

TRIPs, BIODIVERSITY AND COMMONWEALTH COUNTRIES: capacity building priorities for the 1999 review of TRIPs Article 27.3 (b)

A discussion paper

GATT/WTO Agreement on Trade Related Aspects of Intellectual Property
Rights

(TRIPs Agreement)

Article 27.

3. Members may also exclude from patentability: ...

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Paper prepared for the Commonwealth Secretariat and Quaker Peace & Service

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Acronyms

ASEAN	Association of South East Asian Nations
CBD	Convention on Biological Diversity
CGIAR	Consultative Group on International Agricultural Research
CGRFA	Commission on Genetic Resources for Food and Agriculture (FAO)
CHM	Clearing-house Mechanism (CBD)
CHOGM	Commonwealth Heads of Government Meeting
COP	Conference of the Parties (CBD)
CTE	Committee on Trade and Environment (WTO)
DSB	Dispute Settlement Body (WTO)
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
GATT	General Agreement on Tariffs and Trade
GEF	Global Environment Facility
GOs	Governmental Organizations
GPA	Global Plan of Action for the Conservation and Sustainable Utilization of Plant Genetic Resources for Food and Agriculture (FAO)
IATP	Institute for Agricultural Trade Policy
IPGRI	International Plant Genetic Resources Institute (CGIAR)
IP	Intellectual Property
IPRs	Intellectual Property Rights
ITDG	Intermediate Technology Development Group
IU	International Undertaking on Plant Genetic Resources [for food and agriculture]
MFN	Most Favoured Nation (WTO)
NGOs	Non-governmental Organizations
OAU	Organisation of African Unity
PBRs	Plant Breeders' Rights
PGR	Plant Genetic Resources
PGRFA	Plant Genetic Resources for Food and Agriculture
PIC	Prior Informed Consent
PVP	Plant Variety Protection
SADC	South African Development Community
SBSTTA	Subsidiary Body for Scientific, Technical and Technological Advice (CBD)
SPS	Sanitary and Phytosanitary Agreement
TRIPs	Trade Related Aspects of Intellectual Property Rights (GATT/WTO)
UN	United Nations
UNCED	United Nations Conference on Environment and Development
UNDP	United Nations Development Programme
UNEP	United Nations Environment Programme
UNESCO	United Nations Educational, Scientific and Cultural Organization
UPOV	International Convention for the Protection of New Varieties of Plants
WB	World Bank
WFS	World Food Summit (FAO)
WIPO	World Intellectual Property Organisation
WTO	World Trade Organization

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¹ The workshop was attended by people with a wide range of institutional backgrounds from four Commonwealth countries and their respective Geneva-based missions, resource people from four countries and from WTO and WIPO, and representatives from Quaker Peace & Service and the Commonwealth Secretariat. Details of agenda and participants available from QP&S hilaryp@quaker.org.uk.

Glossary

Distinctness - clearly distinguishable in one or more important characteristics from any other plant variety. (UPOV).

Essentially biological processes - in plant biotechnology these can include multi-step processes consisting of the genetic modification of plant cells, the subsequent regeneration of plants and the propagation of these plants (Leskien, 1997). Some definitions are more restrictive: “any process which, taken as a whole, exist in nature or is not more than a natural ... breeding process.” (European Patent Directive - for the legal protection of biotechnological inventions).

Farmers’ Rights - means rights arising from the past, present and future contributions of farmers in conserving, improving, and making available plant genetic resources, particularly those in the centres of origin/diversity.

Genetic material - material of plant, animal, microbial or other origin containing functional units of heredity (CBD).

Genetic Resources - genetic material of actual or potential value (CBD).

Intellectual property rights (IPRs) - the rights granted by a state authority for certain products of intellectual effort and ingenuity (OECD, 1996).

Inventive step - not obvious, having regard to the state of the art, to a person skilled in the art. (Leskien, 1997).

Novelty - the state of the art comprising everything made available anywhere to the public by means of written or oral description, by use, or in any other way, before the date of filing of the patent application. (Leskien, 1997).

Patent on a product or process confers an exclusive right on its owner to prevent a third party from making, using, offering for sale, selling or importing that product or a product obtained directly from that process, without the owners’ consent. (TRIPs).

Prior Informed Consent (from states and/or communities) means that agreement has been obtained by those taking genetic resources from the providers of the resources about the destination of those resources, what they may be used for and, usually, a commitment to share any benefits derived from the enhanced use of those resources.

Stability - means the relevant characteristics remain unchanged after repeated propagation. (UPOV).

***Sui generis* system of rights** - an alternative, unique form of intellectual property protection, designed to fit a country’s particular context and needs (ITDG, 1996). It can have a wider meaning to cover those aspects of intellectual property not protectable under conventional intellectual property laws, or a system embodying community, farmers’ and indigenous peoples’ rights. (Leskien, 1997).

Uniformity - sufficiently uniform in its relevant characteristics with variation as limited as necessary to permit accurate description and assessment of distinctness and to ensure stability. (UPOV).

EXECUTIVE SUMMARY

OVERVIEW

The ownership of plants and animals, and hence national and household food security, will be affected by decisions on a sub-paragraph in a World Trade Organisation (WTO) agreement currently due for review. The review is taking place at a time when attempts by developed country institutions and companies to patent biological materials taken from developing countries are being vigorously contested as is the development and release of genetically modified seeds and breeds (living modified organisms), whose commercial viability, it is asserted, depend on the existence of global intellectual property protection systems for biological materials.

In 1999, Members of the WTO must review Article 27.3(b) of the Agreement on Trade Related Aspects of Intellectual Property Rights - the TRIPs agreement. This sub-paragraph, in the Agreement's section on Patents, describes the WTO rules about the ownership of plants, animals and biological processes. These rules currently allow Members not to have to patent regimes for plants, animals, other than micro-organisms, and biological processes for producing plants or animals. It does, however, require countries to provide some form of intellectual property protection for plant varieties. While everyone is aware that the review must be held in 1999, no date for the start of the review will be fixed until a country formally requests it. This may be discussed at the meeting of the Council for TRIPs on 1st and 2nd December 1998. Commonwealth developing countries need to consider a range of issues, options and capacity building requirements in preparation for this review.

The review is part of a wider process that will determine what choices countries will have over their access to, the sustainable use of, trade in, and benefits arising from the use of plants, animals and biological processes. The results will affect a nation's capacity to provide food and livelihood security for its citizens. It is not a trivial process. The decisions taken on the wording of this sub-paragraph will determine the minimum standards that countries must impose for the protection of intellectual property on plants, animals and biological processes, whether they originate in the country or are imported. It will influence access and benefit sharing agreements with respect to genetic resources. Despite this review, most developing countries should have enacted legislation for the protection of plant varieties (developing or changing seed laws in line with this sub-paragraph) by 1 January 2000 - 1 January 2005 for least developed countries. Introducing legislation at a time when this sub-paragraph and the whole TRIPs agreement are to be reviewed, is causing added difficulties in many countries.

The WTO text defines the legal framework for the ownership of life. The outcome of the review will set precedents for future trade and environment negotiations and will in particular constrain the development of biodiversity-friendly legislation as required by the Convention on Biological Diversity (CBD). The impact of this review will affect all negotiations concerning the ownership, development and use of plants and animals, including, for example:

- subsequent trade negotiations in the WTO such as the full review of TRIPs in 2000 and the renegotiation of the Agreement on Agriculture;
- negotiations on the implementation of the Convention on Biological Diversity (CBD);
- negotiations in the Food and Agriculture Organisation of the United Nations (FAO) on the revision of the International Undertaking on Plant Genetic Resources [for food and agriculture] (IU) and its submission to the CBD as a possible Protocol.

A complicating factor is that each of these negotiations is usually handled by different ministries and departments (e.g. WTO -Trade; Intellectual property - Patent Office; CBD - Environment; FAO - Agriculture), which can lead to a loss of policy coherence and weaken a country's position. Discussions are essential between all relevant ministries in order to agree mutually acceptable negotiating positions for this review and related processes, so countries are able to understand the linkages between, and implications of, all the international negotiations. Good communication with Geneva-based negotiators is also essential to ensure clear communication of positions taken by the competent authorities in capitals. In addition, countries may wish to make effective links among regional blocs to improve their negotiating strength, in advance of the review of TRIPs Article 27.3(b).

OPTIONS FOR CHANGING THE TEXT OF THE SUB-PARAGRAPH

Although there has been no formal discussion in the WTO of the options that countries may consider, informally many options are being discussed, including:

- Doing nothing, simply reviewing progress in implementing the sub-paragraph and leaving the wording as it is, retaining some ambiguity. This would provide countries with maximum flexibility within the existing agreement, particularly because the exact meaning of most of the terms has yet to be agreed, or defined by international jurisprudence. By agreeing to do nothing it also reduces the risk of negative changes being imposed.
- Extending the exclusions to patentability to include all living organisms and the associated knowledge for their conservation and sustainable use. This is the option favoured by many developing countries whose genetic wealth and the food and livelihood security of their citizens could be threatened by monopoly ownership of biological resources through patents. It is a low-cost option removing the need to defend their resources and know how through litigation. Benefit sharing arrangements should be agreed through the FAO/CBD negotiations in the International Undertaking and the CBD itself, which may prove a better arrangement for developing countries.
- Removing the obligation to provide plant variety protection or ensuring that measures adopted are carefully tailored to a country's own needs - the *sui generis* option. Most developing countries do not require this as a priority. The reciprocal arrangements with developed countries for the use of their protected plant varieties or germplasm, which have been produced mainly to meet the needs of northern temperate industrial agriculture, are not usually to the advantage of the majority of farmers in developing countries. With the exception of a few industrial export-oriented commodities, such as flowers, the priority for the majority of people is for the local development of varieties adapted to the needs of sustainable agricultural practices in labour intensive holdings.
- Deletion of the whole sub-paragraph, which would provide for no exclusions to patenting of living organisms and their accompanying intellectual property - an option favoured by

some industrial countries. This would favour the biotechnology industry, which would be able to insist that all countries impose and recognise their patents, and their right to patent material irrespective of its origin.

POSSIBLE COURSES OF ACTION

Countries need to debate internally and within country blocs the best courses of action. These would include actions at three levels:

- Locally within communities, a rapid assessment of the potential implications of these measures:
 - on the conservation and sustainable use of natural resources;
 - on local production from plants and animals;
 - on local communities and producers and their collective knowledge systems; and
 - on local biologically-based industries;

to provide essential evidence of perceptions and possible impacts.

- Nationally, a rapid survey of the work by different ministries and agencies on TRIPs and all related international agreements on the ownership, conservation and use of plants, animals and biological processes. Such a survey could result from, or lead to, the formation of interministerial working groups, or similar bodies, to address all aspects of these issues and ensure national policy coherence. Additionally, an assessment of the legal implications and costs of different courses of action may also prove useful. This could include:
 - the potential impact of these measures on national sovereignty over plants and animals and biological processes,
 - existing and pipeline laws and regulations,
 - international legal obligations, and
 - options for developing so-called *sui generis* legislation, suited to a country's own specific needs, as permitted under existing WTO rules.
- Regionally, within country-blocs, a comparison between the needs, specific circumstances and obligations of different countries would help to identify stronger negotiating positions in this review as well as in the related negotiations.

Given the treaty commitment to start the review in 1999, while simultaneously enacting required legislation and negotiating a number of other related agreements, a further set of options arise, including:

- Seeking to delay the review and the legislative timetable until after the full TRIPs review has been completed.
- Opening the review, as required, but then completing it in parallel with the full TRIPs review and the renegotiation of the Agreement on Agriculture over subsequent years.
- Raising a set of questions concerning the possible conflict between some Members' obligations under the Convention on Biological Diversity and their obligations under TRIPs, that need investigating before the review can be concluded, in one of the WTO's Committee on Trade and Environment (CTE) four-monthly meetings (next meeting on October 22nd 1998 may consider intellectual property issues including the TRIPs review).
- Requiring satisfactory completion of the negotiation of the revision of the IU and its adoption as a Protocol to the CBD, before completion of the review.
- Alternatively, a rapid completion of the review, possibly by agreeing that no changes to the text are required.

Most of the wording in Article 27.3(b) of the TRIPs agreement is deliberately ambiguous and open to interpretation. Until there is a sufficient body of international jurisprudence, countries cannot know definitively whether or not their response to the sub-paragraph will be deemed legal. Other pressures from trading partners, donors and other international agreements may

also be brought to bear on countries, obliging them to comply with this agreement and a specific interpretation of this sub-paragraph. For example, to comply with the requirement for plant variety protection, pressure may be applied to persuade a country to join the International Convention for the Protection of New Varieties of Plants (UPOV). This Convention is considered by some to be the only effective form of *sui generis* legislation, despite there being no specific mention of UPOV in the WTO text and there being other options better suited to a country's own needs that could be developed.

