

Trade and Biodiversity



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TRADE AND BIODIVERSITY

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Sustainable Development Goals and Trade

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1. Introduction

Recent decades have seen unprecedented progress in technology with key advances in areas such as agriculture, health, environmental protection, genomics, information and communications, and energy offering huge opportunities for countries to harness these technologies. However, the ‘technological apartheid’ is also increasing due to the uneven distribution of benefits and constraints dealing with the transfer of such technologies. The UNDP Human Development Report for 2001 emphasises the need for this situation to change. The recent Human Development Report for 2003 reiterates the need for bridging this gap in light of the commitments governments made in 2000 under the Millennium Development Goals (MDGs). Countries have agreed on a set of priorities for reducing poverty and enhancing rates of sustainable development by calling for a “change in policy, not charity”.

Discussions on implementing various development agendas have heavily relied on issues of aid and support. Much of the aid is increasingly being tied to issues of market access, tighter controls of intellectual property rights (IPRs) and implementation of World Trade Organization (WTO) and TRIPs provisions as well as the often side-lined commitments to work on environmental protection as agreed in Rio de Janeiro during the Earth Summit. Issues of trade frequently preclude discussions on development since trade often offers a mechanism for opening markets and reducing subsidies thereby increasing revenues.

This paper examines some of these issues. The paper focuses on the issue of commitments through MDGs coupled with opportunities for renewing discussions, not only under the WTO agenda, but also through the multilateral environmental agreements, especially the Convention on Biological Diversity (CBD).

2. The Millennium Development Goals

At the eve of the UN Millennium Summit in September 2000, countries around the world came together to adopt the Millennium Development Goals (MDGs). Adoption of these goals reinforced the commitment of the international community to a comprehensive and integrated approach to sustainable development and poverty reduction using a set of agreed targets set against dates. The 8 MDGs consist of 18 targets and 40 indicators and provide a framework for measuring development progress. Achieving these targets is the responsibility of national governments.

Broadly, the first 7 goals address issues of poverty, education, gender equality, health and environmental sustainability. The eighth goal considers a means of achieving the first 7 goals through development of global partnerships. The goals, in particular goal 8, also include actions to reduce debt and increase aid, trade and technology transfer to poor countries. Box 1 shows the 8 goals and corresponding targets.

Box 1 The Millennium Development Goals

Goal 1 - Eradicate Extreme Poverty and Hunger

- Halve, between 1990 and 2015, the proportion of people whose income is less than \$1 a day;
- Halve, between 1990 and 2015, the proportion of people who suffer from hunger.

Goal 2 - Achieve Universal Primary Education

- Ensure that, by 2015, children everywhere, boys and girls alike, will be able to complete a full course of primary schooling.

Goal 3 - Promote Gender Equality and Empower Women

- Eliminate gender disparity in primary and secondary education preferably by 2005 and in all levels of education no later than 2015.

Goal 4 - Reduce Child Mortality

- Reduce, by two-thirds, between 1990 and 2015, the under-five mortality rate.

Goal 5 - Improve Maternal Health

- Reduce by three-quarters, between 1990 and 2015, the maternal mortality ratio.

Goal 6 - Combat HIV/AIDS, Malaria and other Diseases

- Have halted by 2015 and begun to reverse the spread of HIV/AIDS;
- Have halted by 2015 and begun to reverse the incidence of malaria and other major diseases.

Goal 7 - Ensure Environmental Sustainability

- Integrate the principles of sustainable development into country policies and programs and reverse the loss of environmental resources;
- Halve, by 2015, the proportion of people without sustainable access to safe drinking water;
- Have achieved, by 2020, a significant improvement in the lives of at least 100 million slum dwellers.

Goal 8 - Develop a Global Partnership for Development

- Develop further an open, rule-based, predictable, nondiscriminatory trading and financial system (includes a commitment to good governance, development and poverty reduction - both nationally and internationally);
- Address the special needs of the least developed countries (including tariff- and quota-free access for exports, enhanced program of debt relief for and cancellation of official bilateral debt, and more generous ODA for countries committed to poverty reduction);
- Address the special needs of landlocked countries and small island developing states (through the Program of Action for the Sustainable Development of Small Island Developing States and 22nd General Assembly provisions);
- Deal comprehensively with the debt problems of developing countries through national and international measures in order to make debt sustainable in the long term;
- In cooperation with developing countries, develop and implement strategies for decent and productive work for youth;
- In cooperation with pharmaceutical companies, provide access to affordable essential drugs in developing countries;
- In cooperation with the private sector, make available the benefits of new technologies, especially information and communications technologies.

2.1 Development Progress

In the past 30 years there have been dramatic improvements in the developing world in areas such as life expectancy, illiteracy and the number of people living on less than \$1 a day. However, development is still proceeding too slowly for many to be satisfied with its rate. For many countries, the 1990s saw setbacks in development with 54 countries being poorer now than in 1990 (UNDP, 2003).

Sustainable growth can only be achieved when countries attain basic thresholds in key areas such as governance, health, education, infrastructure and access to markets. However, structural obstacles and constraints (such as barriers to international markets, high debt levels and the impact of a country's size and location) can make it very difficult for some countries, including those most in need, to attain these basic thresholds, particularly in the absence of external support (UNDP, 2003). Box 2 outlines policy options for developing countries to address structural constraints as well as adjustments to break away from the poverty trap.

Box 2 Policy clusters to help countries break out of their poverty trap

(Source: UNDP, 2003)

Policy responses to structural constraints require simultaneous interventions on several fronts – along with stepped-up external support. Six policy clusters can help countries break out of their poverty traps:

- Invest early and ambitiously in basic education and health while fostering gender equity. These are preconditions to sustained economic growth. Growth, in turn, can generate employment and raise incomes – feeding back into further gains in education and health.
- Increase the productivity of small farmers in unfavourable environments – that is, the majority of the world's hungry people. A reliable estimate is that 70% of the world's poorest people live in rural area and depend on agriculture.
- Improve basic infrastructure – such as ports, roads, power and communications – to reduce the costs of doing business and overcome geographic barriers.
- Develop an industrial development policy that nurtures entrepreneurial activity and helps diversify the economy away from dependence on primary commodity exports – with an active role for small and medium-size enterprises.
- Promote democratic governance and human rights to remove discrimination, secure social justice and promote the well-being of all people.
- Ensure environmental sustainability and sound urban management so that development improvements are long term.

2.2 Financing development and achieving the MDGs

To assist developing countries in reducing poverty and meeting the targets of the MDGs, key areas of assistance from developed countries include increased aid, debt relief, technology transfer and market access (UNDP, 2003). The commitment of developing countries must also be demonstrated through improvements to their policies and institutions.

Increasing the quantity and effective delivery as well as use of aid is essential to ensure the poorest countries have resources to finance the investments required to reach critical thresholds in infrastructure, education and health. In order to achieve the targets of by MDGs by 2015, the World Bank estimates that an increase in foreign aid of between \$40-60 billion a year is required (Devarajan *et al.*, 2002). For rich countries, 0.7% of their GNP is widely accepted as a reference target for official development assistance, however, this figure has not been met even by OECD's Development Assistance Committee (UN, 2000e In: UNDP 2003). To ensure the effectiveness of the aid, countries need to improve economic and democratic governance and implement policies for effective poverty reduction.

Debt relief can help to release resources that could finance additional spending in areas that contribute to attaining the targets of the MDGs. That is, increased debt relief for developing countries will assist in creating an enabling environment for sustainable development. For example, debt relief under the Heavily Indebted Poor Countries (HIPC) initiative has increased spending on education and health in recipient countries. However, current analysis indicates that the HIPC initiative will not be sufficient for countries to escape their debt trap and that more must be done to ensure debt sustainability and to meet the targets of the MDGs.

Dramatic advances in technology in recent decades provide significant opportunities to accelerate progress towards poverty reduction and sustainable development. Technological innovations can increase productivity resulting in increased household incomes and provide solutions to many development problems such as disease, transport, energy, water supply and sanitation (UNEP, IISD, 2000; UNDP, 2003). It is vital that developed countries share technological progress with developing countries and invest more into technology development that addresses issues of poverty reduction.

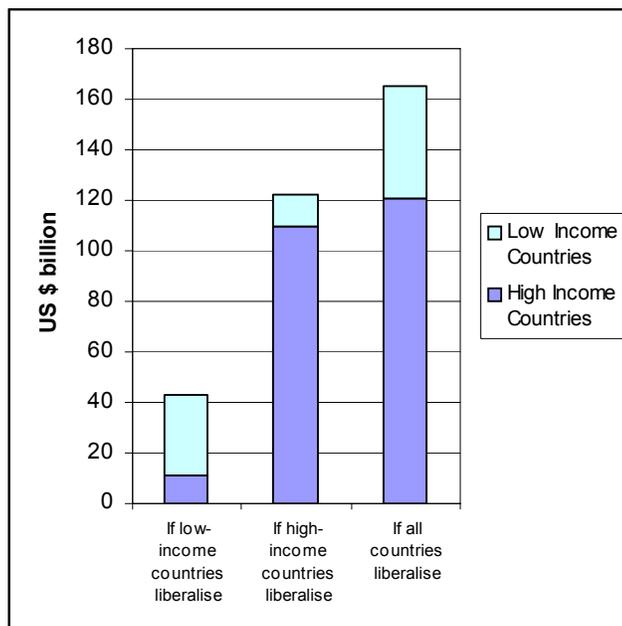
It is recognised that greater market access for developing countries, coupled with development assistance, would significantly contribute to the likelihood of many countries achieving the MDGs by 2015 (Devarajan *et al.*, 2002). Indeed, for many developing countries, the benefits could be much larger than financial transfers through official development assistance (ODA) (Walker, 2001; Devarajan *et al.*, 2002). While aid and debt relief are essential assistance for developing countries, they are not sustainable solutions and developing countries must also to drive their own development.

3. Trade and Development

It is a recognised fact that countries can benefit from trading with one another. The process of systematically reducing and eventually eliminating all tariff and non-tariff barriers between countries, and thus promoting non-discriminatory trade across the board, is based on the theory that an unrestrained market will result in the most efficient pattern of productive activity. For example, the following Figure 1 shows the potential financial benefits of agricultural trade liberalisation for developed and developing countries.

Figure 1 Potential annual welfare gains from agricultural trade liberalisation

(Source: Adapted from Anderson *et al.*, 2000 In Scherr, 2003)



Currently, however, protectionist policies create barriers to trade and distort markets, often having a detrimental impact on developing countries and resulting in lost opportunities for world trade to contribute significantly to poverty reduction and to support economic development. The problem is not that international trade is inherently opposed to the needs and interests of the poor, but that the rules that govern it generally favour the rich (Oxfam, 2003b).

3.1 Developed versus Developing Countries

Over the last two decades, the impacts of trade liberalisation and global economic integration have been influenced by, among other things, the level of development of a given country. Recent statistics indicate that current trade liberalisation rules and policies have led to increases in poverty and inequality, with a disproportionately large negative impact on developing countries (Box 3) (World Trade Organization, 2003a). As developing countries have integrated their economies more intensively with the world economy, they have experienced more vulnerability and inequitable sharing of the benefits between rich and poor (RIS, 2003). This outcome has led to a widespread rethinking of the pros and cons of globalization for developing countries.

Box 3 Trade Liberalisation Statistics

(Source: World Trade Organization, 2003a)

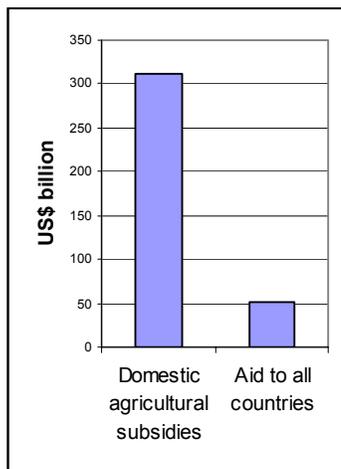
- The world's poorest countries' share of world trade has declined by more than 40 per cent since 1980 to a mere 0.4 per cent. (UNCTAD, Conference on Least Developed Countries 1999)
- The poorest 49 countries make up 10% of the world's population, but account for only 0.4% of world trade. This disparity has been growing. (UNCTAD, Conference on Least Developed Countries 2001)
- 51 of the 100 largest economies in the world are corporations. The Top 500 multinational corporations account for nearly 70 percent of the worldwide trade; this percentage has steadily increased over the past twenty years. (CorpWatch)
- The U.N. estimates that poor countries lose about US\$2 billion per day because of unjust trade rules, many instituted by our organization—14 times the amount they receive in aid. (UNCTAD, Conference on Least Developed Countries 2001)

Severe structural problems, often beyond the control of the developing country and often involving the international trade system, can also block access for developing countries to international markets. Examples include when rich countries block

agricultural and other exports from poor countries or when rich countries heavily subsidize their own farmers, depressing world prices of these products (UNDP, 2003). In OECD countries, domestic agricultural policies have impacts on income levels for rural poor in developing countries, often preventing poor farmers from realising their comparative advantage. For example, agricultural subsidies paid to US farmers enables the farmers to sell maize for 25% less than it costs to grow and harvest. Mexican farmers are unable to compete with US prices and can even lose money with each hectare they plant (McNeely and Milimo, 2003). For rural poor farmers, receiving a fair price for their products is essential to their survival, unless they also receive subsidies at the same levels as those with whom they compete in the market place (McNeely and Milimo, 2003). The following Figure 2 demonstrates the extent of annual agricultural subsidies in rich countries, which can be many times larger than annual aid to developing countries.

Figure 2 OECD Agricultural Subsidies Dwarf Aid, 2001

(Source: OECD, Development Assistance Committee, 2003 In: UNDP, 2003)



It is also difficult for small farmers to overcome advantages of developed country commercial companies, which may have better infrastructure and more efficient market systems (Scherr, 2003). A poorer resource base, less productive technology and less efficient marketing systems make it very difficult for poor farmers to compete in many product markets (Scherr, 2003).

It is unlikely that any country will develop simply by opening itself up to trade and foreign investment. The opportunities offered by the world market must be coupled

with a domestic investment (including trade related infrastructure, transportation and telecommunications and institution-building strategy) (Rodrik, 2001; Devarajan *et al.*, 2002). Better roads and communications and deeper integration with neighbouring countries can increase access to markets. For instance, China's remote inland regions face much longer distances to ports, much poorer infrastructure and much tougher biophysical conditions than the country's coastal regions and have not enjoyed the fast economic growth of the coastal regions (UNDP, 2003). It is also essential for developing countries to strengthen policies and institutions, combat corruption and improve governance (UNDP, 2003).

3.2 The World Trade Organization, the Doha Agenda and the Monterrey Conference

The World Trade Organization (WTO) came into force in 1995 and is the organization responsible for administering the international trade regime. It is an international membership organization that aims to abolish quotas and reduce tariff duties. The most recent round of WTO negotiations, the Doha round, commenced in January 2002 and is scheduled to end in January 2005. The Doha Ministerial Declaration (2001) reaffirmed the commitment of the members of the WTO to developing countries including the commitment to:

“continue to make positive efforts designed to ensure that developing countries, and especially the least-developed among them, secure a share in the growth of world trade commensurate with the needs of their economic development”.

In continuation of these international discussions on trade the Monterrey conference on “Financing for Development” was held in March 2002 to discuss the aid and trade needs of the world's poorest countries, in particular the financing requirements to meet the ambitious targets of development. It was recognised by both developed and developing countries that private sources, mostly trade and foreign direct investment, must be the key sources of new money for development. Participants at the Monterrey conference urged WTO members to proceed with global trade negotiations that placed the needs and interests of developing countries at the center.

Despite these commitments, little progress has been made towards meaningful reform. Deadlines in the negotiations on issues of agriculture and other issues that are of importance to developing countries have been missed (FAO, 2003).

Agriculture is one of the key areas of negotiation in the WTO Doha round of negotiations. The key issues relate to substantial improvements in market access; reductions of, with a view to phasing out, all forms of export subsidies; and substantial reductions in trade-distorting domestic support. However, developed countries have made little progress towards meeting these objectives and the recently released EU-US bilateral agreement on agriculture has been considered to be a long way from achieving meaningful reform in world agricultural trade and unlikely to advance reforms in the near future (Oxfam, 2003a).

Another important area of focus of the Doha round is the resolution of outstanding implementation issues of Special and Differential Treatment (S&DT) for developing countries, particularly for least developed countries. During 2002, discussions on ways to strengthen S&DT rules were unsuccessful and there remains deep division among WTO members on how to improve S&DT provisions (ICTSD, 2003). Progress on this issue would help to restore confidence for developing countries in the Doha Round's ability to deliver (ICTSD, 2003).

The World Bank's Global Economics Prospects (2002) forecasts an increase of US\$355 billion in global income by 2015 as a result of the new round of trade liberalisation. However, it has been predicted that the greatest income gains will accrue to Western Europe, while developing countries, as a whole, are forecast to share around 50 per cent of the extra income, with wide variation among countries (Save the Children *et al.*, 2002). This pattern needs to change to ensure that those most in need are enjoying the benefits of global prosperity – that is, comprehensive changes are required to make the global trading system work in the interests on the poor (Save the Children *et al.*, 2002).

4. Trade and the Environment

The relationship between trade and the environment goes two ways. Firstly, natural resources and agriculture play a significant role in the global economy. Secondly, trading systems can impact on the ways in which natural resources are utilized and the nature and extent of subsequent environmental impacts.

Being fundamental to so many productive activities, natural resources contribute much to the global economy. For example, during the early 1990s, industrial wood

products contributed \$400 billion to the global economy and, in 2000, fisheries accounted for \$55 billion in exports (UNDP, 2003).

Developing countries are the most dependent on agriculture and natural resources (such as forest products, mineral and fish) for export earnings. Accordingly, developing countries are the most vulnerable to resource depletion and worsening terms of trade (UNDP, 2003). For example, environmentally harmful subsidies in developed countries, such as subsidies for marine fisheries, can contribute significantly to global pressure on such natural resources and have a detrimental effect on local fishery communities who depend on fish for their food security (DFID *et al.*, 2002).

The economic well being of a country and increases in international trade can have a substantial impact on the nature and extent of demands on natural resources and ecosystem services. Poverty is an important factor in environmental degradation and, while rising incomes can help to alleviate pressures on the environment, the reverse can also occur. For example, higher incomes tend to increase consumption of ecosystem goods and services but may also increase peoples ability and willingness to mitigate adverse environmental change. The combined rate of growth of GDP, trade and capital flows, and income inequality are crucial determinants of the direction and extent of environmental degradation (Melnick, 2003).

Changes to existing trading systems can have a positive or negative impact on the environment. Some of the key environmental impacts of trade liberalisation are summarised in table below (UNEP & IISD, 2000).

Table 1 Environmental Impacts of Trade Liberalisation

Potential Positive Effects	Potential Negative Effects
<ul style="list-style-type: none"> • Changes in the composition of a countries economy – causing it to make more goods it makes well or has in abundance – could lead to increases in sectors that that are more environmentally friendly. • Trading with a country whose consumers demand green goods may also change the composition of the economy, if exporters respond by creating new products or sectors. • Trade liberalisation may remove subsidies, quotas or other trade-restrictive measures that frustrate allocative efficiency. 	<ul style="list-style-type: none"> • If the goods that a country makes well are based on natural resources or are pollution intensive, then trade liberalisation would increase the share of such industries in the national economy. • In small developing economies, economic openness must be properly staged and accompanied by policies specifically designed to ease the restructuring process. Otherwise, liberalisation may actually work against growth, employment, poverty alleviation, environmental protection and other components of sustainable development, at least in the short to medium term.

4.1 Linkages between the Convention on Biological Diversity and Trade

The Convention on Biological Diversity (CBD) calls on Parties to adopt economically and socially sound measures that act as incentives for the conservation and sustainable use of components of biological diversity (McNeely and Milimo, 2003). Unfortunately, current trade policies throughout the world continue to promote the depletion of natural resources. Broadly speaking, the WTO rules state that environmental, ethical and social considerations cannot be used to discriminate between one tradeable commodity and another (ITDG, 2000). In addition, as the value of international trade increases (in absolute terms and as the percentage of overall economic activity) the potential impacts of trade on biodiversity also increases (Downes, 1999).

While many trade policies act contrary to the CBD objectives, there is also potential for trade in biological resources to be supportive of the CBD. This is most likely to be the case when custodians of biological resources enjoy a portion of the economic or other benefits arising from the use products derived from the resources (for example, genetic resources that are used to develop new commercial products). Through equitable distribution of the benefits arising from trade, trade can create incentives for conserving biodiversity (Downes, 1999) thus supporting the objectives of the CBD.

