

**SIXTH FRAMEWORK PROGRAMME  
PRIORITY 8.1:  
POLICY-ORIENTED RESEARCH**



**UNDERPINNING EUROPEAN INTEGRATION, SUSTAINABLE  
DEVELOPMENT, COMPETITIVENESS AND TRADE POLICIES  
(INCLUDING IMPROVED MEANS TO ASSESS ECONOMIC  
DEVELOPMENT AND COHESION)**

**IMPACTS OF THE IPR RULES ON  
SUSTAINABLE DEVELOPMENT  
(IPDEV)**

Contract number: 503613

**Consolidated Final Research Report**

**Implementing organisations:**

**Queen Mary, University of London**

**Ecologic**

**Universidad de Alicante**

**IP Bulgaria**

**Royal Institute of International Affairs**

**University of Warwick**

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# IPDEV CONSOLIDATED FINAL RESEARCH REPORT

## 1. PROJECT SUMMARY

This project responded to the need identified by the European Commission to assess the impact of IPR rules on economic growth (including investment), environmental protection (including biodiversity) and social goals (including rural development). There were two main scientific and technological objectives. The first was to identify IPR-related policies which the European Commission, the EU and its member state governments, and candidate country governments might consider implementing in support of sustainable development in Europe and elsewhere. The second was to provide data and quantitative and qualitative analysis that are useful especially to EU candidate countries and also to developing countries seeking to take maximum advantage of the provisions of TRIPS in pursuit of their sustainable development objectives. To fulfil these objectives while taking best advantage of the advanced and varied expertise of the participants and their organisations, the research focused on the following three areas: (i) promoting environmentally-sustainable development through the use of geographical indications; (ii) capacity building and technical assistance for policy coherence and sustainable development; and (iii) exploring the flexibilities of TRIPS Article 27.3(b) to maximise policy options in biotechnology and crop breeding by (a) stimulating innovation and technology transfer, and (b) facilitating the equitable sharing of benefits arising from the commercial use of biodiversity. The project was coordinated by Queen Mary, University of London, with the collaboration of Ecologic, Universidad de Alicante, IP Bulgaria, the Royal Institute of International Affairs and Warwick University.

## 2. PROJECT OBJECTIVES

The project sought to fulfil the need identified under Priority 8.1 (Policy-oriented research) area 3.1 ‘to assess the impact of IPR rules on economic growth (including investment), environmental protection (including biodiversity) and social goals (including rural development) through quantitative and qualitative analysis’. In pursuit of this need, the Project produced and disseminated objective and high-quality policy-related research clarifying the costs and benefits of implementing common approaches to IPR rules.

The overriding scientific and technological objectives were twofold.

1. To identify IPR-related policies which the European Commission and the EU and its member state governments might consider implementing in support of sustainable development in Europe and elsewhere.
2. To provide data and analysis useful especially to EU candidate countries and to developing countries seeking to take maximum advantage of the provisions of TRIPS in pursuit of their sustainable development objectives.

### 3. WORKPLAN

Research activities covered three key closely-interrelated areas of research. These were (i) geographical indications, (ii) capacity building and technical assistance, and (iii) the patents section of TRIPS and its relation to biotechnology, related international agreements and benefit sharing.

#### ***Research Cluster 1: Promoting environmentally-sustainable development through the use of geographical indications***

Geographic indications (GIs) have become increasingly attractive to European policy makers, particularly in the context of the phasing out of production-related subsidy programmes for agricultural producers as required by WTO rules. In addition, GIs and other quality-based product labelling respond to changes in consumer preferences and producer strategies both of which give greater credence to product-place links and reject the de-localised and homogenised mass-produced products. Identifying and developing alternative means to improve the competitiveness of EU products that are compatible with international trade law has become an important challenge for EU policy making.

GIs provide legal protection for the use of the name of a place or region of origin associated with specific product characteristics such as tastes, varieties or quality, as marketing instrument. They serve as an identification of specific product properties, reputation, or superior quality. Similarly to brand names and trademarks they improve marketing possibilities, allow for more effective product differentiation, and when successful enable price premiums.

The successful capturing of a price premium through the application of a GI can therefore both generate an income for local producers, which are primarily SMEs, and serve as an incentive to maintain and improve the characteristics of the region that constitute uniqueness. Therefore it is useful to assess whether GIs can be used as a policy instrument that jointly improves competitiveness *and* serves as an incentive for sustainable and conservation oriented production techniques. Such an ecologically oriented policy on GIs would improve the competitiveness of certain EU products on EU and world markets, while the recognition of comparable GI policies in other countries would presumably contribute to sustainable development in those countries.

#### ***Research Cluster 2: Capacity building and technical assistance for policy coherence and sustainable development***

The implementation of international agreements in poor countries is often hindered through a lack of institutional structures that would serve as a basis for or facilitate the implementation of new legislation. In many cases this leads to incomplete implementation or adverse effects, particularly if the interactions between the obligations under several overlapping agreements are not accounted for by the national legislation and institutions for implementation. Capacity building measures aim at the removal of these obstacles to implementation through the transfer of expertise, know how and financial means to those countries with special difficulties in implementation.

One of the ways that policy-related capacity can be enhanced is through the provision of technical assistance. TRIPS Article 67 requires developed country members to provide,

on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country members. The availability of technical assistance is crucial not only for ensuring the effective implementation of TRIPS, but also has the potential to be an effective mechanism for offsetting the adverse administrative costs of TRIPS compliance in developing countries. However, both the quality and the quantity of technical assistance provided under Article 67 and elsewhere through institutional and public-private partnerships have been variable and criticised on a number of levels. In terms of the quality of assistance provided, there have been suggestions that advice given to developing countries relies too much on a developed country model of TRIPS implementation that does not take account of the unique legal, economic and social conditions in different developing nations. In terms of the quantity of technical assistance, there have been complaints that some developed country WTO members could do more, while business interests are also criticised for insufficiently contributing to the establishment of new IPR regimes in developing and least-developed countries, despite the fact that they stand to be major beneficiaries from the introduction of these new regimes. Yet there remains insufficient empirical data to establish the validity of criticisms being made about the current arrangements, a situation that the project will address.

In implementing TRIPS, WTO members must take into account the need for policy coherence, a major challenge for many of them given the existence of other agreements with IPR-related provisions. For example, while there is much dispute over the extent of protectability under TRIPS, a clear limitation of the scope of IPR measures is implied by the recently signed International Treaty on Plant Genetic Resources in Food and Agriculture (ITPGRFA) of the FAO. This treaty suggests a multilateral system for the regulation of the conservation access and use of PGRFA under which all parties will grant mutual access to their PGRFA. The treaty implies certain restrictions to the patentability of genetic resources and obliges the users of PGRFA to pay access fees and royalties of successful innovations into an international fund. The fund will be used to finance conservation measures and capacity building initiatives in developing countries, as well as to ensure adequate compensation for the initial holders of PGRFA such as indigenous and traditional farming communities. In the context of these two agreements, plus the Convention on Biological Diversity (see Research Cluster 3 below), an incomplete or biased implementation in any country may lead to unbalanced environmental, economic or social effects through the establishment of an inadequate IPR system that ignores the need for conservation measures or the rights of traditional owners of genetic resources. Therefore it is necessary to identify the need for specific capacity building measures in countries according to their levels of development in order to furnish effective and balanced support to countries with limited implementation capacities. The EU has a special interest to provide effective capacity building to the current and future accession countries in central and eastern Europe, as well as to those countries that will be the partners for exchanges in genetic resources and agrobiotechnology in the future.

***Research Cluster 3: Exploring the flexibilities of the patents section of TRIPS to stimulate biotech innovation, technology transfer and benefit sharing***

TRIPS Article 27.3(b), which deals with exceptions to patentability in relation to the products and processes of biotechnology and plant breeding, is an enduring subject for trade negotiations and NGO activism on TRIPS. However, the whole of the patents

section of TRIPS is relevant to these issues. Undoubtedly, this part of TRIPS is extremely important for EU candidate and developing countries. What is less clear is how they can take advantage of its provisions to further their sustainable development objectives. There are a number of reasons for this. First, the language is subject to a wide range of possible interpretations. This can be seen as an opportunity, but the fact that many developing countries still lack a clear idea of how biotechnology can benefit their economies and improve the lives of their citizens, makes it very difficult for them to exploit these opportunities by designing an IPR system to promote investment and the introduction and generation of welfare-enhancing biotechnological innovations. Second, while many developing countries are being encouraged to adopt the UPOV standards of plant variety protection, it is far from self-evident that the UPOV system is an ideal one for them. Third, many developing countries have few domestic firms engaged in biotechnology and crop breeding and even fewer that will be able to benefit directly from the availability of IPR protection. Therefore, the priority is likely to be that of encouraging technology transfer from abroad rather than stimulating domestic innovation, which is normally considered to be the main reason to have IPRs. Fourth, developing countries vary widely in their national capacities to absorb foreign biotechnologies and to generate biotechnological inventions of their own. Therefore, there is a limit to how far individual countries can benefit from the experiences of other countries. The result is that many developing countries are still unsure about where their national interests lie with respect to the subparagraph's provisions, and have barely implemented any part of it, except by default in the sense of continuing not to allow plants and animals to be patented. This is not a satisfactory situation.

The situation is somewhat different for the EU candidate countries in that their membership of the EU requires them to adopt the 'acquis communautaire'. Even so, the impacts of the 'acquis' on these countries are uncertain to say the least, and the project will seek to clarify them.

Beyond domestic policymaking in biotechnology and crop development, many developing countries have claimed that implementation of Article 27.3(b), and even TRIPS itself, must take on board the objectives and principles of the Convention on Biological Diversity, which require that the commercial benefits arising from the use of genetic resources be shared with the provider countries. Several measures have been proposed to ensure that the two agreements operate harmoniously, but few have been tested so far.

## 4. THE RESEARCH

The research was divided into six workpackages as follows:

- **Assessing the applicability of geographical indications as means to improve environmental quality in affected ecosystems and the competitiveness of agricultural products from EU regions, candidate countries, and developing countries**
- **Identifying models of best practice in the provision of technical assistance to facilitate the implementation of the TRIPS Agreement**
- **Identifying effective capacity building measures for the implementation of access and property rights legislation in the area of agricultural biodiversity**
- **Assessing the economic implications of different models for implementing the requirement to protect plant varieties**
- **The patents section of TRIPS: exploring its flexibilities to promote biotechnology capacity building and appropriate technology transfer**
- **Disclosure of origin in IPR Applications: Options and Perspectives of Users and Providers of Genetic Resources**

The rest of this report provides summarised versions of the results of each workpackage. Please note that the footnotes have been removed but are retained in the full reports.

## **5. ASSESSING THE APPLICABILITY OF GEOGRAPHICAL INDICATIONS AS MEANS TO IMPROVE ENVIRONMENTAL QUALITY IN AFFECTED ECOSYSTEMS AND THE COMPETITIVENESS OF AGRICULTURAL PRODUCTS FROM EU REGIONS, CANDIDATE COUNTRIES, AND DEVELOPING COUNTRIES**

### **JUSTIFICATION AND GENERAL METHODOLOGICAL ISSUES.**

#### **General Objectives of WP3**

The title of work package 3 (WP3) is “Assessing the Applicability of Geographical Indications as a Means to Improve Environmental Quality in Affected Ecosystems and the Competitiveness of Agricultural Products from EU regions, Candidate Countries and Developing Countries”. The objective of WP3 is to analyse the existing and potential links that can be established between current Geographical Indications (GIs) and regional sustainable development.

A case study approach, centred on European case studies, has been carried out. The European Union appears as a proper laboratory to study socio-economic and environmental effects GI measures, since it possesses a strong system, with a strong market importance and long standing tradition in the trade of “local” products as well having a well established, “special” or *sui generis* legal system of protection. In addition, despite a single legislation, there are different national uses regarding GIs, with countries like Spain, France or Italy which have adhered to “sui-generis” systems long before the a common European Regulation was established, and others such as the UK or the northern European countries which have protected indications through general laws of unfair competition, passing-off and/or trade mark law.

Conclusions will be drawn with particular focus on the utility for regions with a potential to use GIs to enhance the value of ‘local ecology’, in particular in the developing countries.

The study has paid special attention to (i) issues surrounding the relationship between the existence of GIs and environmental quality in regions where local or typical products are produced; and (ii) the contribution of GIs to product competitiveness and development.

Conclusions will be drawn from the case studies, which were carried out in such a way as to enable the effects of GIs to be assessed in terms of their environmental and economic impacts.

#### **Justification**

##### ***1. The Function of Geographical Indications: Identifying and Protecting Origin-Specificity Link***

GIs are form of Intellectual Property employed to protect the “goodwill” of products with characteristics which are obtained from singular, geographically localized conditions of production.

They are perhaps the most ancient distinctive sign to be found in commerce; protection against the illegitimate use of indications was offered from the beginning of the 20<sup>th</sup> century in countries like France. In common law countries, different national legal traditions and specific economic contexts meant that different concepts of protection were developed, namely unfair competition and passing off and collective or certification marks.

GIs are distinctive signs, and some of their economic functions are the same as those of trademarks. First, they diminish the information asymmetries that exist between producers and consumers by giving the latter “information” about a product, thus reducing the transaction costs linked to learning about the characteristics of the good. Second, signs such as GIs and trademarks enable product differentiation. This means producers can invest in the quality of the product and build a reputation around the distinctive sign, occupy new segments of the market, and derive “price premiums” on the standard value of the product.

In synthesis, in both TMs and GIs there is a content of information that allows consumers to identify different products, to associate different characteristics and qualities to each of them, and to attribute different market values. On the other side, from the perspective of the producer, the factor of differentiation (*a distinctive quality, a distinctive image etc.*) allows is an opportunity to search for higher market rewards for the sales of the product.

## ***2. The Bond with the Local Environment***

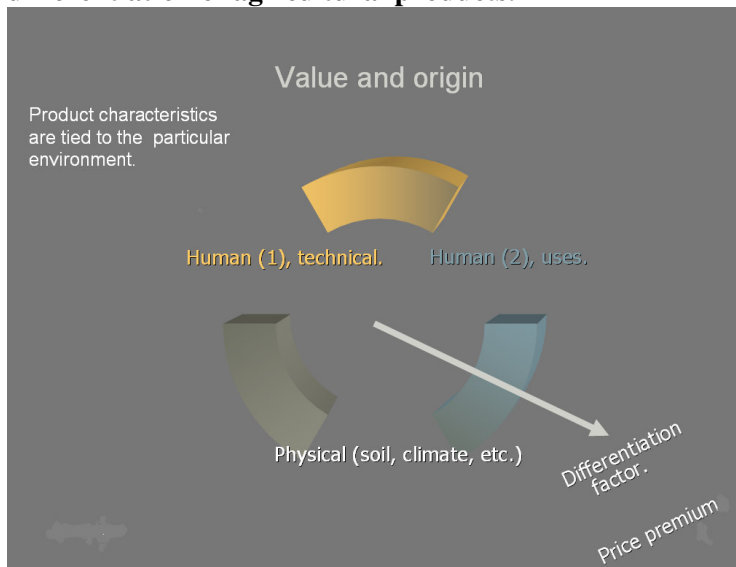
However, the nature of the content of the information given to the consumer by the GI is different to that embodied in a trademark, at least in one aspect. Rather than signalling the entrepreneurial source of a product, GIs indicate a “quality link” composed of three elements: the product, the geographical origin, and the quality of the product which is a result of its geographical origin. The GI, therefore, informs about product specificity (or typicalness); that is, the traits of a product that are unique and derive from the geographical origin.

In most of the literature referring to product specificity and the bond with the *terroir*, we find this link to be understood when taking into consideration the plural factors that make up the product’s final – and unique - characteristics. These can be reduced to the physical and the human dimensions of product specificity.

The first are the set of physical factors such as soil, climate or water, which intervene in the making of the produce. But the construction of “specificity” also has a human dimension, composed by uses as well as by *the manner and solutions* of local inhabitants to overcome climatic, territorial and even socio-economic constraints. It has also been stressed that these practices and knowledge frequently show continuity over time, so that they come to be considered as cultural expressions reflecting established traditions.



**Figure 1 The “Quality Link”: The Origin of Products as a factor of differentiation of agricultural products.**



The distinctive element of the GI, adding value to the product, is the specificity extracted from the origin. It is this element, as well, which conducts suppliers to the occupation of market niches where consumers are willing to pay a higher price for the product.

### ***3. Geographical Indications and Regional Sustainable Development***

The promotion of regional development is one of the objectives of GI policy. In Europe, since GI applies exclusively to agricultural products, the main objective of EC regulations- in this sphere- has concentrated on rural development.

EC regulation N°2081/92, recently replaced by regulation EC N° 510/2006, established the principle of the protection of provenance as a means of protecting rural development:

... whereas the promotion of products having certain characteristics could be of considerable benefit to the rural economy, in particular to less-favoured or remote areas, by improving the incomes of farmers and by retaining the rural population in these areas...

Sustainable rural development objectives have also been cited by European Commission officials, such as the Commissioner responsible for Agriculture, Rural Development and Fisheries, as one of the contributions of GIs:

...”several studies have shown that they have an important role to play in the regeneration” of the countryside since they ensure that agri-foodstuffs are produced in such a way that conserves local plant varieties, rewards local people, supports rural diversity and social cohesion, and promotes new job opportunities in production, processing and other related services. The needs of today's population are met, while natural resources and traditional skills are safeguarded for generations to come”.

When addressing their potential contribution to development, attaching particular attention to the issue of sustainability of such development, a case for GIs may be made using two complementary arguments.

- a) Products and productions susceptible of being protected through GIs have inherent characteristics which make them an ideal objective through which to promote regional/rural sustainable development.
- b) GIs are a means to protect and promote such products and productions.

In relation to the first point; two outstanding traits of GIs, as defined in most of the existing literature, are the close link to the local environment – we will call this “localness”- and the existence of a historic implantation in the territory, where “know-how” related to the production of such products is developed over time -we will call this “antiquity/tradition”.

The “localness” of GI products is relevant to the question of sustainable development for several reasons: First, because the presence of economic actors in the same territory guarantees that socio/economic benefits brought by the GI will be captured locally. This socio/economic aspect has been clearly identified and placed as a policy objective by the European when Regulation EC 2081/92 was drafted (see the text from the preamble cited above).

But the “Localness” of products may have other implications which imply sustainability of the production of GI-products. The production and trade conditions of such goods, are often defined by these goods. For example, as local products are often, although not exclusively, consumed in local markets there is a higher probability that their supply chains will be shorter with smaller scales of production and less intense systems of production.

In addition, the fact that all or most factors of production are concentrated in the geographical area implies a major involvement of local communities in the supply chain contrary to conditions of agricultural mass-production, where horizontal and vertical integration tends to dissociate actors, and above all, “farm”-house interests from the local region and local interests. In the case of most GIs, supply chain actors *are* also part of the local community; *ergo* with a higher and more accurate perception by producers of environmental restrictions and dangers linked to the production and elaboration of the product.

In relation to the second trait attached to GIs, “antiquity/tradition”, it is based on the mentioned fact that the local knowledge related to the production of these goods is often developed over time, incorporating physical and environmental constraints of the land as well as uses. Hence, in this case there is the assumption that belonging to a tradition

*“...seems to guarantee [that their production has] a certain antiquity, so if the components [of biodiversity, of resources] are in existence today then this is because their use is sustainable”.*

However, before defining GI products as *traditional*, one must proceed with caution, as this does not necessarily reflect the present situation of many –if not most- of these

products. For one thing, the existence of tradition for producing a certain product does not imply that the good is actually produced according to methods unchanged over time.

It is a fact that production methods of GI products evolve over the years. This is even recognized by European Union law which, for instance, allows specifications (GI production rules) to be modified by legitimate groups – subject to the authorities' approval - “in light of technological progress”. Besides, as is the case in Europe, there is no requirement for a product to be traditional in order for it to obtain GI protection.

Furthermore, it must be added that “antiquity/tradition” of a product does not exclude the appearance of processes that are detrimental to sustainability, such as the intensification of agricultural productions.

Finally, it is interesting to come back to the question regarding the utility of GIs as a factor of “mobilisation” for local communities; as this is an issue of crucial importance, since there is a widely recognised idea that the mobilisation of local communities is an essential element in achieving the sustainable management of local resources. In the context of agricultural production, this is important because sustainable and unsustainable ways of production may compete on the same territory, so the mobilisation of local people towards the first must be supported in some way.

Such involvement and mobilisation of local communities in support of sustainable agricultural production depends increasingly -in the context of the globalization of agricultural production and consumption- on the existence of appropriate incentives.

In agriculture, the sector to which the application of GIs is exclusively reserved in Europe, the creation of proper incentives towards sustainable processes is more often seen as a question of provision of public goods derived from agricultural activities. This leads to a discussion on the environmental benefits of agriculture, addressed in the next section.

#### ***4. GIs in the Context of the Discussion on the “Environmental Benefits of Agriculture”***

European Union Geographical Indications refer exclusively to products of agriculture or agro-industries. In our study we adopt a comprehensive view of the role of agriculture, which highlights its “multifunctional” character, beyond its acknowledged primary purpose: the supply of food, fibre and industrial products. From this point of view, agricultural activity jointly produces crops and a series of externalities including the provision of certain public goods such as public space and amenities, the preservation of landscapes and the conservation of the wildlife habitats that live on these lands, as well as ensuring food security and preserving cultural heritage.

The *joint* nature of the provision of primary and public goods leads us to consider market failures that are related to the provision of public goods: markets for this type of goods are either non-existent or function poorly. The provision of public goods particularly depends on corrective mechanisms, which may be brought about through State intervention. Three means of intervention are mentioned:

- Direct support for the primary product, e.g. direct support measures in the framework of the Common Agricultural Policy.
- Support that targets joint-outputs, e.g. agri-environmental measures incorporated under the RDR.
- The creation of markets and market conditions for joint-outputs, e.g. “Organic Farming” labels, which are directed at consumers.

GIs, clearly, may be related to the last type of measure. Embedded in Geographical Indications are “messages” or information about product qualities that – if correctly defined and communicated to the public - may be transformed into a “premium” on the value of the product that consumers, in niche markets, would be willing to pay. The advantage of the creation of market conditions for joint-outputs is that, contrary to the other two intervention means mentioned, in this case it is the consumers that pay for the provision of positive attributes.

The challenge, in this regard, is to explore a) the measure in which local products which are protected through GIs contribute to the provision of public goods (*localness, tradition, quality, safety, respect of the environment, etc.*); b) the extent to which the provision of such attributes include, in particular, the provision of “environmental quality”; c) if and how GIs contribute to reducing market failures related to the provision of these non-commodity goods *i.e.* when and under which conditions are consumers ready to pay an extra price for agricultural products because of the attributes they lend to them.

GIs, therefore, may act as part of a valorisation strategy which serves an incentive towards activities in possession of this multifunctional character, creating opportunities for rural communities to undertake these as a means of subsistence. Furthermore, as seen in the previous section, in many cases products susceptible of GI protection (local products) appear –at least *a priori*- as being in possession of certain attributes (localness, antiquity/tradition) which could work in favour of sustainability.

### **5. An Innovative Area of Research**

Despite the attention that GIs have gained in recent years, and regardless of the fact that some of these studies have been conducted in the context of issues that explore certain relations that may be established between geographical indications and sustainable development indicators, there are still many areas left to explore.

In general, most of the work carried out is socio-economic research on GIs. This work was published after the implementation of the EC Regulation and in general takes the form of case studies and the exploration of institutional, organisational and juridical aspects.

Along the same lines, several important inter-institutional research projects were carried out, financed by the European Union. Overall, most of the research has been centred on economic and organisational issues related to the collective nature of production of GI protected goods.

In some –more recent- studies, attention has been paid to the contribution of GIs to rural development objectives. However, the focus has been centred on the economic and social facets of rural development and little attention has been paid to the possible environmental effects of promoting typical or local products through GI protection.

In recent times, some attention has been paid to the issue of how GIs may work in order to bridge gaps between intellectual property law and biodiversity conservation regimes (in particular the Convention on Biological Diversity). Many of these studies show that labels indicating geographical origin may contribute to the *in situ* conservation of biological diversity. Indirect contributions to biodiversity conservation may come through the adaptability of GI laws to the protection of traditional knowledge and practices and the promotion of “bio-commerce”. However, most such studies and works point out the need to contrast this work with empirical findings.