Legal clarity will eventually be achieved only through the WTO's Dispute Settlement Body, which arbitrates in the event of a disagreement between Members. However, these disputes may also need to be tested against the dispute settlement procedures of other relevant conventions, such as the CBD. This could prove a lengthy and costly process in which developing countries may be disadvantaged. It could be avoided by removing the obligation for countries to have intellectual property protection on any plants, animals or biological processes, under the rules of the WTO and leave developing legal protection, as necessary under the CBD.

CAPACITY BUILDING

Most Commonwealth developing countries have the competence to develop clear negotiating positions. The key constraint is lack of access to national and international information. Internet access to international information is necessary to ensure equal knowledge at the negotiating table, but the most pressing task is to gather information nationally and especially within local communities to assess how best to protect a country's plants, animals and associated knowledge systems, perhaps through some form of community rights regime. Work needs to start immediately to develop strong national positions for the revision of TRIPs Article 27.3(b) and, if agreed, the preparation of necessary *sui generis* legislation. Regional negotiating positions are also needed and these could be strengthened through resolutions made by the Commonwealth Heads of Government Meeting (CHOGM) in 1999. In order to develop this programme of work, increased capacity and, in some cases, reordering of current priorities, will be required.

CONCLUSIONS

This is an urgent agenda, which, if not tackled promptly and effectively, will ultimately increase the legislative burden on, and reduce the benefits to, Commonwealth developing countries. These countries have much to contribute because the sovereign rights they have over the biological resources that industrial countries need gives them a potentially strong negotiating position. Commonwealth developing countries must rapidly organise internally and within regional blocs to ensure that they have choice over the immediate outcome, for example, negotiating a delay in the process. This would allow time to assess fully and comprehensively the likely impacts of these measures and to develop *sui generis* legislation, recognised by trading partners, for the protection of their plants, animals and biological processes, especially their food production systems.

INTRODUCTION

The World Trade Organisation's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) came into effect on 1 January 1995 after nearly a decade of negotiations in the General Agreement on Tariffs and Trade (GATT). It is still often referred to as the GATT/TRIPs Agreement. It is the most comprehensive multilateral agreement on intellectual property rights. The TRIPs Agreement covers, *inter alia*, patents in Articles 27 to 34. In one sub-paragraph, Article 27.3(b), it describes the WTO rules about the ownership of plants, animals and biological processes and the protection of new varieties of plants. These rules currently allow Members to exclude from patentability, plants, animals, other than micro-organisms, and biological processes for producing plants or animals. It does, however, require Members to provide some form of intellectual property protection for plant varieties.

This sub-paragraph, 27.3(b), is due to be reviewed in 1999. The exact date for the review will only be set when a country formally requests it and this point may be raised at the meeting of the Council for TRIPs on 1st and 2nd December 1998. This review is part of a wider process being developed in other intergovernmental fora that will determine what choices countries will have over their access to, sustainable use of, trade in, and benefits arising from the use of plants, animals and biological processes. The results will affect a nation's capacity to provide food and livelihood security for its citizens. It is not a trivial process.

Because of the way in which Members can oblige others to implement WTO rules, decisions taken on the wording of this sub-paragraph will determine the minimum standards that countries must impose for the protection of intellectual property on plants, animals and biological processes, whether they originate in the country or are imported, irrespective of what has been negotiated elsewhere. It will influence access and benefit sharing agreements with respect to genetic resources.

Despite this review, most developing country Members of WTO should have fully implemented TRIPs, including enacting legislation for the protection of plant varieties (developing or changing seed laws in line with this sub-paragraph) by 1 January 2000, with an extension for Least Developed Countries until 1 Jan 2005. Introducing legislation at a time when Article 27.3(b) is to be reviewed is causing difficulties in many countries. To exacerbate these difficulties, the whole TRIPs Agreement is due to be reviewed in the year 2000, causing additional concerns.

Commonwealth developing countries need to consider a range of issues, options and capacity building requirements in preparation for the review of Article 27.3(b). To assist with this, this paper describes:

- the special characteristics of biological resources for food and agriculture and the intellectual property they contain;
- the intergovernmental processes, especially the WTO, governing the conservation, development, sustainable use and ownership of biological resources for food and agriculture and their associated knowledge;
- some of the negotiating options for this review; and
- capacity building priorities that Commonwealth developing countries may wish to consider.

Biological Resources for Food and Agriculture: Development, Conservation, Sustainable Use, Access and Benefit Sharing

Biological resources for food and agriculture are special because, unlike other natural resources, they are the basis of life on earth and human existence. They are also capable of self-replication or of being reproduced in a biological system. For 12,000 years, up until the industrialisation of agriculture, there was an increase in the variety of biological resources for food and agriculture - agricultural biodiversity or the genetic resources for food and agriculture, including plant genetic resources (PGR) and domestic animal genetic resources². This agricultural biodiversity was achieved by farmers and herders as they selected seeds and local livestock breeds best suited to their particular tastes, social and economic requirements and local environmental niches, from a common pool of biological (genetic) resources that were exchanged freely. The development, use and open exchange of these resources have provided the food and livelihood security of humankind.

The diversity, development and sustainable use of the wide range of biological resources developed by farmers is severely threatened by industrial agriculture and by intellectual property systems that will reduce free access and availability of resources (ITDG, 1996; Shand, 1997). With the industrialisation of agriculture, the subsequent commodification of natural resources and the concentration of productive resources and markets, increasing areas of arable land were planted to fewer varieties of seed and fewer breeds of livestock were kept. Most striking in effecting these changes were the ‘green revolution’ varieties of rice, maize and wheat, which spread globally in a few years displacing many local varieties (the so-called varietal replacement) (FAO, 1996a), and the widespread dissemination of ‘black and white’ dairy cows containing Friesian or Holstein blood (Scherf, 1995).

Greater investments are now being made in the development of new varieties produced with the aid of biotechnology. Plant breeding companies are seeking increased returns to cover their

² Definition of Agricultural Biodiversity. The variety and variability of animals, plants and micro-organisms used directly or indirectly for food and agriculture (including, in the FAO definition, crops, livestock, forestry and fisheries). It comprises the diversity of genetic resources (varieties, breeds, etc.) and species used for food, fodder, fibre, fuel and pharmaceuticals. It also includes the diversity of non-harvested species that support production (e.g. soil biota, pollinators and so on) and those in the wider environment that support agro-ecosystems (agricultural, pastoral, forest and aquatic), as well as the diversity of the agro-ecosystems themselves.

higher costs through extended marketing of these varieties in new areas. This will add to the pressures for varietal replacement. These seeds use genetic resources mainly taken from farmers' fields and stored in *ex situ* gene banks but the companies are not necessarily seeking to repatriate profits to the countries in which the genetic resources originated.

Claims by the biotechnology industry that it is essential to develop these varieties for human survival and that it will be only through industrial agriculture based on these biotechnologically produced seeds (genetically modified seeds) that a growing world population will be fed, is contested by many people, especially in developing countries (see for example, Shiva, 1998; Action Aid, 1998).

To guarantee increased returns, companies are seeking international protection of their varieties through legally enforceable plant breeders' rights (PBRs) and patents on seeds, breeds and biological processes, including biotechnology. It is this technologically-driven pressure that has provided the main stimulus to provide intellectual property protection on biological resources for food and agriculture. Many observers of these processes have summarised this history (see for example, Mooney, 1998; Pistorius, 1997; Fowler, 1994; Kloppenburg, 1988).

There is a recent technical development that may reduce the pressure from the plant breeding and biotechnology industries for plant breeders' rights and patents on seeds. Technology has been developed that limits or prevents reproduction of farm-saved seed, the so-called 'Terminator Technologies' (RAFI, 1998). Were there to be widespread development and use of these technologies it would limit the need for protection of proprietary varieties as they would not be capable of reproduction by farmers. This technology clearly has potentially serious implications for livelihoods, biodiversity and evolution.

As a result, the Convention on Biological Diversity Conference of the Parties (CBD/COP) has asked SBSTTA to assess whether there are any consequences for the conservation and sustainable use of biological diversity from the development and use of these technologies "for the control of plant gene expression". Moreover it "urges Parties, Governments as well as civil society and public and private institutions to consider the precautionary approach in its application" (CBD/COP Decision IV/6, para 11).

With particular reference to Plant Genetic Resources for Food and Agriculture (PGRFA) the Report on The State of The World's Plant Genetic Resources for Food and Agriculture has a useful summary concerning Access and Benefit Sharing, which is reproduced here (FAO, 1996a).

Access

The fact that the agricultural systems of virtually all countries are highly dependent on non-indigenous species is testimony to the wide dispersal of materials from the earliest days of agriculture itself. More than 1 300 genebanks hold over 6 million accessions (many of which are duplicates), largely as a result of the wide degree of access to PGRFA historically.

Until recently, PGRFA have been regarded as the "common heritage of mankind". Collecting has usually been freely allowed. Recently a voluntary International Code of Conduct for collecting and transfer of germplasm, based on the principle of national sovereignty over plant genetic resources, has been agreed at FAO. The

Code sets out standards and principles to be observed by countries that adhere to it, and proposes a number of mechanisms for benefit sharing. The Convention on Biological Diversity provides for access to plant genetic resources on mutually-agreed terms, based on the prior informed consent of the country providing the resources.

Many of the largest genebanks in the world, including those in Europe, North America and in the CGIAR system, have policies of unrestricted availability to bona fide users. A number of genebanks in developing countries maintain similar policies regarding access, though scarce resources for multiplication and processing may limit or delay availability. Political disagreements between countries on matters unrelated to PGRFA have sometimes made access problematic. In some cases, countries appear as a matter of policy to have restricted access to unique and potentially valuable undeveloped germplasm. However, the great majority of unique PGRFA accessions in ex situ collections has been generally available for plant breeding and research purposes. The FAO Seed Exchange Unit has, over the years, distributed over 0.5 million seed and planting material samples of improved varieties and landraces.

Breeders' lines, special genetic stocks, and other materials under development are generally not freely available, however. And information about and access to PGRFA held by private companies is typically restricted. Use of materials protected by patents or plant breeders' rights is subject to certain conditions.

The Convention on Biological Diversity (CBD) provides for access to be granted on "mutually agreed terms." Such terms might be agreed upon bilaterally or multilaterally. For agricultural biodiversity, the Conference of the Parties has declared its support for the process engaged in the FAO Commission on Genetic Resources for Food and Agriculture for the revision of the International Undertaking (IU).

Benefit Sharing

The contribution of farmer varieties and wild relatives to the modern varieties being grown in many countries today is clearly evident. A number of crops, such as sugar cane, tomatoes, and tobacco, could not be grown on any substantial commercial scale, were it not for the crucial contribution made by wild relatives of those crops to disease resistance. However, no comprehensive agreed estimates exist of the value of genetic material so utilised. Similarly no estimate of the incremental economic value of improved varieties exists.

Economic analysis, however, supports the view that many of those engaged in conserving and developing PGRFA, such as many farmers and their communities, do not receive benefits proportionate to the value of the germplasm originating from their fields. This has been recognized by countries through the FAO resolution on Farmers' Rights (5/89) which calls for farmers' and their communities to participate fully in the benefits derived from the use of plant genetic resources.

Biological resources for food and agriculture are the basis for food and livelihood security and also form the main resource for the biotechnology and plant breeding industries. They are being manipulated, utilised and traded in ways hitherto unforeseen and it is therefore important for human survival that care is taken in providing a technical, regulatory and legal framework for their conservation and sustainable use, that is competent to deal with these new pressures. Countries need to exercise their rights in many intergovernmental forums to ensure this happens.

Intellectual Property

Knowledge Systems

Globally, there are two distinct and potentially conflictive knowledge systems. The knowledge systems of the formal sector, of both private and public institutions, and the knowledge systems of the informal sector of communities and individuals. The formal sector knowledge systems are codified, are recorded in writing and are defended through national and international law; the knowledge systems of the informal sector are often oral, are built on trust and are defended through the norms and practices of traditional institutions. The intellectual property (IP) of the former is recognised in law in industrialised countries and in the industrial sectors of developing countries. The latter has weak jurisprudence in its defence: there are no mechanisms to implement legislation and, in most cases, no legislation has yet been enacted, despite ratification of a number of international agreements, such as the Convention on Biological Diversity (CBD). It is left to individual governments to develop legislation that will ensure the protection of informal knowledge and the equitable sharing of benefits from its use.

The trend of commodification and privatisation of knowledge is prevalent. This is especially through moving knowledge and plant genetic resources from the informal sector into the formal sector, and from public domain to private ownership. It may result in the loss of knowledge and materials by, and benefits for, the originators of that knowledge and the associated biological resources, especially people and communities in the informal sector.

National level institutions clearly need to understand better the range of knowledge systems in their country, who benefits from them, how they are being exploited and how they are being protected. The livelihoods of the majority of people, especially in developing countries, may depend on their informal knowledge systems, which are often subject to predatory acquisition by the formal sector. There are many activities underway to assess these systems but more work is needed in most countries in order that there is a better understanding of the likely impacts of technological, institutional, legal and regulatory changes.

The potential conflict between the two knowledge systems does need to be recognised and social, technical and legal systems of protection for biological resources in the public domain and those used by, and for the benefit of, the majority need to be developed accordingly.