A focus of the WTO's Committee on Trade and Environment is analysis of the trade impacts of environmental policies and, more recently, on ways in which international markets can promote environmentally friendly production as well as conventional gains in income and development (EC, DFID and IUCN, 2001).

Through the CBD, guidance should be provided for ways to incorporate trade into national strategies and policies as a means of regulating trade-related activities that are likely to have an adverse impact on biodiversity. Furthermore, the WTO agreements should be limited to eliminating trade protectionism but should not interfere with environmental objectives (Tarasofsky, 2000)

5. Developing a Global Partnership for Development

Poor countries are not likely to achieve the MDGs on their own. In the WTO Doha Declaration (November 2001) all countries committed to making the needs of development, especially for the least developed countries, a central objective for

future trade negotiations (UNDP, 2003). That is, while it is recognised that the primary responsibility lies with the developing country to drive their own development, activities in developing countries must be complemented with policy changes in developed countries in areas including aid, debt, technology transfer and trade (see Section 1.2).

Concerns regarding the current and emerging asymmetries in the world trading system should be addressed to ensure that the system evolves in such a way that it is responsive to the development needs of its members and that a more level playing field is created (RIS, 2003). There is enormous scope for change to discriminatory trade policies in rich countries that limit market access for developing countries and distort global markets. Changes in policies regarding tariffs, quotas and subsidies in developed countries to open their markets, especially in the agriculture and textile sectors, would be of particular benefit to developing countries.

A genuine undertaking from developed countries towards achieving their commitments made under the Doha Development Agenda must be demonstrated. Poor implementation of the commitments of developed countries to developing countries often receives little attention due to a lack of capacities within developing countries (RIS, 2003). Developing countries often lack physical, analytical and financial capacities to scrutinize the policies of industrialised countries and seek redress under the WTO framework (RIS, 2003). Capacity building in developing countries, coupled with assistance from developed countries to monitor implementation of WTO commitments, is vital to ensure development of a fair and equitable world trading system.

Improved communication and partnerships among developing countries would also assist in building capacities within poor countries. Such cooperation would not only strengthen the analytical capacity in the South on international economic issues, but would also improve the exchange of experiences in moderating the adverse effects of globalization (RIS, 2003). Where possible, a coordinated position on WTO negotiations would raise the voice of the developing world, ensuring more development-friendly negotiation outcomes (RIS, 2003).

In order to protect the environment and the resources and services it provides, it is essential that the industrialized world contribute a fair proportion of the costs of

global biodiversity conservation through direct assistance and through more careful assessment of the impacts of their trade, investment and other interactions with the developing world (DFID *et al.*, 2002). Innovative ways of providing assistance while promoting conservation should also be further explored. For example, debt for nature swaps can be an effective way of maintaining or promoting sustainable management of natural resources in developing countries in exchange for debt relief. Such agreements generally have certain conditions placed on them regarding the ways in which the natural resources are managed and benefits for the developed country which may include logging permits or access to other services provided by the natural resource, however, can improve the long-term sustainability of the resources.

With the growing globalisation of the world economy, there is a greater need for coherence in international economic and environmental policy making in order to support sustainable development in developing countries (DFID *et al.*, 2002). This includes economic and environmental frameworks that provide sustainable growth opportunities, including market access for exports from developing countries (DFID *et al.*, 2002).

6. Conclusions

The Millennium Development Goals reinforced the commitment of the international community to a comprehensive and integrated approach to sustainable development and poverty reduction. Under the WTO Doha Development Agenda the international community has also reaffirmed their commitment to ensuring that developing countries, and especially the least developed among them, secure a share in the growth of world trade commensurate with the needs of their economic development.

To assist developing countries in reducing poverty and meeting the targets of the MDGs, key areas of assistance from developed countries include increased aid, debt relief, technology transfer and market access (UNDP, 2003). The commitment of developing countries must also be demonstrated through improvements to their policies and institutions.

Despite high expectations during the Uruguay Round of trade negotiations, protection to local agriculture afforded by tariffs and subsidies in most developed countries remains extremely high. While the eventual elimination of agricultural export subsidies has been agreed to under the Doha Round of trade negotiations, no

timeframe has been set (UNDP, 2003). Additionally, deadlines in the negotiations on issues of agriculture and other issues that are of importance to developing countries have been missed (FAO, 2003) and little progress has been made towards meaningful reform.

While the willingness of developed countries to work in partnership with developing countries towards poverty reduction and sustainable development has been demonstrated on paper, further implementation of policy changes must occur to further development progress and meet the MDG targets. A key area of focus during future negotiations under the Doha Agenda should be on how multilateral trade regimes can support and foster human development, at the same time ensuring trade strategies and policies are supportive of relevant Multilateral Environmental Agreements.

Ways forward

Discussions under the WTO's Committee of Trade and Development (CTD) and on Trade and Environment (CTE) should embark on an assessment about potential impact of Doha negotiations on developing countries to address issues of poverty reduction as well as human and economic development, operationalisation and implementation of a renewed S&DT and environmental needs and uses. The outcomes need to provide clear and explicit guidelines that negotiating bodies and countries can use to integrate environmental and development considerations.

In addition, it is now clear that special and differential treatment, which is a key issue of discussion both for development and trade is merely turning out to be an instrument for the implementation of current WTO rules and might not make trade supportive of development policies. Discussions should therefore focus on development of provisions addressing developing countries' market access concerns (eg. Case of cotton from Africa), providing 'policy spaces' for development.

A careful review of the Dhaka Declaration that emerged from the Ministerial meeting of trade ministries of Least Developed Countries (LDCs), held in June 2003, reveals that LDCs need is to ensure that they are not subjected to obligations or commitments beyond what is applicable to WTO LDC members. However, there is a growing concern that powerful members of WTO are exerting unnecessary pressure on LDCs in bilateral negotiations. Considering the need for balanced and equitable growth as

well as achieving the development goals set by agencies such as the UN (eg. MDGs) this situation must change.

It is obvious that environment and development, poverty and natural resource degradation, international policy and local livelihoods are all themes that have been subject to much generalization and over simplification. Effective solutions must be guided by a clear understanding of the specifics of these relationships, often determined by local institutions and policies.

Policy and institutional changes are needed to improve governance and enhance the assets of the poor in order to improve the quality of growth and to reform international and industrial country policies.

The following are some suggestions to address the above challenges:

- Integrate poverty-environment-development issues into national development frameworks.
- Decentralise environmental management and prioritize actions on the national development agenda.
- Strengthen institutional and individual capacities at the local level to deal with issues of negotiation as well as implementation.
- Improve poverty-environment-development assessment methods so that monitoring and evaluation can be clear, democratic and objective.
- Reduce the environmental vulnerability of poor by providing appropriate coping strategies.
- Develop anticipatory methods to deal with issues of managing the environment, adoption of new technologies and strengthening resource rights.
- Encourage private sector involvement in development planning as well as implementing pro-poor environmental and fiscal reforms.
- Make foreign direct investment pro-poor and pro-environment.
- Find ways to ensure Multilateral Environmental Agreements (MEAs) more explicitly contribute to poverty reduction in their implementation.
- Encourage sustainable production and sustainable consumption methods.

- Enhance effectiveness of development cooperation and debt relief that is not only based on the WTO principles and negotiations but also on ethics and equity aimed at sustainable development and poverty reduction.

While all of us agree that the situation and scenarios are complex, complexity should not be an excuse for inaction!

Agricultural Biotechnology and Emerging Trade Regime at WTO: Some Issues of Concern

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1. Introduction

In the recent past, the adoption and diffusion of biotechnology has raised several policy challenges for the governance of biotechnology especially in developing countries. In several of them illegal introduction of GM crops has confounded the prevailing confusion over biosafety and other intricate issues. This has important implications for both developed and developing countries, especially for those who are engaged in trade of GMOs. In the context of WTO, the concerns are related to several of its agreements. They include Technical Barriers to Trade (TBT), the Sanitary and Phytosanitary Measures (SPS), Trade-related Aspects of Intellectual Property Rights (TRIPs), Agreement on Agriculture (AoA), along with the overarching issues such as market access and competitiveness. As part of SPS and TBT more than 37 notifications related to trade and biotechnology have been issued by the OECD and other countries. Four cases have already reached the dispute settlement panel while the one between Thailand and Egypt has been amicably resolved.¹ However, the fourth WTO Ministerial Meeting at Doha, while launching the Development Round, did not refer to biotechnology *per se*.

With the coming into force of the Cartagena Protocol on Biosafety on 11th September, 2003, the WTO trade regime will have to respond to this major challenge. Countries like Canada, Argentina and others who have endorsed the protocol are not opposing trade in GMOs unlike United States which has not endorsed the Protocol and is all keen for unrestricted trade in GMOs. This ambiguous position of some of the

countries has made this debate more complicated. Moreover, the TRIPs in biotechnology is likely to move for a very restrictive regime foreclosing options for entry of latecomers in the technology race. The SPS/TBT deliberations have also not resulted in any meaningful gain for developing countries.

This paper makes an effort to look into these dimensions of international negotiations and emerging perspectives for developing countries. Section 2 takes an account of the global status of agricultural biotechnology while Section 3 discusses in detail the Cartagena Protocol and different national regulatory regimes. In Section 4, WTO and trade related implications are analysed while the last section gives the conclusions.

2. Potential and Prospects of Agricultural Biotechnology

The agriculture sector in developing countries is facing tremendous pressure in terms of productivity stagnation, rising input costs and lack of resources. Some of these issues are now being addressed through biotechnology, largely at the Research and Development (R&D) level. This technology offers several ways of addressing different traits, resulting in, for instance, direct increases in average yields. One way is through improvements in the “architecture” of the plant to enable it to absorb more photosynthetic energy or convert a larger portion of that energy into grain rather than stem or leaf. This was, in essence, the “Green Revolution” approach of breeding dwarfing genes into plants so that the plants could make better use of fertiliser and water and produce more grain. This approach is being pursued again and new rice architecture is being studied by the International Rice Research Institute (IRRI). Also, some private sector firms are undertaking research in the fundamental mechanisms that control plant architecture. Another approach, for climates where this is useful, is to modify the plant for a shorter growing season by enhancing its efficiency in the use of fertilizer, pesticides and water. Molecular hybridization has also been demonstrated to increase the productivity of several crops, including rice and wheat, by 15 to 20 per cent (James 2000). But it must be noted that the on-farm yield improvements observed so far have been for transgenic varieties developed to reduce on-farm production costs rather than for the purpose of increasing yields.

¹ Egypt – Import Prohibition of Canned Tuna with Soyabean Oil, G/SPS/GEN/203; G/L/392; and WT/DS205/1.

It is not yet clear whether experiences so far with increasing yields reflect a one-off advance, or reveal the first stage of a continuing process. Considering that there are many new technologies that will, over time, be applicable for plant improvements, the most reasonable conjecture is that the new technologies will continue to provide yield increases, that these will be introduced on a regular basis, and that each of the associated yield increases will be somewhat more than historical trends (Toenneissen 1991).

Another major concern for developing countries is the nutritional security of the masses. There are many possibilities for ways in which biotechnology can improve the nutritional value of cereals by enhancing the presence of special nutrients or chemicals. A commercial example is the increase in the levels of biotin (vitamin H) for application in animal and human nutrition. Biotechnology has also been targeted at rice to address Vitamin A and iron deficiencies. Vitamin A deficiency, which also interferes with the bio-availability of iron, affects 413 million children worldwide, i.e. 7 per cent of the world population. Rice endosperm does not contain any pro-vitamin A. However, through a range of techniques, transgenic plants carrying the genes to produce seeds with yellow endosperm have been developed. The biochemical analysis has confirmed that this yellow colour indicates the presence of pro-vitamin A.² Public sector breeders have also been looking into similar special purpose applications, such as inserting genes so that vitamin A and iron becomes available through the consumption of rice.³

Among the potentially more important applications for specific markets, are those that seek to improve the quality of feed crops. New varieties of transgenic maize that contain higher oil levels to boost energy and improve feeding efficiency or have characteristics to reduce phosphorous in animal waste are examples that are currently under development (USDA 1999). An interesting development that is certainly relevant to feed grains, is a patent covering the insertion of a protein into plants, which when eaten would facilitate control of animal parasites.

Biotechnology in food grains has addressed development of a single trait only. This has mostly been herbicide and pesticide tolerance. However, recently some companies

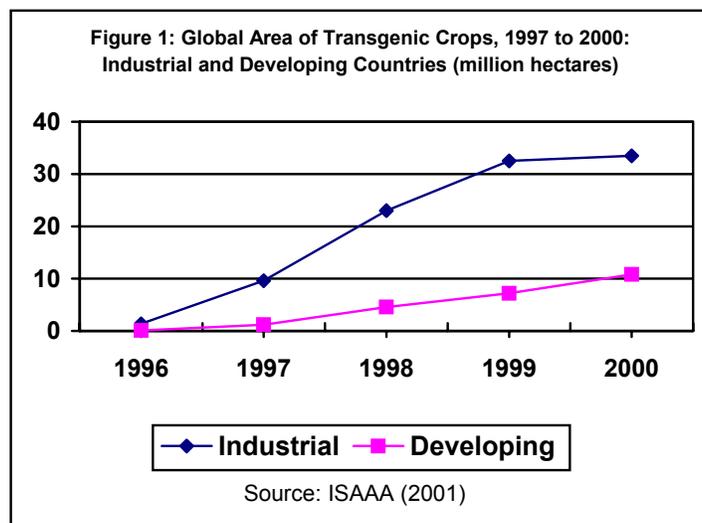
² *Agbiotech* (1999); *Nature Biotechnology* (2001).

³ *Op. cit*

like Garst Seeds, a subsidiary of Advanta, have developed maize hybrids that can tolerate two different classes of chemical herbicides (Spiney 1998). In the United States, currently about 20 per cent of the maize production is destined for such markets, predominantly for the production of high-fructose corn syrup and of alcohol (US International Trade Commission 1998).

Maize and sorghum are among the crops that produce a high yield of starch/energy per hectare, and are the leading temperate zone crops for this purpose. In essence, it has become possible to vary the feed or starch production characteristic of a range of important crop plants, making it possible to use almost any starch producing plant for many industrial purposes.

In the last decade or so the rate of transfer of biotechnology to the field has gone up many times. Figure 1 shows the number of hectares of transgenic crops in industrial and developing countries during the period 1996-2000. In developed countries it has gone up from 1.4 million hectares in 1996 to 33.5 million hectares in 2000, amounting to a growth of 96 per



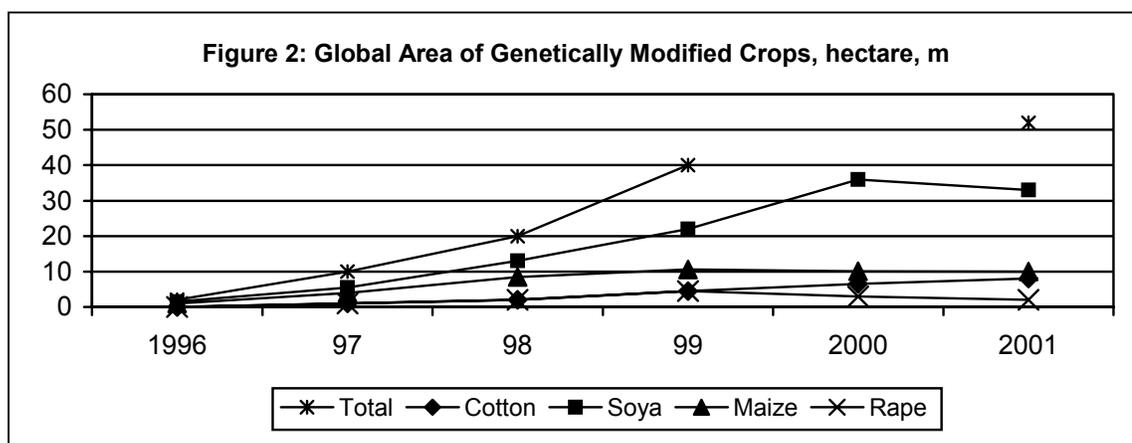
cent. The proportion of transgenic crops in developing countries has increased from 0.1 million hectares to 10.8 million hectares in the same period. The area under GMO in developing countries grew at a rate of 14 per cent in 1997 to 16 per cent in 1998 and 18 per cent by 1999. In 2000, it showed a rise of 24 per cent. Table 1 gives the country-specific details. The total area under transgenic crops at present is 58.1 million hectares as of 2002. Table 1 also shows that smaller Latin America and CIS countries are among other developing countries which have embarked on the GM adoption path in the last two years. However, no agricultural biotechnology product has yet been approved in the EU. In addition, several countries including Japan, Korea and temporarily Sri Lanka have already passed or are considering regulations mandating labels for foods obtained from biotechnology. The details of this we would see later.

Table 1 Global Area of Transgenic Crops 1996-2000 by Country (Million Hectares)

Country	1996	1997	1998	1999	2000	2002
USA	1.5	8.1	20.5	28.7	30.3	39
Argentina	0.1	1.4	4.3	6.7	10	13.5
Canada	0.1	1.3	2.8	4	3	3.5
China	1.1	1.8	---	2.3	2.5	2.1
South Africa	---	---	<0.1	0.1	0.2	---
Australia	0.1	0.1	0.1	0.1	0.2	---
Romania	---	---	---	0.1	0.1	---
Mexico	0.1	0.1	<0.1	0.1	0.1	---
Bulgaria	---	---	---	---	0.1	---
Spain	---	---	<0.1	0.1	0.1	---
Germany	---	---	---	---	0.1	---
France	---	---	<0.1	0.1	0.1	---
Portugal	---	---	---	0.1	---	---
Ukraine	---	---	---	0.1	---	---
Uruguay	---	---	---	---	0.1	---
Total	3	12.8	27.8	42.5	46.9	58.1

Source: *ISAAA Briefing Papers (Various Issues)*

The worldwide acreage devoted to these crops has grown steadily from only about 2 million acres in 1996 to nearly 200 million acres in 2003. This trend is likely to continue with increased planting of transgenic crops in China, India and several other countries. In the United States, 80% of soybeans, 70% of cotton and 38% of maize planted in 2003 were transgenic (Vasil 2003). In Argentina the main biotechnology crop is soyabean while in Canada it is canola. Figure 2 gives details about the global area of genetically modified crops under various different crops.



Accordingly, the global market of biotechnology has grown rapidly in the last few years. In 1995 it was at \$75 million while in 1998 it was \$1.5 billion. The total market for transgenic seed now exceeds \$3 billion. This is now being projected to reach \$6 billion by 2005. This period has also seen a very rapid rise in acquisition, alliances and mergers. There are several factors responsible for these initiatives. James (2000) explains that firms having larger status in pharmaceuticals/biotechnology are now entering in agricultural sector. As a result, there has been major merger and acquisitions among major firms world wide.

Cartegena Protocol and National Regulatory Regimes

At the global level there are two broad sets of regulatory regimes that have become part of agricultural biotechnology. One set emanates from national regulatory mechanisms evolved during last decade and the other from the recently concluded Cartegena Protocol. The former, apart from having individual countries, also have groupings like the EU which has proposed to establish regulations requiring documentation to trace the presence of biotechnology products through each step of grain handling and the food production processes. In fact, the EU has now also proposed to apply similar regulations for animal feeds.

The Cartagena Protocol on Biosafety to the Convention on Biological Diversity was adopted by the Conference of the Parties to the Convention on 29 January 2000. In accordance with its Article 36, the Protocol was opened for signature at the United Nations Office at Nairobi by States and regional economic integration organizations from 15 to 26 May 2000, and remained open for signature at United Nations Headquarters in New York from 5 June 2000 to 4 June 2001. The Protocol has been signed on behalf of 107 States and regional economic integration organizations and the 50th country ratified the Protocol in May 2003. The Protocol became effective 90 days after the 50th ratification, that is from September 11, 2003.

After five years of intense negotiations governments have finalized a legally binding agreement for protecting the environment from risks posed by the transboundary

transport of living modified organisms (LMOs)⁴ using modern biotechnology. Under the Cartagena Protocol on Biosafety, governments will signal whether or not they are willing to accept imports of agricultural commodities that include LMOs by communicating their decision to the world community via an Internet-based Biosafety Clearing House. In addition, shipments of these commodities that may contain LMOs are to be clearly labelled. LMOs include various food crops that have been genetically modified for greater productivity or nutritional value, or for resistance to pests or diseases. Common examples include tomatoes, grains, cassava, corn, and soybeans. Seeds for growing crops are particularly important because they are used intentionally to propagate or reproduce LMOs in the environment. Together, these agricultural LMOs form the basis of a multi billion-dollar global industry. Pharmaceuticals derived using LMOs form the basis of an even larger industry (although pharmaceuticals are not covered by this agreement).