The IPDEV project (WP3) aims to focus on the *lacunae* left by previous research, by addressing such issues as:

- ❖ The incidence of local, GI protected agricultural production on the environment.
- ❖ The capacity of GIs to promote the competitiveness of local products, in particular environmentally valuable agricultural activities vs. alternative unsustainable or damaging activities.
- ❖ The degree of internalization of environmental values in the price paid by consumers for GI products and when it is achieved.
- ❖ The implication of local stakeholders, in particular in relation to the integration of environmental concerns in the GI strategy, as a result of the synergies created.
- ❖ The capacity of GIs to generate socio-economic welfare for local actors,
- ❖ ..in particular the creation of economic incentives tied to environmentally sustainable forms of agriculture.
- ❖ The existence of a “greening” process connected to GI products, with a particular focus on the existence of green clauses in product specifications.

### **A Simplified Approach**

This work package proposes a simplified approach, which reduces the examination of GI impacts to two main spheres: the effect on environmental quality and the effect on local economic indicators.

However, in order to examine the efficacy of GIs in achieving goals of sustainable development in providing social-economic development, as well as other public goods or “amenities” in spheres such as the environment and environmental quality there is, in reality, no simple approach.

For the analysis in both mentioned spheres, the study of GI regulations and institutions, is one step. However, such an institutional approach must be complemented by an approach which takes into account how the GI is constructed and the effectiveness of valorisation strategies of different actors involved. From previous research, it seems that there is no evidence the institutionalization of GIs “per se” will be sufficient for the purpose of promoting regional development (for this it also seems necessary to observe not only the constitution and operation of the supply chain, but also the interaction with other actors and development actions and plans (tourism, natural conservation,

promotion of local agriculture and industry) as well as the incidence of broader national and Community legislation.

For this reason, in complementary form, attention to social and cultural aspects connected to the GIs is paid to, with particular focus on synergies which are created by, or in which communities linked to the GI take part.

**Figure 2** GIs and their relation to sustainable development.



### **A Case Study Approach**

The method proposed was to conduct a series of case studies. Concrete issues to be addressed in each case study were defined previously, through the establishment of a “case-study report template”, covering the facets which would later be interrelated and analysed:

## **Box 1 Case-Study Report Template**

- 1 THE PRODUCT AND ITS REGION OF ORIGIN**
  - 1.1 PRODUCT DESCRIPTION
  - 1.2 HISTORY
  - 1.3 AREA OF PRODUCTION
  - 1.4 ALTERNATIVE LAND USES AND POSSIBLE SUBSTITUTES
- 2 LEGAL ASPECTS: PRODUCT DEFINITION, CONTROL AND PROTECTION**
  - 2.1 STATUS OF PROTECTION/LABELS AND CERTIFICATES
  - 2.2 SPECIFICATION
  - 2.3 MONITORING
  - 2.4 OTHER LEGAL INSTRUMENTS RELATED TO THE PRODUCT  
(SUBSIDIES, ENVIRONMENTAL CONSERVATION, ETC.)
- 3 ENVIRONMENTAL EFFECTS DERIVED FROM THE PRODUCTION OF THE LOCAL GOOD**
  - 3.1 WATER
  - 3.2 SOIL
  - 3.3 LANDSCAPE
  - 3.4 BIODIVERSITY
  - 3.5 ENERGY/RESOURCES/WASTE
  - 3.6 AIR/CLIMATE
- 4 ECONOMIC DATA AND RELATION TO REGIONAL DEVELOPMENT**
  - 4.1 IMPORTANCE OF THE LOCAL PRODUCT FOR THE REGION AND GI INCIDENCE
  - 4.2 MARKETING CHANNELS
  - 4.3 PRICES/PRICE PREMIUMS/PROFITABILITY.
  - 4.4 SUBSIDIES AND SPONSORING
  - 4.5 SUPPLY CHAIN ORGANISATION AND DISTRIBUTION OF RENTS.
- 5 MARKETING/CONSUMER PERCEPTION**
- 6 STAKEHOLDERS AND SYNERGIES**

### **Case Selection**

The general guideline for the selection of cases to be analysed has been to provide a diversity of situations in order to favour cross-comparison and derive conclusions. The final purpose was to examine how a series of pre-established factors applied to each case study, related to different GIs.

The cases studied were selected from a process divided in two phases:

In the first phase, a prospecting task was carried on the basis of information available through official sources, libraries and the internet. A list of 35 potential case studies was then established.

For this initial selection of 35 cases, the following factors were taken into account:

- ❖ Geography: Cases were chosen from countries with different protections and traditions in protecting GIs. The distribution among research institutions is based on criteria of proximity.
- ❖ Variety of Goods: A selection of different types of goods was included. The following categories may be differentiated: dairy products (cheese from cow, sheep or goat milk); vegetables (asparagus, gherkins, artichokes, potatoes, tigernuts); meat (pork including ham, lamb and beef); seafood (mussels); cereals (rice); edible oils (olive, pumpkin seed and argane); intermediate products (argane oil, rose oil); mineral water; wines and beverages (cider); tobacco.
- ❖ Comparable goods: For the purpose of establishing comparisons, some goods are paired to goods of a similar nature or function (cheeses, olive oil, intermediate products, meat) produced in other regions.
- ❖ Plausible links between GIs and environmental quality: Visible or evident elements such as production in protected natural areas (national parks, protected biosphere zones: Idiazábal Cheese, Spreewälder Gurken, Sierra Mágina Oil) and areas of high ecological value (wetlands: Arroz de Valencia), areas with a significant percentage of production under “organic” or “ecological” logos (Sierra Mágina), or those where we find information publicised by *Consejos Reguladores*, or Producer Associations underlining environmentally friendly practices (Mexillón de Galicia). Such indicators of positive linkages were taken into account when selecting cases.
- ❖ The availability of information.
- ❖ Representation of products protected as PDO (Protected Designation of Origin) as well as products protected as PGI (Protected Geographical Indication)
- ❖ Contrast: Some cases were chosen on the basis of their commercial success or notoriety, and not on their visible potential to contribute to environmental quality. These “ambiguous” or “negative” environmental cases may serve to provide contrasting information for the purpose of further analysis.

All information on pre-selected case studies was put into brief standard fact-sheets, exchanged and discussed. Based on the same criteria, a set of cases was selected for further study and analysis (2<sup>nd</sup> phase). In the final phase of the project, only the cases for which qualitative value and reliability of information was considered sufficient were retained for the final analysis and conclusions of the case studies.

It must be outlined that the chosen case studies are by no means a representative selection of European cases (there are more than 720 indications for agricultural products). However, the cases chosen are a very useful sample enabling to explore the effects of GIs for different types of products, with different local social, economic and environmental conditions, in countries with different traditions in protecting local products, and with different forms of supply chain organization –including, a diversity in the objectives pursued when adopting a GI strategy-.

Finally, as explained before, the focus has been laid on Agricultural Products from EU regions. Some insights from candidate countries have been synthesised and added to the report, although they are not part of the analysis carried out in this report, due to problems related with the integration of the results with those of other case studies.

The advantage of this geographical focus is Europe can by that serve as an adequate “laboratory” for the analysis of effects, a stable environment where to test methodology



and extract conclusions which can then be tested against the specific situations in developing countries.

This European based approach, however, does include one weakness: the strong presence of subsidies –both to sustain agricultural production and rural development– create market distortions which impede a more accurate assessment of GI effects on local food production and local sustainable development indicators. The isolation of results on GI impacts in sectors such as the rice or olive oil sector, both organized under CMOs and receiving important Community subsidies, may in effect prove difficult as motivations of actors are not always market-driven.

### **Work-plan**

The general work-plan to perform this study consisted in

- (i) Examining the existing literature and establishing a methodological framework (see Methodological Framework and Literature Review deliverable).
- (ii) Defining relevant information to be retrieved for the analysis of environmental and economic impacts and putting it in a “Case Study Report Template” (see section D, above)
- (iii) Prospecting potential cases to be examined (see Annex 1)
- (iv) Defining the final cases to be studied based on scrutiny of the templates and group comments
- (v) Data and information collection aimed at obtaining complementary information through interviews and direct contact with different case study stakeholders
- (vi) The draft of descriptive “Case Study Reports”, in which all the collected data and information is set out. (see Annex 3).
- (vii) The analysis of the case studies and production of a Draft Final Report, presented before a panel of experts.
- (viii) Final Report, including policy recommendations based on findings and conclusions.

**Table 1 List of case studies.**

<b>Geographical Indication</b>	<b>Type of Geographical Description.</b>	<b>Product</b>	<b>Geographical Area of Production</b>	<b>Associated Trade Mark</b>
Idiazábal	PDO	Cheese (ewe milk)	 Basque Aut. Com and West Navarre, Spain	 
Diepholzer Moorschnucke	PDO	Meat (sheep)	 Diepholz moorlands Lower Saxony, Germany	
Jersey Royal Potatoes	PDO	Potatoes.	 Island of Jersey in the English Channel	 
Sierra Mágina,	PDO	Extra-virgin olive oil.	 Sierra Mágina, Jaén, Spain	 
West Country Farmhouse Cheddar.	PDO	Cheese (cow milk)	 South West England (Somerset, Dorset, Devon, Cornwall)	
Schwäbisch-Hällisches Qualitätsschweinefleisch	PGI	Meat (pork)	 Hohenlohe Baden-Württemberg, Germany	 
Arroz de Valencia	PDO	Rice	 Albufera area of influence, Valencia, Spain	 
Spreewald Gherkins	PGI	Processed (pickled) cucumbers	 Spreewald, Brandenburg, Germany	 

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## CONCLUSIONS

- **A New Role for Agriculture:** Agriculture in the European Union is faced with a rapidly changing political and economic environment. Food self-reliance is no longer an objective in an integrated and globalized world. Product-related agricultural subsidies, as a means of shielding agriculture from foreign competition, have been under heavy criticism from developing countries. New environmental requirements, such as the EU Water Framework Directive, raise the bar for the environmental performance of the European agricultural sector. Consumers become concerned with the quality of agricultural produce as the negative side-effects of industrialised agriculture – such as mad cow disease – become apparent. Wider demographic and social trends, such as the depopulation of remote rural areas and the dying off of small-scale agriculture, continue in many parts of Western Europe. All this reinforces a new perception by a wide array of stakeholders (Consumers, Farmers, NGOs and Policy Makers) on the different impacts of agricultural activities, with particular emphasis on the functions which go beyond the primary purpose of producing food products.
- **Seeking Comparative Advantages through Specialized Products:** Attempts have been made to re-define agriculture in Europe, to give it a new self-understanding and a set of new objectives. It is commonly assumed that, with some local exceptions, agriculture in Europe will generally not be able to compete with North America and developing countries in the production of staple foods. One possible alternative is the production of biomass to be used as biofuel. However, it is unclear whether this would not be subject to the same competitive pressure as food products. The comparative advantage of Europe is therefore rather seen in specialised products, which adhere to particular standards (e.g. organic farming), or high-quality products that require and embody particular local knowledge. For the latter, production strategies ensured by Geographical Indications is essential.
- **What do farmers (and agro-industries) seek to achieve through GIs?** Geographical Indications may be applied for with different motivations in mind. The primary objective of establishing the GI will usually to achieve a price premium for the produce and thus ensure that traditional or unique local products remain competitive and economically viable. Hence the primary motivation for establishing a GI, as results from findings of this Work Package, is based on economic considerations established on the premise of achieving product differentiation (competitiveness) based on goodwill or reputation constructed on unique/locally-woven characteristics and certified quality.
- **Socio-economic contributions of GIs:** There is evidence from many cases that GI protection can help producers to reach their economic objectives, and that it contributes positively to regional economic development. Then again, the potential economic impacts of GIs must be nuanced according to the degree of consolidation achieved by the GI in relation to the total production of the local good and *vis-à-vis* competing economic activities. The commitment of economic actors involved in the supply chain towards the achievement of common goal (i.e. to produce and sell a strictly defined product) is essential for GI success, as mere institutionalization of GIs is not sufficient. In this sense, attention should be brought to the fact it has been seen that actors, in different stages of the supply chain, depend on incentives which may increase proportionally to their capacity of “capturing” the benefits generated by the GIs.

- Two elements have been found to favour the increase in the **capture of rents**: The first element is higher levels of integration. Strategies which have envisaged integration forward have provided producers (particularly in short supply-chains, for ex. artisan or *fermier* cheese producers) with access to the benefits of the entire value-added (the last sale) of the product.
- A second element is related to the **coordination of the supply chain**. Higher degrees of coordination among actors are accompanied by beneficial outcomes such as lower transaction costs and higher synergetic interaction. Coordination is normally ensured by the presence of intermediate institutions, such as producer associations or GI management institutions where producers, as well as other stakeholders participate (*Consejos Reguladores*). The presence – and strength – of such institutions, from the evidence found, seems to favour stability of arrangements among actors (for example, the payment of fixed price premiums to farmers by associated processors/distributors, as in the SHQ – BESH case) and ensure better rent distribution among actors.
- **Environmental quality has been a secondary motivation in GI related strategies**. The GI Regulation of 1992 EC 2081/92 recognized rural economy objectives - restated in similar terms by Council Regulation EC 510/2006 that GIs should help achieve rural economy objectives (improvement of rural local incomes, retention of populations on local areas). No reference is made to environmental objectives, despite the central role that environmental preservation plays in Community rules since the Agenda 2000 reform and notwithstanding the close link of GI products to local environments. Indeed, findings show that there are only very few incidences where environmental objectives have played a central role for the establishment of a GI reinforcing the idea that environmental goals are secondary to economic incentives in GI based strategies.
- There is some evidence to suggest that GI-protected products can be produced in a way that is more environmentally benign than production of standard or industrial substitutes would be. According to the findings of this study, the products protected by GI show **positive results in reference to conservation and maintenance of biodiversity and distinctive cultural landscapes**, and the regions of origin often include protected areas.
- In this sense, GIs may appear as an important complement, to integration strategies for biodiversity-rich farmland areas (such as semi-natural grasslands, areas important for migratory birds and dehesas) in particular to avoid land abandonment in marginal regions.
- On the other hand, there are also examples of GIs where production methods are not at all different from standard agricultural practices, with associated environmental impacts. In particular, processes of intensification –with visible environmental impacts- are present and possible under GI specification rules. In this sense, findings suggest that despite *a priori* assumptions influenced by an idealized characterization of GIs these, *per se*, show **a relatively neutral effect on environmental quality**.
- **GIs may act as an incentive contributing to environmental goals whenever the typical product “definition” incorporates “local” attributes of environmental value**. The existing literature on GIs supports the idea that GI success depends on an optimal functioning of a process which begins with the consecution of product qualities according to product definition (specifications), continues with the certification of these qualities and ends with the communication of certified product qualities to consumers (promotion and

marketing). Findings show that whenever elements connected to the preservation of local environmental quality or biodiversity are a component of the product's definition, then GIs may play a more important role in capturing extra revenues which derive from these environmental attributes.

- **GIs in the context of different available support instruments.** GI products often are integral parts of a region's cultural heritage and are strongly linked to regional identity and profile. GI protection helps to conserve unique traditions and methods and thus contributes to maintaining the diversity and richness of Europe's regions. However, GI is rarely the only instrument used to promote localised production with traditional measures; rather, it usually blends in with a mix of other instruments. Localised production is often supported from other sources (RD funds, agricultural subsidies), and will often be linked with activities in other sectors (tourism) that also exploit the regional identity and the green image of a product and its area of origin. GIs, through their strong perception and through the institutional structures which they support / require (producers' associations) can act as a galvanising point for such developments. The challenge is therefore to find the right place and role for GIs in a wider concert of support instruments.
- **Preserving the nature of GIs.** Regulations on GIs, established in the framework of Europe's Common Agricultural Policy, have not been designed to ensure environmental purposes. Rather, the intention of EU legislator has been focused on rural economy goals. To achieve environmental goals in agriculture the EU has established a specific array of instruments and measures which go from "horizontal measures" affecting the CAP to second pillar instruments, such as agri-environmental measures. Keeping clarity over the role reserved to each instrument is important, as GIs already perform essential economic functions which are central to agricultural reform. Clarity is also essential for consumers, in order to avoid adding difficulties in their understanding of what the PDO and PGI labels, as well as coexisting different logos on the market – organic, quality labels- have to offer.
- **Making sustainability one of the dimensions of the local definition of products.** Despite the observation made in the previous point, GIs may have a role in promoting environmental quality. This is because there is a new understanding of how products and agricultural activity relate to the "origin" (i.e. the environment). Sustainability is increasingly identified by consumers as a positive characteristic of products. In some cases, such as when the product comes from an environmentally valuable geographical area or when a particular form of farm management appears as an essential element in the preservation of landscapes and biodiversity, the concept of geography – which is so at heart of the notion of GI - is expanded so as to include "sustainability".
- **"Greening" of GIs** may therefore be achieved by raising farmers' awareness of this new "dimension" of GIs, relating sustainable ways of production and local product identity, so as to incentivise the incorporation of the elements of sustainability in the product specifications and convey them to consumers. An element which works in favour of this greening element, as observed in some GIs established on naturally valuable geographic areas, is existence of wider synergies created among stakeholders, including local administration, farmers, producers, tourist operators, rural development associations, environmental NGOs, etc.

- Thus, while the wider use of Geographic Indications by itself does not guarantee more environmentally friendly agricultural practices, well-designed Geographic Indications with “green” potential may help support sustainable economic and social production processes. For wisely designed GIs, there are considerable synergies between the objective motivations behind a GI and wider sustainable development objectives. To better target the instrument towards sustainability objectives and to better exploit such synergies, the following approaches might be taken:
  - Develop assistance for the identification of agriculture with “green” potential susceptible of GI protection (e.g. farming on environmentally valuable areas, local products essential for landscape maintenance or GI linked productions which are traditionally achieved through low-impact management systems). Productions on semi-natural grasslands, habitats essential for breeding and migratory birds and unique habitats as the *dehesas* should be a priority. Identification processes would best be carried out at decentralized, local, levels.
  - Incorporate positive environmental attributes of the product in the process of definition/certification/communication to consumers. This implies including environmental and rural development objectives in the specification of the GI and communicating them to the public as an element which characterizes the local product.
  - Use part of the profits from GI to support environmental measures, which can also be of use to promote the product (green image);
  - Search further means of differentiating GI products (vertical brand proliferation) by means of exploiting environmentally friendly productions. In this sense, a clear first step would be to develop the potential in synergies with organic production methods;
  - Combine GI with support instruments available at the local level (rural development, agri-environmental measures etc.).
  - The potential of the instrument to guide consumer choice does not currently seem to be fully exploited. If the PDO and PGI were more distinctive, more easily recognisable, and better known among consumers, they might become labels of similar relevance as organic production certificates.
  - Producers can have a large influence on the success of their products. Important factors seem to be the degree to which they join forces in marketing, how they organise and develop markets and distribution channels, and how they ensure and improve market access for their members. Exchange of information on experiences and best practice examples could help to promote the more widespread use of GI in Europe and to facilitate the start-up of new producer groups.
  - In this sense, EU initiatives in the framework of RD programmes such as LEADER+ may provide support for local stakeholders for actions in the framework of the “Adding Value to Local Products” and “Best Use of Natural and Cultural Resources” project themes, in particular in areas such as the creation of networks of stakeholders and creating efficient marketing schemes.

- **Potential benefits of GIs in developing countries.** Some of the findings of this research work package may also be of assistance in identifying utility of geographic indications in regions and countries where they appear to be less implanted, in particular in developing countries:
- A first question is related to the applicability of “formal” and complex systems, necessary to guarantee the definition, control and certification of local products. This institutional format is central to the European System, as it is corresponded by consumer awareness and sensibility towards receiving increased product information, through institutions and mechanisms ensuring traceability. Moreover, building such a system normally brings reorganization of the supply chains, leading to new forms of entrepreneurial strategies (for example, as seen, farmers searching integration forward towards marketing) and forms of coordination and organization. GI success seems to depend on the actions related to such strategies and organizational issues, with an important role attributed to intermediate institutions where stakeholders of the GI are grouped (producer associations, regulatory councils or –eventually- regional rural development groups with wider objectives).
- The possibility of extending successfully such a system to developing countries goes beyond the mere question of institutionalization of Intellectual Property laws. In some countries, the construction of such a system will be confronted to practical problems due to social reasons and lack of experience in the implementation of GI organization-schemes. In addition, in many cases local agriculture is characterized by lack of formal institutions and codification of production-quality parameters, which may exist under other cultural forms (oral tradition).
- Commercial success, using GIs, will need gradual formalization for processes and knowledge embodied in local products (Larson, 2006). Furthermore, the development of local intermediate institutions are fundamental, to guarantee consensual product definition and to establish appropriate levels of organization, as well as to promote the product in local and distant markets.
- The process of formalization would better be carried out at a local level, rather than under national policy schemes. Localness in definition, control and communication will guarantee a major local cohesion and involvement. Technical Cooperation should be directed to this level.
- At the legal level, a strong protection against usurpation should be combined with flexibility, for instance, in the implementation of traceability schemes. Special protection systems, as in the EU in this sense, may seem appropriate – as compared to trademarks - for the guarantee of high levels of protection beyond mere “risk of confusion”. However, local systems may differ in chapters such as requirements regarding legitimacy, specification rules and other requisites for register, in accordance to the structural development of agriculture.
- Regarding the use for GIs for environmental purposes, such as the protection of biodiversity, a point must be made about the specificity of this instrument: it is an Intellectual Property Right which has been designed to protect local goods, with a reputation related with characteristics recognized by consumers. The results of this study suggest that goods protected by GIs have the potential to bring benefits in terms



of agrodiversity and sustainable agricultural practices. However, the present study is based on a limited number of case studies, and not all insights from European case studies may be applicable to developing countries. Therefore, an expansion of the sample to more case studies which also cover products from developing countries may be desirable.

- A factor to be taken into account, in this sense, is the dimension of the territory defining the GI. “Smaller” indications, defined on specific territories, will probably lead to major agro or bio-diversity. International legislation is of little help in this sense, since it admits Geographic Indications covering, inclusively, a whole national territory. Once more, work must be carried out at a local level, with high intensity of technical cooperation, to increase the involvement of local farmers in the establishment of GIs to protect and promote the products inherent to their land, as conceived in both natural and human ecological terms.

## **6. IDENTIFYING MODELS OF BEST PRACTICE IN THE PROVISION OF TECHNICAL ASSISTANCE TO FACILITATE THE IMPLEMENTATION OF THE TRIPS AGREEMENT**

### **INTRODUCTION**

At present there is a considerable emphasis on international cooperation on intellectual property (IP) rights involving developed countries, developing countries, least-developed countries and various developmental agencies. These international efforts focus on providing technical assistance (TA) on issues relating to intellectual property rights (legislation-making, administration, enforcement, etc) to the recipient nations (usually developing nations) by the provider-nations (generally consisting of developed nations and their agencies).

This issue has risen to never-before prominence mostly due to the uniform minimum-standards relating to intellectual property rights that have been established across the world under the Trade Related Intellectual Property Rights (TRIPS) treaty. Such programmes/efforts, however, have been often criticised on the grounds that they further the interests of provider nations and agencies, rather than addressing the concerns and priorities of recipient nations. Such criticism not only makes recipient nations somewhat hostile towards any future collaboration with the developed nations and their agencies, but also affects the effectiveness of the current programmes. In addition, various authors have argued that technical assistance so far has only achieved a limited objective. It has failed to create sustained capacities in recipient nations to help them participate effectively in international norm-setting, and to understand and evaluate the domestic implication of international treaties. Even the UK Commission on IPR Report has concluded that the technical programmes so far have under-achieved in comparison to the amount of resources and time that has been spent. Moreover, these programmes were not always responsive to the developmental needs of the targeted country. Various authors have therefore emphasised on the need to find novel ways of preparing and conducting technical assistance programmes.

Under this background, the report intends to provide general and specific recommendations for both provider and recipient nation/institution that they should take into account while undertaking any TA programme in a recipient nation. It is emphasised that the report is not exhaustive but nonetheless critically evaluates the needs, concerns and experiences of the recipient organisations and provide suggestions to address them. The proposed guidelines/checklist aims at building better understanding for future collaborations between EU, its member states and any recipient nation in relation to trade, intellectual property rights and development. It may also increase the likelihood of acceptance of any future programme proposed by the EU, its organisations and/or member states to recipient countries.

The recommendations in this report have been formulated on the basis of past and current instances of technical assistance on IP provided by various international agencies and organisations, including the USA, to various stakeholders in developing countries. These stakeholders include government, patent office, business organisations, enforcement agencies, NGOs and educational institutions.