Intellectual Property Rights

Intellectual property rights (IPRs) are the rights given to persons over the creations of their minds – their intellectual property (IP). They are granted by a state authority for certain products of intellectual effort and ingenuity. They usually give the creator an exclusive right over the use of his/her creation for a certain period of time. Intellectual property rights are customarily divided into two main areas: copyright and industrial property rights. The latter covers the protection of trademarks and other distinctive signs and the protection of industrial property primarily to stimulate innovation, design and the creation of technology: inventions (protected by patents), industrial designs and trade secrets. The social purpose is to provide protection for the results of investment in the development of new technology, thus giving the

incentive and means to finance research and development activities. Patents can be conferred on inventions, subject to the normal tests of novelty, inventiveness and industrial applicability. The protection is usually given for a finite term, typically 20 years in the case of patents (OECD, 1996; WTO, 1998).

As Steven Brush has said in his book on local knowledge systems “*Valuing Local Knowledge*”:

Granting intellectual property is a familiar method for converting public goods into private ones (Demsetz, 1967). Intellectual property does not directly convey market value to an idea or plant that is protected. Rather, it allows the market to work where it otherwise would not, by permitting a person to exclude others from using his or her ideas or plants, except under license or royalties. The right to exclude effectively becomes the right to profit from selling the idea or plant. Without intellectual property, all ideas are public goods or common property, and no one can be excluded from using another's idea. The right to exercise temporary monopoly power, however, requires that the claimants of the right prove their eligibility. Defining and defending this eligibility pose very high costs. (Emphasis added) (Brush, 1996).

There is much debate over the suitability of patents and other forms of intellectual property rights (IPRs) for the protection of plant genetic resources for food and agriculture. For example, the Crucible Group, comprising knowledgeable people from all relevant sectors - formal, informal, commercial, academic, trade and policy - made 28 recommendations in their report “*People, Plants and Patents*”, including:

14. *Sovereign states cannot be required to adopt systems of IP in areas that risk the well-being of their peoples or that jeopardise the biological diversity within their borders. Neither should countries be expected to adopt unrealistic time frames to enact IP provisions related to international trade agreements.*
15. *Any potential conflict between IP proposals and other initiatives for plant genetic resources conservation and exchange should be taken fully into account in interpreting responses to the GATT agreement. (Crucible Group, 1994)”*

Whatever the arguments, there is now an overwhelming pressure on all WTO Members, through TRIPs Article 27.3(b) to consider applying IPRs to living material, and an obligation to apply them to plant varieties. In responding to this, countries have to weigh the balance of rights between industrial innovators, often not from the country concerned, and the rights of local communities, farmers, indigenous peoples and consumers within the country (Williams, 1997).

Community Rights

As Darrell Posey points out in “*Beyond Intellectual Property*”, IPR laws are generally inappropriate and inadequate for defending the rights and resources of local communities and indigenous peoples. Traditional community knowledge is usually shared and the holders of restricted knowledge in communities probably do not have the right to commercialise it for personal gain. There are thus a number of models that are emerging to help people develop the basis of future legal systems to protect their knowledge and resources. These rights embody both biological and cultural rights and thus may go beyond other *sui*

generis models (i.e. rights or legally recognised systems that are adapted to the particular needs of a country or community), which concentrate only on the biological resource (Posey and Dutfield, 1996).

Community rights may incorporate rights to manage some aspects of self-governance, natural resource management and economic livelihoods, including control over biodiversity, local knowledge, innovations and practices as required by the CBD.

The movement to set up community registers of biodiversity to thwart misappropriation and initiatives to implement a moratorium on bioprospecting are evidence of concern at community level, in the absence of adequate protection. Farmers' Rights should also be considered within this bundle of rights and, importantly, need to be seen as complementary to, rather than in conflict with, other forms of community or indigenous peoples' rights.

Some of these rights are embodied in the CBD, especially Article 8(j)³, as well as in the FAO Farmers' Rights resolution 5/89⁴, but these have yet to be enacted in national laws in most countries though there are a number of models under consideration (see Posey and Dutfield, 1996). More recently, the Organisation of African Unity (OAU) has developed draft community rights legislation and some countries, including India and Malaysia as well as Andean Pact countries, have developed legislation that protects certain aspects of community rights.

The development of such codes of *sui generis* rights, recognised by trading partners, are seen by some countries as being a preferable alternative to the TRIPs Agreement with respect to biological resources, indigenous, local and community knowledge and locally controllable productive resources. The full review of the TRIPs Agreement in the year 2000 could consider this alternative, if enough countries request it. However, a precursor to this full review, and one which will have a decisive impact on its outcome with respect to the ownership of biological resources for food and agriculture, is the review of Article 27.3(b) in 1999, as will be discussed in the next chapter.

³ **CBD Article 8j**

Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilisation of such knowledge, innovations and practices.

⁴ **FAO Resolution 5/89**

Farmers' Rights mean rights arising from the past, present and future contributions of farmers in conserving, improving, and making available plant genetic resources, particularly those in the centres of origin/diversity. These rights are vested in the International Community, as trustee for present and future generations of farmers, for the purpose of ensuring full benefits to farmers, and supporting the continuation of their contribution, as well as the attainment of the overall purpose of the International Undertaking in order to:

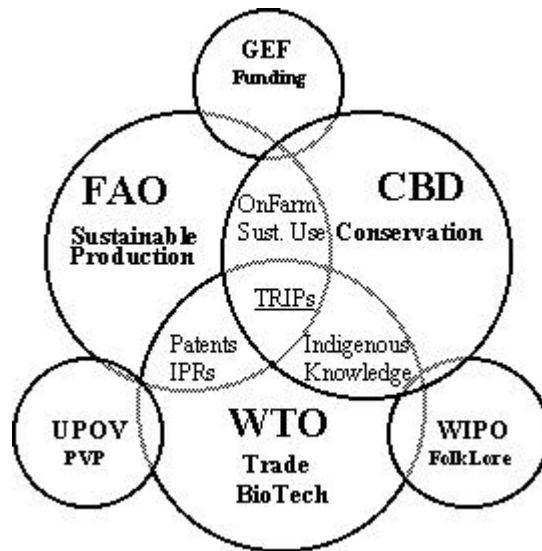
- a) Ensure that the need for conservation is globally recognized and that sufficient funds for these purposes will be available;*
- b) Assist farmers and farming communities in all regions of the world, but especially in the areas of origin/diversity of plant genetic resources, in the protection and conservation of their plant genetic resources, and of the natural biosphere;*
- c) Allow farmers, their communities, and countries in all regions, to participate fully in the benefits derived, at present and in the future, from the improved use of plant genetic resources, through plant breeding and other scientific methods.*

INTERGOVERNMENTAL PROCESSES

The intergovernmental processes that intend, on the one hand, to safeguard biological resources for food and agriculture and, on the other hand, to privatise these resources have a long history. International protection of privately owned resources, guaranteed through legally enforceable plant breeders' rights (PBRs) and patents, is in the ascendancy, because of the WTO's Article 27.3(b). In contrast there are the following international agreements, among others:

- the ratification of the CBD by 171 Parties and the Decisions by the Conference of the Parties (COP) on Agricultural Biological Diversity (Decisions III/11 and IV/6);
- the agreement to the Leipzig Global Plan of Action for the Conservation and Sustainable Utilisation of Plant Genetic Resources for Food and Agriculture (GPA) by 159 Members of FAO,
- the FAO International Undertaking on Plant Genetic Resources [for Food and Agriculture] (IU) agreed to by 111 countries.

Each of these agreements and decisions, which are mutually supportive, may be better suited to providing long-term equitable sharing of the benefits from the use of biological resources for food and agriculture as their purpose is to safeguard these resources for future generations through, *inter alia*, facilitating their sustainable use.



**The key international institutions governing the sustainable use of agricultural biodiversity:
Article 27.3(b) of the WTO/TRIPs Agreement is a dominant influence**

WTO

The World Trade Organisation (WTO) with 132 Members, is the dominant institution because of the trade rules its Members have agreed to, in particular the TRIPs Agreement that permits patents on biological materials in Article 27.3(b). It is this sub-paragraph that is to be reviewed in 1999 with a review of the full TRIPs Agreement scheduled for 2000. These reviews will be

organised through the Council of TRIPs, which may discuss this issue at its meeting on 1st and 2nd December 1998.

The outcome of these reviews will be influenced by, and will have an influence on, the renegotiation of the Agreement on Agriculture by the WTO Committee on Agriculture, by defining the extent of patentability on the primary biological resources for food production. They will also influence the outcome of other negotiations, especially in the CBD and FAO.

The WTO Committee on Environment (CTE) could have an influence on the TRIPs reviews by examining the potential environmental impacts of TRIPs, especially with regard to the patenting of biological materials, and asking the Council of TRIPs to take note of their concerns. The Council of TRIPs meets 6 times a year, the CTE meets each 4 months.

WIPO

The World Intellectual Property Organisation (WIPO), with 171 signatories, is responsible for the promotion of the protection of intellectual property throughout the world through cooperation among States, and for the administration of various multilateral treaties, such as the Patent Cooperation Treaty, Berne and Paris Conventions, dealing with the legal and administrative aspects of intellectual property. It also assists in the implementation of TRIPs through training and capacity building. Its work on intellectual property is carried out by two main branches: industrial property, chiefly in inventions, trademarks, industrial designs, and appellations of origin; and copyright, chiefly in literary, musical, artistic, photographic and audiovisual works.

WIPO has a new programme - the Global Intellectual Property Issues Programme - in which, among other sub-programmes, work originating in the United Nations Educational, Scientific and Cultural Organisation (UNESCO) on 'expressions of folklore' is being revisited to examine how intellectual property systems can protect this type of knowledge. Another sub-programme is looking at the possible links between intellectual property aspects of biotechnology and the conservation, use and benefit sharing of biological resources is being developed as a separate activity. Yet another is considering new approaches to the use of intellectual property systems by holders of indigenous knowledge and innovations in cooperation with, for example, the CBD in its implementation of Article 8(j).

UPOV

The International Convention for the Protection of New Varieties of Plants is known by its French acronym UPOV. It was set up to give plant breeders exclusive rights (PBRs) over the varieties they develop, so long as they comply with the so-called DUS criteria - that they are Distinct from any other variety, Uniform in that all seeds produce similar plants and Stable i.e. breed true in subsequent generations. Its convention originated in 1961 was revised in 1972, 1978 and again in 1991. 37 States are party to one or other of the Acts, mainly UPOV 78, with 28 parties. It is the most recent versions, UPOV 78 and UPOV 91, with 7 parties, that is suggested by some, including the former Director General of the WTO, as being the sui generis alternative to patents for plant variety protection (PVP) as required by TRIPs Article 27.3(b).

Although UPOV 78, and earlier Acts, are still recognised, UPOV 91 came into force on 24 April 1998 and many countries will now upgrade their membership by becoming party to this Act. From 24 April 1999 it will be the only option available to new signatories to the Convention. One of the main changes embodied in UPOV 91 is the possibility to provide

double protection of plant varieties through Plant Breeders Rights (PBRs) and patents. Also the 'right' of farmers to resow farm-saved seed is now an 'optional exception' (Article 15 (2)) - sometimes referred to as 'farmers' privilege' - which countries must specifically include in their national legislation for implementing UPOV, if they wish.

CBD

The CBD has 174 Contracting Parties. Its conservation and indigenous rights articles (for example Article 8(j) concerning the knowledge, innovations and practices of indigenous peoples) and the embryonic BioSafety Protocol, many claim, should take precedence over WTO rules in the event of any conflict. With reference to this, Article 16.5 of the CBD says (emphasis added):

"The Contracting Parties, recognising that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives."

It operates through the Conference of the Parties (COP) which meets every 18 months to two years. The COP is advised by its Subsidiary Body on Technical and Technological Advice (SBSTTA) which meets annually and other specialist working groups. Currently a Working Group on BioSafety is meeting regularly to finalise the Biosafety Protocol which will be submitted to an Extraordinary COP in 1999. There are also various *ad hoc* intersessional groups set up by the COP to discuss specific issues, including issues arising out of COP Decision IV/15 (para 9)

"...need to ensure consistency in implementing the Convention on Biological Diversity and the World Trade Organization agreements, including the Agreement on Trade-Related Aspects of Intellectual Property Rights, with a view to promoting increased mutual supportiveness and integration of biological diversity concerns and the protection of intellectual property rights, and invites the World Trade Organization to consider how to achieve these objectives in the light of Article 16, paragraph 5, of the Convention, taking into account the planned review of Article 27, paragraph 3 (b), of the Agreement on Trade-Related Aspects of Intellectual Property Rights in 1999;"

GEF

The Global Environment Facility is the major source of funding for environmental programmes and projects developed under the conventions agreed at the Earth Summit, UNCED, in Rio de Janeiro in 1992. The funds are released to programmes administered by the World Bank (WB), the United Nations Development Programme (UNDP) and the United Nations Environment Programme (UNEP). It has recently had a replenishment of funds and is in the process of agreeing a framework for activities concerning the conservation and sustainable use of biological diversity important to agriculture.