Stricter ‘Advanced Informed Agreement’ (AIA) procedures will apply to seeds, live fish, and other LMOs that are to be intentionally introduced into the environment (Article 7.2). In these cases, the exporter must provide detailed information to each importing country in advance of the first shipment, and the importer must then authorize the shipment. The aim is to ensure that recipient countries have both the opportunity and the capacity to assess risks involving the products of modern biotechnology. Moreover, the information should also include the modification introduced, the technique used and the resulting characteristics of the LMO, the regulatory status of the LMO in the country of export and the contact details of the importer and the exporter. The notification has to be accompanied by a risk assessment report.

Another important feature of the Protocol emanates from Preamble and Articles 1, 10 and 11. This is “precautionary approach”. This means that if there is scientific uncertainty about the impact of genetic manipulation on biodiversity and human health then the importing country may enforce restrictions on the imports and this flexibility would remain until the importer, on its own, arrives on scientific certainty about implications.

⁴ This international protocol uses the term LMO rather than GMO. It is assumed that this is a more precise term. LMO is defined as, “any living organism that possess a novel combination of genetic material obtained through the use of modern biotechnology” (Article 3 (g)).

One of the most contentious issues that negotiators had to resolve involved the relationship between the Protocol and other international agreements, notably those under the WTO. While environmental agreements are premised on the precautionary principle (which states that potentially dangerous activities can be restricted or prohibited even before they can be scientifically proven to cause serious damage), decisions under trade law require "sufficient scientific evidence". Under the agreement, the Protocol and the WTO are to be mutually supportive. At the same time, the Protocol is not to affect the rights and obligations of governments under any existing international agreements. The SPS Agreement also acknowledges the precautionary principle and in fact this is a well established principle in many other multilateral agreements on environment. However, some of the authors like Van den Belt (2003) have found a stronger precautionary principle logically inconsistent, while some other authors like Isaac (2002) have attempted to juxtapose a social rationality approach with Risk Analysis Framework (RAF) over the Scientific Rationality Approach (SRA) adopted by the US.

Regulatory Regime at National and Regional Level

Over the years the regulatory regimes in different countries have emerged at different rates and have taken different directions. The national responses have largely been driven by specific national situations. For instance "mad cow disease" Europe situation led to extreme consumer rigidity for genetically modified food. Table 2 briefly depicts the evolution and the current shape of biosafety policy across the countries.

Table 2: The Regulatory Framework Regarding GMOs : Selected countries

EU	<p>1990- EC introduced an approval system for the release of GMOs into the environment for experimental and commercial purposes.</p> <p>1997- EC made labelling mandatory for a product containing GMOs.</p> <p>1999- EC provided consent to place GMOs in the market for a limited period on the condition of compulsory monitoring.</p> <ul style="list-style-type: none"> - labelling requirements extended to include foodstuffs and food containing additives or flavouring that have been genetically modified. <p>2000- a directive was introduced that will include a requirement for animal feeds to be labelled.</p> <ul style="list-style-type: none"> - need for prior consent of third countries that are importing GMOs. <p>2005 was set as a definitive date for phasing out the use of GMOs that are resistant to antibiotics.</p>
Japan	<p>1999- Japanese government recognized 22 GMOs as “safe products. All imports containing GMOs other than the approved ones to be rejected.</p> <p>2000- Japan introduced mandatory labelling requirements for final products containing GMOs.</p> <ul style="list-style-type: none"> - Japanese government circulated the official definition of organic farm products. GM products are among the products that cannot be labelled as organic.
United States	<p>1996- US government approved some 50 varieties of genetically modified crops.</p> <p>1999- A bill requiring labelling of all genetically modified entity was introduced, but the issue remains unresolved up till now.</p> <p>2000- A proposal was introduced by the FDA under which biotech industry would notify them four months in advance before marketing a new GM product and provide evidence of the safety of that product. This, however, is not mandatory it is followed on voluntary basis.</p> <ul style="list-style-type: none"> - the FDA released its proposed final rule for definitions of organic foods. Any food labelled ‘organic’ could not have been developed using GMOS.
New Zealand	<p>1999- a pre-market safety assessment to be carried out by the food authority before genetically modified food are sold.</p> <ul style="list-style-type: none"> - Introduced labelling of such products.
Australia	<p>1999- a pre-market safety assessment to be carried out by the food authority before genetically modified food are sold.</p> <ul style="list-style-type: none"> - Introduced labelling of such products.
Canada	<p>1999- the Canadian Council of Grocery Distributors agreed to develop a voluntary GM food labelling regime.</p>
Thailand	<p>1994- Thailand’s legislation on plant quarantine was expanded to cover GMOs. Under this, the release into the environment and the import of GM seeds and crops was subject to strict approval system.</p> <p>2001- The thai food authority intends to impose labelling requirements.</p>
Sri Lanka	<p>2000- The National Food Advisory Committee imposed ban on the import of GMOs and GM foods.</p> <p>2002- The ban was removed.</p>
Republic of Korea	<p>2000- passes a legislation regarding mandatory labelling of genetically modified soyabeans, corn, and soyabean sprouts.</p>

The European Community (EC) introduced an approval system for the deliberate release of GMOs in the environment. In the following years labeling of GMOs was made mandatory. This included foodstuffs and food containing additives or flavouring that have been genetically modified. Gradually even labeling of animal feed has been made mandatory. These initiatives of the EU have created a large public debate throughout the world. However, the European Commission has reserved the right to support biotechnology research. The Commission has also acknowledged that Europe's biotechnology industry is lagging behind. In fact, a strategy has been worked out to catch up in the race of this technology.⁵

Japan has also come out with stringent regulations. A committee in charge of developing rules for biotechnology labeling was appointed in 1997 under the Ministry of Agriculture, Forestry and Fishery (MAFF). This ministry has announced the introduction of mandatory safety checks to guard against imports of unapproved genetically modified crops for human consumption as well as animal feed.⁶ This has almost set a zero tolerance for food imports containing unapproved gene spliced products.

In the United States GMOs have been successfully and rapidly introduced in agriculture. The US Regulatory System dealt with GMOs at par with conventional products for risk assessment and safety purposes. A "Coordinated Framework" for regulating biotechnology products was adopted in 1986 (Economic Research Service 1998). As part of this approach the United States could deal with GMOs through the existing legislation and regulatory agencies based on the principle that biotechnology derived products are not different from other products in terms of safety evaluation. Therefore, existing regulations have not been amended so far. The USDA proposed regulation only for final products and their intended uses, not the method of production. However, methods of production are being monitored from the perspective of worker and environmental safety.

As the global debate over the benefits and safety of genetically modified food rages on, China has passed regulations that require clearer labeling of these types of

⁵ Checkbiotech.org, October 02, 2001.

⁶ Checkbiotech.org, April 02, 2001.

products. It was proposed to be in force by end of March 2002. However, China's State Council considered and passed the regulations concerning the biotech safety management of agricultural gene alteration. In the past, when crops with genetic alterations graduate from the laboratory to the field, they had to be approved by the Ministry of Agriculture. However, when they were transformed into merchandise, there were no such regulations. The new legislation will regulate the biological products with gene alterations requiring the above-mentioned food labeling, for example, so that the issues related to gene alteration can meet international standards.⁷

In countries like India, although biosafety policy evolved in the last decade, it has yet to address trade related issues. A policy was announced in 1987 and has subsequently been revised a couple of times, however, it still lacks clarity in terms of imports of genetically modified goods. One of the recent controversies which highlighted this lacuna was related to the import of genetically modified soyabean from the US by a donor agency serving food programme for children (see Chaturvedi 2001 for details). India's Biosafety and Recombinant DNA Guidelines (1990) falls under the Environment (Protection) Act of 1986. In 1994, after India signed the Convention on Biodiversity (CBD), the Department of Biotechnology (DBT) revised its earlier guidelines to accommodate the safe handling of GMOs in research, application and technology transfer. This includes the large scale production and deliberate release of GM plants, animals and products into the environment. Guidelines are also provided for the shipment and importation of GMOs for laboratory research.

Unlike many other countries, in India there is no permanent secretariat to monitor the trials and post commercialization of GMOs. Instead the regulations are implemented by various *ad hoc* committees. The three tier structure includes: the Institutional Biosafety Committees (IBSC), responsible for the local implementation of guidelines; the Review Committee on Genetic Manipulations (RCGM), a national committee responsible for issuing research/trial permits; and the Genetic Engineering Approval Committee (GEAC), responsible for monitoring the large scale and commercial use of transgenic materials. These committees have statutory authority. Most of the committee members are from the scientific community and staff of (DBT) and the Ministry of Environment and Forestry (MOEF). The DBT appoints the members to

⁷ Genet, May 16, 2001.

the committees. The GEAC is supposed to be assisted by the State Biotechnology Coordination Committees (SBCC) and District Level Committees (DLC). However, very few of the 26 states have established SBCC and DLC committees, not even in areas where field trials are already taking place. Moreover, while committee members are drawn from the scientific community, many are not well versed in biosafety implementation issues and risk assessment.

3. Provisions at WTO

The issues related to biotechnology especially to GMOs span several WTO agreements. They include agreements like sanitary and phyto-sanitary measures (SPS), technical barriers to trade (TBT), Agreement on Agriculture (AOA) and Intellectual Property (TRIPS). However, at WTO committees such as the Trade and Environment Committee (CTE), have also been discussing GMOs from environmental perspectives. Although member governments have notified a large number of regulations related to GMOs to the SPS Committee, most of the discussion on the subject has been in the TBT Committee with the focus on labeling regulations. In the current agriculture negotiations, some members have called for clarity in the WTO rules as applied to products of new technologies. In this section we take up two important agreements in light of GMOs viz. SPS/TBT and TRIPs for further discussion. As debate on labeling has emerged as a major policy challenge we discuss SPS measures in light of the experience of developing countries.

4.1 SPS and TBT Provisions

Generally, the trade impacts of SPS measures can be grouped into three issues: Firstly, they can prohibit trade by imposing trade bans on the product or on the inputs used for production. Secondly, they can divert trade from one trading partner to another by laying down regulations that discriminate across potential supplies. Thirdly, they can reduce overall trade flows by increasing costs or raising barriers for all potential suppliers.

As the liberalization of tariff and quantitative restrictions on trade in agricultural and food products has progressed, attention has focused on technical measures such as food safety regulation, labeling requirement and quality standards. The Agreement on Sanitary and Phyto-Sanitary (SPS) measures seeks to protect consumers by providing

rules for food safety and animal and plant health. However, the SPS Agreement does not permit non-science concerns such as consumer preferences to be considered in the determination of whether a SPS measure is acceptable (Gaisford and Kerr 2001). In certain cases, stricter SPS measures are applied to imports than domestic supplies. Given the nature and depth of existing regulatory structures in case of SPS in developed countries, developing countries often find it difficult to comply with such standards. At times, it seems that SPS measures may impede trade in agricultural and food products since in many instances they are incompatible with prevailing systems of production and marketing. Developing countries often lack appropriate scientific and technical expertise to deal with such standards. Moreover, the multiplicity of standards in developed country markets has further compounded the problems being faced by developing country exporters.

It has been agreed at the recently held WTO Ministerial Conference at Doha that negotiations on issues relating to SPS measures will be addressed on a priority basis in the next ministerial conference. In this regard, the CTE has been instructed to give particular attention to this effect. This has become relevant in light of the fact that the past decade has seen a global proliferation of environment and health related standards along with a rise in the trade in environmentally sensitive goods. Since the inception of WTO, some 2300 notifications have been received and almost 11 per cent of them are related to environment (Nordstrom and Vaughan 1999). The SPS Committee, meeting on 31st October and 1st November 2001, for the first time discussed genetically modified organisms. While considering notifications at the SPS Committee, the US and Canada enquired about the EU's restrictions on genetically modified organisms (GMOs). They complained that the EU had failed to notify its latest directives on traceability and labeling under SPS, even though these indicate that health protection is one of the objectives. The EU delegate said that any comments on this notification should be sent to its authority handling technical barriers to trade issues. Under "other business", the US also complained about the lack of scientific justification for the EU's continued de facto moratorium on approval of GMO products, and Canada said the latest EC measures discriminate against products produced by GM technology, even where no trace remains in the final products.

Experience of Developing Countries with SPS/TBT

The new Agreements on TBT and SPS measures were added to the WTO, with an idea that no country should be prevented from taking measures necessary to ensure the quality of exports, or for the protection of human, animal or plant life, or health of the environment, or for the prevention of deceptive practices, at the level, it considers appropriate. It has been demonstrated that developing countries find it difficult to trade with developed countries due to the differences in the quality requirements, which to some extent may reflect on the prevailing consumer concerns or the nature of government regulation (Murphy and Shleifer 1997).

Maskus and Wilson (2000) have evolved a framework to analyse the quantification of such trade barriers in terms of their impact. The paper also outlines the strengths and weaknesses in Mutual Recognition Agreements (MRAs). This is a model of regulatory harmonisation first developed as part of an internal market reform in the European Community in the late 1980s. Some application on these lines has come from Otsuki *et al* (2000), who have used a gravity equation model to estimate the impact of changes in food related EU standards on African exports. They did a survey of trade and regulatory data for 15 European countries and 9 African countries between 1989-1998. The results suggest that the implementation of the new aflatoxin standards in the EU will have a negative impact on African exports. The EU standards, which would reduce health risk by approximately 1.4 deaths per billion a year, will decrease these African exports by 64 per cent or US\$ 670 million.

Apart from the study by Otsuki *et al.* (2000) very few studies have made an effort to quantify the impact of SPS measures on trade for developing countries. Cato (1998) attempted to quantify the costs of compliance with SPS measures by developing countries. This study assessed the costs of upgrading sanitary conditions in the Bangladesh frozen shrimp industry to satisfy EU and US hygiene requirements. It was estimated that \$ 17.6 million was spent to upgrade plants over 1997-98. This gives an average expenditure per plant of \$283,000. The total industry cost required to maintain HACCP is estimated to be \$ 2.2 million per annum. Finger and Schuler (1999) examined the costs of SPS requirements in the developing countries. They found that the cost of achieving disease and pest free status to enable Argentina to export meat, fruit, and vegetables is reported to have been \$82.7 million over the period 1991-1996. Mutasa and Nyamandi (1998) assessed the degree to which SPS

requirements impede exports of agricultural and food products from African countries. Of the African countries, 57 percent indicated that exported products had been rejected within the previous two years. The main reason was microbiological contamination.

Some standards evolved in developed countries, as voluntary benchmarks for importing goods have become mandatory standards for developing countries. Eco-labelling is one of them. It has generated many concerns in developing countries. They argue that the voluntary Eco-labeling programmes are of discriminatory nature and are thus inconsistent with free trade principles of the WTO (Tieje, 1995). Since they are designed to differentiate products on the basis of their environmental features, they can have a major influence on conditions of competition in a market. Adverse trade effects may arise, firstly from lack of transparency of product selection, criteria development and threshold-setting processes. Exporters may have difficulty gaining information about these measures. In addition, the process of obtaining labels or ensuring compliance may pose greater difficulty for foreign producers. There is also the potential for market fragmentation arising from various eco-labeling schemes. (Chang 1997). Eco-labeling may also have an impact on cost competitiveness and on the attractiveness of the product in the market. (Vossenaar and Jha 2000). A case study on Malaysia by Markandya (2000) states that mandatory and voluntary labeling requirements have had an adverse effect on exports though the study does not give an estimate of the size of this impact. Another study on Thailand estimates the impact of Eco-labeling schemes as negligible in the key markets such as North America, East Asia and Europe. The study notes, however, that in the case of one eco-label developed in Germany to apply to textiles, Thai producers are adversely affected.

Certain developing countries have attempted to absorb these voluntary standards as official standards for exports. For instance, in India, the government has launched an Eco-labeling scheme for various products. However, a study by Jha *et al* (2000) reports that Indian exporters are not interested in subscribing to international eco-labeling schemes. These studies show that most producers do not feel that the evolving eco-labeling schemes have affected their exports significantly yet. However, it is widely acknowledged that these measures could potentially have a detrimental effect on the exports of developing countries.

Various cases have been brought under the WTO's new Dispute Settlement Understanding with SPS or TBT dimension. Hufbauer *et al.* (2000) discuss some SPS disputes that went through the entire WTO Dispute Settlement Mechanism in 1999. The cases discussed include EC- Beef Hormones from US and Canada; Australia- Salmon from Canada; and Japan- Varietals from U.S. In the case of Australia- Salmon from Canada, Australia continues its 1960s era ban against the import of fresh salmon from Canada, citing old evidence. The Appellate body, after a detailed analysis, found that the ban was not consistent with the level of sanitary and phytosanitary precautions applied to domestic salmon.

The WTO website provides the details of various trade related environmental disputes. One of the TBT cases is the 'shrimp-turtle' case brought by India, Malaysia, Pakistan and Thailand against the US. In early 1997, a joint complaint was made against a ban imposed by the US on the importation of certain kind of shrimp and shrimp products. Under the US Endangered Species Act of 1973, the US required its shrimp trawlers use 'turtle excluder devices' (TEDs) and hence, the exporters had to follow similar requirements. It banned exports from the south Asian countries and provided countries in the western Caribbean technical and financial support and longer transition periods. The US lost this case because it was discriminating between WTO members under the pretext of environment protection.

Robertson, D. and Kellow, A. (2000) explore the aspects of risk with special reference to the WTO, where national instruments to reduce risks may conflict with international trade rules. Quarantine regulations, technical/product standards and environmental legislation in some circumstances may conflict with trade rules and principles, and result in trade disputes. WTO's treatment of risk is also important in the context of agreement on SPS and TBT. The authors conclude that the WTO has no role in assessing scientific risk, especially when the environment is involved.

At the Committee on Agriculture this issue came up again in the same context. In the July special session of the Committee on Agriculture, the European Union tabled a controversial paper on food safety, proposing criteria for the application of precaution under the Agreement on Sanitary and Phytosanitary Measures (SPS) that would serve as a guideline for panelists in future disputes. According to the EU, the issue needs to be addressed to avoid the public perception that the WTO requires members to force consumers to accept unsafe food. The EU, other European countries, Japan and Korea

argued that Article 5.7 of the SPS Agreement should be clarified through an Understanding that would send the right signals to consumers. Article 5.7 allows members to take provisional health measures when relevant scientific evidence is insufficient. The substance of the discussions revolved around whether the Article was clear enough to maintain the balance between the need for consumer protection on the one hand and the need to avoid disguised protectionism on the other.

To create predictability for members and to prevent Article 5.7 from being abused for protectionist purposes, the EU proposed that precaution be applied according to the following five criteria: (i) the measure should not be discriminatory; (ii) it should be aimed at achieving consistency in the level of protection that the Member has chosen; (iii) the adopted measure should presuppose an examination of the benefits and costs of action and lack of action; (iv) it should be reviewed if new scientific information is obtained; and (v) the measure must be based on scientific evidence provided by qualified and respected sources, but not necessarily by the majority of the scientific community. The US and many developing countries strongly opposed this effort to bring food safety onto the agriculture negotiating agenda. They argued that the EU's version of the precautionary principle was based on political rather than scientific considerations. Suspecting that the EU was chiefly interested in finding another avenue for addressing the controversial precautionary principle in the WTO, the US, the Cairns Group and India said that instead of the agriculture negotiations, food safety should be discussed at the SPS and the TBT Committees.

4.2 TRIPs Agreement

The developments in biotechnology have been accompanied by a stronger intellectual property rights (IPR) regime. In fact, with the advancements in this technology, stronger instruments are being used for the protection of technology which are highly exclusionist in their approach. This may pose severe challenges for developing countries as advances in this technology are largely in the private sector and these new trends in the IPR regime seems to foreclose the entry of public sector in this domain. This is happening despite of the fact that a large number of developing countries have agreed to a relatively newer IPR regime at the WTO forum. In fact, coverage of the agricultural sector through an IPR regime is a recent phenomenon in developing countries. The emergence of biotechnology has further intensified the

debate. The WTO agreement on TRIPs requires developing countries to provide either patents or an “effective *sui-generis*” protection for the ownership of plant varieties by the year 2000. For the least developed countries, the deadline is extended until the year 2005.