### ***Scope of the Report***

In line with the research priority of developing common approaches to IPR rules, the study, through the analysis of both formal and informal routes for the provision of technical

assistance, has examined the extent to which financial assistance and specialist advice has been an efficient use of resources and whether it has been sufficiently tailored to reflect the best interests of developing country WTO Members. The study has sought to build a comprehensive picture of the quantity, quality and appropriateness of financial assistance and specialist advice by evaluating the extent to which the content of the technical assistance fully represents the best interests of recipient countries rather than simply reflecting the interests of technical assistance providers.

### ***Rationale of the Report***

The study therefore differs, but is complementary to, WP 5. This report will focus on the provision of technical assistance in the form of financial contributions and advice relating to public and private enforcement issues targeted at government policy advisers, patent office officials, judiciary, enforcement officers and other institutions in developing countries, while WP 5 will focus instead on the implementation of access and property rights legislation in the area of agricultural biodiversity and seeks to engage specifically with national policy officials with responsibility for agricultural issues.

### **ACHIEVING BEST PRACTICE IN TECHNICAL ASSISTANCE ON INTELLECTUAL PROPERTY: CONCLUSIONS AND RECOMMENDATIONS**

The primary focus of the majority of technical assistance activity has been on the preparation of domestic legislation for the protection of intellectual property and the strengthening of enforcement measures. The main reason cited for such a trend is the fairly narrow mandate provided to main donors and providers such as WIPO and WTO. If one looks at Article 67, this emphasis on IP protection and enforcement becomes clear:

*In order to facilitate the implementation of this agreement, developed country members shall provide, on request and on mutually agreed terms and conditions, technical and financial co-operation in favour of developing and least-developed country Members. Such co-operation shall include assistance in the preparation of domestic legislation on the protection and enforcement of intellectual property rights as well as on the prevention of their abuse, and shall include support regarding the establishment or reinforcement of domestic offices and agencies relevant to these matters, including the training of personnel.*

In practical terms, the priority areas within TRIPS TA are as follows:

- (i) Implementation of legislation which is consistent with the TRIPS Agreement
- (ii) Modernization of intellectual property offices and collective management societies
- (iii) Strengthening of the means to enforce rights
- (iv) Promoting and encouraging technology transfer to least-developed countries
- (v) The use of intellectual property systems for development purposes; and
- (vi) issues currently under discussion /negotiation in the WTO.

The entire TA programme delivery-exercise can be divided into five stages:

#### **1. Needs assessment**

This part of the delivery programme deals with the identification of the actual needs and priority areas for the technical assistance by the recipient organisations.

**2. Identifying partners and securing funding**

This involves identifying partners, approaching them, securing funding and coordinating technical assistance.

**3. Planning and design**

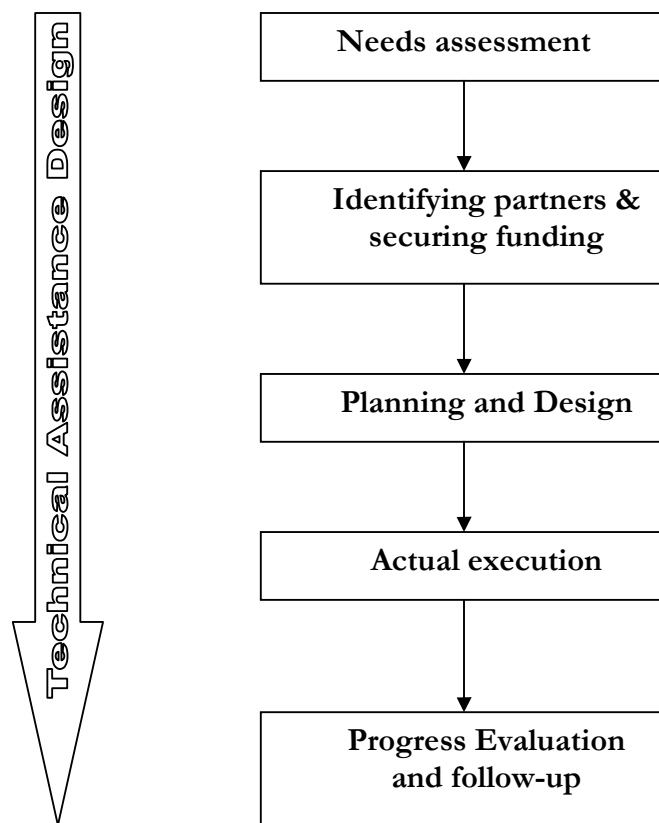
These activities precede actual implementation and involve entering negotiations with a particular provider on issues such as designing the content and delivery exercise of the technical assistance

**4. Actual execution**

This involves undertaking the planned technical assistance and executing the same either at the provider's institution or at the recipient's organisation

**5. Progress monitoring, evaluation and follow-up**

This involves undertaking steps for evaluating the performance of the TA programme both during the execution of the programme and after the programme has finished. On the other hand, the post follow up focuses more on the results achieved vis-à-vis the objectives of the programme undertaken. It is set to undertake an impact assessment of the programme on the recipient institution both on the short-term and long term basis.



**Figure 1: Various stages in technical assistance programme design**

After undertaking qualitative and quantitative analysis of each of these stages through the case studies of stakeholders involved in the TA delivery exercise, our conclusions and recommendations focus on strengthening these important stages. These findings undertake the

SWOT analysis of each stage vis-à-vis the participating stakeholders and provide guidelines that are aimed to equip both the recipients and providers in their quest to provide and receive effective technical assistance.

<p style="text-align: center;"><b>S = Strengths</b></p> <ul style="list-style-type: none"> <li>• Expertise of the organisations in a particular field</li> <li>• Credible institutional structure to carry on the project</li> <li>• Local awareness and grass-root level connections</li> <li>• Strong past experience</li> <li>• Perceived acceptability of the organisation by the recipients.</li> </ul>	<p style="text-align: center;"><b>W = Weaknesses</b></p> <ul style="list-style-type: none"> <li>• Lack of expertise in the field of TA</li> <li>• Lack of institutional strength to undertake the programme</li> <li>• Lack of local knowledge</li> <li>• Lack of past experience in the field of providing TA programmes.</li> <li>• Narrow policy mandate or goals of providing IP related TA</li> </ul>
<p style="text-align: center;"><b>O = Opportunities</b></p> <ul style="list-style-type: none"> <li>• Enhancing capacity of the recipient partners in dealing with IP related matters.</li> <li>• Creating sustained basis for IP creation, enforcement and management in the recipient organisation</li> <li>• Strengthening local legislative and regulatory framework based on local needs and public interest</li> <li>• Increasing efficiency and quality of patent offices</li> </ul>	<p style="text-align: center;"><b>T = Threats</b></p> <ul style="list-style-type: none"> <li>• Affect of local political situation</li> <li>• Affect of the foreign policy of the recipient nation</li> <li>• Vulnerable due to the biases emanating at the providers end</li> <li>• Failure due to lack of commitment from the recipient's side</li> <li>• No adaptation of TA to focus on local needs.</li> </ul>

**Figure 2: A Typical example of SWOT analysis for the TA stakeholders**

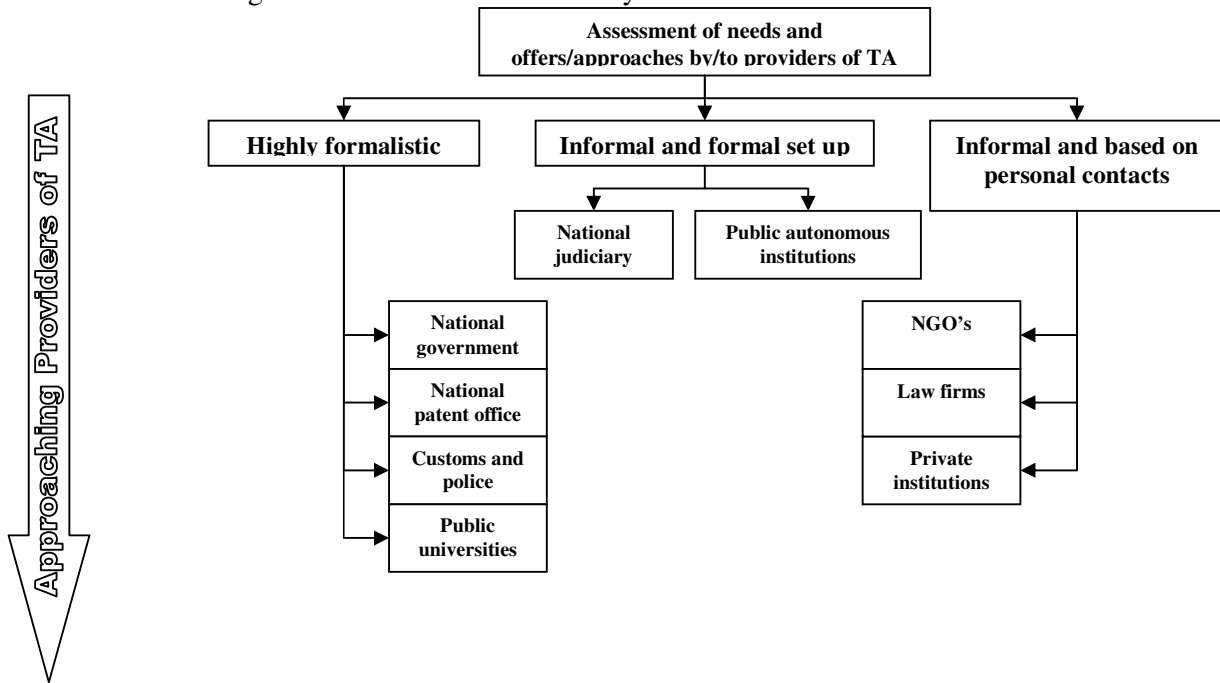
***Needs Assessment***

**Needs assessment procedures**

It was found that the recipient organisations in developing nations have variable “needs-assessment procedures” for identifying priority areas for technical assistance. In some organisations such as patent offices and enforcement agencies, the needs assessment and decision making process was found to be highly formalistic. It is generally based on inputs from several committees and individuals. On the other hand, private institutions such as national NGOs and law firms tend to have no formal setup for evaluating their needs. They are often determined through very informal procedures involving personal interaction. For national NGOs, the existence of such a situation is due to the lack of financial and human resources and want of knowledge of technical assistance opportunities. Several other categories of institutions such as judiciary and the public sector research institutions were found to encompass both informal and formal setups for evaluating their needs.

It is to be noted that each type of setup had its own advantages and disadvantages. The formalistic type of procedures provides both the recipient organisation and provider organisation a sense of objectivity in relation to the need assessment and the evaluation of the proposed technical assistance offer as noticed during the upgrading of patent offices in India in the year 2000. But more often than not, they were also found to be too bureaucratic resulting in loss of time and resources, for example, as happened during the execution of a recent TA programme executed by GTZ, a

German agency, in India. The informal setup on the other hand overcomes these disadvantages due to its inherent flexibility.



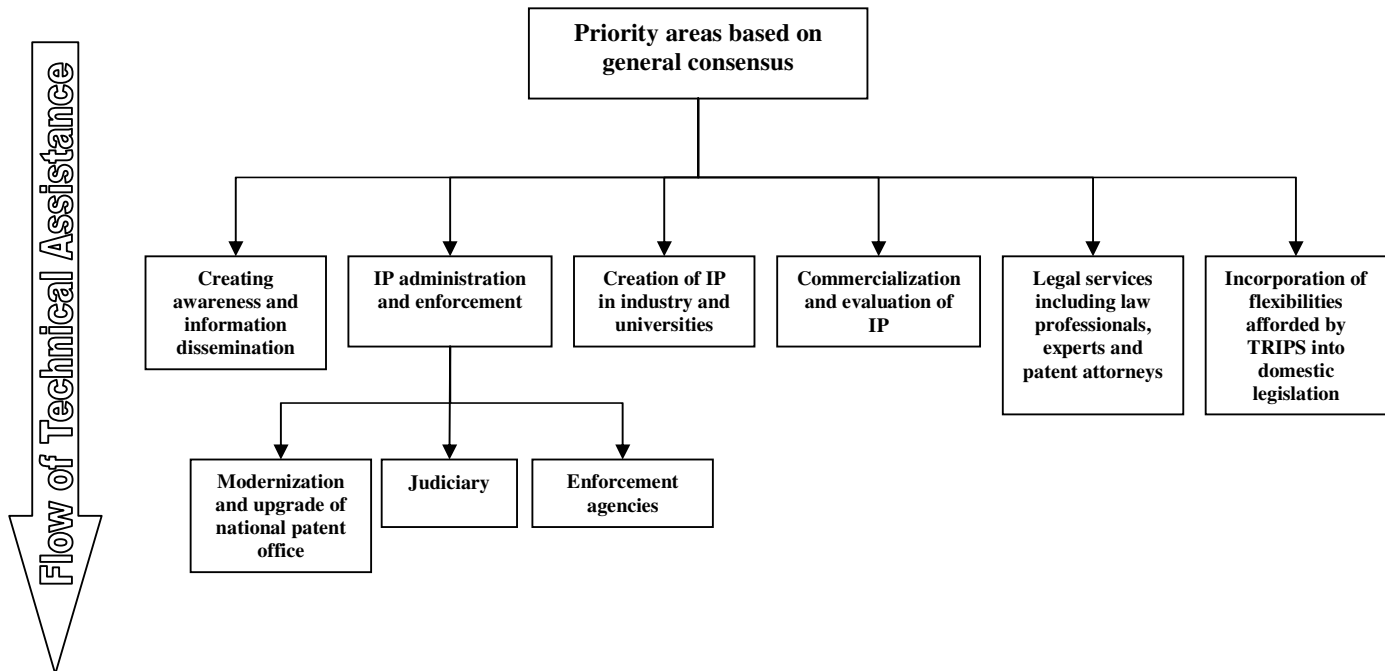
**Figure 2: Needs assessment procedures for different institutions**

**Recommendations:**

- a. *Unless the needs are identified properly by the recipients, the technical assistance exercise will not be able to provide effective results and intended impacts. As a starting point, the financial and technical assistance should be provided to organisations so that they can build effective mechanisms to establish and consolidate their needs assessment procedures and identify specific areas that could be addressed through further assistance by providers who would then be in a better position to direct their resources and personnel to achieve optimum results. Moreover, the fact that there is generally a time gap between the request of TA to an implementing agency and its execution, it is imperative that these procedures be strengthened so that timely TA can be provided.*

**Priority areas for delivery of TA**

The representation below summarises priority areas identified at the national level for TA requirements and is based on the personal views given by individuals during interview. There appears to be a general consensus on this. However, it is important to note that each stakeholder had its own specific further needs which may or may not fall in any of the categories mentioned below.



**Figure 3: Priority areas to be targeted through technical assistance**

### **Recipient need awareness amongst the providers**

The awareness of recipients' needs and their systematic integration into TA activities varies considerably within the two principal modes of technical assistance delivery models: the bilateral North-South cooperation and the South-South Cooperation (involving IGOs such as South Centre, ACWL and regional cooperation agreements such as the Mercosur Agreement). Within the South-South cooperation, providers were highly aware of the needs and hence were able to provide advice suited to the particular recipient country. But on the other hand, the bilateral North-South cooperation often lacked a high awareness level of the actual needs of the recipients. The developed country institutions and countries were more guided by their institutional policy goals and mandates relating to intellectual property. This was highly evident from the instances of technical assistance provided by the US and its various agencies. The participation of the private sector in US technical assistance was also a significant factor for why these activities focussed highly on enforcement and protection of rights. Other reasons for such an approach from the US were:

1. The primary actors in US technical assistance are basically bound by their policy goals of providing technical assistance only on enforcement and protection of rights. For example, grants from the Department of State are tied to the provision of technical assistance relating to enforcement of rights.
2. The participation of right holder organisations such as BSA, ESA etc. further provides a tilt towards the strong right-regime.
3. Even the developmental aid agency USAID seems to be influenced by the right holders rather than impartially focussing on the developmental aspects in which IP could play a positive role.

Such a scenario of North-South cooperation has given rise to many of the problems that negatively affect the quality of the technical assistance delivered:

- a. Provider bias

- b. Content bias
- c. No local adaptations

**Recommendations:**

- a. *The strong success of South-South cooperation is based on the systematic integration and focus on the topical needs and concerns of the recipient countries and organisations. It is suggested that the efforts should be made to replicate this model at regional/national level by creating more such centres.*
- b. *On the other hand, the North-South cooperation especially provided by the US needs to be more open and more cohesive in its approach. Since most of the involved organisations in the US are based on right holders' interests, there is a need to restore balance in the US TA exercise by incorporating other agencies and civil society. This could be achieved by*
  - a. *engaging developmental related NGOs in the US, and*
  - b. *earmarking specific funds of the agencies for specific purposes other than enforcement and protection.*

**South-South cooperation**

Although numerous complaints were made in respect of TA provided by the developed countries and their agencies and institutions such as those concerning content bias, they were generally absent when compared with the work of South-South cooperation of IGOs such as South Centre. Complaints were not forthcoming, however, when developed country financial assistance was used for setting up specialised independent agencies such as ACWL which work in a completely transparent manner, or alternatively where the financial assistance has resulted in the creation of or support for NGOs with credibility and strong transparency such as CIEL, ICTSD etc. Due to the perceived independence and the quality of the institutional facilities being maintained by these institutions, there was a very high level of acceptance, confidence and success.

**Recommendations:**

- 4. *Given that such NGOs tend to be established at an international level mainly concentrated in Geneva, Switzerland, there is a need to replicate their models at the regional and national level so that the TA delivery exercise can be attuned and strengthened at the regional and national level policy debate relating to IP. Providing financial assistance and technical advice towards that end should be a priority.*
- 5. *Other centres can be established focussing on providing key advice on IP related issues such preventing abuse of IP rights, creating public-private partnerships and for IP management practices.*
- 6. *Since the US is one of the key players in providing TA, at the same time it is advisable to strengthen the role of NGOs in the US so that they can play an active role in restoring the balance of IP rights and the public interest.*

**Identifying Partners and Securing Funding for the Programmes**

**Awareness regarding TA opportunities**

This awareness varies not only from the country to country but also from the particular institutions/stakeholders within the country. For example, the governments especially



in respect of the patent offices were generally aware of the needs, but on the other hand, NGOs were not quite considerably aware of the TA opportunities.

**Recommendations:**

- a. *There is a need especially for stakeholders such as NGOs, universities and public research institutions for strengthening information dissemination relating to the technical assistance opportunities. It is recommended that a central web portal be instituted for providing information on technical assistance including financial assistance for the institutions from developing countries. This would be important as many of the institutions are unable to spend manpower and resources looking for opportunities.*
- b. *At the same time, the technical assistance component should also focus on the capacity building of NGOs in the developing countries by providing specific financial assistance.*
- c. *TA should also focus on capacity building by helping in setting-up procedures, infrastructure and employment of dedicated staff for identifying opportunities of TA available at the international level. To this end, the possibility of building an international platform should be considered where recipients and donors can be brought together.*
- d. *Periodic seminars can be organised to provide general information on the TA opportunities that exist at the international and regional level.*

**2. TA project initiation**

Most of the programmes were initiated either through informal talks or through formal procedures. Most often, the offers of TA were made by the providers rather than being initiated by the recipients. Recipients have been rather more passive than proactive. A number of reasons can be attributed to such a situation:

- a. Lack of TA opportunity awareness
- b. Lack of needs-assessment procedures
- c. Lack of cohesive action plan regarding IP

**Recommendations:**

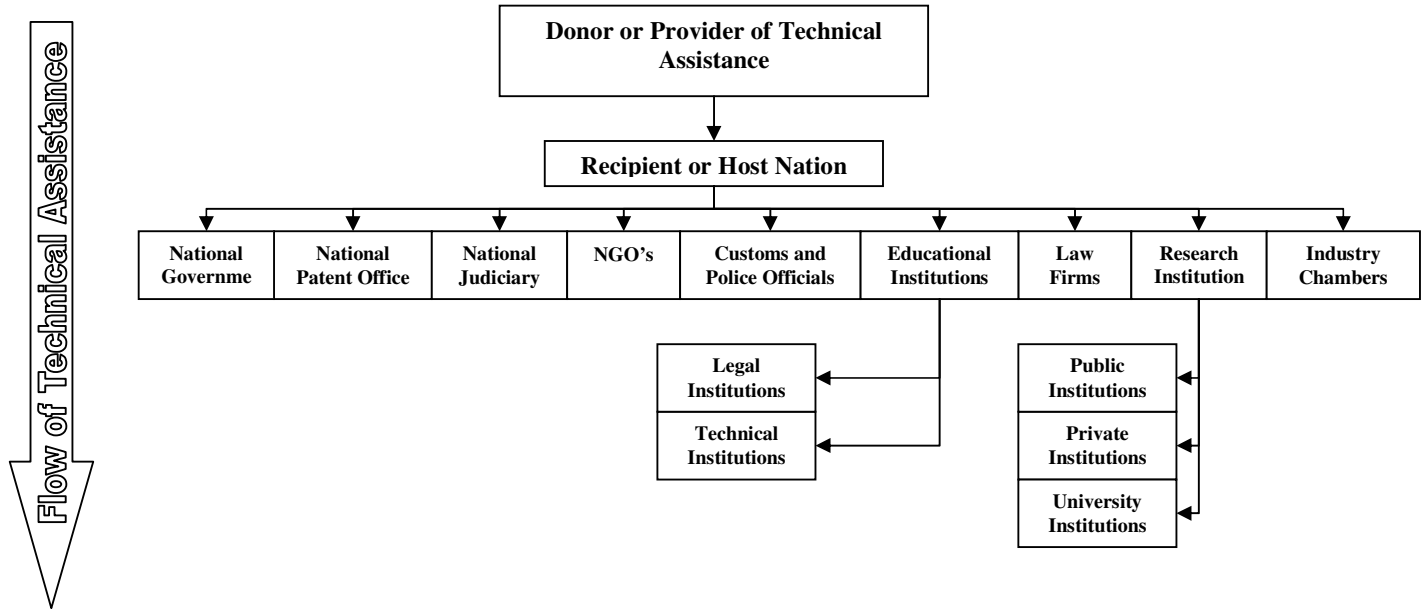
- a. *As stated earlier, the capacity building in terms of need assessment of the recipients organisations coupled with the increased awareness that would be built through the established network, will make the recipients more proactive in their approach for sourcing technical and financial assistance. Since the project would be mostly on the terms of the recipients, one could see significant benefits flowing through the TA exercise.*

**Lack of institutions focussing on developmental aspects of IPRs**

Related to the point explained earlier, there has been a strong presence and focus of the institutions providing TA on enforcement and protection. The other important areas such as management of IP, valuation of IP, use of IP as a commercial and research strategy tool, creating public-private partnerships, strengthening the local innovation system, prevention of abuse of intellectual property rights, have been neglected. These programmes, if available, are generally taken as part of a very large project in which IP management is a small component. Moreover, there are hardly any recognised or well respected TA providers focussing on these issues. There is an urgent need to address this issue if a pro-IP scenario is to be established in the recipient country.

**Recommendations:**

- a. As stated above, this lack could be addressed first by establishing certain IGOs or institutions through financial assistance. This could be achieved either through South-South participation, or following the model of ACWL.
- b. The other possibility could be for enhanced North-South cooperation whereby the developed countries could earmark some percentage of their TA funds specifically for these areas. Such a thematic approach in apportioning funds would ensure that these neglected areas would receive due regard in future.



**Figure 4: New approach to stakeholders in the recipient country**

**Government-centric approach**

There is too much emphasis on the government-centric approach in providing technical assistance to the recipients. This is coupled with the fact that the governments generally lack a specific holistic plan in respect of the technical assistance. It results in the exclusion of other stakeholders such as NGOs, research institutions, public educational institutions. Their participation in the TA delivery exercise is very important to ensure the developmental impacts of IP are felt including the diffusion of benefits of IP to all parts of society.

**Recommendations:**

- a. Although in many cases, due to the international character of the TA involved, it is difficult not to undertake programmes without the participation of government, but this situation is not mandatory or warranted where cooperation is sought with the NGOs, private institutions and autonomous research institutions. It is advisable that positive efforts should be undertaken to enhance participation of other stakeholders such as NGOs, law firms, industry chambers, autonomous research institutions so that the positive impact of TA can permeate across the broad spectrum of recipients and increases the quality of debate of IP in the developing and least-developed countries.