FAO

The Food and Agriculture Organization of the United Nations (FAO) with 175 Members has the principal role in developing international programmes for the conservation and sustainable use of agricultural biodiversity, on behalf of the CBD, for example through coordinating relevant programmes, such as the phased multi-year programme of work on agricultural

biological diversity approved by COP 3. It is also the host organisation for the Commission on Genetic Resources for Food and Agriculture (CGRFA) with 157 Members (and the European Community). The facilitation of access to PGRFA, under appropriate mechanisms, and the sharing of benefits derived from their utilization, are two of the goals of both the International Undertaking and the Convention on Biological Diversity. The International Undertaking is currently being revised with the support of the Conference of the Parties to the CBD, through negotiations between countries in the CGRFA in order to harmonise it with the Convention, and for consideration of the issues of access to plant genetic resources for food and agriculture and the realization of Farmers' Rights. The revised IU could be sent by the FAO Conference in 1999 to COP V for inclusion in the CBD as a Protocol.

In addition, the CGRFA has set up intergovernmental technical working groups on plant and animal genetic resources to consider a wide range of technical issues.

FAO is the host organisation for the Leipzig Global Plan of Action for the Conservation and Sustainable Utilisation of Plant Genetic Resources for Food and Agriculture (GPA) approved by 158 countries in June 1996. This plan with 20 priority activity areas covers all aspects of agricultural biodiversity conservation and sustainable use. It is seen by some donor countries to be an avenue for providing benefits to genetic resource rich developing countries in exchange for their support for a multilateral access agreement to these resources. Many developing countries do not accept this as a legitimate benefit sharing arrangement.

FAO is also a resource for capacity building not only in many areas of agricultural biodiversity conservation and sustainable use, but also in the implementation of WTO agreements, including TRIPs.

There may potentially be conflict between the obligations countries have entered into under CBD and those they have adopted through their membership of WTO. Additionally, some developing countries see particular treaties administered by WIPO, such as the Patent Cooperation Treaty, and the UPOV convention, as the potential *sui generis* alternative to patents on plant varieties, to be in conflict with the conservation and sustainable use objectives of the CBD and FAO.

There is, however, significant synergy between the CBD and FAO particularly through, for example, the multi-year programme of work on agricultural biological diversity and the revision of the IU.

In addition to these intergovernmental processes, many Commonwealth developing countries will also be negotiating the Lomé Agreement and the Multilateral Agreement on Investment (MAI). The former is likely to have WTO compliancy clauses, including TRIPs, for any beneficiary of the Agreement. The latter may form part of the WTO in due course.

Further information on each of the intergovernmental processes listed above is available through Internet web pages (see the Web Resources listing on page 40) as well as from conventional printed sources. These are summarised in the following table:

Summary of Relevant agreements, Decision making forums and Key negotiations

Body	Relevant agreements	Decision making forums	Key negotiations/dates
WTO	Agreement on Agriculture and Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPs), Dispute Settlement Understanding	Council for TRIPs, Committee on Trade and Environment, Sanitary and Phytosanitary Committee, Dispute Settlement Body	Review of TRIPs Article 27.3(b), 1999; Review of TRIPs, 2000; Renegotiation of Agreement on Agriculture (late 1999→)
WIPO	Patent Cooperation Treaty (PCT), Bern Convention, Paris Convention etc. (Advice and training on implementation of TRIPs)	WIPO General Assembly	
UPOV	UPOV 78, UPOV 91		UPOV 78 only available until 24 April 1999
CBD	Decisions III/11, IV/6 of the COP, Biosafety Protocol	SBSTTA, COP	SBSTTA IV in 1999; SBSTTA V, COP V May 2000, Kenya; CBD/TRIPs 'conflict'
GEF	Projects administered through World Bank, UNDP and UNEP	GEF Council	1998 replenishment for projects to implement multilateral environmental agreements (MEAs), such as the CBD
FAO	International Undertaking, Leipzig Global Plan of Action, IPM facility, IPPC, Codex Alimentarius, Right to Food, FAO/CGIAR Accord (Global trusteeship of CGIAR gene bank material)	FAO Council and Conference, CGRFA, various Sectoral Technical Working Groups	Negotiation of revision of IU: 6 th extraordinary CGRFA January 1999; 8 th regular CGRFA May 1999; FAO Conference, November 1999

INTERGOVERNMENTAL NEGOTIATIONS ON AGRICULTURAL BIODIVERSITY CONVERGE

1998

1999

2000

FUTURE?

WTO

- ☉ Second Ministerial Conference (May)
- ☉ Committee on Sanitary and Phytosanitary measures (SPS) - first review
- ☉ General Council Meeting of Dispute Settlement Body (DSB) - full review of rules and procedures
- ☉ Trade Related Aspects of Intellectual Property Rights (TRIPs) Council (1st / 2nd Dec)
- ☉ Committee on Trade and Environment (CTE) (22nd Oct)

- ☉ Agriculture negotiations initiated one year before end of implementation period
- ☉ Council for TRIPs (16th / 17th Feb)
- ☉ TRIPs - Review of Article 27.3(b) re certain exceptions to patentability and protection of plant varieties
- ☉ UPOV *Sui Generis* Seminar (15th Feb)
- ☉ Third Ministerial, Washington DC (Probably 4th quarter Oct - Dec)

- ☉ Agriculture Services
- *New round of negotiations start
- *MPN exemptions first review
- ☉ TRIPs - full review
- ☉ Trade Related Investment Measures (TRIMS) - review of operation and discussion on investment policy and competition policy
- ☉ Tariff bindings - review of definition of principle supplier
- ☉ Trade Policy Review - appraisal of operation of the review mechanism

CBD

- ☉ Fourth Conference of the Parties
- ☉ 5th BioSafety working Group
- ☉ Expert panel on Benefit Sharing
- ☉ Agricultural Biodiversity Workshop (2-4 Dec)

- ☉ Intersessional COP Working Group (June)
- ☉ Ad Hoc Intersessional Working Group 8j
- ☉ 6th BioSafety + Extraordinary COP (Feb)
- ☉ 4th SBSTTA (June)

- ☉ Fifth SBSTTA (Feb)
- ☉ Fifth Conference of the Parties (to ratify IU as Protocol to CBD?) (May)

FAO

- ☉ Codex Alimentarius (May)
- ☉ 5th extraordinary session of CGRFA (June)
- ☉ World Food Summit follow-up -Right to Food
- ☉ Agricultural Biodiversity Workshop (2-4 Dec)

- ☉ 6th extraordinary session of CGRFA (12-16 April)
- ☉ 8th Session of CGRFA (to finalise IU?) (19-23 April)
- ☉ Codex Alimentarius Commission (28 June - 3 July)
- ☉ FAO Council (June) & Conference (Nov) (to send IU to CBD?)
- ☉ Multifunctional Agriculture and Land Management Conference (Sept)

- ☉ CSD 8 - review of Chapters 10 - 15 of AGENDA 21
- ☉ World Health Assembly

UN

- ☉ Right to Development
- ☉ High Commission on Human Rights
- ☉ Committee on Economic, Social and Cultural Rights (ECOSOC)
- ☉ Draft Declaration on Rights of Indigenous Peoples
- ☉ World Health Assembly

Source: adapted by PMM from chart by Kristin Dawkins, IATP, June 1998

Central importance of WTO TRIPs Article 27.3(b)

The WTO text in Article 27.3(b) defines the legal framework for the ownership of life. The outcome of the review in 1999 will set precedents for future trade and environment negotiations and will in particular constrain the development of biodiversity-friendly legislation as required by the Convention on Biological Diversity (CBD). It will set the context for, for example:

- subsequent trade negotiations in the WTO such as the full review of TRIPs in 2000 and the renegotiation of the Agreement on Agriculture starting in 1999;
- negotiations on the implementation of the Convention on Biological Diversity (CBD) and the adoption of the BioSafety Protocol;
- negotiations in the Food and Agriculture Organisation of the United Nations (FAO) on the revision of the International Undertaking on Plant Genetic Resources [for food and agriculture] (IU) and its submission to the CBD as a possible Protocol;
- it may influence the relevance of the outcome of the review of Chapters 10 - 15 (the land-based chapters) of Agenda 21 by the 8th Commission on Sustainable Development (CSD) and the potential impact it might have on future developments.

A complicating factor is that each of these negotiations is usually handled by different ministries and departments. For example trade ministries may deal with the WTO. Intellectual property rights may be the responsibility of a Patent Office, or, in the case of seeds, a Plant Variety Office. Environment is often handled by a separate ministry or agency. Agricultural ministries are usually responsible for negotiations on genetic resources for food and agriculture. Each of these ministries may be advised by formal bodies, often research councils or institutions, in which the detailed analysis is done. This separation of functions among different ministries and agencies can lead to a loss of policy coherence and weaken a country's position.

Discussions are therefore essential between all relevant government offices in order to agree mutually acceptable negotiating positions for this review and related processes, so that countries are able to understand the linkages between, and implications of, all the linked international negotiations. Furthermore, good communication with Geneva-based negotiators is also essential to ensure clear communication of positions taken by the competent authorities in capitals.

The opportunities for convergence of these and other current intergovernmental negotiations by different international institutions have been summarised by Kristin Dawkins of the Institute for Agricultural Trade Policy (IATP) in the chart on the opposite page (as adapted by the author). In this chart the sequencing of meetings in the WTO, CBD, FAO and other UN organisations is crucial. It emphasises the need for exceptionally well coordinated negotiating positions by countries and full access by all negotiators to all relevant information internationally and from within the country.

GATT/WTO AGREEMENT ON TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPs AGREEMENT)

The TRIPS Agreement came into effect on 1 January 1995. Developing countries need to have implemented TRIPs by 1 January 2000, except Least Developed Countries, which have until 1 Jan 2005 to implement relevant legislation. The TRIPs Agreement covers *inter alia* patents including the protection of new varieties of plants (**Articles 27 to 34**). The Agreement sets out the **minimum standards** of protection to be provided by each Member of the WTO. These minimum standards are sometimes referred to as Berne and Paris Conventions plus. It deals with domestic procedures and remedies for the **enforcement** of intellectual property rights. It also makes disputes between WTO Members subject to the WTO's **dispute settlement procedures**. The TRIPS Agreement requires Member countries to make patents available for any inventions, whether products or processes, in all fields of technology without discrimination, subject to the normal tests of **novelty, inventiveness** and **industrial applicability** (see box with full annotated text of **Article 27** on following pages). It is required that patents be available and patent rights enjoyable without discrimination as to the place of invention and whether products are imported or locally produced (**Article 27.1**). There are three permissible exceptions to the basic rule on patentability.

- One is for inventions contrary to *ordre public* or morality; this explicitly includes inventions dangerous to human, animal or plant life or health or seriously prejudicial to the environment. The use of this exception is subject to the condition that the commercial exploitation of the invention must also be prevented and this prevention must be necessary for the protection of *ordre public* or morality (**Article 27.2**).
- The second exception is that Members may exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals (**Article 27.3(a)**).
- The third is that Members may exclude plants and animals other than micro-organisms and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, any country excluding plant varieties from patent protection must provide an effective *sui generis* system of protection. Moreover, the whole provision is subject to review four years after entry into force of the Agreement i.e. 1999 (**Article 27.3(b)**).

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties (**Article 30**). The term of protection available shall not end before the expiration of a period of 20 years counted from the filing date (**Article 33**). The TRIPS Agreement gives all WTO Members transitional periods so that they can meet their obligations under it. For developing countries, the general transitional period is five years, i.e. until 1 January 2000 and for those countries on the United Nations list of least-developed countries, the transitional period is eleven years i.e. until 1 January 2005 (WTO, 1998).

In this context the products of nature could never be subject to a valid patent, as they have not undergone an inventive step: 'discoveries' cannot be patented. Also, plant material that has been developed by humans could only be patented if the patentee could show that she or he had produced something new. No farmers' variety maintained over time in a community could have a valid patent taken out on it by a third party: it would not meet the novelty criterion even if the evidence of prior 'disclosure' was only oral. Despite the provisions of the TRIPS Agreement, institutions have applied for patents on both categories of material and in some cases have been incorrectly awarded patents in the USA. Headline cases draw attention to the myriad abuses of the system and the lack of Prior Informed Consent being sought from communities, even before international implementation has been agreed. For these reasons among others the upcoming review of Article 27.3(b) is of great importance to assuring the sovereignty of biological resources and even to raising the question whether intellectual property rights should be applied to this sector in any circumstances.

Mechanisms for determining the interpretation of TRIPs

Clarify language in the Council for TRIPs

The TRIPs Agreement is a 'work in progress and there is a need to clarify language in time'. Many of its terms have not yet been subject to legal definition and there is little case law concerning its implementation. While there are political and commercial pressures for its adoption in law by all members of the WTO, legally, a Member could contest any of its articles, in particular any which conflicted with existing law at national or international levels, or countries could define terms in ways that suited national interests. It has been said that the agreement contains 'constructive ambiguity to hide disagreements. Such Treaties rely on the intentions of the Parties. Therefore the intentions, although not published, can influence outcomes.' Much of the interpretation is being developed in the Council for TRIPs with a convention that if a country is asked the same question by three or more other countries it has to comply. However, the minutes of the Council are 'closed i.e. not circulated, but are part of jurisprudence'. The report of the Council for TRIPs is published and is available on the WTO WebSite but is tantalising in its hints of discussions that have taken place. For example, in the report on its work in 1996 under the heading of 'The Built in Agenda' it reports that on Article 27.3(b):

[29] Article 27.3(b) states that the provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement. At the Council's meeting in July, some delegations addressed the question of when this work should be initiated.