The debate has remained largely focussed on the Article 27.3(b). Some countries have broadened the discussion to cover biodiversity and traditional knowledge. India, and many other developing countries, have been demanding an explicit position on benefit sharing regarding traditional knowledge systems. The Doha Ministerial statement says:

“We instruct the Council for TRIPS, in pursuing its work programme including under the review of Article 27.3(b), the review of the implementation of the TRIPS Agreement under Article 71.1 and the work foreseen pursuant to paragraph 12 of this declaration, to examine, *inter alia*, the relationship between the TRIPS Agreement and the Convention on Biological Diversity, the protection of traditional knowledge and folklore, and other relevant new developments raised by members pursuant to Article 71.1. In undertaking this work, the TRIPS Council shall be guided by the objectives and principles set out in Articles 7 and 8 of the TRIPS Agreement and shall take fully into account the development dimension.”

Broadly speaking, Article 27.3(b) allows governments to exclude plants, animals and “essentially” biological processes (but micro-organisms and non-biological and microbiological processes have to be eligible for patents). However, plant varieties have to be eligible either for patent protection or through a system created specifically for the purpose (“*sui generis*”), or a combination of the two. For example, countries could enact a plant varieties protection law based on a model of the International Union for the Protection of New Varieties of Plants (UPOV). The review of Article 27.3(b) began in 1999 as required by the TRIPS Agreement.

In this regard, the Joint Communication from the African Group maintains its reservations about patenting any life forms as explained on previous occasions by the Group and several other delegations (WTO 2003a). In this regard, the Group

proposes that Article 27.3 (b) be revised to prohibit patents on plants, animals, micro-organisms, essentially biological processes for the production of plants or animals and non-biological and microbiological processes for the production of plants or animals. For plant varieties to be protected under the TRIPs Agreement, the protection must clearly, and not just implicitly or by way of exception, strike a good balance with the interests of the community as a whole, protect farmers' rights and traditional knowledge, and ensure the preservation of biological diversity.

Though the US and other developed countries proposed a formal review of this article, resistance from other trading nations did not allow for the proposed review, in the WTO. This is of course a temporary relief. If at all this review is pushed back on the formal agenda, it would not come up before the next round of negotiations, which is in 2001-2, and even if it is taken up, it is not likely to be concluded before the completion of the round only (Watal 2000).

There is a large body of literature defining the concept *sui-generis* and whether UPOV 1978 or 1991 is of greater relevance for the developing countries (for details see Dhar and Chaturvedi 1998, Shiva 1996 and Sahai 1996). A detailed discussion of that is outside the scope of the paper. However, it is worth mentioning that the varietal protection is being attempted through a much stronger patent regime that does not allow any kind of exemption and is much narrower in its scope than the plant patents or plant variety protection. There is a continuous growth in what is called the utility patents in the US while the Biotechnology Directive of EU has suggested a similar mechanism for the protection of biotechnological inventions in Europe. Along with this there is also a growing trend of patenting research tools as well (Chaturvedi 2002). Thus, in light of the developments in biotechnology, the profile of the patent regime is changing quickly in developed countries. Needless to mention that a large part of this research is emanating from the private sector.

These changes would have severe implications for developing countries, more so when they are already struggling with the implementational hurdles of the TRIPs regime. There are many developing countries, including India, which have yet to put in place national legislations to position themselves vis-à-vis the international negotiations at the WTO. India has come out with several drafts of biodiversity and patent laws but they have yet to see light of the day. There have been several reasons for this delay but now it seems to be clear that it would not only adversely affect

access to technology per se but patenting of research tools would exclude the late comers in the technology race from imitation or even from product development in any other form.

There are seven debates at TRIPs Council as some countries are seeking clarification on issues such as the meaning of the term “micro-organism” and the difference between “biological” and “microbiological” processes. Some countries say life forms and living creatures should not be patented and that ethical questions should also be discussed. Some developing countries want to make sure that the TRIPS Agreement takes account of more specific concerns such as allowing their farmers to continue to save and exchange seeds that they have harvested, and preventing anti-competitive practices which threaten developing countries’ “food sovereignty”.

4.3 Extending COOL Provisions to GM Products

The Country of Origin Labeling (COOL) on food products has been incorporated in the US Farm Bill (2002). According to the amendments proposed in the Agricultural Marketing Act the COOL provisions would remain voluntary till September 30, 2004, by when USDA is expected to publish relevant regulations. At present the Farm Bill proposes to cover several commodities including beef, lamb, pork, fish, fresh and frozen fruits and vegetables and peanuts. The Bill also requires labeling by retailers of fish and shellfish products as either wild or farm raised (Article 282a). It requires that the label should be legible and should not obscure any required information and that it should be in English only. In the processed food items a combination of ingredients if that include a covered commodity under the Bill and if the identity of processed food item is different from that of the covered item then it is excluded from the purview of the Bill. For example apple slices in a pie crust and peanuts in a candy bar.

This has triggered a major controversy among the closer trade partners of the US. There is a disagreement over whether consumers value information on Country of Origin intrinsically or as a quality or a safety signal (Hobbs 2003). Some of the studies show that the US COOL provisions may affect exports from Canada adversely. For instance, Canadian beef may be discounted 10 to 20 per cent in the market and industry estimates of a 5 to 20 per cent decline in live cattle prices (Thomas 2002). This Bill has again brought the whole issue of “consumers’ right to

know” to the centre stage - something what was already there in form of labeling of genetically modified food.

Article IX on Marks of Origin of 1994 GATT allows Country of Origin Labeling (Hobbs 2003). Imports can be labeled with the Country of Origin as long as the labeling requirement does not seriously damage the good, materially reduce its value or result in an unreasonable increase in its cost (Kerr, 2003).

4. Impact on Trade

As is clear, though international trade regime at WTO has yet to address challenges emanating from advancements in biotechnology, the prohibitive measures have already started affecting the trade. The major producers of GM products have taken EC to the WTO dispute settlement panel. The US, Canada and Argentina introduced their first-time panel requests (respectively, WT/DS291/23, WT/DS292/17, & WT/DS293/17) at WTO. They all have stated that, regarding EC-level measures, the moratorium maintained since October 1998 on the approval of biotechnology products had restricted the imports of agricultural and food products. The US emphasized that the EC procedures are not the focus of the US complaint. It is the EC’s application of its measures governing the approval of biotech products. The US also expressed its concern that the EC measures were hindering the worldwide development and application of agricultural biotechnology – a technology that, according to the US, has great promise for raising farmer productivity, reducing hunger and improving health in the developing world, as well as improving the environment. Argentina added that agricultural products account for over half of Argentina’s total exports, and that it is the second largest producer and exporter of biotech products in the world. Argentina said that the EC’s “behaviour” discourages the introduction of biotech processes, and that it is particularly detrimental because EC has the ability to influence other WTO members. Table 3 shows how US export of Corn and Soyabean has declined in several of those countries which have resorted to these prohibitive tactics. Apart from this, delays in authorization to import some Bt corn from the US by France cost US exporters about \$300 million in exports to the European Union (Cunningham and Unnevehr, 2000). Only about 2 million tonnes of the 42 million tons of US corn exports went to the EU in 1997. In 1998, only 0.3 million tonnes of the 41 million tonnes went to the EU. Factors that have been used to

explain the declines include bans of GM corn by France, Austria and Luxemburg (Cunningham and Unnevehr, 2000). Similar declines have been documented for soyabeans.

Table 3: U.S. Exports of Corn and Soybeans to Selected Regions/Countries, 1997-2000

Region/ Country	Corn (10⁶ metric tones)*			Soyabeans (10⁶ metric tones)		
	<i>1997 Jan-Dec</i>	<i>1999 Jan-Dec</i>	<i>2000 Jan-Dec</i>	<i>1997 Jan-Dec</i>	<i>1999 Jan-Dec</i>	<i>2000 Jan-Dec</i>
Africa	3.95	6.69	6.46	0.11	0.28	0.23
Asia	27.68	31.45	26.73	11.68	12.14	14.94
European Union	1.56	0.09	0.07	8.96	6.46	6.10
Japan	15.45	15.33	14.87	3.70	3.68	3.58
South Korea	3.44	6.16	2.29	1.25	1.17	1.34
Canada	1.03	0.97	1.49	0.26	0.33	0.33
China (Taiwan)	5.44	4.73	4.72	2.27	1.95	1.93

* 1 metric ton = 2,204 pounds. Source: <http://www.ers.usda.gov/db/fatus/>

Many developing countries, including India, are now being exposed to the difficulties in the governance of biotechnology (Chaturvedi 2002). Genetically modified cotton has already been illegally introduced in the production system, which is set to create problems with those countries in which imports of GM variety are banned - a problem similar to what we saw in case of US. However, as Table 4 shows, the total impact on exports of only those crops in which biotechnological applications have been planned (eg cotton, corn, soyabean and vegetables) to only three countries would be \$6201 million. It would be more than \$1700 million to the EU alone. The confusion is further confirmed when one finds that there are very few equipped laboratories in which GMO testing can be done. Therefore, a clear market strategy and options with technological choices would have to be made with precaution. The EU, in its submission to WTO, has made it clear that it has no intention to hold back biotechnological developments and in fact has cleared 18 GMOs and 15 food products derived from GMOs, however, will only do so on case to case basis (WTO 2003b). The US and Canada feel that this may impede the growth in trade.

Table 4: India's Exports of (Potential GM) Crops (US Dollar Million)

	Cotton	Corn	Soyabean	Vegetables	Tot Crops imported by Countries	% Share In Tot Exports of Crops
EU	1725.64 (28.99)	0.05 (2.27)	0.08 (32.00)	41.44 (16.77)	1767.21	28.50
Japan	161.79 (2.72)	--	0.11 (44.00)	1.36 (0.55)	163.26	2.63
South Korea	189.03 (3.18)	--	--	0.52 (0.21)	189.55	3.06
Total	5951.7	2.2	0.25	247.07	6201.22	100.00

Source: India Trade 2001

Note: Figures in parenthesis are percentage share in total exports

5. Concluding Remarks

The above analysis shows that it is desirable that developing countries make choices in biotechnology at selective levels. Even within agricultural biotechnology there are several options which take the horizon far ahead of adoption and diffusion of GMOs. This decision should be subject to a critical evaluation of the need assessment of developing countries. In order to obtain benefits and be competitive in biotechnology, developing countries need to access not only the products but, more importantly, to the technology and certainly the tool for it. In addition, access to genetic resources and the associated traditional knowledge plays a role, highlighting the need for benefit sharing and prior informed consent.

There has to be a multilateral effort to help build capacity related to institutions, infrastructure, policy development and implementation, human resources, local-level ecological data, and research and development in developing countries in general and in underdeveloped countries in particular. These countries also require support to adopt GM products along with provisions for their safe use and capability to handle their trade. As far as international negotiations are concerned, a strategy founded on well-informed opinion on technical aspects should be evolved. This includes participation in international negotiations at the WTO and international standard-setting organisations. As far as scientific substantiation for the precautionary principle is concerned, a large number of studies have been quoted in this paper which suggest that there is a growing convergence of various standards. Thus the distinction in environmental standards and health and quality standards is gradually becoming very blurred. Though empirical evidence on this in the literature is extremely limited,

some developing countries have experienced losses in exports because of difficulties complying with certain sanitary and phyto sanitary measures in the import markets. This shows that the precautionary principle is being exercised against the agricultural exports from developing and least developed countries. The debate pertaining to the precautionary principle should also take this factor also into account while any decision for GM labeling is being worked on.

In the WTO TRIPs regime, Article 27.3 (b) refers to having either a patent regime or an effective *sui generis* system for protection of plant varieties. In the last decade or so, developing countries have strongly debated the various aspects of a *sui generis* system and what it actually constitutes. However, as is evident from the earlier sections, the varietal protection is being attempted through a much stronger patent regime, which does not allow any kind of exemption and is much narrower in its scope than the plant patents or plant variety protection. There is a continuous growth in what is called the utility patents in the US while the Biotechnology Directive of EU has suggested a similar mechanism for the protection of biotechnological inventions in the Europe. Along with this there is also a growing trend of patenting the research tools as well. Thus in light of the developments in biotechnology the profile of the patent regime is fast changing in developed countries. Needless to say, a large part of this research is emanating from the private sector. This poses a great challenge before the late comers in this technology viz. the developing countries for whom biotechnology provides a large potential for economic development. These changes would have severe implications for developing countries, more so when they are already struggling with the implementation hurdles of the TRIPs regime. Developing countries would have to be better prepared for the new trade regime and technologies for instance many countries including India, have yet to put in place national legislations to position themselves vis-à-vis the international negotiations at the WTO.



Mutually Supportive Implementation of Cartagena Protocol on Biosafety and The World Trade Organization Rules

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1. Introduction

The Convention on Biological Diversity (CBD) is one of the three multilateral environmental agreements that was adopted as a result of the Rio Earth Summit in 1992. About 189 countries are Parties to the CBD, agreeing to implement various provisions of the Convention. Also, the CBD is one of the key trade-related multilateral environmental agreements that aims to promote the conservation and sustainable use of biodiversity besides sharing the benefits of such use equitably. One of the significant outcomes of discussions under the CBD has been the adoption of the Cartagena Protocol on Biosafety (hereinafter, the Protocol) which was adopted after a 6 years of tough negotiation in January 2000. This Protocol will enter into force on September 11, 2003 since the minimum number of countries required to ratify the Protocol has been reached. As of July 10, 2003 52 countries have ratified the Protocol. The Protocol is based on the precautionary approach and establishes a core procedures and a set of standards relating to the import and export of LMOs to ensure the Parties are able make informed decisions. Discussions and decisions on implementation of the Protocol will be decided at the Conference of Parties to the CBD acting as the Meeting of the parties to the Protocol (the COP-MOP) scheduled to be held in Kuala Lumpur between 23-27 February 2004.

The World Trade Agreement is a set of internationally binding Agreements negotiated under the World Trade Organisation (WTO). As of July 2003, WTO has a membership of 144 countries and customs territories. The WTO rules are designed to

liberalize market by removing unnecessary, discriminatory and protectionist barriers to free trade.

WTO has been discussing the need to address issues of environmental concerns of trade practices for a long time. More recently, the 4th Ministerial Conference in Doha agreed to launch negotiations on certain aspects of the trade and environmental linkage. This was followed by the Ministerial Declaration at CBD COP6 to the CBD and Plan of Implementation of the World Summit on Sustainable Development (WSSD) who all reaffirmed the importance and the need to design and implement mutually supportive activities with other conventions, international organizations and initiatives.

A quick review of CBD obligations to trade reveals the fact that even though the word ‘trade’ is not mentioned, several Articles relate to trade and associated issues (Table 1). Several decisions of the Conference of Parties relate to trade like the COP 5 decision V/6 on applying an ecosystem approach to conservation that mentions that any ecosystem management programme should:

- a. reduce those market distortions that adversely affect biological diversity;
- b. align incentives to promote biodiversity conservation and sustainable use;
- c. internalize costs and benefits in the given ecosystem to the extent feasible.

Table 1 *CBD Obligations relating to Trade*

Article	What it says
Preamble	Calls on Parties to adopt a precautionary approach
Article 6 (b)	Requests sectoral integration of conservation, sustainable use and benefit sharing issues
Article 8 (h)	Calls for preventing introduction of invasive alien species besides their control and eradication
Article 8 (l)	Calls for regulating or managing processes and activities that will have adverse impacts on biodiversity
Article 10 (b)	Calls on Parties to adopt measure relating to use of biological resources to avoid or minimize adverse impacts on biodiversity
Article 10 (d)	Calls for protection of customary use of biodiversity that is compatible with conservation and sustainable use
Article 11	Calls on Parties to adopt economically and socially sound measures that act as incentives for conservation and sustainable use of biodiversity
Article 14	Calls on Parties to establish sound environmental impact assessment methodologies

Article 15	Establishes the rules on access to genetic resources and equitable sharing of benefits arising out of such use
Article 16	Calls for the transfer of technologies, considering the IPRs
Article 19	Calls for measures to ensure safe use of biotechnology
Article 22	Relationship with other Conventions

A similar review of WTO obligations relating to biodiversity and environment provides mechanisms to address issues of trade and the importance of biodiversity (Table 2). The Doha Ministerial Declaration has implications for environment as well as biodiversity, especially on issues dealing with tariff and non-tariff barriers. These are subject of discussion at the 5th WTO Ministerial Conference.

Given the situation, this paper attempts to provide an overview to: (1) identify and clarify the trade-related measures under the Protocol, including the precautionary approach, the advanced informed agreement procedure, the risk assessment system, the handling, transport, packaging or labeling requirements, the socio-economic considerations on the decision of a import, and national regulation on biosafety of LMOs; (2) analyze the concerns and the potential conflicts between the Protocol and the General Agreement on Tariffs and Trade (GATT), the Agreement on Technical Barriers to Trade (TBT) and the Agreement on Sanitary and Phytosanitary (SPS), including the possibility and uncertainties of risk, the importance to ensure human, animal or plant safety and that of the environment, and the necessity to take appropriate measures to regulate the transboundary movement of LMOs; (3) provide some suggestions to promote mutually supportive implementation of the Protocol and the relevant WTO agreements.

Table 2 WTO Obligations relating to Biodiversity

Issue	What it says
Preamble	Commits for sustainable development and to protect and preserve environment
Article 6 (relevance to Agreement on Agriculture)	Provides framework for reducing subsidies, but exempts certain environmental activities
Article 2 (relevance to SPS)	SPS measures to be applied only to the extent necessary and not to be applied without scientific evidence.
Article 3 (relevance to SPS)	Expresses presumption of consistency for international standards

Articles 3.3, 5 and 5.7 (relevance to SPS)	Risk Assessment procedures as relevant to Member's needs
Article 2.6 (relevance to TBT)	Requests international standards to be set up as per technical regulations
Article 2.2 and 2.4 (relevance to TBT)	Requests members to use international standards for legitimate objectives that include protection to human health or safety, animal or plant life or health, or the environment
Articles 2.9, 2.11, 5.6, 5.8 and 10	Seek to enhance transparency in the establishment of the standards
Article 3.1 (Relevance to Agreement on Subsidies and Countervailing measures)	Prohibits subsidies if they rely on export performance, or are contingent on use of domestic rather than imported goods.
Article 8.2 (c) (relevance to ASCM)	Allows for assistance to existing facilities to promote adaptation to new environmental requirement in specific circumstances; however, this provision is time limited and not renewed in 1999.
Article 27 (2) (Relevance to TRIPs)	Requires that patents be available for all inventions, but adds members can prevent patents to protect <i>ordre public</i> or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
Article 27.3 (b)	Allows members to exclude from patenting "plant, animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological or microbiological processes. However, members are to provide for the protection of plant varieties either by patents or by an effective <i>sui generis</i> system or a combination thereof".
Article 66.2	Calls for developed country partners to encourage transfer of technology to developing countries

2. Identification and clarification of the trade-related measures under the Protocol

At the WTO ministerial conference in Doha, the relationship between WTO rules and multilateral environmental agreements (MEAs) was identified as a key issue for the ninth round of multilateral trade negotiations at the 5th WTO Ministerial Conference. Identification of specific trade obligations (STOs) will be the starting point of the negotiations of the WTO-MEAs' relationship. WTO Members have begun substantive discussions to examine STOs under certain MEAs. However, STOs under MEAs can cover a wide spectrum of possibilities, ranging from trade bans to notification procedures or labelling requirements. For example, Switzerland identified two categories of measures that arose from trade obligations. The first, mandatory trade measures explicitly provided for under the MEAs: This is the case of the Protocol

since it requires advanced informed agreement (AIA) procedure for the first shipment of LMOs; The second category, non-mandatory measures which are not explicitly provided for under MEAs, but appropriate and necessary to achieve an MEAs' objectives. Under the Protocol issues of labeling will come under discussion through this category.

It must be noted that the Protocol is one of the elements of an MEA that has been negotiated by the countries with different backgrounds and interests in biotechnology and the final outcome is a package reflecting the internal balance of rights and obligations. Hence, identifying and clarifying what constitutes the STOs will be helpful to increase the weight of the Protocol on the negotiations on environment and trade (Wang, 2003). A detailed analysis of the text of the Protocol reveals the following aspects as relevant to trade related measures and LMOs.

(1) Advance informed agreement (AIA) procedure (Article 8-10). The procedure is the Protocol's central mechanism regulating the decision-making process for the first shipment of LMOs intended for introduction into the environment of the Party of import. The AIA procedure starts with the notification of the proposed movement (transboundary) of the LMO to the Party of import. This notification needs to contain certain information relating to the exporter, the LMO and its intended use, as well as other information. The next step is that, within 90 and 270 days of receiving the notification, the Party of import must acknowledge receipt and inform its decision to the notifier and the Biosafety Clearing-House (established by the CBD), respectively. According to the AIA procedure, four possible decisions from the Party of import may be made: approve the import of the LMO, with or without conditions; prohibit the import of the LMO; request additional information; or inform the notifier that the import decision will be taken within a further defined period of time.