## **TA coordination**

There appears to be a serious lack of coordination on the part of the providers and recipients. TA often occurs in an ad-hoc and random fashion. There is little coordination amongst the different stakeholders from both provider and recipient sides. From the provider's perspective, there is no coordination amongst them at the international level. This scenario has resulted in two negative implications:

- a. TA Skewed towards a few countries
- b. Duplication of efforts

### ***Recommendations:***

- a. *This is an area which also requires considerable inputs from the both the recipients and the providers. The WTO has a database that provides information on technical assistance activities, but the information presentation is not obligatory on the institutions/countries or agencies. It is envisaged that any technical assistance being provided should as a matter of obligation be reported to the WTO.*
- b. *On the other hand, regional level information centres could be established from whereby the TA could be regulated and coordinated. A portal providing information on these aspects is a necessity and highly desirable.*

## ***Negotiating Technical Assistance Programmes***

### **Content and provider bias**

The training programmes tend to be skewed towards the enforcement and protection of rights without focussing on the other critical areas such as IP valuation, creation of IP, strengthening of the national innovation systems, etc. This scenario is also posing considerable hardship in building a pro-IP scenario in the recipient country because they are unable to appreciate the local benefits that can arise through the better management of IP. The primary reason for such emphasis on the TA is primarily due to the domination of the right holder's interest mainly arising from the developed countries.

### ***Recommendations:***

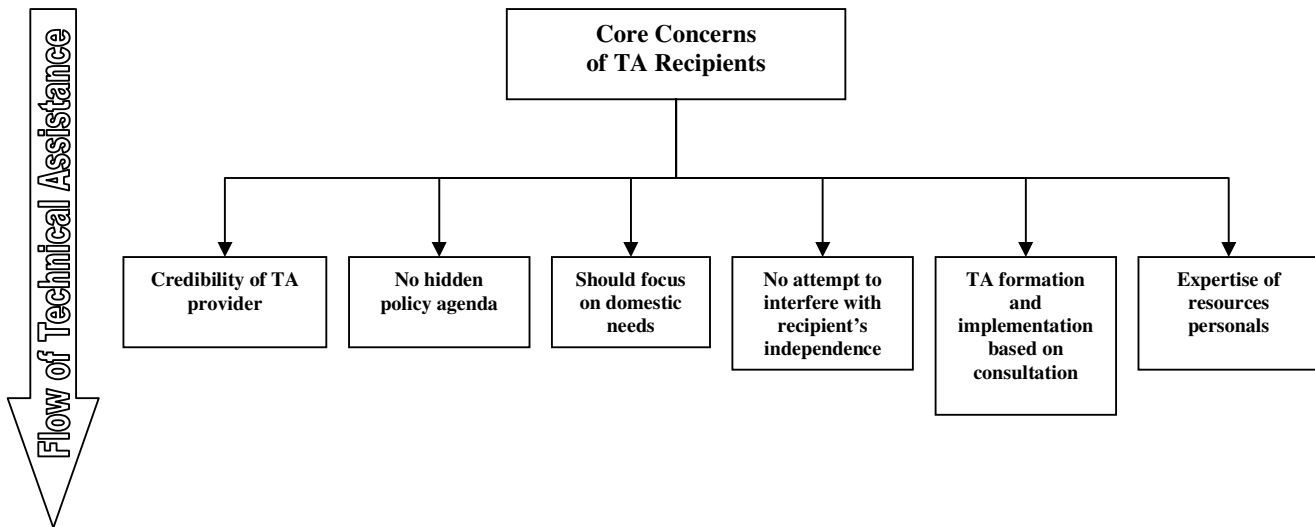
- a. *As stated above, the effective participation of the recipients from the project-conception to project post-follow up, capacity building in establishing need assessment procedures and creating awareness about the opportunities that are available in this area, will significantly address the issue of bias prevailing currently in the TA delivery exercise. Such concerns were found to be mitigated where a local partner was spearheading the programme. Therefore, creating a partnership with local bodies for delivering TA might be a good way forward.*
- b. *At the same time, the use of the term "Partnership Programmes" rather than "Technical Assistance", found more amenable attitude for future programmes amongst the interviewed stakeholders.*

### **Core concerns of TA recipients**

The TA recipient organisations have various concerns regarding the TA programmes conducted in the past. Most of them thought that the credibility of the TA provider is critically important. The other important concerns were: TA is not primarily focussed on the recipients' needs; it is generally driven by the policy agenda of the provider-

institutions; it is not adapted to take into account the local conditions; TA programmes are prepared and delivered without any consultations by the providers; and the technical assistance is generally made with many strings attached to it that interferes with the independence and functioning of the recipient institutions. However, these factors weighed differently for different stakeholders. For example, the NGOs were highly sensitive towards their independence in relation to any future technical assistance including financial grants; while the governments had strict criteria focussing on the credibility and suitability of the provider for executing a particular project.

Another major concern raised by most of the stakeholders was the use of the term “technical assistance”. According to them, the term deprives an equal status to the recipient stakeholder, which is often reflected in the behaviour of the provider institutions. It was suggested that a term such as “partnership programmes” should be used for defining future technical assistance activities.



**Figure 5: Core concerns of TA recipient stakeholders**

**Recommendations:**

- a. *The technical assistance providers should be aware of these core concerns of the recipients. The programmes of assistance should be designed effectively and with due participation of the recipients to address these concerns.*
- b. *The participation should be ensured from the very stage of the project conception to the project execution. Since there will be participation of the recipients organisation at each stage, their concerns arising at every stage will be adequately catered to and responded to.*

**Social, cultural and political factors affecting delivery of TA**

There were other factors that could affect the execution and coordination of technical assistance programmes. These factors do not directly arise from the relationship between recipient and provider, but nonetheless could influence the position of the recipient stakeholder to a major extent, both prior to and during the execution of the

programme. For example, the domestic political scenario is set to play an important role while negotiating a programme with the Indian government, where it has to seek views of its coalition partners. Thus, at any given stage, the Indian government has not only to respect the sensibilities of its coalition partners, but has also to evaluate its foreign policy issues that could arise from any future collaboration in respect of the technical assistance programme. Therefore, the concerned ministry will also seek clearance from the foreign ministry.

***Recommendations:***

- a. *Since in few instances these factors were overlooked and resulted in project delays, it is strongly advised that providers should understand and identify the stakeholders apart from the recipients who might be involved in the decision making or providing clearance to the technical assistance projects. This is of particular importance especially where the project directly involves a recipient's government organisation or department.*

***Actual Execution of the Technical Assistance Programme***

**Technical assistance programme design and methodology**

TA project execution was found often to be highly skewed towards classroom type learning sessions and seminars. This basically resulted in the unidirectional flow of information without providing much emphasis on the information exchange or participation of the recipients.

***Recommendations:***

- a. *It is to be emphasised that although TRIPS provides minimum standards on the intellectual property rights, there is a considerable variance in its actual implementation by many nations incorporating different legislative framework, enforcement procedures (criminal and civil procedure code, evidentiary requirements) and the use of flexibilities enshrined within TRIPS. This requires that the training exercise should be a mix of various techniques such as brainstorming sessions, discussions and case studies that are adapted to local situations. Incorporation of such mechanisms would ensure effective delivery of technical assistance and provide an opportunity to integrate local situations into the programme.*

**Programme duration**

It was also noted that with a few exceptions, most of the TA programmes were of short-term duration varying from either one day seminars to few week courses. Within these programmes, there was too much emphasis on knowledge imparting, and far less on long term skill development.

***Recommendations:***

- a. *The short term programmes are beneficial for imparting knowledge but they are not advantageous for imparting skills for example, in assessing patent application pertaining to a particular field of technology. There should be an urgent focus on undertaking long term programmes within the recipient countries and sustained level of programmes for the recipient organisations if new skills are to be developed for improving IP administration.*

### **Domination of TA delivery by lawyers**

There is too much domination by trade-industry lobbyists and the lawyers who are more active in the facilitation and conduct in the conduct of TA. Such predominance ignores or actually pre-empts the necessary policy dialogue relating to developmental aspects of IP thereby focussing on enforcement and IP protection. Such an arrangement also makes it unlikely to move away from the narrow confines of IP enforcement and protection. This is actually observed in the case of technical assistance provided by the US.

#### ***Recommendations:***

- a. Today IP criss-crosses a diverse range of topics such as health, agriculture and access to information. Apart from that, the creation, management, exploitation and regulation of IP require personnel with diverse professional backgrounds such as management, economics and science. Thus, the TA providers should draw on the strengths of different experts depending on the content of TA delivery exercise.*
- b. As stated above, earmarking of funds for different issues would help in drawing on the experiences of these professionals who have dual expertise in IP and the related subject matter such as agriculture or management.*

### **Obligations of recipients**

Although the effectiveness of TA is compromised to a large extent by the providers' conduct, yet in many instances the recipients were responsible and could not be absolved of the blame. The issues that frequently affected the quality of the TA delivery programme was the commitment levels of the participating personnel, strong bureaucracy, frequent changing of the lead ministry officials, non-coordination between various government ministries, sending non-appropriate personnel abroad for training were some of the issues that impacted the training and technical assistance. The absence of a national level IP policy and an integrated approach to TA needs has an adverse affect on the overall impact of the TA.

#### ***Recommendations:***

- a. The governments and the organisations should formulate long term IP strategy and accordingly once the targets and policies are defined with individual roles, effective participation can be ensured. Such a mindset could only be countered if the TA programme can emanate from needs-orientation of the recipients and emphasise on the benefits that would accrue to the nation in the long term by actual demonstrations.*
- b. At the project level, many of these issues could be addressed by undertaking effective participation of the recipients and joint evaluation exercises whereby issues can be pointed out and addressed.*
- c. Since it is frequently the higher authorities that guide the policy implementation, it is very important to ensure their participation in the programmes.*
- d. More emphasis can be placed to conduct programmes within the country by sending the experts rather than sending invitations for the participation in foreign countries.*

### **WIPO and its Technical Assistance Programme**

Technical assistance relating to legislative reforms by WIPO, a UN institution, and other bilateral providers has not adequately focussed on tailoring the IP regimes of the nations to their developmental needs. The TRIPS flexibilities within which the

countries could operate were either not explained or overlooked. In certain cases, even TRIPS-plus measures were introduced in the recipient country resulting in either excessive protection of subject matter even though there was hardly much creativity on these areas, or resulted in the maintenance of administrative structures resulting in high drainage of resources.

***Recommendations:***

- a. *There is not much transparency and information available on the TA delivery exercise taken by WIPO. Although WTO has initiated an independent evaluation of its TA exercise and has provided all information related to its TA exercise, WIPO has so far abstained from undertaking such an evaluation and information dissemination exercise. There is an urgent need to review the WIPO role in TA delivery as it is by far the largest and strongest player in the field.*
- b. *Although the development agenda seeks to redefine the role of WIPO, there is a further need to reorganise the administration and the practices of WIPO in providing TA.*

***Progress Monitoring, Evaluation and Post-follow up of the TA Programmes***

**Evaluation during project execution and post-evaluation**

Almost every technical assistance programme was subjected to very limited or almost negligible evaluation. Barring one or two projects, none of them involved any independent evaluators to undertake an in-depth assessment of the delivery or project execution. This has failed to provide any kind of quality feedback mechanism to improve future TA programmes.

***Recommendations:***

- a. *Despite a decade of technical assistance being provided by the developed countries and their institutions, there is hardly any remarkable progress in both the IP creation and IP protection in these countries. It is advisable that the programme once sponsored or undertaken should as a necessity have strong in-built independent evaluation procedures.*
- b. *It is advisable that evaluation should be undertaken by independent experts.*
- c. *Furthermore, there is a need felt to incorporate strict procedures for monitoring and evaluation to check regular progress of TA programmes through report preparation and/or financial audit reports. Even surprise personal inspections might be a good idea in order to obtain a first hand account of the efforts. However, these procedures should be put in place in consultation so that the participating institution does not feel that they are being forced into entering this scheme or that their independence is compromised. It is better to emphasize that the procedures are only to regulate the delivery of TA or to check financial viability rather than structured to control the contents of the TA.*
- d. *It might also be a good idea to nominate an independent agency to review the progress of the project/programme.*

**Post-follow up through “development impact assessments”**

Once again this critical area has been completely ignored. There have been no mechanisms or qualitative or quantitative targets being set in order to understand the development impact of the delivered TA and the actual implementation of the knowledge and skills acquired by the recipients.

***Recommendations:***

- a. This area could be addressed partly by providing long term programmes that would have in-built periodic evaluation strategies and benchmarks. However, at the same time, certain qualitative & quantitative targets could be specified in consultation with the recipients. For example, in terms of backlog of patent applications, a time period could be specified based on the training and resources being provided to the patent office.*
- b. Similarly, statistical basis could be used for measuring improvement in the enforcement training, while for research institutions, the best IP management practices could be incorporated with the targets being defined as establishing technology transfer offices and IPR institutional policies.*



## **7. IDENTIFYING EFFECTIVE CAPACITY BUILDING MEASURES FOR THE IMPLEMENTATION OF ACCESS AND PROPERTY RIGHTS LEGISLATION IN THE AREA OF AGRICULTURAL BIODIVERSITY**

### **Abstract**

This report addresses the International Treaty on Plant Genetic Resources for Food and Agriculture (hereinafter ITPGRFA), its implications for developing countries and how developing countries can cost-effectively implement it. The report is based on the review and analysis of existing literature and the pertinent legal and political documents. Moreover, it takes into account interviews conducted with a number of experts in different countries and the results of a survey conducted among other experts on the ITPGRFA and related issues.

In its first section, the report describes deficiencies of the system for the protection and sustainable use of PGRFA existing prior to the adoption of the international treaty and briefly outlines in what way the treaty can be conceived of as a response to these deficiencies. In the second chapter, an overview of the historical context and the negotiation history are presented. The following chapters are dedicated to a more detailed discussion of the provisions of the treaty concerning the conservation and sustainable use of PGRFA as well as farmers' rights. Moreover, the multilateral system for access and benefit-sharing, mechanisms for enforcement and compliance and the financial provisions of the treaty are discussed. With regard to all of these provisions, particular emphasis is put on the obligations and burdens that developing countries are faced with as a result of the treaty as well as the advantages they are likely to have from it. Finally, the study also discusses the relationship of the ITPGRFA with other international agreements related to PGRFA, the TRIPS Agreement, the UPOV Convention and the Convention on Biological Diversity.

### **1 Introduction: The ITPGRFA as a response to pressing problems**

The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) is the first international agreement focusing specifically on the conservation and sustainable use of plant genetic resources for food and agriculture (PGRFA) that is legally binding. It seeks to ensure both the conservation of and access to PGRFA, which are necessary to provide food security in the foreseeable future. The treaty was adopted at the Conference of the Food and Agriculture Organization of the United Nations (FAO) in November 2001. Following its fortieth ratification, the treaty entered into force on 29<sup>th</sup> of June, 2004. The ITPGRFA is largely a response to pressing problems in the field of conservation and sustainable use of PGRFA as well as deficiencies of the legal framework existing at the international level before the adoption of the ITPGRFA. This section will shed light on some of the problems and deficiencies in the realm of conservation and sustainable use of PGRFA, which existed prior to the adoption of the ITPGRFA, and in a second step briefly outline in what way the ITPGRFA provides a response to these problems.

#### ***1.1 Significance of PGRFA***

As stated in the ITPGRFA, plant genetic resources for food and agriculture (PGRFA) are genetic material of plant origin, including reproductive and vegetative propagating material of actual or potential value for food and agriculture. In other words, PGRFA refers to the genetic

resources contained in plants or seeds, as opposed to the plants or seeds themselves that have value for food and agriculture.

PGRFA are of utmost importance to plant breeders and farmers and indeed to all people on the planet. PGRFA are the “raw material” that plant breeders use to improve crops and introduce new traits into them. Thus, PGRFA can and will play an important role in meeting the challenges of local, regional and global food security, as they allow us to optimise crops according to our needs. Drawing on genes from existing varieties of plants, crop breeders are able, using either traditional crop breeding methods or new genetic technologies, to develop new crop varieties that express desirable traits. By incorporating, for example, genes from a drought-tolerant plant species into an existing crop variety, plant breeders could conceivably develop a new variety that grows particularly well in arid conditions.

PGRFA are thus critical for the continued development of new plant varieties and are an integral component in the efforts to:

- meet human needs for food, health and economic security;
- reduce agricultural pressures (chemical inputs, ploughing, etc.) on the environment; and
- adapt to changing weather (drought, salinity) and ever evolving pests and diseases.

Since the advent of agriculture and the domestication of the first crop species, PGRFA have been distributed and exchanged around the world. For each crop there is one or more centre of origin from where it was introduced into other regions. In some cases, local adaptation has led to the emergence of secondary centres of high biodiversity for specific crops. These centres are important natural repositories for PGRFA. High rates of genetic exchange between crop species and their wild relatives and heterogeneous climatic conditions have led to development of a large number of varieties including valuable adaptations to environmental and biological stresses. There has always been substantial exchange of PGRFA between centres of diversity and other regions. Crop species were initially distributed with the expansion of agriculture into new areas. Later, they were exchanged along trade routes between the Arabian Peninsula, East Africa, Europe and Asia. The exploration of the new world opened the way for the collection of new plant species and the introduction of important crops such as maize and potatoes into Europe and wheat and rice in the Americas. Today, the viability of crop species cultivated around the world still relies heavily on the supply of genetic material from the respective centres of diversity. This constant inflow of new genetic information is essential because agricultural production faces the challenge of a continuously changing physical and biological environment. PGRFA contain information that has been generated within the relevant biological context. It is not biodiversity *per se* that is important, but rather the information to be gained from the characteristics that have evolved within a living environment that is most likely to make a contribution. A landrace can thus be seen as a stock of information about previously successful strategies. This information serves as valuable material for innovations in agricultural research, for instance a pest-resistant, high-yielding variety. Over time however, yields in the most intensely cultivated varieties are bound to decline as the environment changes. Traits and characteristics that were advantageous under previous conditions are no longer advantageous under changed ones. Pests and pathogens will adapt sooner or later to the resistance that has been introduced into a crop. Once the pathogen has developed a strategy to break down these defence mechanisms, the genetic information has lost its value. This means that plant breeders need to introduce new traits continuously in order to maintain a certain level of productivity.

Up until now, the majority of these inflows was in the form of transfers of PGRFA from regions of high crop diversity to those of lower diversity. However, studies have shown that most countries' food production is highly dependant on crop species originating in other countries. The rate of dependency ranges from about 30% in West and Central Asia to more than 90% in Europe and almost 100% in North America and Australia. Even those countries that are centres of origin for some crops source more than 50% of their food production from crops domesticated in other regions. Today all countries are net recipients of germplasm for almost all crop species. Companies have to renew their stock of genetic resources at a rate of about 7% per annum in order to compensate for naturally occurring depreciation of genetic information. This implies that wild relatives and landraces are being accessed at a rate that renews the stock of genetic information every 10-15 years. Without this inflow of new genetic information, the current system for maintaining agriculture could not be sustained.

## ***1.2 Deficiencies of the existing system for the protection of PGRFA***

### **1.2.1 Continuing genetic erosion**

Despite their global importance, however, a serious loss of PGRFA has occurred over the last century and there is a threat of further genetic erosion. As far back as 1996 the FAO, in a report based on 151 individual country reports, stated that few could doubt that there had been substantial loss of diversity in PGRFA. In China, for example, approximately 90 per cent of the 10,000 wheat varieties that were grown a century ago have disappeared, and in Mexico an estimated 80 per cent of the maize varieties cultivated there only 70 to 80 years ago are gone. Measuring the precise loss of agro-biodiversity is, however, not an easy task. Efforts are being made to develop reliable methods and indicators to this end.

Modern commercial agriculture is often blamed with being the main culprit for the incurred losses in agricultural biodiversity. Since the advent of agricultural systems, farmers have developed tens of thousands of crop varieties of a wide range of species for food production. Today, however, four crops alone (maize, potato, rice and wheat) provide approximately 65 per cent of the world's caloric intake; rice and wheat alone are each responsible for 25 per cent of the total plant-derived energy supply. Modern systems of agriculture have, in many cases, increased crop yields and food security. However, contemporary agriculture's tendency towards monoculture, global seed production and distribution, the move from traditional agricultural crops to planting cash crops for export, the abandonment of traditional farming practices and heavy reliance on a small group of core crops has had dire effects on the diversity of PGRFA. As old varieties in farmers' fields are replaced by newer ones, genetic erosion frequently occurs because the genes and gene complexes found in the diverse farmers' varieties are not contained *in toto* in the modern variety. In addition, the sheer number of varieties is often reduced when commercial varieties are introduced into traditional farming systems. In subsistence systems, farmers can derive benefits from maintaining a large portfolio of varieties that combine various bundles of traits suitable for specific agronomic and climatic conditions, local consumption preferences, and which help to manage risk in what are often precarious environments. The benefits of diversity diminish with economic development and the geographical expansion of market links. Farmers become less reliant on crop diversity as the market "decides" what crops and varieties they should grow, and these tend to be far more limited in quantity. But this is not all. One problem that prevents the continued maintenance of a high number of varieties is that traditional farmers cannot appropriate the value they generate through the creation and maintenance of PGRFA. Their contribution to the global pool of PGRFA occurs as an externality of their production decisions rather than as a tangible private value that a farmer seeks to create for his own

benefit. Farmers thus have little incentive to continue providing it, once their private interest in maintaining biodiversity has diminished.

In the 1970s the need to preserve and make accessible collections of crops, wild relatives and genetic material led to the establishment of gene banks as *ex situ* repositories for such collections. At present there are nearly 1500 collections of plant genetic resources around the world, holding about 6 million plant samples. Although some of these are duplicates, there are still over 2 million originals. Nearly two thirds of these are in developing countries, and more than one third of all accessions are stored in 15 national gene banks.

### **1.2.2 Lack of institutionalised farmers' rights**

The lack of legal and political recognition of farmers' rights may also be considered a deficiency. The term "farmers' rights" was coined in the early eighties in order to draw attention to the contributions of farmers to conserving and developing biodiversity and the need to legally recognise certain related rights of farmers. Although the term has played a role in international negotiations since then, it remains somewhat vague with respect to its political, and especially to its legal, content. However, several important elements of the concept may be identified and are pointed out in the relevant literature.

First, a central component of implementation of farmers' rights would be to grant farmers continued free access to PGRFA, in particular for breeding purposes, and the freedom to exchange and sell harvested material. There is no international treaty which explicitly and positively recognises such a right while there is, at the same time, no treaty that prohibits countries from setting forth such rights in their respective legal orders. In particular, UPOV 1991, which is generally concerned with the protection of plant breeders' rights, contains the so called farmers' privilege. While the farmers' privilege has changed over time subject to revisions of the UPOV Convention, under UPOV 1991 "each Contracting Party may, *within reasonable limits* and subject to the safeguarding of the legitimate interests of the breeder, restrict the plant breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety..." (italics added). Thus, members of the UPOV are free, within certain limits, to determine what legal competences flow from a plant breeders' right which is granted in accordance with national legislation implementing UPOV. They may restrict breeders' competences in favour of farmers. Nonetheless, the rights that farmers may be granted according to UPOV are conceived of as an exception towards the rights which plant breeders enjoy. It was not the purpose of UPOV to award farmers any legally-binding, self-standing right by UPOV while the rights of plant breeders' are positively stipulated.

The only international document to explicitly recognise rights of farmers not just as an exemption in relation to plant breeders' rights, was the FAO's non-binding 1983 International Undertaking on Plant Genetic Resources ("The International Undertaking" or "IU"). It recognised the "enormous contribution of farmers ... to the conservation and development of plant genetic resources ..." and endorsed the concept of farmers' rights. This recognition, however, ultimately had very limited significance. First, the International Undertaking did not delineate the concrete rights to be guaranteed to farmers, and instead defined them only as "rights arising from the past, present and future contributions of farmers in conserving, improving, and making available plant genetic resources ..." Moreover, the International Undertaking never became a binding agreement, but instead remained voluntary in nature.

Thus, prior to the ITPGRFA there was no international, legally binding agreement acknowledging farmers' rights.

Another important part of a realization of farmers' rights would be to give them some kind of compensation for the use of PGRFA and related traditional knowledge originally developed by them, i.e., to share the benefits arising from the use of such resources with them. Also this right was not recognised in any legally binding way by the pre-ITPGRFA legal framework.

### **1.2.3 Insufficient prior informed consent and benefit-sharing**

The pre-ITPGRFA legal framework was thus considered to be insufficient because it did not efficiently address the loss of agricultural biodiversity, and it did not contain any legally binding recognition of farmers' rights. Moreover, it was also considered to be in need of amendments, with a view towards sharing the benefits arising from the commercial use of PGRFA. As pointed out in the previous section, this can also be understood as a lack of recognition of farmers' rights.