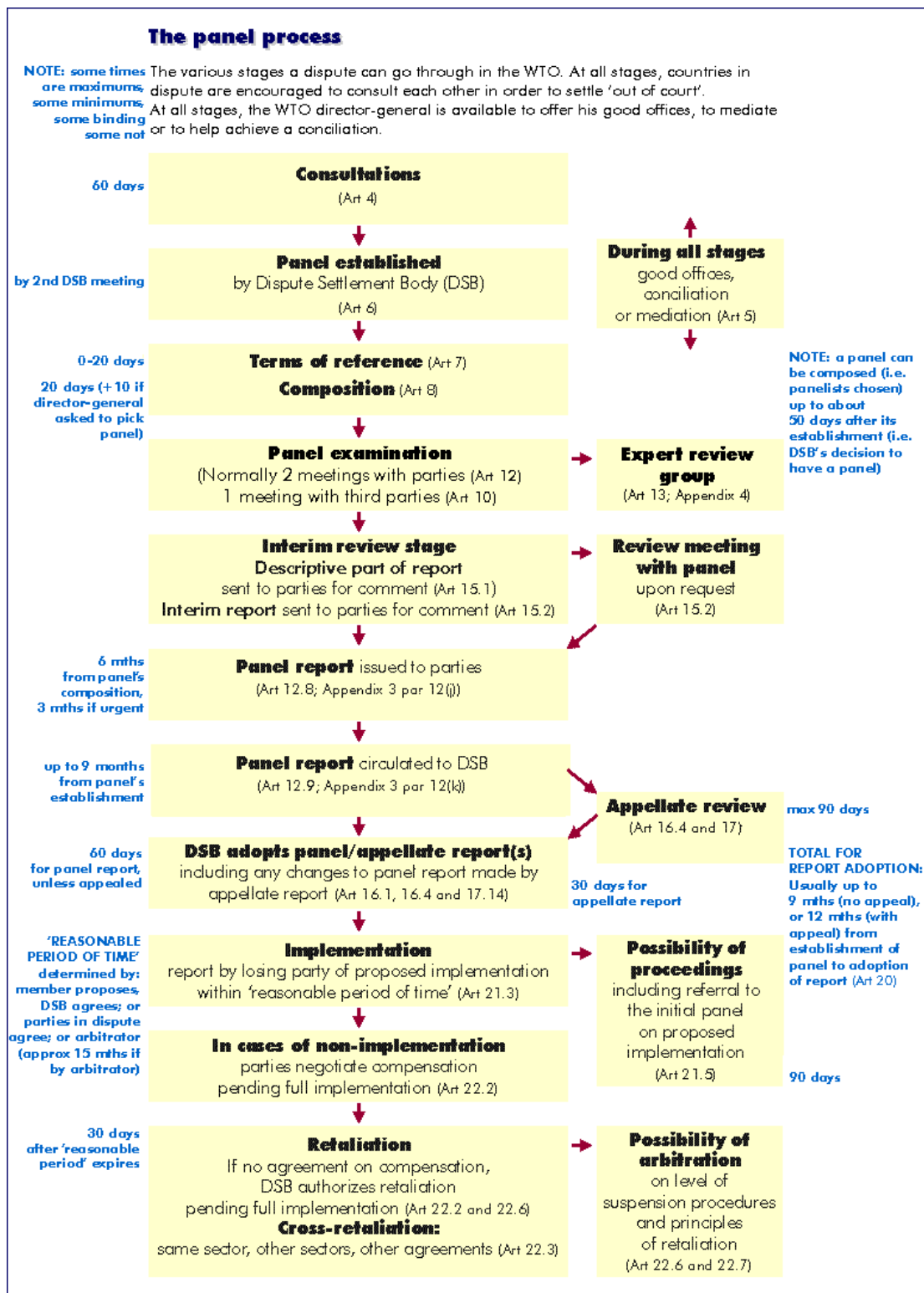
Present formal proposals for new wording

There has been a long debate in the Council for TRIPs between India and the USA on the scope and interpretation of TRIPs but neither of these countries nor any others have put forward formal proposals of how they would wish the Agreement to be changed with regard to the exceptions to patentability included in Article 27. Some countries have raised problems informally especially with regard to the protection of local knowledge, but again no formal presentations have been made. The door is open for any country or group of countries to make their position clear.

Raise questions in other WTO Committees and send these to the Council for TRIPs

Members could use other mechanisms within the WTO to challenge TRIPs. For example the Committee on Trade and Environment (CTE) or the Sanitary and Phytosanitary System (SPS) both allow for questions to be raised, for example about the environmental or health impacts of TRIPs or the products that TRIPs might protect, such as Genetically Modified Organisms (GMOs) or Living Modified Organisms (LMOs). Were three or more countries to ask similar questions in any of these committees, there would be an obligation on the WTO and its Members to examine the issues raised and provide satisfactory answers. Thus far this has not yet occurred in formal sessions, although there are possibilities that some countries will start to use this mechanism in the CTE, hitherto viewed within the WTO as a relatively insignificant body.

WTO Dispute Settlement Procedure



Source: WTO, 1998

Use the WTO Dispute Settlement Procedure to challenge interpretations of TRIPs

The dispute settlement procedure provides the mechanism for enforcement of the rules-based WTO system. The procedure underscores the rule of law, and it “makes the trading system more secure and predictable”, says Renato Ruggiero the Director General of the WTO. “It is clearly structured, with flexible timetables set for completing a case. First rulings are made by a panel. Appeals based on points of law are possible. All final rulings or decisions are made by the WTO's full membership. No single country can block these”.

WTO members have agreed that if they believe fellow-members are violating trade rules, they will use the multilateral system of settling disputes instead of taking action unilaterally. That means abiding by the agreed procedures, and respecting judgements. The process is overseen by the Dispute Settlement Body (DSB).

Typically, a dispute arises when one country adopts a trade policy measure or takes some action that one or more fellow-WTO members considers to be breaking the WTO agreements, or to be a failure to live up to obligations. A third group of countries can declare that they have an interest in the case and enjoy some rights.

The Dispute Settlement Procedure has not yet been used to challenge any interpretation of Article 27.3(b). The Panel Process by which WTO disputes are settled is shown in the table opposite (WTO, 1998).

Use the Settlement of Disputes procedure of the CBD

Another approach would be to bring a test case to the Settlement of Disputes procedure agreed to in Article 27 of the CBD. This might assist in establishing international jurisprudence with regard to intellectual property rights on plants, animals and biological processes.

CBD ARTICLE 27

- 1. In the event of a dispute between Contracting Parties concerning the interpretation or application of this Convention, the parties concerned shall seek solution by negotiation.*
- 2. If the parties concerned cannot reach agreement by negotiation, they may jointly seek the good offices of, or request mediation by, a third party.*
- 3. When ratifying, accepting, approving or acceding to this Convention, or at any time thereafter, a State or regional economic integration organization may declare in writing to the Depositary that for a dispute not resolved in accordance with paragraph 1 or paragraph 2 above, it accepts one or both of the following means of dispute settlement as compulsory:
 - (a) Arbitration in accordance with the procedure laid down in Part 1 of Annex II;*
 - (b) Submission of the dispute to the International Court of Justice.**
- 4. If the parties to the dispute have not, in accordance with paragraph 3 above, accepted the same or any procedure, the dispute shall be submitted to conciliation in accordance with Part 2 of Annex II unless the parties otherwise agree.*
- 5. The provisions of this Article shall apply with respect to any protocol except as otherwise provided in the protocol concerned.*

TRIPS Agreement SECTION 5: PATENTS

Article 27 Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. See footnote 5⁵ Subject to paragraph 4 of Article 65⁶, paragraph 8 of Article 70⁷ and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.
2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public 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.
3. Members may also exclude from patentability:
 - (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
 - (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes.However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement. [1995]

⁵ **Footnote: 5** For the purposes of this Article, the terms "**inventive step**" and "**capable of industrial application**" may be deemed by a Member to be synonymous with the terms "**non-obvious**" and "**useful**" respectively

⁶ **Article 65 [paragraph] 1.** Subject to the provisions of paragraphs 2, 3 and 4, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement. **[Paragraph] 2.** A developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1, of the provisions of this Agreement other than Articles 3, 4 and 5. **[Paragraph] 4.** To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of **Section 5 of Part II [paragraphs 27 to 34]** to such areas of technology for an additional period of five years.

Article 66 Least-Developed Country Members [paragraph] 1. In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under **paragraph 1 of Article 65**. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.

⁷ **Article 70 paragraph 8.** Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under **Article 27**, that Member shall:

(a) notwithstanding the provisions of **Part VI [Articles 65 and 66 - see above]**, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;

(b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and

(c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with **Article 33** of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b). [**Article 33: The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.**]

SUI GENERIS SYSTEMS AND THE REVIEW OF TRIPS ARTICLE 27.3(b)

A *sui generis* system of rights is an alternative, unique form of intellectual property protection, designed to fit a country's particular context and needs (ITDG, 1996). It could apply either to the whole IP system or just to the protection of plant varieties as described in Article 27.3(b).

The revision of the TRIPs agreement in 2000 should consider *sui generis* options, such as 'expressions of folklore' a concept developed into a draft treaty by UNESCO in the 1980s and currently being researched by the Global Intellectual Property Issues programme of WIPO. Alternatively, the concept of Traditional Resource Rights or Community Rights could be considered, as outlined above. The implications of major changes to the TRIPs agreement in 2000 or later on legislation currently being developed, as required under the existing agreement, is an impediment to implementing effective national laws. Likewise any 'freeze' on the implementation of TRIPs that may be called for in the 1999 review of Article 27.3(b) will reverberate on the subsequent review (GRAIN, 1997).

Within Article 27.3(b) it is stipulated that 'Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof.' In implementing this Article 27.3(b) countries need to be assured that what they propose will be recognised as '*effective*'. There is model legislation available through the UPOV Convention either UPOV 78 or UPOV 91. The 1991 version came into force on 24 April 1998 and will be the only available UPOV option from 24 April 1999. The UPOV Convention is derived from the need to protect the interests of plant breeders in industrialised countries: it does not derive from the needs of users in developing countries although the recognition of 'farmers' privilege' to resow farm-saved seed remains an optional exception in national level legislation (UPOV Article 15(2)). While some have suggested that this model is the preferred option it has not been presented formally as such. There is no reason why countries should not develop their own models and submit these to the WTO for their approval. (See below).

The definition of '*variety*' is also confined to the product of industrialised plant breeding which requires a variety to be new, distinct, uniform and stable (UPOV Article 5(1)). It does not cover the majority of varieties nurtured by farmers which by design are often heterogenous and it is unclear how protection of farmers' varieties will be afforded through TRIPs or what other impacts TRIPs might have on the conservation and sustainable use of these varieties.

The interpretation of what are ‘*essentially biological processes*’ is still open. Are these only the growth and development of plants and animals through normal (to be defined) production methods or could these include artificial growth of parts of plants or animals even if these involve some microbiological processes.

This underscores the need for better technical and legal interpretation of the Article, and indeed the whole TRIPs Agreement in order to assist countries in the framing of legislation, if that is the route they elect to take, as obliged by their membership of the WTO.

When the Article is reviewed, there is a radical proposal to delete the whole sub-paragraph, which would provide for no exclusions to patenting, an option antithetical to many developing countries, as well as several other possible negotiating options, very well summarised for the ‘Signposts to *sui generis* rights’ seminar (GRAIN, 1997). A more detailed examination of the options is provided in the next section.

Options for Changing the Text of Sub-Paragraph 27.3(b)

There has been no formal discussion in the WTO of the options that countries may consider, but informally many options are being discussed, including:

- Doing nothing, simply reviewing progress in implementing the sub-paragraph and leaving the wording as it is, retaining some ambiguity. This would provide countries with maximum flexibility within the existing agreement, particularly because the exact meaning of most of the terms has yet to be agreed, or defined by international jurisprudence. By agreeing to do nothing it also reduces the risk of negative changes being imposed.
- Extending the exclusions to patentability to include all living organisms and the associated knowledge for their conservation and sustainable use. This is the option favoured by many developing countries whose genetic wealth and the food and livelihood security of their citizens could be threatened by monopoly ownership of biological resources through patents. It is a low-cost option removing the need to defend their resources and know how through litigation. Benefit sharing arrangements should be agreed through the FAO/CBD negotiations in the International Undertaking and the CBD itself, which may prove a better arrangement for developing countries.
- Removing the obligation to provide plant variety protection or ensuring that measures adopted are carefully tailored to a country's own needs - the *sui generis* option. Most developing countries do not require this as a priority. The reciprocal arrangements with developed countries for the use of their protected plant varieties or germplasm, which have been produced mainly to meet the needs of northern temperate industrial agriculture, are not usually to the advantage of the majority of farmers in developing countries. With the exception of a few industrial export-oriented commodities, such as flowers, the priority for the majority of people is for the local development of varieties adapted to the needs of sustainable agricultural practices in labour intensive holdings.