As per the AIA procedure, the elements which influence the decision of import of LMOs include the accuracy of information provided by the exporter (Article 8(1)), the existing scientific evidence available for risk assessment (Article 10(1)), the efficiency of decision-making of the importing Party (Article 9(2) and 10(2)), and the flexibility of applying the precautionary approach (Article 10(6) and 11(8)). In effect, inaccurate information from the exporter and inefficient decision-making processes of the importing Party will cause the exporter to lose the good chance to occupy the international market of LMOs, while discretion on the risk associated with a LMO, in

the case of insufficient scientific knowledge and evidence may lead to a refusal to the import of the LMO (Mackenzie, 2003).

(2) Precautionary approach (Article 1, 10 and 11). The precautionary principle has increasingly been reflected in many international treaties and national laws on environment and natural conservation since 1970s. However, two different formulations of precautionary principles are in use, ranging from soft to strong formulations (Box 1).

Box 1: Two formulations of precautionary principle

(Source: UNDP-HDR, 2001)

The formulation contained in Principle 15 of the Rio Declaration on Environment and Development is relative soft, where it says “to protect the environment, the precautionary approach shall be widely applied by states according to capability. Where there are threats of serious or irreversible damage, lack of full scientific certainty shall not used as a reason for postponing cost effective measures to prevent environmental degradation”. That is, regulators can take cost-effective steps to prevent serious or irreversible harm even when there is no certainty that such harm will occur.

A strong formulation is set out in the 1990 Third Ministerial Declaration on the North Sea, which requires governments to “apply the precautionary principle, that is to take action to avoid potentially damaging impacts of (toxic) substances...even where there is no scientific evidence to prove a casual link between emissions and effects” The formulation requires governments take action without considering offsetting factors and without scientific evidence of harm.

While examining the Protocol, it is easy to understand that the precautionary principle under the Protocol is a soft formulation. For example, the preamble under the Protocol reaffirms the precautionary approach contained in Principle 15 of the Rio Declaration and Article 1 states that the objective of the Protocol is to be pursued “in accordance with the precautionary approach contained in Principle 15 of the Rio Declaration”.

In addition, the Protocol also contains some strong provisions for actions in circumstances of scientific uncertainty. For instance, the commitment to the precautionary approach is further operationalised in Article 10, which governs the AIA procedure by which the Party decides on the import of LMOs. Article 10 (6) states that “lack of scientific certainty... shall not prevent a Party from taking a decision, as appropriate, with regard to the import of the LMO in question...” A

similar clause is contained in Article 11, which covers the special case of the LMOs intended for direct use as food, feed or for processing (LMO-FFPs). This gives the precautionary principle a significant role in the decision to restrict or prohibit the import of LMOs.

(3) Risk assessment (Article 15). Risk Assessment under the Protocol is a scientific tool for the implementation of the AIA procedure. As per the Protocol, the importing Party's decision must be based on a careful assessment of risk(s) that must be undertaken in a scientifically sound manner, taking into account recognized risk assessment techniques. Such risk assessment shall be based, at a minimum, on information provided in accordance with Article 8 and other available scientific evidence as well as shall be carried out on the case-by-case basis. In addition, the Party of import has a right to require the exporter to carry out the risk assessment and its cost shall be borne by the notifier.

(4) Handling, transport, packaging or labeling requirements (Article 18). Article 18 of the Protocol requires all Parties, prior to export, to identify through accompanying documentation any LMO-FFPs that “may contain” LMOs, and identify any LMOs for intentional introduction into the environment (LMO-IIEs) or LMOs destined for contained use (LMO-CTUs). The Protocol also authorizes both exporting and importing Parties to take measures to ensure this identification takes place. The labeling of LMO-FFPs may lead to better matching of individual consumer preference, but when preferences differ, some consumer shall necessarily be unsatisfied by the social outcome. For example, if consumer perceived genetically modified (GM) foods as posing potential health and environmental risk, then presumably, risk-averse consumers would choose to consume more conventional foods, while the risk-neutral would choose either GM or conventional foods. On the other hand, the labeling of the products derived from modern biotechnology will also cause an increase in the cost of their production. In addition, Article 18 states that handling, transport, and packaging requirements for GM products shall be considered for elaboration in the future meeting of the Party to the Protocol. However, the impacts of this future outcome on LMOs' trade need to be further identified.

While many policy makers and environmentalists weigh the benefits and costs of labeling, they are not always clear on whether labeling can be a useful policy tool.

Labeling may be an appropriate policy tool in the circumstances mentioned in the following box (Box 2).

Box 2: Several circumstances in which labeling may be an appropriate policy tool (Source: Golan E, Kuchler F, and Mitchell L)

- Consumer preferences differ. Labeling may be preferable to other policy tools if consumer preferences differ widely with respect to product characteristics.
- Information is clear and concise. The information on the label must be clear, concise, and informative. Information that is unread or is misunderstood will lead neither to informed consumption decisions nor to a better matching of preferences with purchases. Unclear information may increase search and information costs.
- Information on product use enhances safety. For some products, the manner in which consumers use or consume the product influences the quality attributes of the product. Information that helps consumers avoid or minimize risk is particularly valuable.
- Costs and benefits of consumption are borne by the consumer. If the consumption or production of a food creates externalities (that is, affects someone else's welfare in a way that is not reflected in the market), then information-based policies will usually be insufficient to align private consumption choices with socially optimal choices.
- Standard, testing certification and enforcement services can be established. Mandatory labeling will result in confusion and actually increase transaction costs if it is not supported by clear, achievable quality standards; testing services to measure the validity of labeling claims; certification services substantiating the validity of the quality claim; and mechanisms for enforcing labeling rules.
- No political consensus on regulation exists. In many regulatory policy debates, there is little consensus on the appropriate regulatory response. Some groups may advocate complete product bans while others advocate no government intervention at all. In these cases, labeling may represent the best compromise solution, both domestically and internationally. Labeling in such instances, however, may provide consumers with little real information, particularly when the lack of political consensus arises from a lack of scientific consensus.

This might lead to conflicts under the WTO regime when labeling becomes mandatory. This is why the Protocol discussion is on going about labeling and the 'may contain' clause is becoming contentious. One way out of this impasse will be to make labeling voluntary but based on discussion between importers and exporters.

However, if the importers need, the exporters could have the choice to provide the contents of the labels supplemented by the labels provided by the importing countries.

(5) *Socio-economic considerations (Article 26)*. The Party, in reaching a decision on an import, may take into account the socio-economic considerations arising from the impact of LMOs on the conservation and sustainable use of biodiversity, especially with regard to the value of biodiversity to indigenous and local communities. Article 26 identifies the types of socio-economic considerations and requires that such considerations be taken into account consistent with a Party's other international obligations. Finally, it encourages Parties to cooperate on research and information exchange on the potential socio-economic impacts of LMOs.

Currently, several countries including Australia, New Zealand, Brazil, European Union, U.K. Hong Kong, Japan, Russia, Korea, Switzerland, Taiwan, U.S.A and Thailand have voluntary labeling requirements under implementation or consideration.

(6) *National regulations on biosafety* The reference to the development of domestic regulatory framework is made at least 10 articles of the Protocol in order to deal with the activities required by the AIA procedure, such as the importing decision of LMO-FFPs, risk management, public participation, transboundary movements and socio-economic considerations in making a decision of a LMO. The Protocol also provides a minimum standard to regulate the transboundary movement of a LMO. The national biosafety frameworks are intended to be the legal or regulatory mechanisms not only to deal with safe use of biotechnology and its products / processes but also to decide on the issues of guiding trade of LMOs. However, current guidelines for developing such frameworks are not considering this even though they are addressing elements of all the above issues. Thus, the trade-related specific measures under national regulation will affect the import of LMOs, even though it is consistent with the objective of the Protocol.

In summary, the AIA procedure under the BSP should be regarded as a mandatory trade-related measure with regard to LMOs. However, it should be noted that other measures mentioned above serve as indispensable components for the operation of the AIA procedure and thus should fall into the scope of the STOs

Treatment of different categories of LMOs under the Protocol

On the basis of their intended use, the LMOs under the Protocol may be divided into four categories: LMOs for human pharmaceuticals (LMO-HPHs), LMOs for contained use, LMO for food, feed and processing, and LMOs intended for introduction into the environment. In fact, the formation of these categories is a compromised result of five groups (the Miami Group, the G77, the EU, the Central and Eastern Europe Group, and the Compromise Group) with different economic interests in the international trade of biotechnology products during the negotiation of the Protocol (Mackenzie et.al. 2003).

Each of categories under the Protocol is subject to different treatment. The precautionary approach and risk assessment shall apply to the transfer, handling and use of all the LMOs resulting from modern biotechnology. In reaching a decision of importing a LMO, socio-economic impacts may also be considered. AIA procedure shall not apply to the movements of LMO-HPHs. The transboundary movement of LMO-CTUs is not required to comply with AIA procedure, but shall meet the national standards as CTUs. LMO-FFPs are not required to comply with AIA procedure, but shall need inform the import decision to BCH and meet the requirements set by the relevant regulations of importing country. LMO-IIEs shall be subject to AIA procedure when they are proposed for the first introduction into the environment in the Party of import (French 2001; Mackenzie et.al. 2003).

3. Concerns and conflicts between the Protocol and WTO Rules

3.1 Relevance of the Protocol with the WTO Rules

Article I of the GATT requires any trade advantage conferred by one country on another to be extended to all WTO members (Most-Favoured-Nation Clause). Article III prohibits discriminatory treatment between “like” or competing domestic and imported products (National Treatment Clause). Article XI forbids any quantitative restrictions other than duties, taxes or other charges. Article XX, which contains a general exceptions' clause. The relevant parts of Article XX states that “nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures: (b) necessary to protect human, animal or plant life or health;...(g) relating to the conservation of exhaustible natural resources if such

measures are made effective in conjunction with restrictions on domestic production or consumption;...”

The Technical Barriers to Trade (TBT) and the Sanitary and Phytosanitary Standards (SPS) Agreements were adopted to “further the objectives” and to “elaborate rules for the application of the provisions” of the GATT. The TBT and the SPS both are exclusive from each other. If a trade-related measure does not fall within the scope of the SPS Agreement, it can be covered by the TBT Agreement. The TBT Agreement applies to all measures affecting the trade in any products that are technical regulations or technical standards, as long as those measures do not fall under the SPS Agreement. The most specific of the three Agreements is the SPS Agreement. This Agreement, in simplest terms, governs all measures that may directly or indirectly affect international trade in any product. Unlike the SPS Agreement, the TBT Agreement does not expressly require a Member to analyze its regulation on the basis of a risk.

The scope of the Protocol implies that its implementation has implications for following the WTO rules. For example, the AIA procedures for the import of LMOs are likely to fall under the SPS Agreement, while labeling required under Article 18 of the Protocol will likely fall under the TBT Agreement. The GATT applies to all measures affecting any product in international trade, including LMOs.

3.2 Issues between the Protocol and the WTO Rules

Both the SPS and the TBT Agreements promote the use of science and risk assessment as a means for justifying trade-related measures. The Protocol’s risk assessment procedures were designed along similar lines, namely scientific evidence. In analysis of the texts of the Protocol and the three WTO rules, the following issues emerge that both the Protocol and WTO rules:

- (1) recognize the impact of international trade activities on the environment and biodiversity in which species are basic components;
- (2) realize the importance and necessity to ensure the safety for human, animal or plant life and health as well as environment;
- (3) recognize the possibility of risks arising from of the transboundary movement of the products which contain harmful living organisms, including LMOs;

- (4) recognize that it is necessary to take appropriate measures to regulate the transboundary movement of the products which contain harmful living organisms, including LMOs;
- (5) recognize that risk assessment is rather critical to take appropriate measures to regulate the transboundary movement of the products which contain harmful living organisms, including LMOs and emphasized that the risk assessment must be based on scientific information and data, as well as should take into account internationally recognized techniques and methodology (Table3);
- (6) consider that application of the precautionary principle to the decision in the case of insufficient scientific knowledge and evidence;

Table 3 Similarities in risk assessment elements under the Protocol and SPS

Risk assessment under the Protocol	Risk assessment under the SPS
In a scientific sound and transparent manner (Article 15 and Annex III)	Take into account available scientific evidence (Article 5(2))
Taking into account expert advice of , and guidelines developed by, relevant international organizations (Annex III)	Taking into account risk assessment techniques developed by the relevant international organizations (Article 5(1))
Based on the available scientific evidence (Article 15(1))	Take into account available scientific evidence (Article 5(2))

3.3 Potential conflicts between the Protocol and the WTO Rules

Even though the WTO Rules and the Protocol took into consideration respective needs of trade and environment safety, the distinction of their fundamental objectives may lead to the potential conflicts in regulatory measures taken to ensure the achieving of their respective objectives. From the drafting and negotiation of the Protocol through its finalization, among the most contentious subjects are the application of precautionary approach in the conditions that scientific evidence is insufficient and the socio-economic considerations in the decision of importing LMOs. Following are the analyses of some potential conflicts between the Protocol and the three WTO rules (Mackenzie et.al. 2003).

- (1) From the risk assessment perspective, the LMOs considered under the Protocol are equivalent to the organisms that are regarded as pests, diseases, disease-carrying or disease-causing under the SPS. This means if substantive equivalence exists between

the both, there is a possibility to undertake risk assessment in same or similar manner for the products under the Protocol and the SPS. Otherwise, it may be scientifically sound and reasonable to undertake risk assessment in line with the nature of the organism.

(2) The specified risks that LMOs may pose to biodiversity and to human health are not identified in the Protocol, while three categories of risks have clearly been identified in annex A of the SPS. Hence, it is not possible to determine in advance, which WTO Agreement (the SPS or the TBT) will apply to a trade-related measures taken under the Protocol.

(3) There are clear differences in the details of carrying out risk assessment for a LMO (Table 4). This may lead to a different risk estimate made on the basis of the assessment. As shown in Table 4, with regard to a certain biotechnology product, the details needed to be considered for risk assessment under the Protocol and the SPS are very different. Cosbey and Burgiel (2000) identified several differences in the approach to risk assessment between Article 5.7 of the SPS and the relevant provisions of the Protocol. First, the SPS does not specify exactly what a risk assessment is, but the Protocol elaborates this in detail in Annex II. Secondly, the SPS does not mention risk management, but merely risk assessment. The Article 15 and 16 of the Protocol mentions both exercises, respectively, defining the latter as the gathering of the data, and the former as the building of a regulatory regime based on that data. It gives detailed guidance as to the establishment of the regime, e.g. asking parties to try to ensure that any LMO should undergo an appropriate period of observation commensurate with its life-cycle or generation time before it is put to its intended use (Mackenzie *et.al.* 2003).

Table 4 Different elements to be considered in the risk assessment

The risk assessment under the Protocol	The risk assessment under the SPS
Lack of scientific knowledge or scientific consensus should not necessarily be interpreted as indicating a particular level of risk, an absence of risk, or an acceptable risk (Annex III)	In the case of insufficient relevant scientific evidence, a Member may provisionally adopt sanitary or phytosanitary measures which will be subject to following points: <ul style="list-style-type: none"> (i) they must be adopted on the basis of available pertinent information; (ii) the Member must seek to obtain the additional information necessary for a more objective assessment of the risk; and

	(iii) the Member must review the measure within a reasonable period of time. (Article 5(7))
Details needed to be considered for the LMO in risk assessment (Article 15 and Annex III): -Recipient organisms or parental organisms -Donor organism(s) -Vector -Insert and/or characteristics of modification -Characteristics of LMOs -Detection and identification of LMOs -Information relating to the intended use -Receiving environment	Details needed to be considered for the product in risk assessment (Article 5(2)): -Processes and production methods -Relevant inspection, sampling and testing methods -Prevalence of specific diseases or pests --- Existence of pest- or disease-free areas; -Quarantine or other treatment. -Relevant ecological and environmental conditions
The steps to carry out risk assessment (Annex III)	Not specified
The cost of risk assessment may be borne by the exporter (Article 15.3)	Not specified

(4) The application of the precautionary approach under the Protocol and the SPS is different. Under Article 10 (6) of the Protocol, lack of scientific certainty shall not prevent a Party from taking a decision, as appropriate, with regard to the import of the LMO in order to avoid the adverse effect of the LMO on conservation and sustainable use of biodiversity, taking into account risks to human health. Because the Protocol does not give a limit to the application of the precautionary, its application is very flexible based on the different purposes. However, the SPS clearly indicates that the level of sanitary or phytosanitary protection shall be appropriate (Article 3.3). The measures are not more trade-restrictive than required to achieve their appropriate level of sanitary or phytosanitary protection, taking into account technical and economic feasibility (Article 5.4). To sum up, the significance of the precautionary provisions in the Protocol is that they fill in some of the gaps in the SPS. Indeed the some precautionary provisions (Article 10(6) and 11(8)) of the Protocol is even stronger than the general expression of the precautionary principles in Principle 15 of the Rio Declaration and obviously geared towards an area in which there is a great deal of uncertainty and concern.

(5) The socio-economic considerations applied to a decision of import in regard to a LMO aroused debates during the negotiation of the SBP. Pursuant to Article 26 of the Protocol, in reaching an import decision of a LMO, the Party of import shall consider:

the impact of LMOs on the conservation and sustainable use of biodiversity, and the value of biodiversity to indigenous and local communities. Hence, the scope of socio-economic considerations under the Protocol is wide, while SPS puts strict limits on the economic considerations: the potential damage in terms of loss of production or sales in the event of the entry, the establishment or spread of a pest or disease, the costs of control or eradication in the territory of the importing Member, and the relative cost-effectiveness of alternative approaches to limiting risks.

(6) The mandatory labeling of LMO-FFPs under the Protocol may be in conflict with the WTO rules. Firstly, under the Protocol, each party takes measure to require that documentation accompanying LMO-FFPs clearly identifies that they “may contain” LMOs. This involves very costly identity preservation mechanisms all along the supply chain from input suppliers and farmers to retailers. As a result, this will also put those wishing to sell non-LMO products at a considerable commercial disadvantage. Secondly, the TBT and the SPS in the WTO cover issue of labeling, but the labeling must have a scientific basis and a risk assessment must be undertaken before labeling. However, the Protocol mandates a risk assessment without making clear which part the precautionary principle will play a role in the risk assessment process. Further, what a risk assessment under the Protocol is carried out for purposes of labeling is also not defined.

4. Options for mutually supportive implementation of the Protocol and WTO Rules

4.1 Main activities to promote mutual supportiveness between the both multilateral regimes

The dynamic development under the application of modern biotechnology in various fields and the international trade requires relevant international bodies to make every effort to ensure that both multilateral regimes remain coherent and to further enhance their mutual supportiveness. In the past two years, the CBD and the WTO Secretariats undertook a series of activities and put forward some practical proposals and ideas to deal with the issues. They primarily include:

(1) Increased dialogue and collaboration between the CBD and the TBT and SPS Committees.

(2) Enhanced exchange of information between the WTO and the CBD for the facilitation of discussion regarding the potential conflicts of the Protocol with the WTO rules, and the harmonization of the activities under the CBD and the WTO. One welcome development has been the easing of derestriction procedures for many of the WTO document types; The WTO Secretariat had hosted a side event at the COP6; A representative of the WTO Secretariat gave a very useful briefing at the CBD Secretariat in Montreal; The CBD had submitted a number of practical proposals to further improve cooperation and information between the WTO and the CBD and its Protocol. Such proposals were presented during the last Multilateral Environment Agreement Information Session of the Committee on Trade and Environment in June 2002 and at the back-to-back meeting held by UNEP on 11 November 2002.

(3) The CBD COP sought granting of observer status on a reciprocal basis between the CBD and its Protocol and the relevant WTO bodies. The CBD Secretariat had extended an open invitation to the WTO Secretariat to participate as an observer in all meetings held under the CBD and its Protocol. The CBD Secretariat has submitted a requests for observer status in many relevant WTO bodies, but, the requests for observer status for CBD Secretariat in the SPS and TBT meetings is still pending.

4.2 Suggested options to regulate the relationship between WTO rules and specific trade obligations in the Protocol

In accordance with the Note by the WTO Secretariat, several approaches were proposed prior to the Doha Ministerial Conference for clarifying the relationship between the rules and provisions of the WTO system and those of MEAs which were most likely to prove incompatible: (1) leave the issue to be settled by the dispute settlement mechanism; (2) amend Article XX of the GATT 1994 by introducing a reference to the environment; (3) adopt an interpretative decision. These three options, may also provides appropriate framework of clarifying the relationship between WTO rules and the STOs in the Protocol.