The 1992 Convention on Biological Diversity (CBD) was a landmark agreement in that it was the first international treaty to link access to genetic resources to "fair and equitable" sharing of benefits derived from those resources (Articles 1, 8 (j), 15, 16 and 19 of the CBD). In the wake of the adoption of the CBD huge expectations arose, since the annual global market for products derived from genetic resources lies at an estimated US\$ 500 to 800 billion.

However, the current benefit-sharing system under the CBD has been disappointing, since there have been very few transactions so far. This is partly due to the fact that the treaty itself is quite flexible with regard to required benefit-sharing. There are two major problems. First, the CBD does not give much guidance as to who are the responsible institutions for implementing benefit-sharing and who are the holders of rights and obligations. Second, the rights and obligations related to benefit sharing are not clearly defined. For example, the term "fair and equitable" has never been defined. A number of recommendations of what could constitute benefits have been adopted, but the CBD ultimately leaves the decision about benefits up to the parties involved, which opens the door to controversies about how high a percentage of the final product is to be attributed to the original genetic resource. The non-binding Bonn Guidelines of the CBD, adopted in 2001, are an attempt to set forth more in detail rules for access to genetic resources and the sharing of benefits resulting from their use. The guidelines stipulate that resource recipients are required to disclose the intended use of and expected profits from the genetic resource in question and obtain the consent of the country of origin, and relevant indigenous and local communities. This procedure is called prior informed consent (PIC), and the Bonn Guidelines recommend it for reasons of fairness. In addition, resource recipients shall pay in proportion to the benefit they receive from using the genetic resource. Such benefits, e.g. resulting from the marketing of a product developed from a certain PGR will normally be higher than the value of the as-yet undeveloped resource.

Unfortunately, the CBD system of benefit-sharing proved to suffer from some very serious shortcomings. In the first place, the Bonn Guidelines are a non-binding, non enforceable addition to the vaguely formulated Article 15.1 CBD. This also makes the PIC and benefit-sharing requirements a voluntary mechanism, although the Bonn Guidelines recommend it for all exchanges of genetic resources. Accordingly, the international framework's inability to prevent or discourage the uni-directional and uncompensated appropriation of genetic resources, which is also sometimes called "biopiracy", has been cited as one of its primary

failures. While such “biopiracy” cases tended to be associated with pharmaceuticals rather than agricultural products, cases of use of agricultural PGRFA without obtaining the necessary prior informed consent and conclusions of any benefit-sharing arrangement exist as well. Some well known cases where genetic resources were patented without an existing access contract with the provider country or PIC of the indigenous peoples concerned include the enola bean and the ayahuasca plant, as well as basmati and jasmine rice.

Moreover, the complexity of the process, the requirement of including all stakeholders, the difficulty of determining the relevant governmental body or the relevant indigenous tribe from whom to get PIC, the complicated procedure of including third parties and the initial inexperience of lawmakers have led to great confusion and administrative problems.

Aside from the procedural difficulties associated with PIC and benefit-sharing under the CBD, the “international” nature of PGRFA made a bilateral approach towards benefit-sharing, like the one that has been preferred under the CBD so far, seem inappropriate. As noted earlier, PGRFA have been developed through the exchange of genetic material over thousands of years. It is in many cases difficult to establish a sole nation of origin for a plant variety. Indeed, as noted by Brush, “[t]he diffusion of crops beyond their original cradle areas ... is a dominant pattern of crop evolution”. This presents a clear challenge for a system of access and benefit sharing that, like the CBD, emphasises national sovereignty over genetic resources. Because in many cases it is impossible to definitively identify the source of origin for a lot of PGRFA, it is equally impossible to identify the sovereign body authorised to provide access to them.

Finally, even in the event that sources of origin *could* be identified for all PGRFA, it would nevertheless be the case that a huge amount of genetic resources, often from a number of countries, are used together in plant breeding activities. Pursuing bilateral access and benefit-sharing (ABS) agreements with each country of origin for PGRFA used in developing a new variety could be very expensive, to the extent that the transaction costs could end up outweighing the benefits to be shared.

### ***1.3 The ITPGRFA as a response to existing deficiencies***

As we have seen, the pre-ITPGRFA legal framework on PGRFA suffered from several shortcomings. Three important limitations were the progressive genetic erosion of PGRFA and loss in agricultural biodiversity, a lack of institutionalisation of farmers’ rights as well as the frequent absence of prior informed consent and benefit-sharing arrangements.

The ITPGRFA is a response to some of these shortcomings. It is aimed at the conservation and sustainable use of PGRFA. To this end, it does not only stipulate obligations for the contracting parties concerning their conservation, sustainable use and pertinent measures, but it also creates a mechanism for access to at least many of the most important PGRFA and benefit-sharing resulting from their commercialisation. This so called Multilateral System will be described in greater detail in section 6 of this report. It should, however, be noted at this point that the Multilateral System is a response to some of the shortcomings of the CBD concerning the consent of providers for access to PGRFA, pertinent arrangements for benefit-sharing and the distribution of monetary benefits. The Multilateral System essentially creates a mechanism for facilitated access to many of the most important PGRFA by the contracting parties and sets out detailed rules to this end. Moreover, a model contract, the so called standard Material Transfer Agreement (SMTA), has been agreed upon pursuant to the ITPGRFA, which individuals or legal entities obtaining PGRFA from the system have to sign.

Therein rules for benefit-sharing are set forth. Moreover, a fund has been established to which monetary contributions which are part of the benefit-sharing arrangements will flow. The Governing Body of the ITPGRFA is entrusted with the task of distributing the incoming payments. The ITPGRFA thus makes it much clearer than the CBD who is to get access to the PGRFA that are part of the Multilateral System, and under which conditions. Moreover, the rules are easier to understand and abide by. In addition, the ITPGRFA sets up an international enforcement mechanism. Thus, the rules are also enforceable to an extent - at least there is a mechanism for settling controversies. Due to all these factors, compliance with the ABS rules of the ITPGRFA is more likely to occur than under the CBD. Finally, the ITPGRFA also is the first legally binding international agreement to recognise farmers' rights, even though it does so in a relatively weak form. As will become clearer in section 5 of this report, the recognition of farmers' rights by the ITPGRFA may thus not be as big a step forward as some claim.

## **2 Brief history and background of the ITPGRFA**

Having outlined some of the factual background why the adoption of the ITPGRFA was necessary, the report will now provide a brief history of the events and legal developments leading to the negotiation and eventual adoption of the ITPGRFA.

### ***2.1 Historical Context***

The international treaty (IT) is a very recent development, having been adopted on 3 November 2001 and entering into force on 29 June 2004. Moreover, the treaty is still in the process of being put in its final shape, as negotiations continue in a number of areas. The treaty is innovative in a number of ways, yet it is also best understood as the result of a process originating over 20 years ago with the FAO's International Undertaking on Plant Genetic Resources for Food and Agriculture.

As stated above, in 1983 the FAO adopted the non-binding International Undertaking on Plant Genetic Resources for Food and Agriculture, the first comprehensive international document dealing with plant genetic resources for food and agriculture. The objective of the International Undertaking, set forth in its Article 1, was "to ensure that plant genetic resources of economic and/or social interest, particularly for agriculture, would be explored, preserved, evaluated and made available for plant breeding and scientific purposes". Importantly, the International Undertaking was "based on the universally accepted principle that plant genetic resources are a heritage of mankind and consequently should be available without restriction". Given this principle, the International Undertaking obliged parties to make genetic resources under their control available "free of charge, on the basis of mutual exchange or on mutually agreed terms".

Concerns were, however, raised with regard to the International Undertaking's compatibility with plant breeders' rights under UPOV, lack of recognition of farmers' contributions to innovation and conservation, and lack of recognition of sovereign rights over genetic resources. Recognising the concerns that had been raised by some countries with regard to the International Undertaking, in 1989 the FAO Conference adopted a series of agreed interpretations of the International Undertaking. These agreed interpretations stated that plant breeders' rights, as provided for under UPOV, were not incompatible with the International

Undertaking, and recognised “the enormous contribution that farmers of all regions have made to the conservation and development of plant genetic resources, ...” Furthermore, they endorsed the concept of farmers’ rights in order to, *inter alia*, provide farmers with financial and other assistance for the conservation and protection of plant genetic resources, and “... 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...” In 1991, the FAO Conference explicitly stated that nations had sovereign rights over their plant genetic resources and that breeders’ lines and farmers’ breeding material should only be available at the discretion of their developers during the period of development. Furthermore, the Conference recognised that “... conditions of access to plant genetic resources need further clarification; ...” These interpretations of the International Undertaking complicated its originally clear purpose of ensuring unrestricted access to genetic resources.

Apart from the International Undertaking, one of the antecedents to the ITPGRFA is the Convention on Biodiversity (CBD), with which the IT shares many commonalities. Although there is substantial overlap between the CBD and the ITPGRFA, the CBD is directed at all biodiversity, which in a number of ways described above already, limited its usefulness as an instrument for dealing with PGRFA. Moreover, the CBD is also firmly based on the principle of national sovereignty over plant genetic resources, which is a clear departure from the common heritage principle contained originally in the International Undertaking. Resolution 3 of the Nairobi Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity of 1992 referred to two outstanding PGRFA issues to the FAO for further consideration. The first of these issues was access to those *ex situ* collections, which are not covered by the CBD’s provisions, because they were established prior to the adoption of the CBD. The second of these issues was farmers’ rights which are not explicitly addressed by the CBD, even though the CBD does recognise that the individuals and communities who contribute towards developing and maintaining biological diversity are entitled to getting a share of the benefits arising from its use.

## **2.2 Brief negotiating history**

Pursuant to Resolution 7/93 of the 1993 FAO negotiations commenced at the first extraordinary session of the Commission on Genetic Resources for Food and Agriculture (CGRFA) held in Rome from 7-11 November 1994. Although the original duration of the negotiations was planned for less than two years, negotiations would not be concluded for more than seven years and would span more than 15 meetings, including regular and extraordinary sessions of the CGRFA and a series of inter-sessional contact group meetings in 2000/2001. On 3 November 2001 the International Treaty on Plant Genetic Resources for Food and Agriculture was adopted by the 31<sup>st</sup> session of the FAO Conference. The Treaty has since been signed by 78 countries, and entered into force on 29 June 2004, 90 days after the deposit of its fortieth instrument of ratification, acceptance, approval or accession.

## **3 Conservation of PGRFA**

One of the stated goals of the treaty is the conservation of PGRFA. Article 5 outlines a general framework to this end.

### **3.1 Obligations in the ITPGRFA**



Article 5.1 states that contracting parties shall, “*subject to national legislation*“ [emphasis added] ...promote an integrated approach to the exploration, conservation and sustainable use of PGRFA. This includes conservation of PGRFA both *in situ* (in its natural habitat) and *ex situ* (in seed banks and other artificial repositories of genetic material). Article 5.1 states that contracting parties shall, “*as appropriate*“ [italics added], undertake a series of actions outlined in Articles 5.1 (a) to 5.1 (f). It should be noted that the phrases “subject to national legislation” and “as appropriate” clearly indicate that while the contracting parties are obliged to have some sort of legislative framework and the necessary institutions to promote this integrated approach, the specific features of that framework are left at the discretion of the contracting parties.

Specific non-binding suggestions of the Article include to:

- a) survey and inventory PGRFA,
- b) collect PGRFA,
- c) promote farmer management of PGRFA,
- d) facilitate *in situ* conservation of PGRFA,
- e) finance the *ex situ* collection, preservation and maintenance of PGRFA, and
- f) monitor the status of PGRFA.

There is a wide range of possible interpretations of the “requirements” concerning the ITPGRFA’s first purpose of conserving PGRFA. A Member State could interpret the text to require extensive wildlife preserves for the *in situ* protection of the distant genetic relatives of currently used PGRFA. On the other hand, a Member State could determine that the requirement of conservation demands no more than the minimal protection that the nation already provides.

Article 5.2 states that parties shall, again “as appropriate”, take steps to minimize or eliminate threats to PGRFA. Concrete steps in line with this provision could include, for example, “collecting resources for *ex situ* maintenance, the development of *in situ* conservation actions, adoption of agricultural practices which enhance the use of a diverse mix of varieties and the maintenance of genetic diversity in crop varieties by broadening the genetic base of materials in production”. *Ex situ* conservation of genetic resources is essential to provide ready access to germplasm where needed, but also to conserve biodiversity that might otherwise be lost in nature. However, better understanding of the relationship between *in situ* and *ex situ* is needed to facilitate the “inclusion of *ex situ* conservation efforts within current environmental policies conserving global diversity”. *In-situ* conservation programmes are often very expensive, even for developed nations. In 1991, the World Bank estimated that the cost of total world biodiversity conservation programmes would be between \$500 million and \$50 billion per year (based on an estimate of \$35,000 per square km). While *in situ* conservation must generally be achieved through national programmes and international assistance, *ex situ* conservation can be achieved through the use of existing international repositories of genetic material. The Consultative Group on International Agriculture Research (CGIAR) oversees the operation of 15 International Agriculture Research Centres (IARCs) throughout the world. These centres collect and maintain all forms of genetic material, which ITPGRFA Member States may obtain from the Multilateral System. *Ex situ* conservation may, however, also be costly. The CGIAR’s total expenditures in 2004, for example, were USD 425 million, and over 12 per cent, more than USD 50 million, was spent on the collection of germplasm.

### 3.2 Consequences for developing countries

As is the case with any international treaty, implementation requires some effort by the parties to the treaty. This may be especially problematic for developing countries where resources are scarce. In the following, we will briefly shed some light on what the ITPGRFA demands from developing nations with regard to conservation in light of the above mentioned general requirements. It should be noted, however, that at least among the experts interviewed for purposes of this study, there is significant disagreement about whether the ITPGRFA will increase conservation activity costs.

Fortunately, most nations, developing nations included, have already established some national framework for the conservation of biological resources in general, thus limiting the start-up costs of establishing such a framework. However, the environmental or conservation programmes in some countries are so rudimentary and under-funded that, despite their stated goals, they do not even provide the above protections. Moreover, *in situ* conservation is disproportionately burdensome for developing nations, which contain most of the world's biodiversity and yet have fewer financial resources available for governmental programmes in general.

The ITPGRFA attempts to alleviate the burden of implementing conservation measures by including qualifications for developing nations and requiring developed nations to provide developing nations with technical and financial assistance. Article 18.4 (b) of the treaty requires Member States to accord due priority in their national plans to programmes that build capacity in PGRFA. However, national conservation programmes are only required to the extent that they are "in accordance with [the Member State's] national capacities and financial resources" (Article 18.4 (d)). In other words, developing nations are only required to comply with the conservation requirements of ITPGRFA to the best of their abilities. What that "best ability" might entail in the short, medium or long term is unclear, but it may be assumed that in some cases it will be insufficient to satisfactorily conserve the existing PGRFA. Moreover, the ITPGRFA also requires developed nations to assist developing nations in meeting their obligations under the treaty. This capacity building will be directed towards conservation, documentation and preservation (as well as benefit-sharing and access) in particular (Article 7.2 (b)). Furthermore, the FAO will provide legal assistance to developing nations in drafting harmonious national legislation.

Moreover, with regard to *ex-situ* conservation, developing nations could benefit from outsourcing most of the responsibilities for *ex situ* conservation to IARCs, since the collection of material and its effective storage require great amounts of expertise and money. In addition, developing nations relying on IARCs would not be burdened with the costs of processing MTAs, training staff, expert review, overhead, etc. As a potential drawback, it might be too great a workload for CGIAR to effectively take on the additional burden of being the sole *ex situ* repository for most developing Member States of ITPGRFA. However, if the benefit-sharing system is successful in exacting payments from recipients, the Governing Body can devote an appropriate share of the aggregate benefits to CGIAR to help the institutions meet this burden.

Moreover, Article 5 ITPGRFA requires surveying existing PGRFA and monitor existing *ex-situ* collections. These could be integrated with the reporting requirements of at least the CBD and possibly other conventions. Existing databases could be used. Most of the work on reporting under the CBD is ongoing and could be easily enlarged in scope to accommodate special reference to PGRFA. Currently, CBD members are involved in preparing their third

national reports that will focus on the state of implementation of their respective National Biodiversity Strategy and Action Plans (NBSAPs) or have already submitted such reports. Such reporting requirements and present opportunities for developing countries to adjust existing activities which are already largely funded under the CBD to fulfil their obligations under Article 5 ITPGRFA. Moreover, the 7<sup>th</sup> Conference of the Parties to the CBD (COP7) stated that new and revised NBSAPs should be formulated. Decision VII/30 suggests a set of indicators to assess the progress made in preventing further loss of biodiversity at the global or regional levels. Such indicators may also be used by parties to the ITPGRFA in order to comply with their surveying and monitoring obligations.

Moreover, governments have an obligation to report on the progress of the implementation of the Global Plan of Action (GPA), which was adopted at the International Technical Conference on Plant Genetic Resources on 23 June 1996. A growing number of databases and networks on PGRFA, including on traditional knowledge, have been established, subsequent to the adoption of the Global Plan of Action. A cost-effective alternative to establishing new databases would be to survey the existing databases and initiatives and to standardise them to make them easily searchable. For example, the FAO Seed and Plant Genetic Resources Service, which manages programmes for seed policies, seed improvement, seed production, seed security and germplasm exchange, runs several databases containing information on crop varieties and breeding and research activities worldwide, including plant genetic resources for food and agriculture.

#### **4 Sustainable use of PGRFA**

The ITPGRFA is tailored to promote access to genetic material for purposes of research and breeding. However, access to genetic resources alone is not enough. As noted above, genetic erosion may also occur under conditions of open access to PGRFA (see section 1.2.1 about problems with the pre-seed treaty framework). The treaty therefore promotes the sustainable and responsible use of PGRFA.

##### ***4.1 Obligations in the ITPGRFA***

Article 6.1 states that parties shall “develop and maintain appropriate policy and legal measures that promote the sustainable use of [PGRFA]”. Importantly, this article represents the first substantive, unqualified obligation of all parties to the treaty (as opposed to Article 5, which is “subject to national legislation” and “as appropriate”). However, it only requires parties to promote “appropriate” policy and legal measures, which allows the contracting parties to exercise discretion with regard to which measures they want to take. Moreover, the list of illustrative measures that may be considered “sustainable use”, outlined in Articles 6.2 (a) to (g), is not binding, and rather serves to give some examples of actions that could be used to comply with Article 6.1. Problems may not only arise from the lack of definition of sustainable use and the neither exclusive nor binding list in Article 6, but also due to the open wording of some of the measures named, e.g. “desirable farming” or “beneficial research”, as these allow countries to assess themselves what they consider to be “desirable” or “beneficial”. Countries could thus come to very different results depending on the political will and goals of the respective country.

The measure specified in Article 6.2, include:

- a) sustaining beneficial farming systems;
- b) maximising intra- and inter-specific variations of plant varieties;

- c) promoting plant breeding efforts with farmers;
- d) broadening the variety of genetic material available to farmers;
- e) promoting locally adapted varieties;
- f) promoting crop diversity, sustainable use and conservation as well as developing links between farmers and plant breeders; and
- g) reviewing and adjusting breeding strategies and regulations concerning which varieties are released for use.

The Governing Body of the ITPGRFA during its first session in June 2006, while refraining from taking any concrete decisions concerning the implementation of Article 6, decided that it should be a priority issue on the agenda of future meetings.

#### ***4.2 Consequences for developing countries***

Again, fulfilling these obligations may be especially problematic for developing countries where resources are scarce. In the following, we will briefly discuss some consequences of the ITPGRFA obligations relating to sustainable use for developing countries.

Generally, the ITPGRFA requires developed nations to assist developing nations in meeting the treaty's second purpose of promoting sustainable use. Article 7.2 (a) requires developed nations to help developing nations to strengthen their capabilities for sustainable use of PGRFA. Article 13.2 specifies some of the capacity-building activities that developed nations should promote in developing nations. These activities include:

- establishing programmes and facilities for scientific and technological education and training in conservation and sustainable use of PGRFA; and
- conducting research in developing nations in co-operation with their own experts.

*In situ* on farm conservation is an effective strategy of sustainable use. PGRFA that are being used are being actively conserved. However, trends in recent years of farmers switching from the traditional landraces to higher yield crops are also visible in developing countries. The value of incentive schemes to conserve agricultural biodiversity *in situ* on the farm has been explored and is suggested as a useful mechanism by some donor agencies. Non-economic incentives used could be information, capacity building and awareness-raising. One way to arrive at a coherent strategy is to study examples of good practice which have been successful in assuring conservation and sustainable use of traditional landraces and farming practice and find a way to replicate them. In doing so, existing networks and databases under the FAO and CGIAR can be utilised.

An example of good practice, initiated by ITDG (Intermediate Technology Development Group), is the setting up of regional seed exchange fairs in Zimbabwe and Kenya. In Peru, seed exchange fairs are a traditional, agricultural and spiritual practice. Exchange visits between Zimbabwe and Peru resulted in seed exchange fairs being established in Zimbabwe. The seed fairs started in 1997 with 134 displayed varieties. In 2001, 206 varieties were displayed. The shows have many advantages such as offering a possibility for farmers to obtain rare crop varieties; identifying seed sources; offering a forum for exchange of ideas on farming and exchange of seeds; and exposing farmers to national agricultural research work.

The fairs thus enhance food security indirectly and offer a venue for interaction between students, farmers, researchers and other stakeholders.

## 5 Farmers' Rights

### 5.1 Farmers' rights in the ITPGRFA

Article 9, one of the most important articles of the treaty, addresses the issue of farmers' rights. The question of farmers' rights was one of the driving forces for the revision of the International Undertaking and the eventual adoption of the treaty.

Article 9.1 recognizes "the enormous contribution that the local and indigenous communities and farmers of all regions of the world, particularly those in the centres of origin and crop diversity, have made and will continue to make for the conservation and development of plant genetic resources which constitute the basis of food and agriculture production throughout the world." While these contributions are not explicitly linked to farmers' rights, the preamble clearly states that farmers' contributions serve as the basis for farmers' rights, and the linkage may be regarded as implicit.

Article 9.2 states that "the responsibility for realizing Farmers' Rights, as they relate to [PGRFA], rests with national governments." Furthermore, the article states that each contracting party should, "*as appropriate*", "*subject to its national legislation*" and "*in accordance with their needs and priorities*", take measures to protect and promote farmers' rights. The article thus makes very clear that the responsibility for realizing farmers' rights lies with national governments. Moreover, governments are not obligated to take any substantive actions to guarantee farmers' rights, but are rather encouraged to do so. Similarly to UPOV, the treaty effectively makes the realization of farmers' rights dependent upon national legislation. Paragraphs 9.2 (a) to (c) outline the primary features of farmers' rights as interpreted by the treaty: the protection of traditional knowledge relevant to PGRFA, the right to equitably participate in sharing benefits, and the right to participate in making decisions, at the national level, on matters related to the conservation and sustainable use of PGRFA.

Article 9.3 makes clear that nothing in Article 9 shall be interpreted as limiting any rights that farmers have to save, use, exchange and sell farm-saved seed, *subject to national law and as appropriate*. As noted by Moore and Tymowski, Article 9.3 represents a compromise between parties who sought the positive recognition of farmers' rights and those who feared a limitation of plant breeders' rights that would be inconsistent with UPOV 1991.

Some observers have enthusiastically welcomed the inclusion of these provisions on farmers' right into the ITPGRFA, among other the article has been called an "important landmark in contemporary treaty law". Even though it is true that the ITPGRFA is the first binding international agreement to recognise farmers' rights as positive, self-standing rights, the practical impact of the provisions should not be over-estimated. Several elements of farmers' rights were pointed out above (in section 1.2.2). The first of those components is to grant farmers continued free access to PGRFA, in particular for breeding purposes, and the freedom to exchange and re-use harvested material. The ITPGRFA only achieves partial progress in this respect, inasmuch as it establishes a system for facilitated access to PGRFA of which farmers may also benefit. With regard to farmers' rights to freely exchange and re-use harvested seeds, the ITPGRFA does not substantially alter the legal situation as it does not require countries to legally recognise any such rights in their legal orders. Thus, the

ITPGRFA does not prevent countries from choosing to restrict such rights, e.g. in the course of implementing other agreements like the UPOV. Another important component of farmers' rights that was mentioned above already is the right of farmers to receive a share of the benefits resulting from the commercial use of PGRFA. In this respect, the ITPGRFA does constitute a major step forward as it establishes a system of benefit-sharing which is, predominantly, to serve farmers, in particular in developing countries.