- Deletion of the whole sub-paragraph, which would provide for no exclusions to patenting of living organisms and their accompanying intellectual property - an option favoured by some industrial countries. This would favour the biotechnology industry, which would be able to insist that all countries impose and recognise their patents, and their right to patent material irrespective of its origin.

Given the treaty commitment to start the review in 1999, while simultaneously enacting required legislation and negotiating a number of other related agreements, a further set of options arise, including:

- Seeking to delay the review and the legislative timetable until after the full TRIPs review has been completed.
- Opening the review, as required, but then completing it in parallel with the full TRIPs review and the renegotiation of the Agreement on Agriculture over subsequent years.
- Raising, a set of questions concerning the possible conflict between some Members' obligations under the Convention on Biological Diversity and their obligations under TRIPs, that need investigating before the review can be concluded, in one of the WTO's Committee on Trade and Environment (CTE) four-monthly meetings (next meeting on October 22nd 1998 may consider intellectual property issues including the TRIPs review).
- Requiring satisfactory completion of the negotiation of the revision of the IU and its adoption as a Protocol to the CBD, before completion of the review.
- Alternatively, a rapid completion of the review, possibly by agreeing that no changes to the text are required.

Most of the wording in Article 27.3(b) of the TRIPs agreement is deliberately ambiguous and open to interpretation. Until there is a sufficient body of international jurisprudence, countries cannot know definitively whether or not their response to the sub-paragraph will be deemed legal.

Other pressures from trading partners, donors and other international agreements may also be brought to bear on countries, obliging them to comply with this agreement and a specific interpretation of this sub-paragraph. For example, to comply with the requirement for plant variety protection, pressure may be applied to persuade a country to join the International Convention for the Protection of New Varieties of Plants (UPOV). This Convention is considered by some to be the only effective form of *sui generis* legislation, despite there being no specific mention of UPOV in the WTO text and there being other options better suited to a country's own needs that could be developed.

Legal clarity will eventually be achieved only through the WTO's Dispute Settlement Body, which arbitrates in the event of a disagreement between Members. However, these disputes may also need to be tested against the dispute settlement procedures of other relevant conventions, such as the CBD. This could prove a lengthy and costly process in which developing countries may be disadvantaged. It could be avoided by

removing the obligation for countries to have intellectual property protection on any plants, animals or biological processes, under the rules of the WTO and leave developing legal protection, as necessary under the CBD.

Possible elements of a *sui generis* IPR system for plant varieties

Possible elements of a *sui generis* IPR system for plant varieties have been developed by IPGRI in Intellectual property rights and Plant Genetic Resources: options for a *sui generis* system and are quoted below. It is being refined and further paper should be published soon by IPGRI.

- *Firstly, the protectable subject matter must be defined. There are several ways to define the term plant variety. Furthermore, the TRIPS Agreement leaves the option to protect additional subject matter.*
- *Secondly, the requirements for protection must be set up. The 'traditional' requirements for the protection of plant varieties – that they be novel, distinct, uniform and stable – can be altered substantially. But the plant grouping to be protected still has to be distinct from other plant groupings and it must be possible to clearly identify it with reasonable effort. Moreover, additional requirements for protection may be set up, such as Value for Cultivation and Use (VCU) or declaration of origin. While the former may allow member states to provide for incentives to fit their specific priorities in plant breeding, the latter may, for example, be helpful in verifying whether the Prior Informed Consent (PIC) of the providers of breeding material has been obtained.*
- *Thirdly, the scope of protection must be defined. The physical elements (representing a plant variety) which are to be covered by the right may include vegetative or reproductive propagating material, and they may also include the harvested material. Also in modelling the scope of the sui generis right, the legal acts will have to be defined which shall require the authorization of the right-holder. Member states could follow the models provided by current patent law or by the different UPOV Acts. They may also define a different scope of protection subject to the general requirements as set out in Chapter 2. This includes, for example, the option to grant the exclusive right to use a PVP seal for material of a specified, registered variety in combination with its registered denomination. Such a seal would not relate to the material as such.*
- *Fourthly, the definition of the duration of the sui generis right – which is not specified under TRIPS – is an important factor to deal with.*
- *Fifthly, the interface with other IPR should be clearly regulated to avoid the problem of overlapping claims.*
- *Finally, there is a package of elements that can be introduced to balance the privilege conferred to the right-holder, such as community gene funds, registers to facilitate benefit-sharing mechanisms and the institute of a public defender. Each single element must be carefully designed, but the main focus should be directed at balancing the different interests in the overall package of elements establishing the sui generis system.*

While there is no universal agreement on the merits of these proposals the authors do explore the legal obligations posed by the TRIPs Agreement. They make readers aware that there is a broad range of possible TRIPS-compatible *sui generis* systems, which should be explored and discussed before adopting industrialised country models (Leskien and Flitner, 1997).

Protection of Geographical Indications

Another mechanism that might be useful to explore as an alternative form of *sui generis* protection is the use of Geographical Indications, as allowed by TRIPs Article 22. These identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin. In order to establish this, members also have to provide the legal means for interested parties to prevent the misuse of the designation, which might mislead the public as to the geographical origin of the good. So it might be possible to protect, for example, a variety of fruit grown in a specific area of a country and known by the name of that area and thereby prevent the use of that name and that variety by others. It would not protect the variety from being grown elsewhere, but when marketed, the name could not be used.

Development of *Sui Generis* legislation as an alternative to the TRIPs Agreement

There are several proposals for alternative legislation which will address some of the perceived weaknesses of the TRIPs Agreement with respect to the protection of plants, animals and biological resources. Several countries, including India and Brazil have developed draft laws.

The Organisation of African Unity (OAU) has adopted a resolution supported by draft legislation on Community Rights and Access to Biological Resources (see Annex 1 for the full text). The scope of this legislation applies to biological resources both *in situ* and *ex situ* as well as their derivatives and to community knowledge and technologies. But it is not designed to apply to the traditional way of access, use or exchange of biological resources as well as knowledge and technologies by and between local communities and the sharing of benefits based upon their customary practices.

The objectives of this legislation are to:

- a) ensure the conservation and sustainable use of biological resources and of knowledge and technologies in order to maintain and improve their diversity as a means of sustaining the life support and health care system of the country;*
- b) recognize, protect and support the inalienable rights of local communities over biological resources and their knowledge, innovations and practices;*
- c) provide an appropriate system of access to biological resources and community knowledge and technologies subject to the prior informed consent of the State and the concerned local communities;*
- d) promote appropriate mechanisms for a fair and equitable sharing of benefits arising from the use of biological resources, community knowledge and technologies;*
- e) ensure the effective participation and agreement of concerned communities in making decisions as regards the distribution of benefits which may derive from the use of their biological resources, knowledge and technologies;*
- f) promote and encourage the building of national and grass roots scientific and technological capacity relevant to the conservation and sustainable utilization of biological resources;*
- g) provide appropriate institutional mechanisms for the effective implementation and enforcement of community rights and conditions of access to biological resources, community knowledge and technologies.*

This model legislation is comprehensive in scope and covers many of the deficiencies in the TRIPs Agreement, noted above. Countries should examine it carefully to see the extent to which it could be adapted to their particular circumstances and, together, present this within the WTO as a form of *sui generis* legislation. They will need to be united in their defence of this legislation as it will almost certainly be subject to scrutiny through the dispute panel procedure.

SUMMARY OF POSSIBLE COURSES OF ACTION

Countries need to debate internally and within regional country blocs the best courses of action. These would include actions at three levels:

- **Locally within communities, a rapid assessment of the potential implications of these measures:
on the conservation and sustainable use of natural resources;
on local production from plants and animals;
on local communities and producers and their collective knowledge systems;
and
on local biologically-based industries;
to provide essential evidence of perceptions and possible impacts.**
- **Nationally, a rapid survey of the work by different ministries and agencies on TRIPs and all related international agreements on the ownership, conservation and use of plants, animals and biological processes. Such a survey could result from, or lead to, the formation of interministerial working groups, or similar bodies, to address all aspects of these issues and ensure national policy coherence. Additionally, an assessment of the legal implications and costs of different courses of action may also prove useful. This could include:
the potential impact of these measures on national sovereignty over plants and animals and biological processes,
existing and pipeline laws and regulations,
international legal obligations, and
options for developing so-called *sui generis* legislation, suited to a country's own specific needs, as permitted under existing WTO rules.**
- **Regionally, within country blocs, a comparison between the needs, specific circumstances and obligations of different countries would help to identify stronger negotiating positions in this review as well as in the related negotiations.**

POSSIBLE PRIORITY ACTIONS BY COMMONWEALTH DEVELOPING COUNTRIES

Commonwealth Developing Countries have differing capacities (legal, commercial, institutional, scientific, technological, informational and human) for addressing intellectual property issues relating to plants, animals and biological processes and including genetic resources for food and agriculture. These capacities are unequally distributed not only between countries but also within them among the various competent institutions and authorities, giving rise to potentially inconsistent approaches to international negotiations by individual countries as well as by country blocs.

In this context and bearing in mind any work that may already be in progress, some possible priority actions in relation to these issues are listed below. They are comprehensive in scope but abbreviated in detail.

- 1) **Negotiating priorities: assessment and information sharing**
 - a) Assess the capacities and competencies of, and negotiating positions held by, the different relevant authorities and institutions (e.g. Plant Variety Protection offices, Patent offices, Agriculture, Environment, Trade, Foreign relations, Finance and so on) that represent national interests in the relevant international negotiations, in forums such as:
 - i) WTO (especially the Council for TRIPs, The Committee on Trade and Environment and the Committee on Agriculture)
 - ii) WIPO (especially the Patent Cooperation Treaty (PCT) and forums discussing 'Expressions of Folklore' and other alternative *sui generis* systems)
 - iii) UPOV (ratification of UPOV 78 or UPOV 91 through developing enabling legislation)
 - iv) CBD (SBSTTA, COP, *ad hoc* intersessional working groups, Biosafety Working Group)
 - v) FAO (CGRFA, FAO Council and Conference, Codex Alimentarius, Food Security Committee, Committees on Agriculture, Fisheries and Forests)
 - vi) other UN bodies (e.g. World Health Assembly, High Commission on Human Rights) and so on.

Such an assessment could include information gathering, including information about meetings and processes already initiated within the country, and additional roundtable discussions, as necessary, between negotiators from all the different authorities and institutions with assistance from competent informants and resource people.

- b) Conduct similar multidisciplinary and multi-institutional assessments and discussions between the competent institutions and authorities within negotiating blocs of countries e.g. ASEAN, SADC, Africa Region and so on, with especial reference to other Commonwealth developing countries.
- c) As part of this assessment, identify the information needs within and between countries as well as from international sources and propose how to achieve improved communication and access to information, including access through electronic communications, especially the Internet, through using local WebPages, listservers, email conferencing and so on.
- d) On the basis of the above, revise or determine national positions with respect to imminent negotiations such as:
 - i) 1999 review of TRIPs Article 27.3(b)
 - ii) 2000 Review of TRIPs
 - iii) The renegotiation of the WTO Agreement on Agriculture (from late 1999 onwards)
 - iv) Revision of the FAO International Undertaking in 1999
 - v) Implementation of the CBD and COP Decisions especially III/11 and IV/6.

Such positions could include:

- i) detailed negotiating positions with respect to each process
- ii) requests for time to conduct required assessments at national level (see point 2 below)
- iii) development of legislation compliant with Industrialised Countries systems and jurisprudence
- iv) development of alternative *sui generis* systems
- v) non-implementation of aspects of international agreements
- vi) recognition of the incompatibility of international measures with national level concerns about, for example:
 - potential environmental damage;
 - exacerbating social equity;
 - legal incompatibility with existing national legislation;
 - lack of clarity in the interpretation of these international agreements and the changes that may be agreed during upcoming review processes;
 - and so on.

2) **Priorities for protection and development of biological resources for food and agriculture: assessment of existing knowledge, skills and resources and of future needs**

- a) As necessary, bearing in mind the need to avoid duplication, and with the help of local communities, competent institutions (including national gene banks, national seeds programmes, relevant NGOs and so on) and other resource people, make a rapid assessment of the portfolio of biological resources for food and agriculture and their associated knowledge systems that exist within the country and the capacities that exist to protect and develop these.
- b) On the basis of national plans and projections, of locally perceived needs, resources, knowledge and skills, and competent advice make a rapid assessment of future needs, both of resources (including seed technology, if necessary) and knowledge and skills.

- 3) **Industrial priorities: assessment of needs**
 - a) Assess the current and future access, legislative, trade and commercial requirements of the national plant breeding and biotechnological industries.
 - b) Determine how these may be met.