(1) Dispute settlement mechanism

The first proposed solution is to let this issue be settled in a specific case by a Panel or by the Appellate Body in a dispute settlement proceeding. For instance, it is said that, although WTO Members have not been able to clarify this relationship, the Appellate

Body has done so in its decision on the Shrimp-Turtle case. In any case, this decision clarified the order in which recourse could be made to the exceptions under Article XX of the GATT 1994: the Appellate Body began by assessing whether one of the exceptions in Article XX(a) to (j) of the GATT 1994 could be cited, and then went on to assess whether such a measure generally met the requirement in the introductory clause of Article XX of the GATT 1994, namely whether the measure was arbitrarily discriminatory or protectionist. Moreover, this decision clarified the term “exhaustible natural resources” in Article XX(g) of the GATT 1994 and held that, according to that Article, living natural resources, such as turtles, could be “exhaustible natural resources”. Though the option has not been tested in regard to the TBM of LMOs adversely affecting the conservation and sustainable of biodiversity, it indeed is the one to be considered in addressing similar issues regarding national resources.

(2) Reference to the environment in Article XX

The second solution proposed is the adoption of an environmental clause which would explicitly define the relationship between WTO rules and the Protocol. Such a clause would enable the principles governing the coexistence of the two systems, namely the trade and environmental systems, to be defined. Introducing an environmental clause would mean reviewing Article XX of the GATT 1994, and more particularly, amending Article XX(b) and (g) of the GATT 1994, and inserting a new provision in that Article.

(3) Interpretative decision

Adoption of an interpretative decision by WTO Members to settle the issue of the relationship between WTO rules and specific trade obligations in the Protocol is the third proposed solution. An interpretative decision would be able to indicate clearly that the relationship between the trade and environmental systems is governed by the general principles of no hierarchy, mutual supportiveness and deference.

5. Concluding remarks

The WTO Agreements reflect the need to take into account other existing international agreements. Both the SPS Agreement and the TBT Agreement make reference to international standards. The Protocol contains potentially widely accepted international standards of treatment for LMOs in international trade. However, they

are two different multilateral regimes with their own objectives and there is little experience in addressing the issue on the relationship between environment and trade.

Therefore, in order to facilitate mutually supportive implementation of multilateral environmental and trade agreement with a view to achieving sustainable development, it is necessary for relevant WTO bodies and the CBD and its Protocol to clarify the relationships between both the Protocol and the WTO rules by gradual negotiations. Perhaps, the best time to begin would be the forthcoming Meeting of Parties serving as Conference of Parties (COP-MOP) on Cartagena Protocol to be held in Kuala Lumpur during February 2004.

Safeguarding Intellectual Property Rights in the Use of Medicinal Plants: The Case in Sri Lanka

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1. Introduction

For nearly three millennia, plant and plant products have been systematically used by mankind for treating illnesses. In Sri Lanka, this traditional form of medicine has been in existence for almost as long, and over the centuries it has developed to such a level that it is now an established system of medicine. When last listed, 1,414 plant species have been used in traditional medicine. These species include several endemic species which are becoming increasingly rare and under threat of extinction. Approximately 200 species of medicinal plants are in common use, and of these 50 are heavily used in *ayurvedic* and traditional health care systems. Nearly 80 medicinal plant species are now considered threatened. In addition to recognizing their curative and therapeutic value, Sri Lankans use medicinal plants in rituals, cultural activities and in religious functions.

About 35% of the population in the country is primarily dependent on *Ayurveda* and traditional systems of health care, and there is a long history of traditional knowledge associated with plant use. In particular, rural populations depend heavily on these systems. In the villages, *ayurvedic* physicians and traditional practitioners of medicine are a part of the society, and there is an interwoven relationship between the communities and such practitioners.

In the rural areas, traditional healers and people collect their requirements of medicinal plants from forests, which are their natural habitats. Since only the minimum required is collected, communities practiced sustainable use concepts, with minimal damage to the habitats in which these precious plants are found. The local supply of medicinal plants for *ayurveda* cannot meet the demand. Currently, about 30

– 40% of the local requirements of medicinal plants are imported (Hettiaratchi and Abeywardene 2001). With the increased demand for herbal medicine worldwide, the demand for medicinal plants has significantly increased. Combined with the increased interest from the pharmaceutical sector, there is now an unsustainable exploitation of both plants and knowledge.

Equally threatened is the knowledge on which the traditional medicinal systems are based, as only a small proportion of the traditional knowledge (TK) and the ethnobotanical information is documented. The majority of TK remains recorded in ancient, obscure *ola* (palm leaf) manuscripts scattered around the country or in the memory of elderly practitioners. These practitioners would normally not pass on such information, except to those trusted acolytes, preferably from the family. This *gurukula* system of ancient teaching of traditional knowledge is fast disappearing. This knowledge not only addresses health care of individuals, but also addresses the traditional care and management of the natural resources surrounding the rural communities. In the light of these developments, it is necessary to preserve the traditional knowledge, particularly as it relates to the use of medicinal plants in order to reap benefits of their use.

2. The Conservation & Sustainable Use of Medicinal Plants Project

In order to arrest the rapidly declining medicinal plants population in Sri Lanka, a five-year project was launched in 1999 with the support of the Global Environment Facility, for the conservation of medicinal plants and for promoting their sustainable use. This project seeks to secure conservation of globally and nationally significant medicinal plant species, and their habitats. The project was expected to achieve these objectives through (a) *in situ* conservation by establishing five medicinal plant conservation areas (MPCAs) in different ecological zones of Sri Lanka, as a part of, or adjacent to existing natural forests which are the home for some of the threatened species of medicinal plants, (b) *ex-situ* cultivation by promoting nurseries, home garden and plantation cultivation, and supporting propagation and agronomic research, and (c) by providing information and institutional support including promotion of appropriate legal and policy environment.

An important element of the strategic approach adopted is to define and demarcate medicinal plant reserves in biogeographically representative areas and use these as

centers for a wide range of activities covering conservation, propagation, basic processing, ethnobotanical and ecological studies, and awareness promotion. From these centers activities will spread to other areas through extension and outreach programmes. For this purpose, five Medicinal Plant Conservation Areas (MCPAs) have been established in Bibile and Ritigala (dry zone), Rajawake and Naula (intermediate zone) and Kanneliya (wet zone) adjacent to natural forests which harbour medicinal plant species.

The Project has identified the local communities living within the selected Medicinal Plant Conservation Areas (MPCAs) as primary target groups. Community-based organisations (CBOs), organized women groups, local forest users, traditional medical practitioners, commercial collectors, and traders of non-timber forest products also come within the definition of the primary target group. The secondary target group consists of state functionaries (eg. Beat Forest Officers, Forest Rangers, and agricultural field workers) and line agencies of the central and provincial governments. Non-governmental organizations (NGOs), educationists and research personnel also come within the secondary target group of the project.

Each MCPA consists of about 10 *Grama Niladhari* Divisions (GND) abutting the core conservation forest. The GND is an administrative unit and will contain several villages. The project strives to actively involve the communities living in the MPCAs for promoting conservation and sustainable use of medicinal plants. Each MCPA has developed a site consisting of a medicinal plant garden, which will serve as a demonstration site, a medicinal plant-processing centre for use by the communities, an ayurvedic dispensary, which is expected to mainly depend on preparations made by the communities, and an information centre.

Aspects of community participation

The communities include the traditional practitioners of medicine and healers. The project's interventions, particularly in baseline data collection, have a bearing on intellectual property issues. This aspect was clearly spelt out during the mobilization of the communities and during the formation of community organizations during the first year of the project itself. Indeed, their active support was enlisted for surveys in order to bring transparency to the activities.

The community organizations were also given, amongst others, the following responsibilities:

- Identification of rare species of medicinal plants in the respective natural habitats and dissemination of related knowledge.
- Identification of relevant problems threatening rare species of medicinal plants and implementation of mitigatory actions together with the community organizations of the MPCA.
- Dissemination of knowledge relating to methodologies and wider uses of medicinal plants and promotion of sustainable use.
- Promotion of indigenous medical practices of the MPCA with a view to prevent diseases prevalent in the area.

Intellectual Property Rights Issues

As would be seen from the foregoing, the Project activities include several tasks that have a bearing on issues of intellectual property rights. Essentially, these include the ethnobotanical survey for data collection, establishment of a database, collection of herbarium material, publications, and transcription of ancient palm leaves (*ola* leaves).

The Project's approaches to address the IPR issues were two fold: firstly, a set of guidelines was required to address IPR issues pertaining to the launching and implementation of project activities. Secondly, the Project formulated the legislation on safeguarding IPR on the use of medicinal plants as a long-term measure.

Initially, a separate Intellectual Property Rights Committee was established to oversee the implementation of project activities and to ensure that IPR issues are addressed properly. It was also required to advise the implementing agencies on the relevant areas that need attention.

The Guidelines (Nanayakkara 1999):

The Project's Guidelines for addressing IPR issues related to the Project were developed through a series of consultations with stakeholders including communities and emphasize the need to regularly consult the communities in Project activities,

enhance the knowledge of the communities on benefit sharing and sustainable use of biological resources, involve communities in all project activities, particularly in surveys and research, to the extent possible, and enhance the skills of communities for project-related activities. The staff involved in the project-related work were required to enter into a confidentiality agreement in relation to the information accessed by them. In addition to these General Guidelines, Specific Guidelines were provided for the conduct of the ethnobotanical survey and the establishment and operation of the database.

The Ethnobotanical Survey:

The Ethnobotanical Survey (EBS) was designed to be implemented in two Phases, as follows (Milliken 1999):

Phase 1: to provide a sound understanding of the roles of medicinal plants and other forest products in the livelihoods of the communities, with a preliminary focus on species of particular importance. No specimens were collected and plants were discussed at the level of local names. Details of plant uses were not collected.

Phase 2: Collection of voucher specimens and identification, and collection of limited amount of information on how medicinal plants are used (Milliken 2000).

Resource Inventory:

The resource inventory provided (a) a baseline assessment of the distribution, associated population structures and densities, and ecological requirements of medicinal plant species in MPCAs, and (b) an informed basis for ongoing *in situ* conservation of medicinal plant species and *ex situ* cultivation in home gardens and nurseries

In view of the sensitive nature of information, a Memorandum of Understanding was signed between the communities and the Project, prior to the commencement of Phase 2 of the survey. Additionally, all personnel involved in the survey were required to sign a confidentiality agreement.

Salient features of the (draft) law on Safeguarding IPR on the Use of medicinal Plants

The scope of the (draft) law applies to: access to TK relating to the use of medicinal plants; equitable sharing of benefits derived from the access to TK relating to

medicinal plants; and registration of TK relating to the use of medicinal plants in the **Register of Traditional Knowledge**. However, the proposed Act does not hinder or affect access to and the transfer of TK relating to the use of medicinal plants for traditional purposes.

The Register, to be established under the proposed law will collect and preserve TK, encourage and promote the use of TK, prevent unauthorized use and patenting of TK, and ensure equitable sharing of benefits from access to TK. Registration of TK is voluntary, and non-registration shall not affect the rights of the holder of TK.

The proposed law provides protection for the lifetime of the holder and a further 50 years. Thereafter, access will be subjected to prior informed consent (see also Karunaratne 2003).

3. Position of Sri Lanka's Proposed Law vis-à-vis International Agreements and inter-governmental processes relating to TK

Legal protection of TK is being addressed in several international agreements and fora. The main ones are (1) the Convention on Biological Diversity (CBD) and its CoP and Subsidiary bodies, (2) the World Intellectual Property Organization (WIPO), which has recently taken an interest in TK; and (3) the World Trade Organization (WTO), which administers the TRIPS agreement. In addition, UNCTAD and WHO too have an interest in TK.

The main developments are as follows:

CBD's current approaches of exploring the possibility of addressing the issue of *sui generis* systems for protection of TK and in identifying the main elements to be taken into consideration in the development of *sui generis* systems; proposal for an international regime on access and benefit sharing (Secretariat of the Convention on Biological Diversity 2003).

WIPO's current position requires patent applicants to disclose the origin of genetic resources and/or associated TK, which would make patents supportive of CBD, and would prevent private monopoly rights from extending to illegally acquired genetic resources/TK; and improve the availability of public domain TK (by making inventories of TK Registers) (World Intellectual Property Organization 2002).

The **WTO/TRIPS** is currently examining, *inter alia*, the relationship between the TRIPS agreement and the CBD for the protection of TK and folklore. It has been proposed (World Trade Organization – TRIPS Council 2002) that an applicant for a patent relating to TK to provide (a) disclosure of the source and country of origin of TK; (b) evidence of prior informed consent through approval of authorities under the relevant national regimes; and (c) evidence of fair and equitable benefit sharing under the national regime of the country of origin.

As would be seen, the major international agreements are currently developing protocols. The proposed Sri Lankan legislation is congruent with the approaches of the international agreements. In particular, the proposed Register will provide the necessary strength to provide the information pertaining to the positions adopted by both WIPO and WTO/TRIPS. Nonetheless, it is essential that Sri Lanka keep abreast of the developments in order to adjust her legislation to meet the new challenges in international trade aspects.

Access, Benefit Sharing, Biosafety: Status of Domestic Law in Bangladesh

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1. Introductions

Bangladesh is yet to enact a law to protect its biodiversity and regulate access to and benefit sharing of the same. The issue of bio-safety has received policy coverage while draft laws on all the three issues are pending approval. As a party to the CBD, and given the realities of the TRIPs, issues pertaining to access, benefit sharing and biosafety would demand special attention in any legal regime as may be proposed on bio-diversity and protection of plant variety.

2. Draft Laws Pertaining to Access and Benefit Sharing

At the moment, there are two sets of draft legislation on plant variety protection that are pending before the government for finalization. Two different committees constituted by the Ministry of Agriculture (MoA) made these drafts. The first Committee, namely National Committee on Plant Genetic Resources constituted on 18 September, 1997 submitted two separate but inter-linked drafts on Bio-diversity and Community Knowledge Protection Act and Plant Varieties Act of Bangladesh on 29 September, 1998. The second Committee consisting of six members formed vide Gazette notification dated 26 January, 2002 submitted a draft on Plant Variety Protection Act.

While the draft law on bio-diversity protection deals with community knowledge, collective innovation and community rights, the draft on plant protection deals with the introduction of newly innovated plant varieties to recognize and reward the role of human agency, individually or in groups.

The first two drafts were prepared prior to the International Treaty on Plant Genetic Resources, 2001 (Gene treaty) and hence do not mention the obligation of Bangladesh

under this Treaty. However, desperate attempt to match with the obligations of Convention on Biological Diversity (CBD) is noted. On the other hand, the later version of the Plant Variety Protection Act emphasizes on the obligations under the debated TRIPs agreement of the WTO, which, under the present arrangement, will become effective in Bangladesh from January, 2006.

Since all these drafts may be considered in the final decision-making process in exploring the *sui generis* option for the country as required under the TRIPs, main features of all these drafts are given below.

i. Main Features of the Draft Biodiversity Act

The draft Biodiversity Act reaffirms sovereign right of the State over natural and biological resources and the authority of the national governments to determine access to such resources⁸. It also reaffirms Article 8 of the CBD that seeks to promote wider application of innovation of the local and indigenous community with their approval and on equitable benefit sharing. Following CBD, the draft includes provisions to determine *access to biological and genetic resources and related knowledge based upon prior informed consent and fair and equitable sharing of benefit arising from use of such resource and knowledge*.

The draft recognizes the global tendency towards affirmation of IPR over biological diversity and related products and processes and declares it imperative for Bangladesh to protect her own resources against such a backdrop.

The draft Biodiversity Act declares the patenting of life forms as being against the moral, intellectual and cultural values of the people of Bangladesh. Access, use and innovations that have biological and genetic resources at the center shall be guided by this principle (Section 5.3). It also prohibits all forms of monopolization of biological and genetic resources and related knowledge and culture (Section 5.16).

In line with Article 8 (g) of the CBD, one of the objectives of the draft law is to protect the biological and ecological environment of the country from the potential and actual pollution caused by the release of GMO in the environment. The NBA shall monitor the importation and introduction of Genetically Modified Organism (GMOs) and the research and processes of biotechnology and Genetic Engineering

(GE) in order to protect the environment and safeguard the citizens from biological pollution, hazards and dangers of such technologies (Section 11.13.1). The NBA shall have the authority to declare unlawful any material, research facilities and experiments related to GE and GMO that exist within the boundary of Bangladesh without its permission (Section 11.14.d).

Scope of the Draft Law

The draft shall include all biological and genetic resources, related knowledge and their derivatives within the jurisdiction of the country. It implies all varieties in life forms including plants, animals, fish, micro organism, cell lines, genetic materials characteristics, traits, products and processes involved therein. The traditional use and exchange of biological and genetic resources shall remain outside the purview of the proposed law.

For the purposes of this draft, biological resources include all biological resources, organisms or parts thereof, populations, or any other biotic components of ecosystems of Bangladesh. Genetic resources shall mean resources related to the genetic material and includes material of plant, animal, microbial or other origin containing functional units of heredity (Section 4).

Provisions on Access includes Prior Informed Consent and Mutually Agreed Terms

The draft declares the indigenous, local, fishing and farming communities as the stewards and custodian of biological and genetic resources. No access to such resources shall be allowed without the prior informed consent of the communities. Inventions arising out of such resources shall not be sold or otherwise transferred without prior informed consent of the communities. Access to and use of such resources for economic transactions and trade will be based on mutually agreed terms beneficial to both the economic agents and the communities. The state shall not have the power to negotiate access by foreign/commercial interests without the full participation of other co-owners (Section 8.2.a). Where access is allowed, the state shall ensure payment of royalties or compensation where applicable (Section 8.2.b).

⁸ Preamble and Article 15

The state shall ensure the right of the communities to deny collection of biological and genetic resources (Section 7.9). The community of the country of origin must also be informed about entry of such resources to Bangladesh.

No IPR on Accessed Resource or Products

The general conditions regulating access to biological and genetic resources declare certificate of intellectual property or similar certificate and licenses over such resources or products of such resources and process invalid and illegal. Any certificate of IPR or similar certificate of licenses upon resources/products/processes resulting from any such access shall be invalid and illegal (Section 13.21). The draft Act, however, requires the NBA to study and recommend policies and regulations on the utilization of biological and genetic resources including intellectual property rights and community rights in accordance with the draft (Section 11.13.d).

Access shall be allowed

- to undertakings being carried out within Bangladesh (Section 13.1)
- to undertaking outside Bangladesh when NBA can ascertain benefits in terms of enhancement of biodiversity (Section 13.2)
- With written prior informed consent of NBA and concerned community (Section 13.4)

Access shall be denied

- to Collector accused of irregular and unauthorized transaction (Section 13.3)
- to Collector who has collected specimen in any country without prior informed consent (Section 13.3)
- without written commitment from the Collector that research reports and results shall be provided to NBA and concerned community (Section 13.7)

Procedure for Access

Section 13 lays down detail procedure as to how request for access would be made and also the requirements and conditions for such access. The proviso to Section 13.9 also requires the Collector to inform the NBA while applying for access about

proposed mechanism and arrangements for benefit sharing. Such sharing of benefit shall include knowledge, technology and/or financial transfer, involvement of the country in research and development (Section 13.9.vi). The collector shall also give an indication of the benefits, whether economic, technical, biotechnological, scientific, cultural, social or otherwise that might derive to the country and concerned communities (Section 13.9.xi).

Access is Conditional to Benefit Sharing

After fulfilling all the requirements of Section 13 and upon scrutiny of the application for access by the NBA, an agreement may be signed by the NBA and the Collector allowing access (Section 13.13). As a minimum requisite, such agreement shall be specific on the terms and conditions of equitable benefit sharing including transfer of technology, sharing of research results, participation by Bangladesh in the economic, social, environmental benefits as may accrue from processes and products obtained through use of collected resources (Section 13. 15. a.b.e.f.g). Where the collector is not a national of Bangladesh, the state in the jurisdiction of which s/he operate must guarantee compliance with the mutually agreed terms of the agreement and enforce the same (Section 13. 20).

In case commercial benefit is derived or products result, the Collector shall pay at least a defined percentage of benefits, not less than 50 per cent of net monetary gain from direct or indirect use of biological and genetic resource for which access was given (Sections 7.5/16.6).

Collector to Comply with Biosafety Law

The agreement for access shall also contain a commitment from the Collector to abide by the law and other relevant rules including rules on bio-safety (Section 13.15.h). Access may be restricted or prohibited in cases of non-compliance with rules on bio-safety and food security (Section 22.6).

Frequent reference in the proposed draft to bio-safety rules will make the related provisions of this draft irrelevant as such rules have not been drafted nor are there any such initiatives.