## ***5.2 Developing country perspectives on farmers' rights***

The question of farmers' rights is of specific interest for many developing countries where - on average - a much higher percentage of the population is directly dependent on agriculture and where practices like the exchange of farm-saved seed among farmers is much more common than in developed countries. While parties to the ITPGRFA are thus not obliged to strengthen the rights of farmers at the national level, they may still wish to do so.

There is a considerable body of research and commentaries which elaborate on the nature of farmers' rights and the best way to realise and implement them. Some authors suggest they can be implemented within the scope of current international agreements, while others favour the creation of a separate parallel system of protection.

A number of developing countries have already enacted legislation which recognises and protects farmers' and community rights. In the Philippines, the Indigenous Peoples' Rights Act contains a broad recognition of community rights. The Costa Rican Law No. 7788 offers a regulatory framework through which indigenous communities can assert their rights over biodiversity related traditional knowledge (TK). However, it only refers to the knowledge of indigenous communities rather than farmers. Other developing nations have created national laws to formally secure the farmers' privilege to seed save and the farmers' right to benefit share. India has done this by including the farmers' privilege to save and sell seeds in its plant IPR regime. The Indian "Protection of Plant Varieties and Farmers' Rights Act, 2001" aims at extending protection to both plant breeders' varieties and farmers' landraces. However, the question has been raised whether this system for the protection of both farmers' and plant breeders' rights, even though it aims at distributing the rights equitably, might actually be counter-productive, because too many parties at the "same time possess the right to exclude others from utilising a resources." The evaluation argues that the law leads to under-utilisation of PGRFA and may thus have negative effects on conserving plant genetic diversity. Some experts have suggested that the African Union "Model Legislation on the Protection of Rights of Local Communities, Farmers and Breeders and the Regulation of Access to Biological Resources" could serve as a good example to other developing countries wishing to establish farmers' rights in their national legislation. The model law greatly limits the IPR that plant growers can hold over genetic resources by clearly pointing out that patents over life forms and biological processes are not recognized and cannot be applied for (Article 9). It also protects, in its parts IV and V, farmers' and communities' rights. Moreover, in Article 31 it contains very broadly worded exemptions to plant breeders' rights.

The implementation of Article 9 offers the opportunity for synergies with other international agreements. Notably, Article 8 (j) of the CBD contains similar provisions with regard to the protection of TK similar to Article 9 of the ITPGRFA. Moreover, the draft UN Declaration on the Rights of Indigenous Peoples developed by the Working Group on Indigenous Populations also "recognizes the communities' rights to political and legal autonomy and the rights of indigenous peoples over cultural and genetic resources."

## **6 The Multilateral System for access and benefit-sharing**

One important feature of the ITPGRFA is its “Multilateral System to Facilitate Access and Benefit Sharing”. Article 10 of the treaty calls for the establishment of an efficient, effective and transparent multilateral system “both to facilitate access to [PGRFA], and to share, in a fair and equitable way, the benefits arising from the utilization of these resources, on a complementary and mutually reinforcing basis”. Thus, the Multilateral System aims to both ensure the continued conservation, maintenance and development of PGRFA through facilitated access and to contribute to sustainable development through equitable benefit sharing. 64 important crops and forage species are listed in Annex I of the ITPGRFA as belonging to the Multilateral System. Access to these PGRFA is to be provided by contracting parties to other contracting parties at low or no cost, and “equitable” benefits from the commercialisation of Annex I crops are to be paid to a trust fund managed by the ITPGRFA’s Governing Body. Ultimately, those benefits are to be paid primarily to farmers, especially in developing countries, that conserve and sustainably use PGRFA.

In line with Article 12.4 of the ITPGRFA, facilitated access under the Multilateral System is to be provided pursuant to a “standard material transfer agreement” (SMTA), which was adopted by the Governing Body in June 2006. MTAs are the contracts that are used for the transfer of genetic materials under the multilateral system, and include the terms and conditions of the transfer. MTAs are used by commercial firms, but have also been used by the CGIAR centres since 1995 and can take a number of forms (from short shipment documents to fully negotiated contracts). By providing for the adoption of a SMTA, the ITPGRFA creates a mechanism to avoid potentially expensive individual negotiations. The Governing Body agreed on a SMTA during its June 2006 session. Thus, legal relations within the Multilateral System are not only governed by the ITPGRFA itself, but also by the SMTA and by further decisions of the Governing Body.

The name “Multilateral System” may seem confusing at first reading, as it is a very general term and many international treaties contain provisions which may be considered a multilateral system for purposes of the respective treaty. The term “multilateral” is, however, used in order to contrast the ITPGRFA system for access and benefit-sharing with the prior, bilateral approach under the CBD and for indicating that the system is administered by an international organization. We will now look at the pertinent provisions of the ITPGRFA and the rules set forth in the recently adopted SMTA in more detail and in a second step outline in greater depth the legal relations that are part of the Multilateral System and the role of developing countries therein.

### ***6.1 The Multilateral System and the underlying provisions in detail***

#### **6.1.1 Articles 10 and 11 – the basics of the Multilateral System**

Article 10 of the ITPGRFA establishes the “Multilateral System to Facilitate Access and Benefit Sharing”, and makes clear its purposes. Article 10.1 affirms - like the preamble - the principle of sovereign rights of states over PGRFA, including the sovereign right to determine access to those resources. Article 10.2, however, states that in the exercise of those rights the contracting parties agree to establish a multilateral system both to facilitate access to PGRFA and to fairly and equitably share the benefits arising from the utilisation of those resources. Moreover, Article 10.2 states that these two purposes must be “complementary and mutually reinforcing”.

Article 11 outlines the coverage and scope of the Multilateral System. Importantly, while the treaty as a whole applies to PGRFA, Article 11.1 makes clear that the Multilateral System shall cover only the PGRFA listed in Annex I of the treaty, which were selected “according to criteria of food security and interdependence”. Among the 64 crops and forage species included are many of the species most important for food and agriculture at the global level such as rice, potatoes, maize, wheat and beans. Still, many observers hold the view that the list of species included is too short. While PGRFA found *in situ* will also be covered by the Multilateral System, access to these resources will according to Article 12.3 (h) be provided in accordance with national legislation. Article 12.3 (a) notes that “in the case of multiple-use crops (food and non-food), their importance for food security should be the determinant for their inclusion in the Multilateral System and availability for facilitated access”.

Importantly, Article 11.2 explains that the coverage of the Multilateral System shall extend only to the Annex I PGRFA “under the management and control of the contracting parties and in the public domain”. While the article also encourages other (non-public) holders of Annex I PGRFA to include their PGRFA in the Multilateral System, they are not legally bound to do so. On a related note, Article 11.3 states that contracting parties agree to encourage those Annex I PGRFA-holders in their jurisdiction to include their PGRFA in the Multilateral System. Furthermore, Article 11.4 states that within two years of the entry into force of the treaty, the Governing Body of the ITPGRFA shall assess the progress in including those non-publicly held PGRFA in the Multilateral System. The Governing Body, however, decided at its first session in 2006 to defer the assessment until its third session. Following the eventual assessment, the Governing Body may decide “whether access shall continue to be facilitated to those ... persons ... that have not included these [PGRFA] in the Multilateral System”. In other words, Article 11.3 makes clear that those non-public holders of Annex I PGRFA who fail to include the PGRFA in their possession in the Multilateral System may face eventual exclusion from the Multilateral System’s benefits. Article 11.5 states that the Multilateral System shall also include the Annex I PGRFA held in *ex situ* collections of the IARCs of the CGIAR, as well as other international institutions that sign agreements with the Governing Body.

### **6.1.2 Article 12 - Facilitated access under the Multilateral System**

Article 12 outlines the means by which the Multilateral System shall provide “facilitated access” to Annex I PGRFA. Articles 12.1 and 12.2 state that the facilitated access shall be in accordance with the provisions of the treaty, and the contracting parties agree to take the necessary legal or other measures to provide such access to other contracting parties and legal and natural persons under the jurisdiction of any contracting party.

Article 12.3 sets out the agreed conditions for facilitated access under the Multilateral System. Articles 12.3 (b) and (c) state, respectively, that access shall be provided expeditiously, without the need to track individual accessions and at no charge or at minimal cost and that any and all other material-associated, identifying and descriptive information should be made available along with the PGRFA provided. According to Article 12.3 (a), facilitated access shall only be provided “for the purpose of utilization and conservation for research, breeding and training for food and agriculture...” and not for chemical, pharmaceutical and/or other non-feed/feed industrial uses. This provision has also been incorporated into Article 6.1 of the SMTA. It should be noted that Article 12.3 does not bar the use or provision of Annex I PGRFA by contracting parties for non-agricultural uses, but merely precludes facilitated access under the Multilateral System for such purposes.



Paragraph 12.3 (d) provides that recipients of PGRFA shall not claim any IPR or other rights that limit the facilitated access to that PGRFA, or their genetic parts or components in the form received from the Multilateral System. This clause retains significant ambiguities. In particular, the terms “genetic parts or components” and “in the form received” remain undefined and open to interpretation. The SMTA does not resolve these ambiguities. In its Article 6.2 it merely incorporates *verbatim* the treaty clause and states: “The Recipient [of PGRFA from the Multilateral System] shall not claim any intellectual property or other rights that limit the facilitated access to the Material provided under [the SMTA], or its genetic parts or components, in the form received from the Multilateral System.” This is what Correa has called a pragmatic approach, which, however, leaves the settlement of a political dispute to judicial bodies, in the case that disputes should arise over the meaning of this clause in the future.

Articles 12.3 (e) and (f) note, respectively, that access to PGRFA under development is at the discretion of the developer, whether a plant breeder or farmer, during the period of development, and that access to PGRFA protected by IPR or other property rights shall be consistent with relevant national laws and international agreements. Article 12.3 (g) states that PGRFA accessed under the Multilateral System and conserved shall continue to be made available to the Multilateral System by the recipient. Thus, while this provision does not require that materials be conserved, it *does* mandate that materials that *have* been conserved continue to be made available. This provision is also part of the newly adopted SMTA (Article 6.3). Finally, Article 12.6 states that in the event of emergency disasters, contracting parties agree to provide facilitated access to PGRFA needed to re-establish (adversely impacted) agricultural systems. The recipients of materials in these cases need not be contracting parties.

### **6.1.3 Article 13 – Benefit-sharing under the Multilateral System**

Article 13 addresses the fair and equitable sharing of benefits arising out of the utilisation of PGRFA from the Multilateral System, one of the stated objectives of the treaty. Article 13.1 recognises that facilitated access to PGRFA from the Multilateral System is itself a major benefit, and states that benefits accruing therefrom shall be shared fairly and equitably.

Article 13.2 specifies that such benefit sharing shall occur through the exchange of information, access to and transfer of technology, capacity building, and under the sharing of benefits arising from commercialisation. This benefit sharing is to occur under the guidance of the Governing Body.

With regard to access to and transfer of technologies, Article 13.2 (b) (i) first states that contracting parties shall provide or facilitate access to technologies for the conservation, characterisation, evaluation and use of PGRFA that are part of the Multilateral System, and second recognises that some (embedded) technologies can only be transferred through genetic material itself. Importantly, subparagraph (iii) states that such technology transfers, when to least developed countries, developing countries and countries with economies in transition, shall be provided and/or facilitated under “fair and most favourable terms”, in particular for conservation technologies and technologies for the benefit of farmers. When mutually agreed, these technology transfers may also occur under concessional and preferential terms.

With regard to capacity building (Article 13.2 (c)), the treaty specifies that contracting parties shall give priority to:

- establishing and/or strengthening programmes for scientific and technical education and training in conservation and sustainable use of PGRFA;
- developing and strengthening facilities for conservation and sustainable use of PGRFA, particularly in developing countries and countries with economies in transition; and
- carrying out scientific research, again preferably in developing countries and countries with economies in transition.

Article 13.2 (d) (ii) states that the SMTA shall include a clause that a recipient who commercialises a product that incorporates material accessed from the Multilateral System and who restricts the availability of that product for further research and breeding has to pay an equitable share of the benefits from commercialisation into the financial mechanism referred to in Article 19.3 (f). This provision is ambiguous in several respects. First, the treaty does not specify what activities “restrict the availability“ of a product. Second, it does not make clear what constitutes “commercialisation“. Third, it does not clarify the meaning of the term “incorporates“. The SMTA only partially remedies these ambiguities. Article 6.7 of the SMTA reads: “In the case that a **Recipient commercializes a Product** that is a **Plant Genetic Resource for Food and Agriculture** and that incorporates **Material** as referred to in Article 3 of this **Agreement** [i. e., a PGRFA covered by the Multilateral System] and where such **Product** is not **available without restriction** to others for further research and breeding, the **Recipient** shall pay a fixed percentage of the **Sales** of the **commercialized Product** into the mechanism established by the **Governing Body** for this purpose, in accordance with *Annex 2* to **this Agreement**.“ The terms printed in bold letters here and in the original SMTA as well are defined in Article 2 of the SMTA. Accordingly, “to commercialize“ means to sell a product or products for monetary consideration on the open market. A “product“, in turn, means a PGRFA that incorporates the material received from Multilateral System or any of its genetic parts or components that are ready for commercialisation, excluding commodities and other products used for food, feed and processing. The parties thus chose to adopt a rather narrow definition of “products“ for which benefit-sharing payments are due. Essentially propagation material is covered by that definition, while many other PGRFA that are consumed directly by animals or human beings are not covered, so that benefits arising from their sale will not have to be shared.

Finally, a product is “available without restriction” when it is available for research and breeding without any legal or contractual obligations or technological restrictions that would preclude using it in the manner specified in the ITPGRFA. As will be explained more in detail in section 9.1, the ensemble of provisions very likely implies that the sale of a product that in one way or the other “incorporates“ material obtained from the Multilateral System and has a patent on it will trigger the compulsory payment of monetary benefits to the ITPGRFA system. The sale of a plant variety that in some way “incorporates“ material obtained from the Multilateral System and has a plant breeders’ rights (PBR) on it will not trigger such mandatory payments. The reason for this is that a PBR normally does not give the holder the right to bar others from using the protected variety for research and breeding activities. Moreover, the term “technological restrictions“ implies that restricting the use of a certain PGRFA, for example, by so called genetic use restriction technologies (GURT) will also result in a benefit-sharing obligation.

Article 13.2 (d) (ii) of the ITPGRFA also states that where a commercialised product continues to be available without restriction to others for research and breeding the recipient of a PGRFA from the Multilateral System shall be “encouraged“ to make a payment to the ITPGRFA system. This clause has also been made part of the SMTA in Article 6.8.

Article 13.2 (d) (ii) of the ITPGRFA further stipulates that the Governing Body shall determine and later review the level, form and manner of the payment. This subparagraph is critical to the functioning of benefit sharing under the Multilateral System. Fortunately, the SMTA has brought some clarity about the level and form of payments to be made. According to Appendix 2 of the SMTA, which sets forth the default option for payments in the framework of benefit-sharing, recipients shall regularly pay a sum corresponding to 1.1% of the sales of a product, i.e. a PGRFA that incorporates material obtained from the Multilateral System, minus 30 % of that sum. The SMTA also contains exceptions for some categories of products for which payments do not have to be made.

Article 13.3 states that benefits shared should flow primarily to farmers in all countries, but especially in developing countries and countries with economies in transition, who conserve and sustainably use PGRFA.

#### **6.1.4 Legal relations within the Multilateral System**

What is remarkable about the ITPGRFA is the rather complex web of legal relations it creates as part of the Multilateral System.

International treaties normally stipulate rights and obligations for states, not for individual or private legal entities. The ITPGRFA, however, goes much beyond this and comprises a type of private international law, which specifies which rights and obligations for individuals and private or public legal entities contracting parties have to set forth. The ITPGRFA itself lays out these rights and obligations, concerning mainly access and benefit-sharing, but it is ultimately only through the SMTA that they become binding upon private parties. The SMTA is, in turn, a private contract. In contrast to the regular freedom of contract approach prevailing in private law, parties are obliged to sign this contract if they wish to transfer PGRFA from the Multilateral System. The effect of such a standardised procedure is, on the one hand, to make matters easier for recipients of PGRFA, but, on the other hand, to also level the playing field for negotiations between providers and recipients of PGRFA, which are otherwise often characterised by inequalities in negotiating power and leverage among the parties involved. This is, in principle, beneficial for developing countries, individuals or legal entities from those countries, which are often the weaker party in terms of know-how and power in negotiations as compared to multinational seed companies.

It is also important to acknowledge that the ITPGRFA stipulates obligations both for providers and recipients of PGRFA from the Multilateral System. It is not only the recipients that are bound by its rules. This is also clearly reflected in the newly adopted SMTA, which contains a section on “Rights and Obligations of the Provider“ and on “Rights and Obligations of the Recipient“ respectively. The main obligation for providers is to grant access to PGRFA in line with pertinent rules. The main obligations for recipients are, as stated above already, to use the PGRFA obtained from the Multilateral System only for certain purposes and not to claim IPR on them or any of their parts and components “in the form received”, and to share benefits in the event of the commercialisation of a PGRFA.

Next to providers and recipients of PGRFA, the ITPGRFA also envisions a role for its treaty bodies in the context of implementing the ABS provisions. Thus, one more peculiar feature of the ITPGRFA is the position of the Governing Body of the ITPGRFA as a fiduciary for the payments made in fulfilment of the benefit-sharing obligations under the ITPGRFA. The Governing Body, which is composed of all contracting parties, is entrusted in Article 13.4 of the ITPGRFA with developing a funding strategy, of which according to Article 18.4 (e) the use of the monetary benefit-sharing contributions is also part. During the first session of the Governing Body in June 2006, it was decided that mandatory and voluntary contributions under Article 13.2 (d) of the ITPGRFA, i.e., payments made in fulfilment of the benefit-sharing obligations of the treaty, are to be placed in a so-called benefit-sharing fund. This fund is placed under the “direct control“ of the Governing Body who decides the allocation of money from this fund. While the monetary benefit-sharing contributions made under the Multilateral System are thus administered by the Governing Body, they are not ultimately destined for the ITPGRFA, but rather a compensation and reward for farmers and breeders that were the original developers of the PGRFA in the Multilateral System (see Article 13.3 of the ITPGRFA). Thus, while the Governing Body administers those funds, it is not ultimately free to do with them whatever it deems appropriate, but is bound by the provision of the treaty that stipulates that the funds should, at least predominantly, be passed on to farmers, particularly in developing countries.

In sum, the ITPGRFA contains and regulates a sophisticated architecture of legal relations of both private and public actors, located both in developed and developing countries and at the international level.

## **6.2 The position of developing countries in the ITPGRFA Multilateral System**

Looking at the position of developing countries and actors from those countries within this system, the first point to note is the widely acknowledged fact that historically and also presently developing countries tend to be rather on the provider side with regard to plant genetic resources, while developed country tend to be rather on the receiving end. This is due to the fact that *in situ* agricultural biodiversity tends to be much higher in developing countries, and relevant centres of origin are situated in such countries (e.g., Mexico for corn). In contrast, commercial breeders and biotech firms are predominantly from developed countries. The result of this is that, frequently, in international negotiations about PGR a polarisation occurs between developing and developed countries’.

It should, however, also be noted that while this statement is true at the general level, there were in the past, and continue to be also at present, instances where the role distribution is the reverse. For example, the main ingredient of Aspirin, which is today used all over the world as an important medicinal drug, is contained in a plant endemic to Europe and has been known for a long period of time as a medicinal plant. This is clearly a case of a plant genetic resource from a developed country having being exploited by a developer from such a country, but being used globally today. Thus, not all plant genetic resources (PGR) that are made use of commercially are from developing countries. Moreover, the developed world holds a larger percentage of PGR *ex situ*. While the original developers of such resources may have been farmers from developing countries whose achievements were later incorporated into *ex situ* repositories by developed countries scientists, this makes the dividing line between developing countries as providers and developed countries as receivers even fuzzier. Moreover, there is also a demand in developing countries for receiving PGRFA. For example, the CGIAR centres between 1992 and 1994 gave almost one third of the overall number of samples distributed to national research centres to developing countries. Another 50% was

distributed to other CGIAR centres, which, in turn, are also partially situated in developing countries. Some of the experts interviewed also pointed to developing countries' need for an inflow of germplasm. Finally, some developing countries like India are also in the process of building a certain infrastructure in biotechnology research and are thus likely to also become *demandeurs* of PGRFA in the long term.

Let us finally take a brief look at what providers (read: mainly (in) developing countries) and recipients of PGRFA (read: mainly (in) developed countries) are likely to gain from the Multilateral System. Some observers have warned not to overestimate the amount of tangible, and particularly monetary, benefits that providers of PGRFA may expect to gain from the Multilateral System. Some of the experts interviewed in the course of this study also underlined that it was still too early to assess the benefits of the ITPGRFA. Nonetheless, the Multilateral System of the ITPGRFA is the most efficient and feasible mechanism for sharing the benefits arising from the use of PGRFA in existence as of today. What is equally important is that it creates a mechanism which at least attempts to prevent further privatization of PGRFA through IPR. Thus, even though providers are not likely to earn huge sums, they are very likely to obtain at least something in both monetary and non-monetary benefits, and they are not likely to lose much. Equally, from the angle of recipients of PGRFA, the Multilateral System is clearly useful, because it creates a transparent and rather easy way of obtaining access to PGRFA for purposes of research and breeding. Thus, it significantly lowers transaction costs.

## **7 Adjudication**

In every legal framework, compliance and dispute settlement mechanisms are an important aspect, because their existence and quality is likely to determine the proper application and thus the effectiveness of the legal framework.

Compliance mechanisms are not adversarial. Compliance regimes recognise that non-compliance with a treaty can be due to the lack of expertise rather than bad will. In this sense, it is particularly important with regard to developing countries. They have been developed to promote treaty compliance as a general treaty interest rather than to remedy the detrimental effects that non-compliance of one party has on another. They take place in an international framework.

Dispute settlement, on the contrary, is adversarial in nature. It may take the form of amicable dispute settlement/negotiation, mediation, or arbitration. Different from negotiation and mediation, arbitration constitutes a generally final and binding form of dispute settlement. Arbitration can be practised within a national or international framework, and is especially popular in the international commercial world. National arbitration should be distinguished from international arbitration. International arbitration can generally grant neutrality and thus appears to be attractive in international trade disputes. One can also differentiate between administered and unadministered arbitration. Administered arbitration provides an institutional infrastructure, whereas unadministered systems refer only to a series of rules for the procedures. Administered arbitration services are provided e.g. by the International Chamber of Commerce (ICC), the Arbitration Institute of the Stockholm Chamber of Commerce (SCC Institute), the London Court of International Arbitration (LCIA), the American Arbitration Association (AAA) and others. These bodies provide arbitration according to their rules and offer institutional supervision of the arbitral proceedings, including such services as the appointment and operation of panels or expert arbitrators and

the dissemination of arbitral awards. Unadministered arbitration is typified e.g. by the United Nations Commission on International Trade Law (UNCITRAL), which created the UNCITRAL Arbitration Rules (UAR) of 1976. In 1980 they were supplemented by the UNCITRAL Conciliation Rules (UCR) and the Notes on Organizing Arbitral Proceedings of 1996. The UNCITRAL Rules are “stand alone” arbitration rules.

The ITPGRFA and related provisions provide for both compliance and dispute settlement mechanisms. Whether compliance and/or dispute settlement mechanisms apply depends on the kind of provisions that are allegedly violated. We can, thus, distinguish those provisions which deal with the abidance by the provisions of the ITPGRFA (Articles 21 and 22, and annex II ITPGRFA), those provisions which concern disputes over obligations contained in an MTA (Article 12.5 ITPGRFA, Article 8.4 SMTA), and finally those provisions which concern the fulfilment of the obligations under an agreement between the Governing Body of the ITPGRFA and international agricultural research centres or other relevant international institutions (Article 15.1 ITPGRFA, Article 7 model agreement).

It should be noted that the framework for compliance and dispute settlement continues to be developed, and some issues remain unresolved at present. Additional details are contained in the FAO-background papers on international arbitration by Moore and on compliance by Goote & Lefeber.