- 4) **Legislative priorities**
 - a) Document legislation already developed or under development by different authorities.
 - b) Determine the types of further measures needed to protect national resources and interests and the local productive base and achieve access to required external resources and markets.
 - c) Identify where possible model legislation that may be relevant.
 - d) Estimate the likely costs of developing, implementing and defending relevant legislation.
 - e) Recognising the relatively strong negotiating position of most developing countries with respect to their sovereignty over plant genetic resources for food and agriculture, develop legislation and other measures as necessary.
 - f) Test the validity of the WTO Dispute Settlement Procedure against the dispute settlement mechanism agreed to in Article 27 of the CBD.

- 5) **Commonwealth priorities: building on the strengths of the Commonwealth**
 - a) Use existing Commonwealth communication and institutional mechanisms to exchange information about these issues.
 - b) Use the resources of the Commonwealth Secretariat's and Commonwealth Science Council's various programmes (e.g. of the Commonwealth Secretariat's Science and Technology and Constitutional and Legal Affairs Divisions) to develop capacities as required.
 - c) Find additional financial resources to support this work.
 - d) As possible, develop Commonwealth developing country positions in the various international forums, especially with regard to the revision of TRIPs Article 27.3(b) where there would appear to be a vacuum with regard to clearly articulated international positions in the proposed negotiations.
 - e) Build a Commonwealth developing country position on these issues for discussion at Commonwealth Heads of Government Meeting (CHOGM) in South Africa in 1999.

Overall Priorities for Capacity Building

- 1. Developing alternative *sui generis* systems, especially in compliance with TRIPs Article 27.3(b), and improving understanding of the interpretation of specific terms and aspects of relevant agreements and developing negotiating positions for the upcoming Review.**
- 2. Improving availability of information technology and access to electronic information through the Internet, for all those who are involved in developing positions in these negotiations and in developing relevant legislation, policies and programmes.**
- 3. Improving understanding, awareness, co-ordination and synergies on these issues within and between different national institutions, professional bodies, local communities as well as the wider public.**
- 4. Strengthening regional approaches to these negotiations and improving regional coordination.**
- 5. Improving working relationships with international bodies that can provide technical assistance.**
- 6. Enhancing networks and campaigns relevant to these issues.**

CONCLUSIONS

Overall Priorities for Capacity Building

Most Commonwealth developing countries have the competence to develop clear negotiating positions. There is a wealth of knowledge and skills in both the formal and informal sectors, which can be drawn upon to implement agreed measures and in developing national positions for negotiations, although there is often a lack of co-ordination at national, regional and international levels and limited communication between negotiators at international meetings and in missions and expertise in capitals. Internet access to international information is necessary to ensure equal knowledge at the negotiating table. The un-level international playing field that denies equal access to information to all countries is perhaps the most severe impediment to progress in the development of the WTO.

Despite this, the most pressing task is to gather information nationally and especially within local communities to assess how best to protect a country's plants, animals and associated knowledge systems, perhaps through some form of community rights regime. The internalisation of WTO measures within countries lacks as much if not more than the negotiation and implementation of WTO compliant legislation. The capacity to carry out these activities needs to be realised.

While these are overriding priorities, because of the severe time shortage, especially with regard to the review of TRIPS Article 27.3(b) in 1999, if it has not already commenced, work needs to start immediately to develop strong national positions for the revision and, if agreed, the preparation of necessary legislation.

Regional negotiating positions are also needed and these could be strengthened through resolutions made by the Commonwealth Heads of Government Meeting (CHOGM) in 1999. In order to develop this programme of work, increased capacity and, in some cases, reordering of current priorities, will be required.

The list of priorities in the table opposite could form the basis for priorities in capacity building work in-country and across the Commonwealth: it gives some entry points to the large agenda presented in the previous section.

Requirements for Achieving Desired Outcomes

To make progress will require increased awareness at all levels. It will also require the national focal points for the different agreements and programmes to meet together and exchange information in order to fully exploit potential synergies at national, regional and international levels. In summary it will require:

- increased effort to ensure adequate coordination within and between competent authorities at national level in order to achieve policy coherence,
- effective multidisciplinary linkages within regional country blocs in order to achieve improved common positions in international negotiations,
- use of international bodies, such as the Commonwealth, to strengthen these positions internationally, and
- increased financial resources, using to the extent possible the Global Environment Facility.

This is an urgent agenda, which, if not tackled promptly and effectively, will ultimately increase the legislative burden on, and reduce the benefits to, Commonwealth developing countries. They have much to contribute because the sovereign rights they have over the biological resources that industrial countries need gives them a potentially strong negotiating position.

Commonwealth developing countries must rapidly organise internally and within regional blocs to ensure that they have choice over the immediate outcome, for example, negotiating a delay in the process. This would allow time to assess fully and comprehensively the likely impacts of these measures and to develop *sui generis* legislation, recognised by trading partners, for the protection of their plants, animals and biological processes, especially their food production systems.

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van Wijk, Jeroen and Walter Jaffe (1996) *Intellectual Property Rights and Agriculture in Developing Countries*, University of Amsterdam, The Netherlands

Vellvé, Renée (1992) *Saving the Seed*, Earthscan Publications, London.

Williams, O. (1997) "Sui Generis Rights: a balance misplaced". In "Signposts to Sui Generis Rights". Resource material from the international seminar on *sui generis* rights, Bangkok, 1-6 December 1997. BIOTHAI and GRAIN, Bangkok.

WTO (1998) See WTO WebSite <<http://www.wto.org/wto/intellect/intellect.htm>> for full text.

INTERNET RESOURCES

FOR LINKS TO CURRENT INFORMATION, SEE:

[Agricultural Biodiversity Resource Page](#)

Introduction to issues concerning sustainable use, conservation and protection of agricultural biodiversity. Links to many sites and documents.

[UK Agricultural Biodiversity Coalition \(UKabc\) HomePage](#) Most of the sites listed below can be accessed through this page.

<<http://dspace.dial.pipex.com/ukfg/ukabc.htm>>

INTRODUCTION TO ISSUES

[People, Plants and Patents: the impact of intellectual property rights](#). Report of the Crucible Group (1995).

<<http://www.idrc.ca/books/725/725.html>>

For selected extracts from this document see

<http://dspace.dial.pipex.com/ukfg/UKabc/TRIPs/intro_IDRC.htm>

[The Convention on Biological Diversity and the Agreement On Trade-Related Aspects of Intellectual Property Rights \(TRIPS\): relationships and synergies](#). 1996 paper to COP 3.

<<http://www.iisd.ca/linkages/biodiv/cop3/COP3-23-vfinal.htm>>

For selected extracts from this document see

<http://dspace.dial.pipex.com/ukfg/UKabc/TRIPs/intro_CBD.htm>

[Intellectual Property Rights and Plant Genetic Resources: Options for a Sui Generis System](#) by Dan Leskien and Michael Flitner. IPGRI Issues in Genetic Resources No. 6 June 1997.

<<http://www.cgiar.org/ipgri/policy/intro.htm>>

For selected extracts from this document see

<http://dspace.dial.pipex.com/ukfg/UKabc/TRIPs/intro_IPGRI.htm>

[Human Nature](#): Agricultural Biodiversity and farm-based food security by Hope Shand, RAFI.

<http://www.rafi.ca/publications/human_nature.html>

[Beyond Intellectual Property](#): Toward Traditional Resource Rights for Indigenous Peoples and Local Communities by Darrell A. Posey and Graham Dutfield

<<http://www.idrc.ca/books/799.html>>

INSTITUTIONAL SITES WITH USEFUL DOCUMENTS

[Convention on Biological Diversity \(CBD\)](#)

[Fourth Conference of the Parties - Documents](#) and [Draft decisions](#)

<<http://www.biodiv.org/cop4/cop4docs.html>>

<<http://www.biodiv.org/cop4/FinalRep-/finrep.html>>

Food and Agriculture Organization of the United Nations (FAO)
Plant Genetic Resources pages including the papers for the 5th extraordinary session of the CGRFA and Leipzig Global Plan of Action
<<http://web.icppgr.fao.org/>>
<<http://web.icppgr.fao.org/ITCPGR/Leipzig.html>>
<<http://web.icppgr.fao.org/CGRFA/Ex5/docs.html>>
Institute for Agriculture and Trade Policy (IATP), USA.
TRIPS99 website. Resources for upcoming negotiations on the review of TRIPs Article 27.3(b).<<http://www.iatp.org/trips99>>

Especially note the following:

Sterile Fields: The Impacts Of IPRs And Trade On Biodiversity And Food Security,
by Kristin Dawkins (IATP) November 1996
<[http://www.iatp.org/trips99/library/admin/uploadedfiles/showfile.cfm?FileName=Sterile Fields The Impacts Of Intellectual Pro.htm](http://www.iatp.org/trips99/library/admin/uploadedfiles/showfile.cfm?FileName=Sterile%20Fields%20The%20Impacts%20Of%20Intellectual%20Pro.htm)>

Signposts to Sui Generis Rights (GRAIN, BioThai) Resource material from an international seminar on *sui generis* rights (1-6 Dec 1997).
<[http://www.iatp.org/trips99/library/admin/uploadedfiles/showfile.cfm?FileName=SIGNPOSTS TO SUI GENERIS RIGHTS, Chapter 1, Fe.htm](http://www.iatp.org/trips99/library/admin/uploadedfiles/showfile.cfm?FileName=SIGNPOSTS%20TO%20SUI%20GENERIS%20RIGHTS,%20Chapter%201,%20Fe.htm)> [Chapters _1 to _8]

Of especial note is Chapter 3 - Signposts to Sui Generis Rights: Strategy Ideas for the 1999 TRIPS Review & Beyond. Also available at:

<<http://dspace.dial.pipex.com/ukfg/UKabc/suigen1.htm>>

For selected extracts from this document see

<http://dspace.dial.pipex.com/ukfg/UKabc/TRIPs/intro_GRAIN.htm>

The outcome of the Seminar was the Thammasat Declaration.

<<http://www.twinside.org.sg/souths/twn/title/tham-cn.htm>>

IUCN Environment and Law programme

Including:

The Trade & Environment Agenda: Survey of Major Issues and Proposals - From Marrakesh to Singapore, Tarasofsky, R.G., K. Ewing 1996

< http://www.iucn.org/themes/law/elp_publications_trade.html>

A Guide to the Convention on Biological Diversity, Glowka, L., et al., 1994

<http://www.iucn.org/themes/law/elp_publications_guide-e.htm>

Plant Breeding and Seed Industry

UPOV - the Union for the Protection of Plant Varieties. Main resource page including 'What is UPOV?', Brief Outline of the Role and Functions of the Union, 'Texts of the UPOV Convention (Acts of 1961, 1978, 1991)'

<<http://www.upov.int/eng/index.htm>>

UPOV 91 comes into force - 24 April 1998 UPOV Press Release

<<http://www.upov.int/eng/prssrlss/30.htm>>

World Seed Industry Associations including ASSINSEL

< <http://www.worldseed.org/~assinse/>>

Organisation for Economic Cooperation and Development (OECD)

Intellectual Property, Technology Transfer and Genetic Resources: An OECD Survey of Current Practices and Policies (1996) <<http://www.oecd.org/dsti/sti/s t/biotech/>>

World Intellectual Property Organisation (WIPO)

Global Intellectual Property Issues programme

<<http://www.wipo.org/eng/newindex/intellct.htm>>

For selected extracts from this document see

<http://dspace.dial.pipex.com/ukfg/UKabc/TRIPs/intro_WIPO.htm>

World Trade Organisation

WTO: Intellectual Property including 'What is Intellectual Property?', 'An overview of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)', 'The text of the TRIPS Agreement', 'Other intellectual property conventions incorporated by reference into the TRIPS Agreement'

<<http://www.wto.org/wto/intellec/intellec.htm>>

For selected extracts from this document see

<http://dspace.dial.pipex.com/ukfg/UKabc/TRIPs/intro_WTO.htm>

WTO: Trade and Environment including 'Background to WTO work on trade and environment' 'The Marrakesh Ministerial Decision on Trade and Environment', 'The relationship between the provisions of the multilateral trading system and trade measures for environmental purposes, including those pursuant to multilateral environmental agreements'.

<<http://www.wto.org/wto/environ/environm.htm>>

WTO: Trade in Agriculture including Implementation of the Uruguay Round Reform: the Programme for Trade in Agriculture

< <http://www.wto.org/wto/goods/agrintro.htm>>

OTHER DOCUMENTS OF INTEREST

USA pushes Ecuador to sign IPR agreement by Susanne van de Wateringen

<<http://www.pscw.uva.nl/monitor/3309.htm>>

WTO Disputes Panel charges India with non-compliance Indian Express

report<<http://expressindia.com/fe/daily/19970813/22555213.html>>

A worldwide fight against biopiracy and patents on life by Martin Khor (TWN)

<<http://www.capside.org.sg/souths/twn/title/pat-ch.htm>>

Implement TRIPs in an "informed, democratic and specific manner". Briefing from TWN.