It is not clear how the proposed draft matches with the obligation of Bangladesh under the TRIPs. It is noted that in deviation from the TRIPs agreement, the draft exempts

all life forms from patentability. To ensure that such aspirations of the drafters of the proposed law get recognition, the same must receive appreciation at the policy level. A law of such vital importance must not be kept pending and must be finalized immediately with wider public participation.

ii. Main Features of the Plant Variety Act

The Draft Plant Varieties Act of Bangladesh regulates the commercial transaction of plant varieties including new plant varieties in Bangladesh. The provisions of this draft Act is to be interpreted in the context of the draft Biodiversity Act and so would be the provisions on access and benefit sharing. The draft law has overriding power and any other law that to the extent of its inconsistency with this draft shall be void and discarded (Section 4.9).

For the purposes of this draft ‘plant’ shall mean any living organism in the plant kingdom, fungus kingdom excluding bacteria and other micro-organism. The other definitions provided in the draft include plant variety, community variety, local variety, transgenic plant, genetic material, propagation material and so on.

Nature of Protection

‘Protection’ to be accorded under this Act shall always mean defined and specific commercial privileges, whether explicitly mentioned or not, approved and granted to an innovator by the NBA. Such protection shall not constitute any generalized IPR and may vary from applicant to application on the basis of the nature of innovation. It is to be noted that unlike this draft, the draft on bio-diversity protection does not define ‘protection’.

In general it can be said that the draft Plant Variety Act does not recognize any claim of new variety for private IPR protection. It is only when communities recognize an independent human agency over and above the social process and the innovation serves definite and useful to the needs of the people of Bangladesh that protection may be accorded under the draft (Section 7.2; 7.3).

A new plant variety for protection under the law must be a hitherto non-existent variety and have consistent, stable and distinctive specific traits. For a new plant variety, the NBA may either give ‘citation of award’ (where no protection for personal gain or commercial privilege is sought) or ‘commercial permit’ (Section 7.1)

in the name of New Plant Variety Certificate (Section 8.1). To be eligible for consideration for commercial privileges, the New Plant Variety must meet definite and useful needs of the people of Bangladesh (Section 7.3).

It is only the recipient of the New Plant Variety Certificate who can commercially produce, sell or distribute, offer, import into or export from Bangladesh such variety or the propagation material (Section 21.1/21.2). The permission for export must be pre-conditional to the fact that there will be no claim of IPR over such exported material (Section 21.3).

Breeders Rights

A breeder may claim commercial privileges over hybrid only if the parents are available in Bangladesh as community variety in the public domain (Section 7.3). The protection shall in no way affect the rights of farmers to have unencumbered access to biological and genetic resources of Bangladesh and related knowledge. Also the rights to collect, conserve, use etc. plants for personal and non-commercial purposes shall not be affected under the privileges proposed under the draft Act (Section 4.5.6/Section 20.5). For improvement or development of local variety, common variety and wild variety for commercial purposes and also for commercial transaction of plant varieties or materials to propagate plants, a commercial permit shall be needed (Section 20.6; 20.8).

Treatment of Foreign Nationals

The draft law is specific in naming those who can apply. Nationals of Bangladesh and other countries also may apply for protection provided the country to which s/he belongs

- recognizes the bio-diversity law of Bangladesh;
- allows Bangladeshi nationals to apply for similar protection in that country;
- has headquarter in a country that is a signatory to the CBD. (Section 9.1/9.2)

Provisions on Biosafety

The NBA, proposed implementing agency for the law, shall refuse to protect a new plant variety potentially harmful to the environment, ecology, health and welfare of

the public (Section 7.5). Transgenic plants shall also not be eligible for protection without a positive EIA result and bio-safety assessment. Release of transgenic plants for commercial use shall only be permitted if the owner agrees in writing to pay compensation for hazards and damages that may be caused by its use and handling and labels his product declaring this (Section 7.7). All these requirements would necessitate incorporation of enabling provisions in the laws on environment and standardization. Also the appropriate agencies, such as the Department of Environment and BSTI, would need to develop technical know-how to make proper assessment and compliance.

The draft clearly distinguishes between local/widespread/common plant variety and new plant variety. This draft shall protect the latter for commercial privileges and award while the former are protected under the draft Biodiversity Protection Act.

The great challenge that remains to be met is to ensure that the 'nature of protection' as proposed under the draft is 'effective' as envisaged in the TRIPS. The conditional approval to foreign nationals may well contradict Article 3 of the TRIPS that requires members to accord to the nationals of other member countries treatment no less favorable than that it accords to its own nationals with regard to IPR protection. Although the protection proposed under the law is not IPR and hence it does not call for application of Article 3, in ensuring its 'effectiveness', if the obligations under TRIPS have to be met, it may need modification both in the nature of protection and treatment of foreign nationals.

Institutional Arrangements

Both the original drafts propose for the formation of a regulatory body called the National Biodiversity Authority (Section 11 of the draft Bio-diversity and Traditional Knowledge Protection Act, 1998) comprising both public and private sector representatives to ensure proper implementation and enforcement of their provisions. The NBA shall, amongst others, be responsible for the establishment of a National Biodiversity Information System that again shall prepare a Community Biodiversity Register and a National Biological Inventory.

iii. Main Features of the Draft Plant Variety Protection Act, 2002

In contrast with the earlier version (The draft Plant Variety Act, 1998) that referred to the obligation of Bangladesh under the CBD, this new draft seeks to fulfill the obligation of Bangladesh under Article 27 of the TRIPS that requires countries to give protection to their plant either by

- patents or
- *effective sui generis system (a system of its own kind)* or
- a combination of both.

Other than TRIPS, the draft, in dealing with eligibility for applying for protection, also refers to the Gene Treaty (Section 9). Thus it can be said that the earlier draft (which refers to CBD) and latest version of the draft laws (which refer to TRIPS and Gene Treaty) are not based on the same premises to the extent the treaties differ. Such reference has not addressed the complexity of issues like ‘access’, ‘benefit sharing’, ‘prior informed consent’ and so on. Instead by not referring to the draft Bio-diversity Act, 1998 the latest version of the draft Plant Varieties Protection Act, 2002 has left these issues unapprised. Although the applicant for a New Plant Variety Protection must show that s/he has permission of the community in using their variety or knowledge and append an appropriate arrangement for benefit sharing (Sections 13.4 and 13.5), the mechanism and detailed of these are not prescribed as done in the draft Biodiversity Act, 1998.

The draft proposes the formation of a statutory authority to be called the Plant Variety Protection Authority (PVPA) to grant either New Variety Certificate or Citations of Awards (Section 4). The PVPA shall be the implementing agency of the draft and not the National Biodiversity Authority (NBA) as proposed under the earlier draft. It shall consist of 11 members (Sections 5 and 6) with apparently no representation from the civil society or farmers community (Section 38 of the draft Bio-diversity Act required representation of farmers in the NBA). However, if the recipient of a citation of award is a citizen of Bangladesh, s/he shall be eligible to be represented in the PVPA (Section 22), a provision that does not match with section 6 outlining composition of PVPA.

In addition to its function to grant certificates of New Plant Variety/Citation of Award, the PVPA shall also have the authority to negotiate benefits for new plant

variety that were derived with the use of community variety and/or related knowledge (Preamble).

The draft has a different title than the earlier one. It has added the term ‘protection’ to the title but, as with the earlier draft, has not defined ‘protection’. Also the term ‘propagating material’ as defined in the early draft has not been defined in the latest version although the use has been targeted for regulation (Sections 16 and 17).

A statement in the preamble shows that the draft aims at ‘providing *incentives to breeders, individually or in groups or in collaboration with farmers*, for better and stepped up breeding of new crop varieties’. The text in section 23 (2) rather suggests the opposite. According to the said section, the National Plant Variety Development Fund (NPVDF) to be established shall be utilized ‘*to provide a range of incentives measures for farmers and local community to participate in various form of activities related to the development of new plant varieties in collaboration with private and public funded breeders...*’. Since farmers and breeders have two distinct definitions, incentive to the one shall not necessarily mean and include the other. The definition of farmers recognises the role of farmers in the development of varieties (Section 2.e), but the definition of breeder has excluded the informal communities and has apparently referred to the formal sector by mentioning the breeder as ‘employer’ (Section 2A). It is felt that the law should put more priority in providing incentives to the farmers while breeders may be given the necessary protection for commercial purposes.

Nature and term of Protection

For Breeders

As stated earlier, the draft seeks to protect two groups, namely the ‘breeders’ and ‘farmers’. The protection to be accorded to the breeders under a New Plant Variety Certificate shall entitle them to exclusive commercial exploitation of the protected variety (Section 16.1). However, for a New Plant Variety Certificate, the varieties must have the characteristics of novelty, distinctness, uniformity, stability and utility (Sections 10 and 11). A variety that uses genes involving terminator technology shall not be protected (Section 8.8.e). Also transgenic plants/GMOs without EIA indicating

harmlessness shall be rejected any protection (Section 8.8.d). The draft, however, omits the definition of transgenic plants/GMOs.

The protection to a breeder shall be 20 years for fruits, tree species and vines and 15 years for all other species of annual habit.

In dealing with eligibility for application, the new draft adds one more condition in stating that the applicant shall be eligible if s/he is a national of a country that is party to the Gene Treaty (Section 9.1.c). Also the new draft is more stringent in declaring applicants having headquarters in a country that has not *ratified* the CBD as not eligible (Section 9.2.b). The earlier draft in section 9.2.b only demanded *signing* of the CBD and not ratification. It is felt that such conditions of the drafts may be made a condition for eligibility rather than non-eligibility for application.

For Farmers'

The PVPA shall not only protect but also promote the rights of the farmers. These rights of the farmers include (Section 26):

- right to protect their traditional knowledge relevant to plant genetic resources from being accessed in formal sector without compensation
- right to claim significant contribution to a registered variety
- right to claim an equitable share of benefits if their varieties have contributed to the registered variety
- right to save, use, exchange and sell farm-saved seed/propagating material of registered variety for non-commercial purposes.

Violation of the provisions of this Act (draft) shall be liable to either imprisonment/fine or both (Section 24). Such penal provision is an addition to the earlier draft.

3. Regulatory Regime on Biosafety

i. The Biosafety Guidelines, 2000

A detailed and elaborate guideline on Bio-safety prepared under the auspices of the Ministry of Science and Information and Communication Technology was officially adopted since 31 May, 2000.

The Guidelines define ‘biotechnology’ as a technique that uses living organisms or substances from these organisms to make or modify a product, to improve plants or animals or to develop microorganisms for specific uses.

In line with the Cartagena Protocol, the Biosafety Guidelines have attempted to set out criteria for ‘risk assessment’ and also ‘risk management’. The Guidelines applicable for all research works prescribe for violators sanction in the nature of forfeiture of government research grants and withdrawal of incentives that will be addition to legal sanction under existing laws.

Although the Draft Bio-safety Act does not refer to biodiversity, the Guidelines have aimed to ensure safe transfer, handling, use and transboundary movement of LMOs to safeguard human and animal health, environment, biodiversity and also socio economic welfare of the society.

In addition to setting out general guidelines for risk assessment, the Guidelines have proposed risk assessment criteria for five specific areas. These include laboratory work, use of GMOs and hazardous organisms in the field, release of foreign GMOs/hazardous organism, industrial use of GMOs/hazardous organism and products intended for release into the market. The Guidelines do not define ‘hazardous organism’. Also risk management measures for controlled releases for plants, animals, microorganisms have been separately spelt out in the Guidelines.

Laboratory work with GMOs or hazardous organism have been subjected to permit process. Laboratories permitted to work shall follow the principles of Good Laboratory Practice (GLP) suggested in Annex 2. Although the objective of the Guideline is to regulate transboundary movement of LMOs in dealing with the five targeted areas of regulation, the Guidelines has opted the term ‘movement’ and not ‘transboundary movement’. All movement of regulated material has been subjected to permit and advanced agreement between the participating laboratories and the IBC or concerned officer. This provision would suggest that the prescribed regulations on movement have not targeted the transboundary movement of GMOs.

Institutional Arrangements

The Guidelines have proposed the establishment of a National Committee on Biosafety of Bangladesh (NCBB) to oversee compliance with policies that is yet to be

formed and function. Institutional Biosafety Committees (IBC) and Field Level Biosafety Committees have also been recommended to ensure compliance with the Guidelines. The NCBB shall have wide representation from the government sector and shall also include representation of farmers, business chambers, NGOs and general public.

The guidelines are a mere policy document and are not enforceable. To ensure that Bangladesh does not become a dumping ground of 'frankenstein food' or a field for testing LMOs, it is necessary that the issue of bio-safety is given legal coverage. Also the NCBB must be made functional without delay. More delay in these regards would mean more danger of being exposed to the risks of bio-technology.

Following the Biosafety Guidelines and tremendous pressure from groups working on consumers' rights, two separate drafts of Biosafety Act and Consumer Protection Act (with no reference to bio-safety) have also been prepared that are learnt to be under active consideration of the Government.

ii. Draft Biosafety Act, 2000

The draft Biosafety Act has, without defining the constitution, proposed the formation of an authority called the Bangladesh Biosafety Monitoring and Control Authority (BMCA). The BMCA, on the advice of National Committee on Biosafety of Bangladesh (NCBB), would undertake a number of activities with regard to composition of committees, laying down procedures for regulated materials, risk potential categorization, large scale industrial undertaking and so on.

The draft has three specific sections on risk management, contained use and permit for field release of GMOs that shall primarily be the responsibility of the BMCA. Detailed procedures for transit, direct use for food and feed, transport, packaging, identification have not been dealt with. Again, compared to the 'risk management' requirement of the Cartagena Protocol, the 'risk management' mechanism of the proposed act can be misleading and inadequate. All functions of the BMCA shall depend on subsequent formulation of rules and procedures that would only be framed once the law is enacted meaning more time before the law can be meaningfully implemented.

Under the proposed law, the NCBB, on one hand, shall be responsible for overall policy guidance to the BMCA and on the other hand, shall ensure safe management of biotechnological activities including research, development, field introduction and commercial and industrial use of GMOs. The draft defines the formulation, review and amendment of the national policies and guidelines concerning ‘risk assessment’ and ‘risk management’ as the functions of NCBB leaving it uncertain as to who should be responsible for implementation. All the proposed responsibilities of the NCBB, including giving policy direction as well as implementation, may well create a dilemma as to its intended role. Again, the draft, while requiring the NCBB to assist in formulating amendment to pertinent laws, rules and regulations, does not address who should be initiating the process of such amendments.

The draft law attempts to commensurate with the requirement of the Cartagena Protocol on ‘public awareness’. It proposes to invite public opinion prior to release of a GMO into the market/field. However, the law is silent on the process of officially recording such opinion. Also the legal implication of such opinion in finally deciding for releasing the GMO remains unclear. The draft does not detail the regulations for import (or conditions for obtaining permit) of LMOs, rather attempts to restrict import without a ‘required permit’.

The draft law, by attempting to deny people the right to sue the authorities has, in fact, denied the principles of natural justice. Again, the proposed punishment may be deemed grossly inadequate compared to risk involved in the technology.

In addition to addressing the above issues, it may also be recommended that the act follows definitions of the certain key terms that are already available and should attempt to define clearly the objects it aims to protect/regulate. In this regard it may be noted that nowhere in the draft does it refer to ‘bio-diversity’. Also, the draft fails to define ‘regulated material’ (although defined in the Guidelines) for which the rules on introduction, movement and field release have been developed.

Biosafety vs World Trade:
A Case study on Food Safety Regulations in Sri Lanka

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Conservation of biological diversity in Sri Lanka is of national interest and of global relevance as Sri Lanka is considered as one of the 25 biodiversity hotspots of the world, especially the South Western region. Sri Lanka's native biodiversity is at risk and the trade of LMOs/GMOs in an open economy and the lack of legal instruments and an institutional framework to control and regulate import of LMOs/GMOs and their products will have adverse impacts. Genetically Modified Organisms possess a novel combination of genetic material obtained through the use of modern biotechnology. Even though the benefits of modern biotechnology, that is recombinant DNA technology, are high, the associated risks could also be high.

When considering genetically modified food, genetic engineering of food from genetically engineered organisms poses inherently high risks. Therefore, food safety is another important area that needs to be considered. Genetically modified crops are associated with a high degree of herbicide tolerance, insect resistance, altered sugar/starch/oil compositions, antibiotic resistance, etc. The side effects of genetically modified foods include unanticipated mutations that create very toxic contaminants and allergens (Environment Foundation Limited, 2002). Current understanding of genetics is extremely limited and scientists do not know the long-term effects of releasing these unknown things with unpredictable effects into the environment and to the diets. However, genetically engineered ingredients are freely entering in our food without adequate safeguards in place and without explicit consumer consent and knowledge. Therefore, a precautionary approach to public health and safety is necessary where risks are unpredictable

(<http://archive.greenpeace.org/~geneg/reports/food/intrfood.htm>).

Even though the benefits from the modern biotechnology are immense, there are growing concerns regarding the safety of genetically engineered food among

consumer organizations, scientists and others. As a precautionary measure, Sri Lanka decided to impose restrictions on importation of certain food items. The restrictions were to be revised when the safety of these foods was found to be promising.

Sri Lanka imposed a ban on importation of six Genetically Modified Foods and some food products containing these as ingredients because safety for human consumption was not known and the safety evaluation procedures were not in place. However, compatibility issues arose with the World Trade Organization (WTO) agreements where Sri Lanka is a signatory.

The Food Advisory Committee of the Ministry of Health formulated the regulations, which were gazetted on 06th April 2001. The regulations were made under section 32 of the Food Act No. 26 of 1980 as amended by Food (Amendment) Act No. 20 of 1991. The regulations were cited as Food (Genetically Modified Foods) Regulations – 2001. The food ban totally prohibited importation, manufacture for commercial purposes, transportation, storage, distribution and selling of selected genetically modified food (raw or processed) or any ingredient of food/food additives/preservatives that had been subjected to genetic modification. The ban was to come in to effect from 1st May 2001. Any food belonging to the specified schedule of the regulations needed to be certified from the competent government authority or an accredited laboratory of the exporting country to demonstrate that the food product did not contain any material or ingredient that has been subjected to genetic modification. The schedule I included 21 food items, mainly 6 derivatives/products of Soya, Corn/ Maize, Tomato, cheese, potato, yeast, beet sugar and microbiological starter cultures used in foods.

The Food Regulations 2001 could not be imposed in compliance with WTO agreements. One of the WTO agreement, the agreement on the Application of Sanitary and Phytosanitary Measures, known as the SPS agreement, sets out the basic rules for food safety, animal and plant health standards

(http://www.wto.org/english/tratop_e/sps_e/spsund_e.htm).

The SPS agreement clearly permits the taking of precautionary measures when a government considers scientific evidence is insufficient, to permit a final decision on the safety of a product or a process.

Article 2, paragraph 2 of the SPS agreement states, Members shall ensure that any sanitary or phytosanitary measure is applied only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence, except as provided for in paragraph 7 of Article 5.

Article 5, paragraph 7 of the SPS agreement states, in cases where relevant scientific evidence is insufficient, a member may provisionally adopt sanitary or phytosanitary measures on the basis of available pertinent information, including that from the relevant international organizations as well as from sanitary or phytosanitary measures applied by other members. In such circumstances, members shall seek to obtain the additional information necessary for a more objective assessment of risk and review the sanitary or phytosanitary measure accordingly within a reasonable period of time.

Further, according to the agreement, members shall ensure that all sanitary and phytosanitary regulations that have been adopted are published promptly in such a manner as to enable interested members to become acquainted with them. Notifications of regulations to the members through the Secretariat should take place at an early stage, where amendments can be introduced and comments taken into account.

Therefore, as the time period provided was not sufficient, a second gazette notification was issued on 26th June 2001 as the Genetically Modified Foods (Provisional) Regulations including the same prohibitions as in the previous gazette, making the ban to come in to effect on 1st September 2001.

This is in harmony with the precautionary principle set out in the Rio Declaration, which states that lack of scientific certainty shall not be used as a reason for postponing preventive measures (Environment Foundation Limited, 2002).

As there were representations / pressure made by various governments, institutions, etc. on this, a special committee was appointed by the Ministry of Health to review regulations on genetically modified food. Therefore, pending the report of the committee, another gazette notification was issued on 30th August 2001 deferring the Genetically Modified Foods (Provisional) Regulations until further notice (Ministry of Health, 2002).

A panel of experts is still working on regulations for a labeling process instead of the proposed ban (Environment Foundation Limited, 2002). In Sri Lanka there are no laws stipulating labeling is a mandatory requirement, a legal framework in place is therefore, very important. The consumers would have their choice in what they consume.