### **7.1 *Adjudication of the provisions of the ITPGRFA***

The ITPGRFA provides for both compliance and dispute settlement procedures for the adjudication of its provisions. The provisions of the ITPGRFA are binding upon its parties. These can be those states and organisations referred to in Article 25 of the treaty. Their abidance by the provisions of the treaty is subject to a compliance mechanism and -to the extent determined by the parties - to dispute settlement mechanisms. The ITPGRFA also contains provisions addressed to international organisations or their organs who are not parties to the treaty. Their abidance by the provisions of the treaty does not appear to be the subject matter of compliance and dispute settlement.

#### **7.1.1 Compliance**

According to Article 21 of the ITPGRFA, the Governing Body shall at its first meeting consider and approve cooperative and effective procedures and operative mechanisms to promote compliance with the treaty provisions and to address issues of non-compliance, including measures like monitoring and legal assistance. At its first meeting in June 2006, the Governing Body established a compliance committee, which shall commence its work pending the adoption of compliance procedures and operational mechanisms. This is, however, only foreseen for the Governing Body’s second session. In the meantime, the Governing Body itself shall consider a matter raised by a party with regard to its compliance with the treaty.

According to Article 21 of the ITPGRFA, the cornerstones of an ITPGRFA-specific compliance framework are the following: Participation in compliance procedures and mechanisms is – arguably – obligatory for all Contracting Parties to the ITPGRFA. Article 21 lays down “promotion of compliance” and “addressing issues of non-compliance” as objectives of the compliance procedures and mechanisms. They shall, *inter alia*, be achieved through “monitoring”. Responses to compliance difficulties shall be “effective” and may include the provision of “advice or assistance including legal advice or legal assistance”.

Article 21 requires that the nature of the compliance procedures and mechanisms be "cooperative" as opposed to adversarial. By referring to "operational" mechanisms, Article 21 suggests the possibility of setting up an institutional structure, although it is not limited to this. This approach was chosen by the Governing Body at its first meeting.

The further details on compliance procedures and mechanisms will be decided upon by the Governing Body when setting up the compliance mechanisms and procedures. It will do so on the basis of the draft procedures and operation mechanisms to promote compliance and address issues of non-compliance (the draft) and submissions made by parties and observers. Some of the issues, which still have to be resolved, as designated in the draft and the submission, are outlined below.

The question of which responses to non-compliance, other than those mentioned in Article 21, should be provided for is still open. Discussed are non-binding facilitative measures (such as assistance with the development of a compliance action plan) as well as binding enforcement measures. Enforcement measures might include the publication of a case of non-compliance, the issuance of a caution, or the suspension of rights and privileges of a Contracting Party. The draft provides that binding decisions may only be taken by the Governing Body on a recommendation of the compliance committee as opposed to by the Committee itself. The frequency of meetings of the compliance committee, its size and independence are further open questions. As to the triggers of compliance procedures, the draft mentions a self-trigger, i.e. a country which does not feel in a position to implement the treaty can indicate this to the compliance committee in order to receive assistance. Still controversial is a Party-to-Party trigger and a trigger by the Governing Body.

### **7.1.2 Dispute Settlement**

Article 22 of the ITPGRFA, which deals with the settlement of disputes, is decisive for arbitration between Contracting Parties to the ITPGRFA. It offers different options for settlement in "the event of a dispute between Contracting Parties concerning the interpretation or application of this Treaty". The third paragraph states that any party "may declare [...] that for a dispute [...] it accepts one or both of the following means of dispute settlement as compulsory: (a) Arbitration in accordance with [...] Annex II to this Treaty; (b) Submission of the dispute to the International Court of Justice." These possibilities essentially conform with Article 33 of the United Nations Charter, which enumerates the various dispute settlement mechanisms available to States, and are almost identical to the procedures set out in Article 27 of the CBD.

Article 22 of the treaty states that arbitration may be one method of dispute resolution regarding the interpretation or application of the treaty after diplomatic methods of dispute settling have failed – if the Contracting Parties agree on it. The treaty clarifies that Parties should first aim at reaching an amicable solution via e.g. negotiation and mediation. Part 1 of Annex II of the treaty specifies the arbitration procedures to be applied. According to these rules, first, the Secretary has to be notified and after this the arbitral tribunal is established. The tribunal renders its decisions in accordance with the treaty and international law, determines its rules of procedure, and recommends interim measures of protection. Its decision is confidential and final.

As for the procedures before the ICJ, the rules in the Statute of the International Court of Justice must be observed.

If Contracting Parties have not accepted the ICJ Statute or any other procedure, they cannot submit the dispute to the ICJ, but can only resort to conciliation in accordance with Part 2 of Annex II unless the Parties otherwise agree.

## 7.2 *Adjudication of MTAs*

Adjudication of MTAs is governed by Article 12.5 of the ITPGRFA and Article 8.4 of the SMTA, which provide for the applicability of dispute settlement mechanisms. Articles 21 and 22 of the ITPGRFA, on the other hand, are not relevant in this context. This is supported by a quote in the Report of the Expert Group on the SMTA stating that “[a] dispute resolution/arbitration mechanism should be included in the MTA”. This would be separate and different from Article 21, Compliance, and Article 22, Settlement of Disputes, which refer to relations between Contracting Parties to the Treaty [...]. Article 21 and 22 relate to dispute settlement within the Treaty and are not relevant here.” This opinion is supported by the Secretariat. An extension of the ITPGRFA compliance mechanism to the adjudication of MTAs by a decision of the Governing Body had been promulgated by Switzerland without success.

The situation is somewhat unclear with regard to the question of the applicability of national and/or international dispute settlement regimes. Article 8.4 of the SMTA adopted by the Governing Body provides for international dispute settlement. It shall take place via amicable dispute settlement, failing this via mediation, failing this via arbitration under the arbitration rules of an international body agreed by the parties, failing this under the Rules of Arbitration of the International Chamber of Commerce. Article 12.5 of the ITPGRFA, on the other hand, provides that “Contracting Parties shall ensure that an opportunity to seek recourse is available, consistent with applicable jurisdictional requirements, under their legal systems, *Prima facie* the Governing Body’s decision on the SMTA, thus, seems to contradict the ITPGRFA, as the former seemingly prescribes that MTA-related disputes be settled under national law before national courts, while the latter seemingly rules this out by referring to international dispute settlement mechanisms only. According to the Legal Advisor to the Expert Group on the Terms of the Standard Material Transfer Agreement (“Expert Group”), it is, however, “up to the Contracting Parties to decide the opportunities for recourse to be made available, including both resort to national courts and arbitration”. For the Contracting Parties, in the exercise of their sovereign rights to provide for binding international arbitration, would not, in the Legal Advisor’s opinion, be contrary to the provisions of the Article 12.5 ITPGRFA. In any case, it would still be open to parties to the MTA to have recourse to national courts to enforce international arbitral decisions, should this prove necessary.”

According to Article 8.1 and 8.2 of the SMTA, dispute settlement procedures may be initiated not only by the parties to an MTA, i.e. the provider and recipient of PGRFA, but also “by an entity designated by the Governing Body on behalf of the Governing Body and the Multilateral System.” While this entity has not yet been designated, the paragraph clearly implies that the Governing Body and the Multilateral System together are eligible to initiate dispute settlement procedures to enforce rights and obligations of the provider and recipient of the MTA. The fact that a non-party to an MTA can initiate proceedings for the enforcement of rights and obligations arising under the MTA for the parties of that MTA seems to contradict the wording of Article 12.5 of the treaty, which states “that obligations arising under such MTAs rest exclusively with the parties to those MTAs”. For this reason, during negotiations, it was proposed to formally recognise the Multilateral System as a party to the



SMTA, or to define the provider of the PGRFA as an agent for the Multilateral System. These constructions were not taken up. Instead, the SMTA foresees that the parties to an MTA agree to confer upon the Governing Body and the Multilateral System the right to initiate proceedings for the enforcement of their obligations. This seems to be in line with Article 12.5 of the treaty for two reasons: First, the parties to an MTA do not have any right to demand that a third party enforces their obligations under the MTA; rather, it is the discretion of the third party to initiate proceedings or not. Thus it is still the parties that are responsible for the enforcement of their rights contained in the MTA. Second, the possibility of the third party to initiate proceedings depends on a mandate by the parties to the MTA. By using the SMTA the parties of the contract permit the entity acting on behalf of the Governing Body and the Multilateral System to initiate dispute settlement proceedings on their behalf. The fact that the Governing Body and Multilateral System can initiate proceedings seems to confer legal personality on these two entities acting together.

The dispute settlement procedure agreed upon could - as opposed to non-administered international arbitration, national arbitration, or pleadings before national courts - provide for a consistent interpretation of the provisions of the SMTA, despite the more than 60 Parties to the ITPGRFA, should parties to a dispute choose to use the default option of letting their disputes be resolved by the International Chamber of Commerce. A consistent interpretation of the SMTA would likely help the Governing Body to develop a coherent practice with respect to the implementation of the SMTA.

In addition, arbitration offers the advantage of high flexibility with regard to procedures (e.g. venue, language, timetable) and to the choice of arbitrators. The possibility of choosing the arbitrators is of special interest, as experts can be asked to join. This is of particular relevance in matters of high complexity. International arbitration is notable in that it may ensure the neutral adjudication of disputes in which Parties from different countries are involved.

Unlike many national jurisdictional systems, an arbitration system can grant privacy and confidentiality. Furthermore, it is usually without appeal and can therefore serve as a quick form for dispute settlement.

A crucial disadvantage of arbitration may be seen in the potential difficulty of enforcing arbitral awards. The enforceability of a judgement of a national court usually does not constitute a legal problem, provided that the judgement is final. Arbitral awards, on the other hand, are not automatically enforceable. If a party fails to comply with the award, recourse to national courts will be necessary. In this context, however, international agreements and conventions should be kept in mind. The so called New York Convention of 1958, for example, offers an international framework for the enforcement of arbitral awards. According to Article 3 of the Convention, "[e]ach Contracting State shall recognise arbitral awards as binding and enforce them in accordance with the rules of procedure of the territory where the award is relied upon", under the conditions laid down in the following articles. There shall not be imposed substantially more onerous conditions or higher fees or charges on the recognition or enforcement of arbitral awards to which this Convention applies than are imposed on the recognition or enforcement of domestic arbitral awards."

### **7.3 *Adjudication of agreements between the governing body of the ITPGRFA and the IARCs and other relevant international institutions***

According to Article 15.1 ITPGRFA, the Contracting Parties call upon the the IARCs to sign agreements with the Governing Body with regard to *ex situ* collections. At its first session in June 2006, the Governing Body adopted a model agreement. According to Article 7 of the model agreement, the settlement of disputes concerning the implementation of the agreement shall take place in a similar by negotiations between the parties, failing this by arbitration in accordance with the procedures set out in Part I of Annex II of the Treaty.

### **7.4 *Developing country perspective***

From the perspective of developing countries, the solution that has so far been negotiated may be considered a positive step from the perspective of developing countries. The fact that a compliance mechanism exists may be particularly beneficial for developing countries in the sense that it can be used to acquire support the implementation of the provisions of the ITPGRFA. In addition, the solution relieves developing countries, to an extent, from the burden of having to create their own national system for the settlement of disputes on MTAs. Still, it is difficult to judge whether arbitration is generally more or less costly than national court proceedings, as this depends, *inter alia*, on the specific action, the national jurisdictional system in place and the amount in dispute. The fact that the Governing Body and Multilateral System can initiate proceedings is an advantage for that party to an MTA, which may not otherwise have been in a position to initiate proceedings because of a lack of financial and technical resources.

## **8 Financing of tasks assigned to Governing Body**

An important aspect of how well the ITPGRFA will function is how much financial resources its bodies will have at their disposition. In its first session in June 2006, the Governing Body was, among many other tasks, to adopt a comprehensive funding strategy for the IT and for its own workings.

Appendix E of the report of the Governing Body meeting states that the funding structure will be as follows:

1. The Core Administrative Budget, relating to the amount provided by FAO, the "voluntary contributions of Contracting Parties [...] and the voluntary contributions of States that are not Contracting Parties, of inter-governmental organizations, of non-governmental organizations and other entities, [...] and miscellaneous income, including interest [...]"
2. The Special Fund, relating to "additional voluntary contributions by Contracting Parties, and voluntary contributions by States that are not Contracting Parties, by inter-governmental organizations, by non-governmental organizations and other entities." These are to be used to support the participation of contracting party representatives of developing countries and countries with economies in transition and funds that were pledged by donors and bound to fulfil certain specified tasks.
3. Contributions relating to 13.2(d) that are to be used for the benefit sharing fund.

However, the receipt of funds is still scarce. The Governing Body acknowledged the contribution of the FAO of USD 1,124,000 for the biennium 2006/2007, but remarked at the same time that these resources were not sufficient to cover the core administrative budget of the treaty for this time period. It therefore called for additional contributions. In addition, the funding strategy laid out in Annex F is still not fully elaborated. It stipulates that only benefit-sharing contributions related to Article 13.2 (d) (ii) of the treaty, voluntary contributions (including relating to Article 13), and resources provided through FAO's regular program are under the direct control of the Governing Body. Other financial resources enumerated in Annex F are financial resources provided bilaterally or through multilateral mechanisms for purpose of the treaty. Such other resources are not under the direct control of the Governing Body, however.

## **9 The relationship of the ITPGRFA with other international agreements**

It has been outlined so far why and how the ITPGRFA came into existence and what its main provisions and mechanisms are. However, how effectively the treaty will be implemented depends not only on how much countries are willing to do, but is also influenced by the relationship of the ITPGRFA with other international agreements. This is the issue which this section is dedicated to. The first part discusses the relationship between the ITPGRFA and two multilateral IPR treaties, TRIPS and UPOV, the second part discusses the CBD and its relationship with the ITPGRFA.

### ***9.1 The ITPGRFA and its relation with multilateral IPR treaties***

TRIPS, UPOV and the ITPGRFA are the most important parts of the current complex of legally binding agreements that regulate IPR over plant genetic resources. Wherever there are several legally binding international agreements dealing with similar matters, conflicts between them may arise. When the agreements do not purport to regulate the same subject matter or when one treaty contains a norm on a certain issue while the other does not, there is no conflict. Otherwise, conflicts are conceivable at different levels. Firstly, norm collisions may occur. A norm collision in the narrow sense exists where one legal norm prohibits what a second one prescribes. Moreover, a situation may arise in which one legal agreement allows what a second one prohibits. Even if this does not create an outright conflict because a country party to both agreements in such a situation is not legally bound to take the prohibited action, it will still lead to the nullification of the effect of one of these agreements. Thus, it is justified to talk of a conflict in this situation as well. Secondly, conflicts between different agreements may occur at the programme level, i.e. the level of objectives or underlying regulatory strategies. While legal conflicts may be solved through interpretative means, it has been observed that programme level conflicts have to be solved through political decisions.

The possibility of conflicts between the ITPGRFA on the one hand and UPOV and TRIPS on the other arises from the fact that they deal with similar subject matter, but do not necessarily pursue identical goals. TRIPS and UPOV are based on the idea that IPR are necessary to generate adequate incentives for investment in research and development in agricultural biotechnology, predominantly plant breeding. This is contrasted by the ITPGRFA, which aims to channel a part of the commercial benefits generated by products that make use of genetic resources to those who have contributed to the conservation and development of genetic resources and seek to keep a system of open access to PGRFA.

In the following section, we will discuss the relationship between the treaty on the one hand and the UPOV and the TRIPS agreement on the other, with a view to potential conflicts.

### 9.1.1 General rules on norm collision in international treaty law

Before embarking on an investigation of potentially conflicting substantive norms of the different agreements, however, it is pertinent to note that conflicts between different treaties, which frequently contain indeterminate norms, may often be avoided by interpreting their provisions in harmony with each other. Of several possible interpretations of a certain treaty norm, the one that does not lead to a collision with the norm of a second treaty is to be preferred. Only where such interpretation is not possible, because the unequivocal formulation of a norm prohibits it, the question of how to deal with a collision between two norms arises. The first place to look in an attempt to answer this question is, of course, in the treaties under scrutiny. The ITPGRFA indeed contains a collision norm in its non-binding preamble. Therein it is stated that the ITPGRFA and other international treaties shall be mutually supportive and that nothing in the treaty „shall be interpreted as implying in any way a change in the rights and obligations of the Contracting Parties under other international agreements“. In the subsequent recital it is stated, moreover, that this clause „is not intended to create a hierarchy“ between the ITPGRFA and other international agreements. This wording essentially constitutes a compromise. As the IT was concluded later than the other agreements, the clauses in the preamble avoid the application of the *lex posterior* rule, which is contained in the Vienna Convention on the Law of Treaties (VCLT). This rule, which also exists in customary international law, stipulates that when two treaties signed by the same parties regulate the same subject matter, the treaty concluded later will supersede the provisions of the earlier treaty. By explicitly referring to other treaties in the preamble of the ITPGRFA, the parties to this treaty have, however, expressed that they do not consider the IT to regulate the same subject matter as other treaties. Thus, the *lex posterior* rule cannot apply. The preambular provisions of the IT are thus the relevant rules for determining the relationship between the ITPGRFA and other treaties. The combined effect of the preambular provisions contained in the IT is, however, essentially ineffective. While it is made clear that the treaty does not automatically take precedence over other treaties, it is equally made clear that other treaties do not supersede the provisions of the IT. Thus, Article 30.2 of the VCLT is not applicable. Both UPOV and TRIPS do not contain any specific provisions guiding their relationship with other international agreements. Hence, neither the treaties under review nor general public international law provide any general rules on which treaty takes precedence in the case of a norm collision. In sum, there is no choice but to look at the individual norms contained in the ITPGRFA, UPOV and the TRIPS Agreement and to seek to interpret them harmoniously.

### 9.1.2 The relationship between the ITPGRFA and UPOV

The ITPGRFA and UPOV both apply specifically to PGRFA and their products, taking into account the problems arising out of their special characteristics. It is therefore the relationship between these treaties that will be investigated first.

Only two problematic areas exist where actual norm collisions are conceivable between the ITPGRFA and UPOV. The first one concerns access and benefit-sharing under the Multilateral System. With regard to a conflict between the ABS rules of the Multilateral System and plant breeders' rights as provided for in the UPOV, two norms of the ITPGRFA are particularly critical. Firstly, the IT stipulates that recipients of plant genetic resources from the multilateral system “shall not claim any intellectual property or other rights that limit the facilitated access to the plant genetic resources for food and agriculture, or their genetic parts or components, in the form received from the Multilateral System“ (Article 12.3 (d)). The

very same clause is contained in the newly drafted SMTA. Secondly, it is stated in Article 13.2 (d) (ii) that a recipient of PGR from the Multilateral System who commercialises a PGRFA that incorporates material accessed from the Multilateral System shall pay a part of the benefit to the fund established by the IT for this objective. This rule has also been incorporated, albeit complemented by some definitions, into the SMTA. The second area where conflicts may potentially arise concerns the issue of farmers' rights, most notably Article 9.3 of the ITPGRFA. Each of these provisions requires separate consideration.

### **Article 12.3 (d) ITPGRFA and UPOV**

The problematic aspect about the first norm is that plant breeders' rights as stipulated by the UPOV are, obviously, intellectual property rights in the sense of Article 12.3 (d) of the ITPGRFA and Article 6.2 of the SMTA. These clauses could be interpreted as limiting the extent to which PBR over such PGRFA may be claimed, a limitation not contained as such in UPOV. Under UPOV, the extent to which PBR on plant varieties may be claimed depends, in turn, on the fulfilment of the requirement that the variety for which protection is sought is novel, distinct, uniform and stable. Before discussing the relationship between the respective norms in more detail, it is worth noting that there is no conflict between diverging rights and obligations of the parties to the treaty. While the UPOV members are required to establish a system for the protection of plant varieties, they are not required *not* to grant any IPR which might be seen as contradicting Article 12.3 (d) of the ITPGRFA. This norm is addressed towards private entities or public entities within the states that receive material from the Multilateral System. Thus, there is no conflict at the level of state obligations between the ITPGRFA and UPOV on this point.

If there is, in fact, a conflict between diverging rights and obligations, it is a conflict between rights and obligations of individuals which derive from the ITPGRFA and the SMTA on the one hand, and UPOV on the other. Moreover, even if there should be a conflict between the ITPGRFA and UPOV because of these norms, it is only a conflict in the more extended sense of the word, as described above. UPOV, while it obliges states to provide plant variety protection, does not oblige private entities to seek protection for newly bred crops. The ITPGRFA and the SMTA, in turn, only oblige the recipients of material from the Multilateral System not to seek plant variety protection in certain instances. Thus, at worst, the ITPGRFA and the SMTA might be seen as prohibiting an action of private actors which the UPOV permits. Still, if the IT prohibited an action or restricted a right that should be permitted or granted according to UPOV, the IT would partially nullify rights guaranteed under UPOV, which is quite a serious effect. Thus, it is worth investigating in greater depth the relationship between the norms mentioned and whether there is a way of interpreting them in a mutually supportive way. Nonetheless, it should also be noted that Article 12.3 (d) of the ITPGRFA only concerns a limited number of cases, as it only applies to PGR that are part of the Multilateral System.

If and to what extent a conflict exists between private obligations deriving from Article 12.3 (d) ITPGRFA and the right to seek plant variety protection, which must be granted according to UPOV provisions, depends to a certain degree on how Article 12.3 (d) and Article 6.2 SMTA are interpreted. The wording of the norm is unclear and represents a compromise struck between different positions in the course of the negotiations, which obviously could not be altered during the negotiation of the SMTA. The wording of the clause clearly forbids applying for PBR on an accession received from the multilateral system, which has not been altered in any innovative way, e.g., by traditional breeding techniques or modern biotechnology. Such an accession will not qualify for plant variety protection anyway;

according to UPOV plant variety protection shall be granted only to novel and distinct varieties. Thus, if the competent national authorities act in accordance with UPOV and relevant national laws, the case of non-modified accessions is not problematic.

More troubling is the issue whether the ITPGRFA and SMTA clause might be construed to prohibit the granting of PBR on a new variety, which is eligible under UPOV for plant variety protection and was developed through traditional breeding-methods or genetic modification from material received from the multilateral system. Several authors have convincingly argued that the prohibition on claiming IPR contained in the ITPGRFA must be understood not to prohibit the seeking of PBR for varieties which are derivatives of the accession obtained from the Multilateral System. The first argument to be made in favour of this position is that Article 12.3 (d) prohibits only IPR which restrict the facilitated access to the resources received from the Multilateral System. Facilitated access is access which is granted to the Multilateral System in line with the modalities set forth in the ITPGRFA. Among these conditions is that access may be granted for purposes of research, breeding and training for food and agriculture only. A PBR granted in line with the conditions laid out in the UPOV does not, however, forbid any of those uses. According to Article 14 of UPOV 1991, a PBR holder has the right, *inter alia*, to produce, sell and export the propagation material of the protected variety. Using a protected variety for training, in turn, is an action which will normally not conflict with the exclusive rights of the PBR holder. Moreover, the breeders' privilege as stipulated in Article 15 of UPOV permits the use of protected varieties for "experimental purposes" and breeding. Thus, any protected variety may be used in research and breeding activities. In sum, PBR in the form laid out in the UPOV do not restrict "facilitated access" to any PGR received from the Multilateral System. The second argument why Article 12.3 (d) cannot be construed to prohibit PBR on varieties derived from the accessions obtained from the Multilateral System is a contextual one. The ITPGRFA requires benefit-sharing whenever a PGR or a related product is commercialised, unless it is freely available. As the act of commercialisation as conceived of by the ITPGRFA normally involves some kind of IPR protection, the ITPGRFA does not categorically reject the granting of any IPR on cultivars derived from the material obtained from the Multilateral System. If it did disapprove of PBR not only on accessions in the form received from the Multilateral System, but also on their derivatives, the provisions on benefit-sharing would be largely without meaning. Therefore, the clause in Article 12.3 (d) cannot be interpreted to have such a broad meaning as to prohibit nearly any PBR on derivatives of material obtained from the Multilateral System. It must be construed more narrowly. Then, however, there is no conflict between the rights of private entities to be granted plant variety protection in accordance with the UPOV standards and the limits that Article 12.3 (d) of the ITPGRFA and Article 6.2 SMTA impose on them in this regard.