<<http://www.capside.org.sg/souths/twn/title/impl-cn.htm>>

In defence of Local Community Knowledge and Biodiversity by Gurdial Singh

<<http://www.twinside.org.sg/souths/twn/title/in-cn.htm>>

TRIPs and BIODIVERSITY by Gurdial Singh

<<http://www.twinside.org.sg/souths/twn/title/trip-cn.htm>>

[Smallholder Farmers', Pastoralists' and Artisanal Fisherfolk's Intellectual Rights and Agricultural Biodiversity, in Kenya, by ITDG](http://dspace.dial.pipex.com/ukfg/UKabc/ipr2.htm)
<<http://dspace.dial.pipex.com/ukfg/UKabc/ipr2.htm>>

DRAFT MODEL LEGISLATION ON COMMUNITY RIGHTS AND ON ACCESS TO BIOLOGICAL RESOURCES

Whereas, the State and its people exercise sovereign and inalienable rights over their biological resources;

Whereas, the rights of local communities over their biological resources, traditional knowledge and technologies that represent the very nature of the livelihood systems and that have evolved over generations of human history, are of a collective nature and, therefore, a priori rights taking precedence over rights based on private interests;

Whereas, it is necessary to protect and encourage cultural diversity, valuing the knowledge, innovations and practices of the local communities with respect to the conservation, management and use of biological resources;

Whereas, it is the duty of the State and its people to regulate access to biological resources and to community knowledge and technologies;

Whereas, the State recognizes the necessity of providing adequate mechanisms which guarantee a just, equitable and effective participation of its citizens in the protection of their collective and individual rights and in making decisions which affect the biological and intellectual resources as well as the activities and benefits derived from their utilization;

Whereas, there is the need to promote and support the traditional and indigenous technologies that are important in the conservation and sustainable use of biological resources and to complement them by modern technologies;

Whereas, there is the need to implement the relevant provisions of the Convention on Biological Diversity, in particular Article 15 on access to genetic resources, and Article 8(j) on the preservation and maintenance of knowledge, innovations and practices of indigenous and local communities;

Whereas, all forms of life are the basis for human survival, and, therefore, patenting of life, or exclusive appropriation of all life forms violates the fundamental human right to life;

Now, therefore, it is hereby legislated as follows:

Article 1

Definitions

[to be provided later]

Article 2

Objectives

The objectives of this legislation shall be to:

- a) ensure the conservation and sustainable use of biological resources and of knowledge and technologies in order to maintain and improve their diversity as a means of sustaining the life support and health care system of the country;
- b) recognize, protect and support the inalienable rights of local communities over biological resources and their knowledge, innovations and practices;
- c) provide an appropriate system of access to biological resources and community knowledge and technologies subject to the prior informed consent of the State and the concerned local communities;
- d) promote appropriate mechanisms for a fair and equitable sharing of benefits arising from the use of biological resources, community knowledge and technologies;
- e) ensure the effective participation and agreement of concerned communities in making decisions as regards the distribution of benefits which may derive from the use of their biological resources, knowledge and technologies;
- f) promote and encourage the building of national and grass roots scientific and technological capacity relevant to the conservation and sustainable utilization of biological resources;
- g) provide appropriate institutional mechanisms for the effective implementation and enforcement of community rights and conditions of access to biological resources, community knowledge and technologies.

Article 3

Scope

1. This legislation applies to biological resources both in situ and ex situ as well as their derivatives and to community knowledge and technologies.
2. This legislation shall not apply to the traditional way of access, use or exchange of biological resources as well as knowledge and technologies by and between local communities and the sharing of benefits based upon their customary practices.

Article 4

Access to Biological Resources and Community knowledge and Technologies

1. Research and development on biological resources shall be carried out within the country.
2. Without prejudice to the discretion of the national competent authority to grant appropriate privilege to academic and research institutions, public agencies and intergovernmental institutions, any access to biological resources and community knowledge and technologies shall be subject to the prior informed consent of the State as well as the concerned local

communities. Application for access to biological resources and community knowledge and technologies shall be consistent with the requirements set out below:

a. The Collector shall request the national competent authority for access to biological resources and community knowledge and technologies by application in writing that contains information on, inter-alia:

- i) the identity of the applicant and the documents which testify to her/his legal capacity to contract;
- ii) the resources to which access is sought, including its present and potential uses, its sustainability and the risks which may arise from access;
- iii) whether any collection of the biological resource endangers any component of biological diversity;
- iv) the purpose for which access to the resource is requested including the type and extent of commercial use expected to be derived from the resource;
- v) description of the manner and extent of intended involvement of nationals in the necessary research and development of the biological resource concerned;
- vi) the identification or the assignment of the national scientific institution which will participate in the research and be in charge of monitoring the process;
- vii) the precise sites where the resource is located as well as the places where the proposed research and development activities will be carried out. In the case of ex situ biological resources, information about the ex-situ centre of conservation shall be included;
- viii) the primary destination of the resource and its probable subsequent destination(s);
- ix) The benefits, whether economic, technical, biotechnological, scientific, environmental, social or otherwise, that may derive to the country and the concerned local communities and proposed mechanisms or arrangements for benefit sharing;
- x) description of the knowledge, innovation or practice associated with the resource;
- xi) environmental and socio-economic impact assessment covering the likely impacts for at least the coming three generations;
- xii) any other matter deemed relevant by the competent authority.

b. Once the application is complete, the national competent authority shall place it in a public registry for a period of ___ months which may be consulted by any person.

c. The national competent authority shall ensure that the concerned local communities are consulted and their prior informed consent is obtained, and that all the relevant information is disseminated widely and effectively to the concerned communities and other interested parties.

3. The national competent authority shall grant access after the signing of an agreement with the collector. The agreement shall, as a minimum requisite, contain commitments by the collector to:

a. adhere to a limit on the quantity and specifications of the quality of the biological resources that the collector may obtain and / or export;

b. guarantee of a deposit of duplicates of all specimens of biological resources and the records of community knowledge collected with a duly designated governmental entities and local community organizations;

c. inform the competent authority and the concerned local community of all findings from the research and development on the resources;

d. not to transfer the biological resources and the community knowledge and technologies to any third party without the authorization of the national competent authority and the concerned local community;

e. not to apply for a patent or other intellectual property right over the biological resources and their derivatives or community knowledge and technologies. In the case where the collector transfers such biological resources, knowledge or technologies to third parties, it shall guarantee that the concerned third party will not establish patents or other intellectual property rights over them;

f. pay the state and/or concerned local communities for their contribution in the generation and conservation of the biological resources, their knowledge and technologies to which access is sought;

g. submit to the national competent authority a regular status report of research and development on the resources concerned and where biological resources are to be collected in large quantities, on the ecological state of the area; and

h. abide by the relevant laws of the country particularly those regarding sanitary control, biosafety and the protection of the environmental as well as the cultural practices, traditional values and customs of the local communities.

4. The national competent authority shall approve the granting of access to the biological resources or the community knowledge and technologies in question with or without conditions, upon determining that the applicant has fulfilled all the requirements of this legislation and regulations issued thereunder;

5. No import or export of any biological resources shall be allowed to and from the country unless the national competent authority confirms that a prior informed consent has been obtained from the country of origin and the concerned local communities.

6. The national competent authority, in consultation with the concerned local community, may unilaterally withdraw its consent and terminate the agreement and/or further use of the biological resources concerned whenever it has become apparent that the collector has violated any of the provisions of this legislation, or the agreed terms, or the overriding public interest so demands.

7. The national competent authority shall ensure that a guarantee has been obtained from the State in whose jurisdiction the collector operates regarding the latter's compliance with the provisions of this legislation and the agreed terms and conditions of access to the biological resources and the community knowledge and technologies in question.

8. Any claims upon biological resources obtained or used in violation of the provisions of this legislation or terms and conditions entered into shall not be recognized.

9. The national competent authority may, when it deems it necessary, establish restrictions to or prohibitions on those activities which are directly or indirectly related to access to or introduction of biological resources, particularly in cases of:

- a. endangered taxa;
- b. endemism or rarity;
- c. adverse effects upon human health or upon the quality of life or the cultural values of the local communities;
- d. environmental impacts which are undesirable or difficult to control;
- e. danger of genetic erosion or loss of ecosystems, their resource or their components, because of undue or uncontrolled collection of germplasm;
- f. non-compliance with rules on biosafety or food security; and
- g. use of resources for purposes contrary to national interest and to relevant international agreements entered into by the country.

Article 5

Community Rights

1. The State shall recognize and protect the rights of the local communities over their biological resources and to collectively benefit from their knowledge, innovations and practices acquired through generations and for the conservation and sustainable use of biological resources.

2. The local communities shall be recognized at all times and in perpetuity to be the sole and legitimate creators, users and custodians of the biological resources, community knowledge, innovations and practices.

3. Local communities shall have the right to be informed and give their consent prior to any access to their biological resources, knowledge and technologies is effected.

4. Local communities have the right not to allow the collection of biological resources and access to their traditional technologies, knowledge, innovations and practices, as well as to demand restrictions upon such activities when they may threaten the integrity of their natural or cultural heritage.

5. Local communities have an inalienable right to keep, use, exchange or share their biological resources that sustain their livelihood systems. The State shall ensure the removal of any barriers against the traditional exchange system of biological resources by and among local communities.

6. The State shall ensure that fifty per cent of benefits obtained from any commercial use of biological resources and/or community knowledge and technologies are channelled to the concerned local communities.

7. Subject to the above paragraphs of this Article, the State shall take regulatory measures to establish and implement a system of Community Intellectual Achievement Rights through a process of consultation with and participation of the local communities. Such measures shall include:

a. the identification of the types of Community Intellectual Achievement Rights that are recognized in each case;

b. the identification and definition of the requirement and procedure necessary for the recognition of the Community Intellectual Achievement rights and the title to same;

- c. definition of a system of collective registration and specific rights and obligations that arise from the entitlement;
- d. criteria and mechanisms for the standardization of procedure; and
- e. licenses for the exploitation and commercialization of the protected species, varieties or lineages.
- f. identification of relevant technical institutions that assist local communities in the identifications and characterization of their innovations.

Article 6

Institutional Arrangements

1. The State shall designate or establish a national competent authority which shall implement and enforce the provisions of this legislation.
2. A national inter-sectoral coordination body at the highest level, composed of representatives from relevant public sectors, scientific and professional organizations, NGOs and local community organizations, shall be created as a body to coordinate and follow-up the proper implementation of this legislation by the national competent authority. The national inter-sectoral coordination body shall have, inter-alia, the following functions:
 - a) ensure that the minimum conditions for agreements with collectors are strictly observed and complied with;
 - b) ensure that the rights of local communities wherein the collection of or research on biological resources and community knowledge and technologies are being conducted are protected, including verifying that the requirement of prior informed consent by the local communities are complied with;
 - c) recommend policies and laws on the sustainable use of biological resources including new laws on intellectual property rights and community rights over their knowledge, innovations and practices; and
 - d) perform such other functions as may be necessary for the effective implementation of this legislation.
3. The national competent authority shall provide a technical advisory body for the national inter-sectoral coordinating body with a view to support the latter's work. The technical advisory body shall have, inter alia, the following functions:
 - a) study policy options that promote the protection of community rights and the regulation of access to biological resources;
 - b) prepare lists of taxa threatened by extinction and deterioration, and of the places threatened by serious loss of biological diversity;
 - c) issue and update, at regular intervals, reports on the implementation of this legislation or actual or potential threats to biological diversity and the likely impacts on the pursuit towards sustainable development;
 - d) recommend a mechanism to enable the identification and dissemination of information regarding threats to biological resources; and

e) perform such other functions as may be necessary to implement this legislation.

Article 7

Establishment of a National Information System

There shall be established a National Information System with regard to biological resources which include the following aspects:

- a) the creation of appropriate capacity and facilities required to maintain an up-to-date system of information about the research and development activities on the biological resources and community knowledge and technologies; and
- b) compile information on piracy of biological resources, knowledge and technologies, and disseminate the same to all relevant and concerned bodies.

Article 8

Funding

The funds required to undertake activities towards implementing the provisions of this legislation shall be obtained through budgetary allocation and the establishment of a national trust fund.

Article 9

Appeals

Decisions on approval, disapproval or cancellation of agreements regarding access to biological resources may be appealed through appropriate administrative channels. Recourse to the courts shall be allowed after exhaustion of all administrative remedies.

Article 10

Sanctions and Penalties

1. Without prejudice to the exercise of civil and penal actions which may arise from violations of the provisions of this legislation and subsequent regulations, sanctions and penalties to be provided may include:
 - a) written warning; b) fines; c) automatic cancellation / revocation of the permission for access; d) confiscation of collected biological and genetic specimens and equipment; e) perpetual ban from access to biological resources in the country.
2. The violation committed shall be publicized in the national and international media and shall be reported by the national competent authority to the secretariats of relevant international agreements and regional bodies.
3. When the collector conducts its operations outside of the national jurisdiction, any alleged violations by such a collector may be prosecuted through the cooperation of the government under whose jurisdiction the collector operates based on the guarantee that the latter has provided.