Parties with economies in transition, including through existing global, regional, subregional and national institutions and organizations and, as appropriate, through facilitating private sector involvement.

2. For the purposes of implementing paragraph 1 above, in relation to cooperation, the needs of developing country Parties, in particular the least developed and small island developing States among them, for financial resources and access to and transfer of technology and know-how in accordance with the relevant provisions of the Convention, shall be taken fully into account for capacity-building in biosafety. Cooperation in capacity-building shall, subject to the different situation, capabilities and requirements of each Party, include scientific and technical training in the proper and safe management of biotechnology, and in the use of risk assessment and risk management for biosafety, and the enhancement of technological and institutional capacities in biosafety. The needs of Parties with economies in transition shall also be taken fully into account for such capacity-building in biosafety.

Article 23

PUBLIC AWARENESS AND PARTICIPATION

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 24

NON-PARTIES

1. Transboundary movements of living modified organisms between Parties and non-Parties shall be consistent with the objective of this Protocol. The Parties may enter into bilateral, regional and multilateral agreements and arrangements with non-Parties regarding such transboundary movements.

2. The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Biosafety Clearing-House on living modified organisms released in, or moved into or out of, areas within their national jurisdictions.

Article 25

ILLEGAL TRANSBOUNDARY MOVEMENTS

1. Each Party shall adopt appropriate domestic measures aimed at preventing and, if appropriate, penalizing transboundary movements of living modified organisms carried out in contravention of its domestic measures to implement this Protocol. Such movements shall be deemed illegal transboundary movements.

2. In the case of an illegal transboundary movement, the affected Party may request the Party of origin to dispose, at its own expense, of the living modified organism in question by repatriation or destruction, as appropriate.

3. Each Party shall make available to the Biosafety Clearing-House information concerning cases of illegal transboundary movements pertaining to it.

Article 26

SOCIO-ECONOMIC CONSIDERATIONS

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

2. The Parties are encouraged to cooperate on research and information exchange on any socio-economic impacts of living modified organisms, especially on indigenous and local communities.

Article 27

LIABILITY AND REDRESS

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 28

FINANCIAL MECHANISM AND RESOURCES

1. In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.
2. The financial mechanism established in Article 21 of the Convention shall, through the institutional structure entrusted with its operation, be the financial mechanism for this Protocol.
3. Regarding the capacity-building referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need for financial resources by developing country Parties, in particular the least developed and the small island developing States among them.
4. In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties, in particular the least developed and the small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building requirements for the purposes of the implementation of this Protocol.
5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, mutatis mutandis, to the provisions of this Article.
6. The developed country Parties may also provide, and the developing country Parties and the Parties with economies in transition avail themselves of, financial and technological resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

Article 29

CONFERENCE OF THE PARTIES SERVING AS THE MEETING OF THE PARTIES TO THIS PROTOCOL

1. The Conference of the Parties shall serve as the meeting of the Parties to this Protocol.
2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.
3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.
4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall

make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:

(a) Make recommendations on any matters necessary for the implementation of this Protocol;

(b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;

(c) Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;

(d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 33 of this Protocol and consider such information as well as reports submitted by any subsidiary body;

(e) Consider and adopt, as required, amendments to this Protocol and its annexes, as well as any additional annexes to this Protocol, that are deemed necessary for the implementation of this Protocol; and

(f) Exercise such other functions as may be required for the implementation of this Protocol.

5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied, mutatis mutandis, under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

6. The first meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat in conjunction with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held in conjunction with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.

7. Extraordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the Conference of the Parties serving as the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.

8. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, that is qualified in matters covered by this Protocol and that has informed the Secretariat of its wish to be represented at a meeting of the Conference of the Parties serving as a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5 above.

Article 30

SUBSIDIARY BODIES

1. Any subsidiary body established by or under the Convention may, upon a decision by the Conference of the Parties serving as the meeting of the Parties to this Protocol, serve the Protocol, in which case the meeting of the Parties shall specify which functions that body shall exercise.
2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under the Protocol shall be taken only by the Parties to the Protocol.
3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to the Protocol, shall be substituted by a member to be elected by and from among the Parties to the Protocol.

Article 31

SECRETARIAT

1. The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.
2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, mutatis mutandis, to this Protocol.
3. To the extent that they are distinct, the costs of the secretariat services for this Protocol shall be met by the Parties hereto. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, decide on the necessary budgetary arrangements to this end.

Article 32

RELATIONSHIP WITH THE CONVENTION

Except as otherwise provided in this Protocol, the provisions of the Convention relating to its protocols shall apply to this Protocol.

Article 33

MONITORING AND REPORTING

Each Party shall monitor the implementation of its obligations under this Protocol, and shall, at intervals to be determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, report to the Conference of the Parties serving as the meeting of the Parties to this Protocol on measures that it has taken to implement the Protocol.

Article 34

COMPLIANCE

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of this Protocol and to address cases of non-compliance. These procedures and mechanisms shall

include provisions to offer advice or assistance, where appropriate. They shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms established by Article 27 of the Convention.

Article 35

ASSESSMENT AND REVIEW

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall undertake, five years after the entry into force of this Protocol and at least every five years thereafter, an evaluation of the effectiveness of the Protocol, including an assessment of its procedures and annexes.

Article 36

SIGNATURE

This Protocol shall be open for signature at the United Nations Office at Nairobi by States and regional economic integration organizations from 15 to 26 May 2000, and at United Nations Headquarters in New York from 5 June 2000 to 4 June 2001.