Sri Lanka signed the Biosafety Protocol on 24 May 2000 and is planning to ratify it as early as possible. Before the ratification, Sri Lanka should establish domestic legal measures and build capacity in the area of biosafety. The Ministry responsible for the subject of Environment is the National Focal Point and is obliged to implement the articles of the protocol.

The Ministry of Environment has established a Committee on Domestic Legal Measures on Biosafety to discuss and clarify important matters relating to the existing legal framework, to identify legal gaps, etc. The committee has reviewed the relevant national legislation and prepared a document on *Importation of Genetically Modified Organisms and related issues – a Review of relevant National Legislation*.

Sri Lanka is in the process of establishing a biosafety framework. It is identified as a potentially eligible country to participate in the UNEP-GEF Biosafety Project in the Asia-Pacific region and has already begun implementation of the project. It is expected to have a National Biosafety Framework, which includes a legal framework, a regulatory system, an administrative system and a decision-making procedure on genetically modified organisms.

Issues of Traditional Knowledge and IPRs in Nepal

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1. Introduction

Most of Nepal's people live in villages. They are directly dependent on various locally available plant and animal resources for their livelihoods. However, as is the case in many parts of world, these resources and the knowledge associated with their use are under severe threat. Genetic resources and traditional knowledge are being lost due to ecological degradation, through the introduction of more "modern" agricultural practices, displacement by development projects, overexploitation and by the new market forces unleashed by liberalization and globalization, bringing with it an increase in the threat of biopiracy. The misappropriation of genetic resources and traditional knowledge across the world has been helped a great deal by changes in regulation—principally by the introduction of intellectual property rights (IPRs). Governments all across the region are increasingly trying to manage these rights to biodiversity and traditional knowledge through this exclusive monopoly system, while at the same time mechanisms and efforts to protect and strengthen collective rights of local communities over their resources and knowledge remain poor.

2. TK and IPR: A Global Context

There has been a growing concern in recent years regarding the role of traditional knowledge (TK) and the knowledge holders. TK has been developed, practised, preserved and shared within traditional cultures and indigenous groups over generations and the global community has realised the role of the traditional communities in conservation and sustainable utilisation of biological resources. In order to safeguard the knowledge as well as the right of these people, an appropriate Intellectual Property (IP) system, a *sui generis* system, that safeguards national interest yet responds to global realities, is necessary.

According to World Intellectual Property Organization (WIPO), the rationale for IP protection of TK is: to enable TK holders to preserve their identity and will against any use they do not wish their TK to be put to; to increase legal security for a clear, transparent and effective system of TK protection and predictability to the benefits of TK holders and society as a whole; to promote economic development and poverty alleviation; and to create a conducive environment for international trade relations.

However, traditional IP regimes have their limitations and inherent dangers, especially with their stringent criteria such as the requirements to meet standards of novelty and originality, identifying the inventor/innovator of the protected subject matter and providing substantive scientific basis for any claim. The reasons that are cited for why the patent system does not work for traditional knowledge holders, particularly in the Asia-Pacific region, include: because it is impossible to identify an individual inventor due to the collective nature of traditional knowledge; because traditional knowledge can not always be attributed to a particular geographical location; because ownership of varieties of plants is alien to many social and cultural beliefs; because the required criteria of “novelty” and “inventive step” are not always possible, particularly in cases where the traditional knowledge has been in existence over a long period of time; and, finally because the costs of applying for a patent and pursuing patent infringement cases are prohibitive.

3. Biodiversity and TK: Nepal's Context

Nepal is one of the richest countries in the world in terms of biodiversity and it has been ranked 25th from the top in the global biodiversity context (NBAP, 1998). The main reasons for this richness are the sharp altitudinal variation (60-8848masl), the country's geographical position, climatic variation (tropical to arctic), and the interaction of these factors, causing diverse ecosystems of great floral and faunal diversity. A total of 118 ecosystems, 75 vegetation types and 35 forest types have been identified so far (NBS, 2002). Nepal is rich in species diversity—it reports a very high biodiversity/land area ratio. It is estimated that about 6500 species of flowering plants (angiosperms) and 450 species of ferns occur in Nepal (Hara *et al.*, 1978). Although the country makes up roughly 0.03 percent of the world's total landmass, it is home to at least 2.33 percent of flowering plants, 3 percent of

pteridophytes and 6 percent of bryophytes of the world's recorded flora. The species diversity in fungi and lichens is also notable. There is also great endemism within this species richness—some 246 species of flowering plants and 248 species of non-flowering plants are reported to be endemic to Nepal.

In terms of cultural diversity, Nepal has over 61 ethnic groups/communities and over 100 languages and dialects are spoken in the Country. Cultural diversity often follows the patterns of biophysical diversity because of the intimate relationship between rural people and natural resources. This relationship has led to a wealth of traditional knowledge. This traditional knowledge is associated under the rubric of biodiversity conservation, human health, plant and animal diversity maintenance, water and soil use and several other issues.

4. Access and Benefit Sharing Legislation in Nepal

Recognising the valuable contribution of Nepal's local traditional and indigenous knowledge, the draft bill and policy on Access to Genetic Resources and Benefit Sharing has been developed in 2002. The Draft Bill defines Traditional Knowledge (TK) as “the body of knowledge, practices, skills, innovations and technology belonging to, within and among local communities and individuals associated to utilisation, conservation and commercialization of biological resources”. The objectives of the draft bill are:

- to create conditions to facilitate access to genetic resources for environmentally sound uses by other contracting parties of the Convention on Biological Diversity
- to ensure sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial utilisation of the genetic resources of the kingdom of Nepal
- to promote and ensure TK
- to discourage and control biopiracy
- to utilise an intellectual property rights regime for optimum benefit of the kingdom of Nepal, promotion and protection of traditional knowledge and benefit sharing from bioprospecting
- to promote cooperation between Contracting Parties to the Convention on Biological Diversity for access to genetic resources and benefit sharing.

The Draft Bill and Policy recognises the sovereign right of the individuals, community and the Government over biological/genetic resources and related TK. It proposes a *sui generis* system that documents and registers biological resources and associated TK as a formal document to deal with intellectual property issues. A multidisciplinary and inter-sectoral National Genetic Resources Conservation Authority would be established that prohibits collection and export of any biological/genetic resources/material without government approval and Prior Informed Consent from the knowledge holders. The bill sets out a formal process to be adopted by those seeking access for research purposes and prohibits them for any IP related claims in future. As specified in the Draft bill, consumers/exporters and bioprospectors seeking access to and use of genetic resources must submit a proposal to National Genetic Resources Conservation Authority. After the Authority's scrutiny, the proposal is subject to public hearing. A full EIA is mandatory for selected proposals prior to entering into any contractual agreement. The Bill also sets out the clauses for contractual agreement ensuring IP arrangements between providers and recipient of biological/genetic resources. Prohibition to enter into contractual agreement could be made if the proposal is detrimental to the soil quality and productivity as well as human, animal and plant community health or if the proposal does not comply with existing environment and Biodiversity related regulations.

5. *TK Documentation Project*

In line with the Government's initiative to protect biodiversity and TK, IUCN Nepal has launched a project that aims to strengthen the capacity of HMG/Nepal and other local institutions to facilitate biodiversity conservation and promotion of traditional knowledge through the documentation of TK and the development, establishment, promotion and use of a registry of TK related to biological resources.

The long term objectives of the project are: to promote biodiversity related TK for promoting conservation and sustainable use; to protect TK holders' right through registration as a databank for guaranteeing such rights; and to standardize access and benefit sharing regime for equitable sharing of benefits. The project would be accomplished in three phases. The first is a learning phase, during which the project will facilitate learning from TK documentation experiences in various countries

including Nepal. The second phase focuses on the development and testing of appropriate systems, processes and partnerships related to TK documentation and registration. With the experience and understanding from the two phases, TK identification, documentation and registration will be carried out across the country in the third phase in collaboration with other organizations and projects.

6. Issues concerning TK and its IP Protection

In order to ensure IP protection to TK, some outstanding issues need to be resolved at various levels. This section does not cover all the issues or even cover in depth the issues that are raised. However, some of such issues include:

1. **Requirement for disclosure of source of origin of biological material and traditional knowledge at the international level.** A lot of genetic material from Nepal and the rest of developing world is housed in *ex situ* collections abroad, and a great deal of documentation of the use of a lot of these genetic resources is in the public domain. Hence, any patent claim based on the use of either the resource or knowledge associated with its use must involve a process of disclosure of origin so that the traditional knowledge holders can challenge the award of the patent right or claim the benefits arising from the use of resource or knowledge.
2. **Identification of benefit sharing mechanisms of TK application at national and international levels.** There have been several examples and ‘best practices’ concerning benefit sharing mechanisms tested around the world. However, equally important is that there is greater investment into research at the national level to secure the maximum benefit from the use of local resources and traditional knowledge. The only way that the country and the knowledge holders can benefit is by gaining a greater knowledge of these resources and uses, and to use this knowledge to improve the delivery of services to improve livelihoods. This should ideally be where investment of resources and trained human capital should take place—the government should help promote the growth of this industry and ensure that communities with the traditional knowledge and resources share the benefits.

3. **Characterize elements of a *sui generis* system at the national level.** Several *sui generis* forms of protection have been developed in various countries and it is necessary for Nepal to draw from these protection systems to develop and characterize one for the country that could respond to global realities—especially in the area of plant variety protection and IP concerning TK. Some of the more progressive legislation has been dismissed as too conservative but only they do address in full measure the rights of farmers and indigenous groups.
4. **Identification of the custodians of documented information/biodiversity registers at the national level.** Regulations that are imposed under the new access and benefit sharing law will not benefit TK holders unless there is a national registry that identifies species, cultivars, or breeds and the communities who hold the knowledge of their use. Thus, there should be a systematic inventory of genetic resources and knowledge originating from indigenous and local communities. This documentation, while distinct from the awarding of actual patent rights, could form the basis for IPR protection. The knowledge holders themselves should be the custodianship of the documented information. Then there is the potential for conflict between nations that share genetic resources—for example, during the uproar over the award of a patent over Basmati rice, there was not mention of Nepal as a Basmati rice producer. In such cases, any legal rights, compensation or benefit sharing over the name, knowledge or plant in favour of India and Pakistan (acknowledged as producers) could leave Nepal out altogether. The countries of South Asia share hundreds of species of plants and animals and much of the knowledge too is shared.
5. **Analysing the need for scientific validation of TK at national and international levels.** Traditional IP systems cater largely to the dominant model of innovation and little or no recognition for protection of traditional knowledge, innovations and practices of indigenous communities. However, it is widely acknowledged today that many of the innovations and products worldwide would not exist today without inputs derived from indigenous knowledge. Therefore there is a need for a law that will provide for a separate *sui generis* system for the protection of community intellectual property rights.

In essence, protection for traditional knowledge and biodiversity should facilitate community sovereignty and collective control, allow for benefit sharing through some form of community intellectual property regime or comprehensive resource rights, and offer real alternatives to the traditional IPR regime.

Recommendations from the workshop on Access and Benefit Sharing, Biosafety – Relevance of Issues to Trade and IPRs

Considering the issues of access to genetic resources and benefit sharing, biosafety and the impacts of trade and intellectual property rights on such issues, the participants suggest the following actions:

AT NATIONAL LEVEL

Access To Genetic Resources And Benefit Sharing (ABS)

- Develop an inventory of biological resources, beginning with those actually used to sustain livelihoods or with potential for such use
- Promote community-based small and medium sized enterprises producing pharmaceutical products to assist local communities in adding value to their genetic resources
- Use the CBD's Bonn Guidelines on Access and Benefit Sharing (ABS) to establish a national framework for regulating access and benefit sharing
- Create awareness of market value of biological resource products, particularly genetic resources

Biosafety

- Develop capacity and establish infrastructure for identification, tracing, quarantine, and segregation of genetically modified products
- Develop national policy on labeling genetically modified products
- Promote the private and public sector partnerships needed for advancements in biotechnology and biosafety
- Identify and develop complementarities between the World Trade Organisation (WTO) sanitary and phytosanitary standards (SPS) and National Biosafety Frameworks
- Explore the possibility of extending special and differential treatment (S&DT) to biotechnology and its products
- Develop an understanding of the precautionary principle and how to operationalize it in implementing Cartagena Protocol on Biosafety provisions
- Establish inter-agency coordination mechanisms to manage biosafety issues
- Identify and explore the impacts of bilateral free-trade agreements in relation to biotechnology and biosafety and build capacity to take appropriate actions

Traditional Knowledge (TK) and Intellectual Property Rights (IPR)

- Compile and disseminate information for policy options for the legal protection of TK, including through patent law reform, particularly concerning utility patents and patents on research tools. An annotated menu of policy options should be produced as referenced in document WIPO/GRTKF/IC/5/8⁹ of the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (“the WIPO Committee”).
- Build the capacity of national institutions to keep up with new global trends in intellectual property rights, and build capacity for granting patents and for patent law enforcement
- Encourage enhanced public sector investment in biotechnology and bioprospecting
- Take existing *sui generis* systems, where available, and other forms of IPR protection, whichever are applicable to TK, into account when considering options and developing legislation related to TK. The development of options for such legislation could be based on comparative analysis of existing *sui generis* systems for TK protection undertaken by the WIPO Committee
- Consider CBD Article 8j when developing national *sui generis* systems for protecting traditional knowledge
- Consider the options under the International Treaty on Plant Genetic Resources while considering national protection for breeders and farmers
- Make explicit links with the existing intellectual property rights regime, and put in place a mechanism for reviewing the existing regime in light of developments at the global level
- Review and analyze the mechanisms contained in existing law and how they operate in practice, and make necessary reforms
- Use a combination of legislation and voluntary measures to regulate use of traditional knowledge and its relationship with the existing intellectual property rights regime. To this end, the WIPO Toolkit for Intellectual Property Management When Documenting Traditional Knowledge and Genetic Resources, should be consulted by TK holders, governments and other stakeholders. Voluntary measures should include:
 - Creating awareness among local communities about the necessity of having a national register on TK
 - Mechanisms to ensure that local communities understand that they have the option to prohibit or restrict access to their TK

⁹ See, “Composite Study on the Protection of Traditional Knowledge,” document WIPO/GRTKF/IC/5/8, issued April 28, 2003.

- A format for registering TK that takes existing biodiversity registration systems into account, where they exist
- A format for database(s) for storing and managing data on TK
- Guidelines for protecting information in TK registers
- Guidelines for managing, securing and using TK databases, particularly:
 - Defining the levels of security/access that are related to use, user, and the type of information requested
 - Defining the levels of security/access that are related to the wishes of the community/TK-holder
 - Establishing strong mechanisms for inter-agency coordination
 - Ensure that TK/IPR issues are appropriately taken into account in national decision making processes
 - To promote access and not to prejudice any patent search

These voluntary measures should build upon the Technical Proposals on Databases and Registries of Traditional Knowledge and Genetic/Biological Resources which were developed by the Asian Group and submitted to the WIPO Committee (WIPO/GRTKF/IC/4/14¹⁰). The GBF recommends the adoption of the Asian technical proposals by the WIPO Committee.

Cross-cutting themes

- Recognize and reinforce the role played by the media, along with governmental and non-governmental organizations, in creating awareness among the general public and grass-root organizations on issues related to biosafety, TK, and ABS
- Include multilateral environmental agreements (MEAs) and the World Trade Organization (WTO) and the linkages among them into national formal education curricula at university level
- Integrate MEAs and the WTO and the linkages among them into existing non-formal capacity building systems
- Identify the socio-economic issues involved in administering biosafety, ABS, TK and IPR and include them in decision-making processes
- Adopt a multidisciplinary approach to developing policy and administering the issues of access to genetic resources and benefit sharing, traditional knowledge and intellectual property rights, and biosafety, and create a mechanism to coordinate among the responsible institutions

¹⁰ See, “Technical Proposals on Databases and Registries of Traditional Knowledge and Biological/Genetic Resources,” document WIPO/GRTKF/IC/4/14, issued December 6, 2002.

AT REGIONAL LEVEL

Access to Genetic Resources and Benefit Sharing

- Identify basic common elements for ABS regulations

Biosafety

- Develop a regional position on minimum standards for residual content of genetically-modified organisms (GMOs)

Cross-cutting

- Work toward a South Asia regional mechanism that would:
 - develop a common framework on ABS and biosafety
 - explore the complementarities in biotech research and the possibilities for harmonizing laws and regulations on biosafety
 - develop a common framework on TK and IPR
- Create a sub-regional clearinghouse for information related to MEAs and the WTO
- Develop a regional position on conflicts between the WTO, the CBD and other biodiversity-related MEAs
- Promote regional efforts for valuation of biological resources and biodiversity-related services
- Develop tools and methods for capacity building in the fields of ABS, biosafety and TK/IPR and the linkages between them that can be adapted for use at national level. Such tools could be based on, or take into account, the WIPO Toolkit for Intellectual Property Management When Documenting Traditional Knowledge and Genetic Resources

AT INTERNATIONAL LEVEL

Access To Genetic Resources And Benefit Sharing

- Provide linkages to discussions of the Like-Minded Group of Megabiodiverse Countries with respect to ABS

Traditional Knowledge/Intellectual Property Rights

- Discussions under the World Intellectual Property Organisation (WIPO) need to take into account elements of the Bonn Guidelines as well as existing experiences with implementation
- Patent applications should have a provision requiring disclosure of the source(s) of genetic material and/or associated TK, require evidence of prior

informed consent, and require that there be evidence of means to share benefits, all of which are consistent with the Bonn Guidelines

- Promote resolution of the conflict between TRIPS 27.3(b), articles 8(j) and 15 of the CBD, and International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR)

Cross-cutting Themes

- Promote special and differential treatment (S&DT) for biotech goods and services within the WTO
- Promote adding environmentally friendly goods to the list of environmental goods under debate within the WTO



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Useful Information on the World Wide Web

International Institute for Sustainable Development IISD – Trade and Investment

<http://www.iisd.org/trade/>

IISD looks at areas of synergy where trade, environment and development can be mutually beneficial, and how to help policy makers exploit those opportunities. The website contains up-to-date briefs on issues of trade, environment and development, WTO negotiations as well as links to reports and publications.

RIS - Research and Information System for the Non-Aligned and Other Developing Countries <http://www.ris.org.in/>

RIS provides a 'Think Tank' on global issues in the field of international economic relations and development cooperation. The web site includes up-to-date policy briefs, information on seminars and conferences and links to a range of publications including books, discussion papers and journal articles.

The World Bank Group <http://www.worldbank.org/>

Provides links to information and publications on issues of trade and development at the global and country levels as well as statistics on development progress. Information is provided on projects, research activities and conferences dealing with various aspects of trade and development and there is space for on-line discussions.

United Nations Development Programme <http://www.undp.org>

Provides links to websites and publication on issues of trade, development and environment as well as an outline of UNDP Policy Notes on issues of Trade.

United Nations Development Programme – Trade Liberalisation and Women <http://www.undp.org/unifem/trade/>

Provides data on trade issues and their gender-differentiated impact on women. The website provides a situational analysis of the relationship between trade issues and women, provides links to websites and relevant books, articles and documents and presents recommendations from recent conferences.

World Trade Organization <http://www.wto.org/>

The WTO website includes updates of recent trade negotiations, covering issues such as Doha Development Agenda, Development, Environment, Intellectual Property Rights, Regional Trade Agreements and Trade Policy Reviews. This site provides an introduction to the WTO and also contains a large database of official documents

United Nations Conference on Trade and Development <http://www.unctad.org>

The UNCTAD aims at the development-friendly integration of developing countries into the world economy. The website contains links to publications and press releases, up-to-date information and links to inter-governmental meetings, information on UNCTAD programmes and technical cooperation initiatives as well as statistics that are relevant for the analysis of international trade, foreign direct investment, commodities and development.

IUCN - The World Conservation Union

Founded in 1948, The World Conservation Union brings together states, government agencies and a diverse range of non-governmental organizations in a unique world partnership: over 980 members in all, spread across some 140 countries.

As a Union, IUCN seeks to influence, encourage and assist societies throughout the world to conserve the integrity and diversity of nature and to ensure that any use of natural resources is equitable and ecologically sustainable.

The World Conservation Union builds on the strengths of its members, networks and partners to enhance their capacity and to support global alliances to safeguard natural resources at local, regional and global levels.

Regional Biodiversity Programme, Asia (RBP)

IUCN's Regional Biodiversity Programme, Asia (RBP) was established 1996 to assist countries in Asia implement the Convention on Biological Diversity. Working with 12 countries in Asia. RBP is creating an enabling environment in the region through partnership with governments, NGOs, community based organisations, donors and other stakeholders on technical as well as policy issues.

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