Article 37

ENTRY INTO FORCE

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.
2. This Protocol shall enter into force for a State or regional economic integration organization that ratifies, accepts or approves this Protocol or accedes thereto after its entry into force pursuant to paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organization deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organization, whichever shall be the later.
3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

Article 38

RESERVATIONS

No reservations may be made to this Protocol.

Article 39

WITHDRAWAL

1. At any time after two years from the date on which this Protocol has entered into force for a Party, that Party may withdraw from the Protocol by giving written notification to the Depositary.
2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.

Article 40

AUTHENTIC TEXTS

The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

IN WITNESS WHEREOF the undersigned, being duly authorized to that effect, have signed this Protocol.

DONE at Montreal on this twenty-ninth day of January, two thousand.

Annex I

INFORMATION REQUIRED IN NOTIFICATIONS UNDER ARTICLES 8, 10 AND 13

- (a) Name, address and contact details of the exporter.
- (b) Name, address and contact details of the importer.
- (c) Name and identity of the living modified organism, as well as the domestic classification, if any, of the biosafety level of the living modified organism in the State of export.
- (d) Intended date or dates of the transboundary movement, if known.
- (e) Taxonomic status, common name, point of collection or acquisition, and characteristics of recipient organism or parental organisms related to biosafety.
- (f) 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.
- (g) Taxonomic status, common name, point of collection or acquisition, and characteristics of the donor organism or organisms related to biosafety.
- (h) Description of the nucleic acid or the modification introduced, the technique used, and the resulting characteristics of the living modified organism.
- (i) Intended use of the living modified organism or 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.
- (j) Quantity or volume of the living modified organism to be transferred.
- (k) A previous and existing risk assessment report consistent with Annex III.
- (l) Suggested methods for the safe handling, storage, transport and use, including packaging, labelling, documentation, disposal and contingency procedures, where appropriate.
- (m) Regulatory status of the living modified organism within the State of export (for example, whether it is prohibited in the State of export, whether there are other restrictions, or whether it has been approved for general release) and, if the living modified organism is banned in the State of export, the reason or reasons for the ban.
- (n) Result and purpose of any notification by the exporter to other States regarding the living modified organism to be transferred.
- (o) A declaration that the above-mentioned information is factually correct.

Annex II

INFORMATION REQUIRED CONCERNING LIVING MODIFIED ORGANISMS INTENDED FOR DIRECT USE AS FOOD OR FEED, OR FOR PROCESSING UNDER ARTICLE 11

- (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.

Annex III

RISK ASSESSMENT

Objective

1. The objective of risk assessment, under this Protocol, is to identify and evaluate the potential adverse effects of living modified organisms on the conservation and sustainable use of biological diversity in the likely potential receiving environment, taking also into account risks to human health.

Use of risk assessment

2. Risk assessment is, *inter alia*, used by competent authorities to make informed decisions regarding living modified organisms.

General principles

3. Risk assessment should be carried out in a scientifically sound and transparent manner, and can take into account expert advice of, and guidelines developed by, relevant international organizations.

4. Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk.

5. Risks associated with living modified organisms or 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, should be considered in the context of the risks posed by the non-modified recipients or parental organisms in the likely potential receiving environment.

6. Risk assessment should be carried out on a case-by-case basis. The required information may vary in nature and level of detail from case to case, depending on the living modified organism concerned, its intended use and the likely potential receiving environment.

Methodology

7. The process of risk assessment may on the one hand give rise to a need for further information about specific subjects, which may be identified and requested during the assessment process, while on the other hand information on other subjects may not be relevant in some instances.

8. To fulfil its objective, risk assessment entails, as appropriate, the following steps:

(a) An identification of any novel genotypic and phenotypic characteristics associated with the living modified organism that may have adverse effects on biological diversity in the likely potential receiving environment, taking also into account risks to human health;

(b) An evaluation of the likelihood of these adverse effects being realized, taking into account the level and kind of exposure of the likely potential receiving environment to the living modified organism;

(c) An evaluation of the consequences should these adverse effects be realized;

- (d) An estimation of the overall risk posed by the living modified organism based on the evaluation of the likelihood and consequences of the identified adverse effects being realized;
- (e) A recommendation as to whether or not the risks are acceptable or manageable, including, where necessary, identification of strategies to manage these risks; and
- (f) Where there is uncertainty regarding the level of risk, it may be addressed by requesting further information on the specific issues of concern or by implementing appropriate risk management strategies and/or monitoring the living modified organism in the receiving environment.

Points to consider

9. Depending on the case, risk assessment takes into account the relevant technical and scientific details regarding the characteristics of the following subjects:

- (a) Recipient organism or parental organisms. The biological characteristics of the recipient organism or parental organisms, including information on taxonomic status, common name, origin, centres of origin and centres of genetic diversity, if known, and a description of the habitat where the organisms may persist or proliferate;
- (b) Donor organism or organisms. Taxonomic status and common name, source, and the relevant biological characteristics of the donor organisms;
- (c) Vector. Characteristics of the vector, including its identity, if any, and its source or origin, and its host range;
- (d) Insert or inserts and/or characteristics of modification. Genetic characteristics of the inserted nucleic acid and the function it specifies, and/or characteristics of the modification introduced;
- (e) Living modified organism. Identity of the living modified organism, and the differences between the biological characteristics of the living modified organism and those of the recipient organism or parental organisms;
- (f) Detection and identification of the living modified organism. Suggested detection and identification methods and their specificity, sensitivity and reliability;
- (g) Information relating to the intended use. Information relating to the intended use of the living modified organism, including new or changed use compared to the recipient organism or parental organisms; and
- (h) Receiving environment. Information on the location, geographical, climatic and ecological characteristics, including relevant information on biological diversity and centres of origin of the likely potential receiving environment.