#### **Article 13.2 (d) (ii) ITPGRFA and UPOV**

With regard to the second norm mentioned above, the provision in Article 13.2 (d) (ii) that benefits arising from the commercialisation of PGRFA received from the multilateral system must be shared by paying into the IT's fund, there is no conflict between the ITPGRFA (or Article 6.7 SMTA which contains the same requirement) and UPOV either. First of all, while UPOV obliges states to perform certain actions, the ITPGRFA and the SMTA require private entities or public actors within a state to share benefits. Thus, there is no conflict at the treaty level. Moreover, there is no conflict concerning individual rights and obligations deriving from these treaties either. Generally, it is not clear whether the granting of an PBR on a variety developed from material received from the Multilateral System will trigger the

benefit-sharing mechanism of the ITPGRFA, as benefit-sharing is not required where the commercialised product is available for further research and training without restriction. As UPOV provides for research and breeders' exemptions, varieties which are subject to a PBR may continue to be available for further research and training without restriction. Thus, whether PBR will trigger the benefit-sharing mechanism depends to a certain extent on how the terms research and breeding are interpreted. Even if one holds, as some do, the view that PBR may also trigger the benefit-sharing mechanism of the ITPGRFA and the concomitant SMTA, there is no legal conflict between the ITPGRFA and UPOV in this respect. Of course, the provisions in the ITPGRFA and the SMTA may factually reduce the profit that a holder of an intellectual property right on a certain PGRFA may eventually gain from selling the protected plant variety. Nonetheless, such a provision is not in conflict with any of the articles of UPOV. UPOV is concerned only with the conditions under which plant breeders' rights must be granted and the legal consequences resulting from the granting of such rights. It is not concerned about how much a holder of such a right will earn from exploiting his or her rights.

### **Farmers' Rights**

Besides ABS, the second area where a conflict between both treaties is conceivable is, as described above, the issue of farmers' rights. In line with the respective objectives of UPOV and the IT, Article 9 of the ITPGRFA places a much higher emphasis on the recognition and protection of farmers' rights than UPOV does. The paragraph of Article 9 which is most prone to claims about conflict with the UPOV is Article 9.3. It sets forth that nothing in the paragraph on farmers' rights "shall be interpreted to limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate." Article 14 of UPOV 1991, in turn, requires authorisation by the breeder, *inter alia*, for producing, selling and exporting the propagating material of a protected variety. Hence, there might be a conflict between an obligation for states to grant plant variety protection in line with UPOV standards on the one hand, and the obligation to guarantee farmers certain rights on the other.

The formulation of Article 9.3 indicates, however, that the norm is not meant to stipulate additional, genuine rights for farmers, but that it rather serves as a safeguard against curtailing rights already existing. Parties are not required to grant any additional rights. As the UPOV Act was signed and ratified earlier than the ITPGRFA, the rights of farmers that existed when the ITPGRFA entered into force were, at least, in many countries already shaped by requirements in UPOV. Thus, a conflict between those rights and UPOV is not likely to occur.

But even in the case of new signatories of UPOV which are also party to the ITPGRFA, no conflict between Article 9.3 of the ITPGRFA and UPOV exists. It has been suggested that no such conflict exists, because Article 9.3 of the ITPGRFA generally does not apply to PGR which are protected by PBR or patents. This suggestion is, however, not entirely convincing. According to Article 31 VCLT, which reflects customary international law, the wording of Article 9.3 would be the relevant starting point for any treaty interpretation. Article 9.3, however, does not contain any explicit restriction of application to those PGR not protected by PBR. Still, there is a different reason for why there is no norm collision between the ITPGRFA and UPOV in this respect. Both UPOV and the ITPGRFA offer national governments broad discretion when implementing these norms. The ITPGRFA states that farmers' rights are to be granted "as appropriate" and "subject to national law". UPOV 1991 in turn contains, in Article 15.2, an optional exception, allowing parties to the treaty to permit

farmers certain uses of the harvest obtained from a protected variety. While these formulations and exceptions avoid a formal legal conflict between UPOV and ITPGRFA rules, they open significant leeway for countries to decide whether and how strongly they will protect farmers' rights.

## **Conclusion**

In sum then, there is no legal conflict between provisions of the ITPGRFA and UPOV.

### **9.1.3 The relationship between the ITPGRFA and TRIPS**

Unlike UPOV, TRIPS is not specifically concerned with IPR on PGR, but with the granting of IPR in general. The norms of TRIPS, which are most likely to collide with some of the provisions to the ITPGRFA and the SMTA, are the provisions that regulate the granting of patents. As was the case with UPOV, TRIPS provisions are most likely to be in conflict with Article 12.3 (d), Article 13.2 (d) (ii) and Article 9.3 of the ITPGRFA and the pertinent rules in the SMTA. In addition, conflict of municipal laws adopted in the process of implementing Article 27.3 TRIPS with the ITPGRFA may arise. We will consider each of these areas of potential conflict in turn.

#### **Article 12.3 (d) ITPGRFA and TRIPS**

With regard to Article 12.3 (d) and Article 6.2 SMTA, which prohibit the claiming of IPR and limit the facilitated access to the PGRFA or their genetic parts or components in the form received from the Multilateral System, much of what has been said above in the section on UPOV also applies. Like PBR, patents are intellectual property rights in the sense of Article 12.3 (d) of the ITPGRFA, and this norm could hence be seen as limiting the extent to which patent protection might be sought. Again, such limitation is not contained in TRIPS, which stipulates that a patent must be granted on any inventions, whether a product or a process, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Like under UPOV, there is no legal conflict at the level of treaty obligations which states must fulfil, but potentially at the level of the rights of individuals derived from these treaties. Again, even if a conflict between the two treaties exists, it is only a conflict in the more extended sense of the word, as described above. While individuals or other legal subjects may seek patent protection, which must be granted according to TRIPS standards, they are not compelled to do so. The ITPGRFA and the SMTA, in turn, only oblige the recipients of material from the Multilateral System *not* to seek patent protection in certain instances. Thus, the ITPGRFA and the SMTA might, at worst, be seen as prohibiting an action which TRIPS permits.

Moreover, it should be noted that the members of TRIPS have the option to further reduce potential conflicts at the level of individual rights and obligations derived from the respective agreements, because the TRIPS Agreement does not oblige them to grant patents on the inventions most sensitive from the point of view of the ITPGRFA. Even though Article 27.1 TRIPS sets forth the requirements under which patents must be granted, i.e. novelty, non-obviousness and utility, it does not define these requirements with greater precision. Equally, there is no case law of the World Trade Organization (WTO) dispute settlement bodies, which are the competent judicial institutions to decide on how these requirements must be interpreted. Hence, TRIPS does not require, for example, that a state considers an extracted and purified gene patentable subject matter. As a matter of fact, some countries have excluded genes from patentability when implementing TRIPS.



Even if one holds a different view with regard to how the TRIPS patent requirements are construed, the TRIPS Agreement contains certain exemptions from the principle that every new, innovative and commercially applicable invention must be patentable. According to Article 27.3 of the agreement, members may exclude from patentability plants and animals other than micro-organisms. Moreover, Article 27.2 TRIPS provides that patents need not be granted when it is necessary to protect *ordre public* or morality, including human, animal or plant life or health or to avoid serious prejudice to the environment. On top of this, Article 8 of the agreement contains an – albeit weakly formulated – exemption in favour of policies to protect public health and nutritional needs as well as the public sector.

Still, even though TRIPS does not require the patenting of isolated genes, for example, some countries have opted for granting such rights. As national patent laws are politically related to TRIPS and as there is an international trend towards TRIPS-plus standards, it is still worth investigating whether and to what extent there is a conflict between Article 12.3 (d) ITPGRFA and Article 6.2 SMTA on the one hand and national patent provisions, which contain a broad definition of patentable subject matter, on the other. Some observers have suggested that the situation with regard to a legal conflict between the ITPGRFA and patent law is more complex than is the case with regard to plant variety protection. This is an accurate observation. While plant variety protection will regularly only be granted to novel and distinct varieties, and thus not on any variety in the form received from the multilateral system, in some countries it is legally possible to patent individual genes, certain substances which might be extracted from a PGR, or even certain characteristics of such material. In addition, patents are also granted on plant varieties in some countries. It is thus conceivable that genes contained in an accession received from the Multilateral System, a certain substance extracted from such an accession or certain characteristics of that accession hitherto unknown might be patentable in some countries. The question whether and to what extent Article 12.3 (d) and Article 6.2 prohibit the claiming of patents on extracted and purified genes seems to have been among the most controversial issued during the entire negotiating process. This question is hard to answer. The first reason for this is that Article 12.3 (d) ITPGRFA is a compromise formula. This formula has also been transported to Article 6.2 of the SMTA. Moreover, much is in flux in the field of patents on PGR in general, and genes more specifically. What seems rather clear is that a patent on a gene isolated from an accession obtained from the multilateral system, which inhibits further facilitated access to that accession, would be in violation of Article 12.3 (d) and Article 6.2 of the SMTA. As national patent laws do not, or at least do not always, contain an exemption in favour of breeders or researchers, and as a patented gene is at least sometimes understood to restrict the use of material in which it is contained without the consent of the patent holder, a patent on a purified gene extracted from an accession obtained from the Multilateral System may, in principle, limit facilitated access to PGR obtained and therefore be in conflict with Article 12.3 (d) of the ITPGRFA. The issue, however, needs more detailed research and depends much on the individual patent. As pointed out above already, country parties to both treaties have the option to evade such conflict by using a narrow approach towards what is patentable subject matter in their national patent legislation.

Still, it should be noted that while there is currently no conflict between Article 12.3 (d) of the ITPGRFA and Article 6.2 of the SMTA on the one hand and TRIPS (or UPOV) on the other, Article 12.3 (d) cannot be understood to be merely declaratory in nature. Rather, it imposes limits with regard to what IPR can and should be obtained on material in the form received from the multilateral system. These limits may not be all that relevant today from the

viewpoint of public international law, but will become more important if current discussions about multilateral TRIPS-plus standards should result in additional and stricter IPR treaties at the international level. At the WIPO, negotiations on a so called Substantive Patent Law Treaty (SPLT) have been going on for several years now; major controversies, in particular between developing and developed countries have, however, so far prevented their conclusion. According to the most recent draft version of the SPLT, parties to the treaty would be obliged to grant patents on products and processes in all fields of technology, excluding, however, mere discoveries. Depending on the final formulation of this clause and its interpretation as well as the future inclusion of potential exemptions from patentability into the treaty - which some countries would like to keep much narrower than in TRIPS – the SPLT might require members to provide for the patentability of genes in their respective national legal orders. This could, in the future, lead to conflicts with Article 12.3 (d) of the ITPGRFA which restricts such patents, as far as there are PGRFA-related, to a certain extent. As it is neither certain that the SPLT will eventually be concluded nor how precisely it will look like, it is too early for any definitive statements on this issue, however.

### **Article 13.2 (d) (ii) ITPGRFA and TRIPS**

As was pointed out in the very beginning of this section, there are, however, two other provisions which might be problematic with regard to a potential conflict with TRIPS. One of these is the provision in Article 13.2 (d) (ii) that benefits arising from the commercialisation of PGRFA received from the multilateral system must be shared by paying into the IT's fund and the respective clause in the SMTA. Patent laws tend not to contain a research exemption broad enough to permit commercially oriented research, but merely allow a certain degree of private experimental use on a patented invention to be done without infringing the patent. Hence, the clause that benefits must be shared applies when a PGRFA received from the Multilateral System has been modified in a way that a patent is granted and is subsequently commercialised, because such a patent inhibits further unrestricted availability for research and breeding. Nonetheless, and similar to what we found above with regard to UPOV, there is no legal conflict between this provision of the ITPGRFA and TRIPS. Again, Article 13.2 (d) (ii) ITPGRFA does not contain any obligation for the state parties themselves. Even at the level of individual rights derived from the treaties, there is again no genuine conflict. While the ITPGRFA provision may factually reduce the profit that a holder of a patent on a certain PGRFA eventually gains, TRIPS is not concerned with whether an applicant for a patent will have to pay some fees to obtain it or how much a patent holder will gain from exploiting the patent.

### **Farmers' Rights**

Another issue is we must, again, discuss are farmers' rights under the ITPGRFA and their relationship with the TRIPS. Again, the most challenging paragraph of the ITPGRFA is Article 9.3, which sets forth that nothing in the paragraph on farmers' rights "shall be interpreted to limit any rights that farmers have to save, use, exchange and sell farm-saved seed/propagating material, subject to national law and as appropriate." TRIPS, in contrast, states that among the rights of the holder of a patent is to make, use, offer for sale, sell, or import the protected product or to use, offer, or sell a protected process or the product directly obtained from that process. The most critical issue here is whether the right of farmers to exchange and sell farm-saved seed obtained from patented plants without the consent of the patent-holder is in conflict with the rights of the latter from the patent. It is a plausible assumption that this is indeed the case. Again, however, an outright legal conflict is avoided

by the ITPGRFA's formulation that the farmers' rights described need only be granted subject to national law and as appropriate.

### **UPOV-style plant breeders' rights as *sui generis* protection in the sense of Article 27.3 TRIPS**

Finally, another problematic issue concerning the ITPGRFA and a potential conflict of municipal law resulting from the implementation of TRIPS should be noted. Article 27.3 TRIPS, while stipulating that members may exclude from patentability plants and animals other than micro-organisms, also requires members to provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. While TRIPS makes clear that some sort of protection for plant varieties is required, it fails to specify the minimum conditions for a *sui generis* system for plant varieties. Equally, the TRIPS Council has so far not provided much guidance in this regard, apart from informal recommendations to adhere to UPOV. While there is thus no conflict between the ITPGRFA and TRIPS in this respect, conflicts may arise depending on how WTO members implement Article 27.3 TRIPS. The leeway granted by TRIPS has motivated a number of countries to develop and implement their own *sui generis* systems. Since some of these have been adopted before the entry into force of the ITPGRFA, they may include some provisions that need to be revised. For instance, the legislation of some countries is very restrictive with regard to access to genetic resources (e.g. legislation of the Andean Community or that of the Philippines). Such norms may be in conflict with provisions of the ITPGRFA such as Article 11, which sets forth that facilitated access shall be granted to all PGRFA that are part of the Multilateral System.

### **Conclusion**

In sum, there is hence no conflict between the ITPGRFA and TRIPS.

#### **9.1.4 Consequences for developing countries**

The fact that there is no legal conflict between the ITPGRFA and either the TRIPS Agreement or UPOV is, of course, fortunate from the viewpoint of countries that are parties to several of these agreements. This is especially true for developing countries that do not face a situation of legal ambiguity and are granted, by each of the treaties, a degree of flexibility in implementation.

### **9.2 Relationship with the CBD**

The CBD is a multilateral environmental agreement offering a multilateral system for collecting and distributing financial resources (Articles 20, 21), financing its main bodies and for the negotiations to further develop the CBD through the Conference of the Parties. However, most of the requirements to establish legal, institutional and policy frameworks are addressed to "each contracting party".

#### **9.2.1 The CBD's system for access and benefit-sharing**

The CBD pursues a similar rationale as the ITPGRFA. It seeks to link the conservation of biological diversity to sharing the benefits arising from its use. The CBD was the first international treaty to link access to genetic resources to the equitable sharing of benefits derived from those resources (Articles 1, 8 (j), 15, 16 and 19 of the CBD). Importantly, while

the CBD affirms that the conservation of biodiversity is a "common concern" of humankind, it also recognises that states have sovereign rights over their biological resources.

Where it addresses genetic resources, the CBD states that negotiations on access to genetic resources and the fair and equitable sharing of benefits arising out of their utilization (Article 15) and related provisions (Article 8 (j), 10, 16, 19) are to be held bilaterally between the providers and recipients, provider and user countries. At its sixth meeting in May 2002, the COP adopted the Bonn Guidelines on access to genetic resources and the fair and equitable sharing of the benefits arising from their utilization. The guidelines are to serve as inputs for drafting legislative, administrative and policy measures on ABS with particular reference to CBD Articles 8 (j), 10, 15, 16 and 19. They give recommendations for regulating PIC, contracts and mutually agreed terms for ABS. The guidelines are voluntary and shall not substitute for national legislation. COP 6 further invited parties to provide financial and technical support to developing countries in implementing the Bonn Guidelines (VI/24B).

Just a few months later, the World Summit on Sustainable Development (WSSD) decided on a plan of implementation that calls upon states to negotiate within the framework of the CBD an international regime to promote the fair and equitable sharing of benefits arising out of their utilization, taking into consideration the Bonn Guidelines.

However, even twelve years after the adoption of the CBD, less than 20 countries and regional organisations have adopted ABS legislation. In many cases there are doubts as to whether the legislation is effective or has been fully implemented.

### **9.2.2 Towards an International Regime on Access and Benefit-Sharing: what role for the ITPGRFA?**

In light of these deficiencies of the existing system, the CBD COP 7 in 2004 (VII/19) mandated the Ad Hoc open ended working group on ABS, with help of the working group on Article 8 (j) and all stakeholders and governments, to "elaborate and negotiate an international regime on ABS with the aim of adopting an instrument to effectively implement the provisions in Article 15 and Article 8 (j) of the CBD and the three objectives of the CBD".

The eighth Conference of the Parties to the CBD (COP8) made considerable progress toward establishing an international regime (IR) on ABS. COP8 approved and sent the report of the Ad Hoc Open-ended Working Group on ABS back to the said Working Group to further develop the IR, in accordance with decision CBD/COP/VII/19 D, for further consideration during its fifth meeting. It also invited all stakeholders, including international organizations, to submit information on existing legal regimes to govern ABS. Further, it instructed the Working Group to "complete its work at the earliest possible time" before COP10.

There are indications that in the negotiation of an international regime on ABS, the IT might become prominent. For example, the World Conservation Union (IUCN) ABS project has suggested considering "re-linking the suite of genetic resource issues" for an international regime on ABS and include issues relating to GMOs, biosafety and agriculture. Others suggest that the negotiators for the international regime take into account the special nature of PGRFA and reflect it in the design of the regime and embrace the Multilateral System of the ITPGRFA as part of the international regime.

An IPGRI study mentions that access to genetic resources for pharmaceutical research and use offers potentially high benefits resulting from access to a very small number of resources and would be best governed through a bilateral regime. On the other hand, most crop varieties combine a multitude of genetic resources from many different sources, and a large number of stakeholders would be entitled to benefits. Therefore, bilateral negotiations do not seem to be feasible in this case. "Thus, bilateral approaches tend to be negotiated quicker due to the fewer parties involved and are more flexible because they can be tailored to the needs of the parties, whereas "multilateral approaches offer participants access to a greater range of germplasm...".

The ITPGRFA is fairly detailed in how transfers of PGRFA "will take place, but makes no attempt to specify how they integrate with the CBD's ABS provisions, or how they will fit into an international ABS regime." Therefore, some voices suggest treating the ITPGRFA with more priority as (a) the ABS regime might take much longer to be negotiated, let alone be implemented and (b) as the ITPGRFA is linked more closely to the Millennium Development Goals. Therefore, others have recommended to treat the IT with regard to ABS policies and laws as "an exceptional regime, with its own set of rules and principles, which should not be affected by the outcome of the laws and regulations" pertaining to the establishment of an international regime on ABS.

Although the international regime on ABS has not been established, let alone been thoroughly negotiated, the outcome of these negotiations nevertheless will be important for the implementation of the ITPGRFA, especially with reference to the concept of using a system of internationally approved certificates of origin, possibly incorporated in disclosure requirements for patent applications.

The current draft of the international regime on ABS specifically excludes PGRFA governed by the FAO ITPGRFA from its scope as long as PGRFA are used for purposes specific to the ITPGRFA. Most of the proposed text is, however, still in brackets suggesting great controversy around it:

3. [The international regime will not apply to the plant genetic resources [of those plant species] that are considered by [under annex 1 of] the International Treaty on Plant Genetic Resources for Food and Agriculture [or by the Commission on Genetic Resources for Food and Agriculture], [when those resources are used for the purposes of that Treaty].
4. [The international regime is without prejudice to the FAO International Treaty on Plant Genetic Resources for Food and Agriculture and will take into account the work of the WIPO/IGC on the intellectual property aspects of sui generis systems for the protection of traditional knowledge and folklore against misappropriation and misuse].

Moreover, it remains to be seen if an international regime will be legally binding.

### **9.2.3 The Multilateral System of the ITPGRFA and the bilateral system of the CBD - compatibilities**

There are essential differences between the two systems of the ITPGRFA and the CBD. Where the CBD is built on the idea of national sovereignty over genetic resources, the ITPGRFA provides a multilateral system, giving access to a pool of PGRFA named in Annex I of the treaty.

It is argued that due to the specific interdependence of countries with regard to PGRFA, a bilateral approach towards benefit-sharing would be difficult to implement. In order to breed a new variety, up to 80 different varieties from different origins are needed, which means that is often impossible to trace a single source of origin. Thus a bilateral approach to benefit-sharing would be complicated and costly, or even impossible to implement. The CBD on the other hand divides its signatories into user and provider countries of genetic resources, assuming that each genetic resource has ideally one country of origin, and entities located mainly in other countries would like to use the resource. Another substantial difference is that in the ITPGRFA access is decoupled from benefit-sharing and guaranteed continued access to the PGRFA under Annex I constitutes itself a fundamental benefit for the signatories to the IT. Under the CBD, access is not a benefit in itself but is coupled to benefit-sharing. Benefits arise as a result of the utilization of genetic resources and are to be shared between the users and the providers of said resource.

While there are thus differences between the CBD and the ITPGRFA, there are also many similarities. Both treaties aim for conservation, sustainable use and fair and equal sharing of benefits arising from the utilisation of biological resources, although the ITPGRFA concentrates on PGRFA, whereas the CBD covers all biodiversity. PGRFA are a part of biodiversity; however, they differ in that by definition they are put to human use and therefore need human intervention to be protected and conserved, which is not necessarily the case for all other biodiversity. The ITPGRFA covers all PGRFA, whereas the multilateral system, only applies to those PGRFA listed in Annex I. Some authors have suggested that means that PGRFA other than the Annex I crops are to be covered by the benefit-sharing mechanism of the CBD when it comes to ABS.

**Table: The legal situation with regard to the facilitation of access to crop genetic resources**

<b>FAO</b>	<b>CBD</b>	<b>Accessions acquired <i>before</i> the entry into force of the CBD</b>	<b>Accessions acquired <i>after</i> the entry into force of the CBD</b>
<b>Crops listed under the multilateral system of the IT</b>		Access to be facilitated under the IT Multilateral System	Access to be facilitated under IT Multilateral System
<b>Crops NOT listed under the multilateral system of the IT</b>		Access is not regulated by international law	Access is regulated internationally by the CBD

Both agreements explicitly state that they are in harmony with each other. The ITPGRFA in Article 1 affirms its objectives are to be achieved "in harmony with the Convention on Biological Diversity", and "Articles 19 and 20 of the treaty and decision VI/6 of the Conference of the Parties to the Convention on Biological Diversity require cooperation between the secretariats and the governing bodies of the two instruments". FAO is furthermore a leading partner in the CBD's programme of work on agricultural biodiversity, and COP8 of the CBD extended specific invitations to the Governing Body of the IT to

collaborate on its cross-cutting initiative (on biodiversity for food and nutrition). Other initiatives where the Governing Body of the ITPGRFA is explicitly invited to participate include the review of the impact of GURT on farmer's rights. Further, synergies between the CBD bilateral system and the IT multilateral one are overlaps in funding and priorities for capacity building.

## 10 Conclusions

The fact that the ITPGRFA entered into force on 29 June 2004 is itself a major achievement. The treaty is the result of a process originating over 20 years ago with the International Undertaking. The ITPGRFA marks a major new development in the move towards an international regime on PGRFA, combining the objectives of access to PGRFA and fair and equitable benefit sharing, as well as conservation and sustainable use of existing PGRFA.

The ITPGRFA creates the first multilateral system of access and benefit sharing at the international level. This system allows states and private actors to gain access to a large pool of PGRFA in exchange for granting access to their own resources. The ITPGRFA aims to allocate part of the commercial benefits generated by products that make use of genetic resources to those who have contributed to the conservation and development of genetic resources. In this way, the ITPGRFA creates an incentive to continue conservation and development and aims at benefiting farmers, especially in developing countries.

The ITPGRFA, while creating obligations for developing and developed countries alike, also contains provisions which aim at easing the burden of implementation for developing countries, which, after all, host the biggest share of agricultural biodiversity in their territories. Thus, the ITPGRFA attempts to alleviate the burden of implementing conservation measures by requiring developed nations to provide developing nations with technical and financial assistance. Besides using these mechanisms of support built into the treaty, developing countries may also use existing institutions and mechanisms to meet their treaty obligations. For cost-effective implementation of the IT, certain institutions established under the CBD, such as national focal points, could have their mandate extended to also serve the ITPGRFA. With regard to the establishment of databases or registers, it is also advisable to resort to the growing number of networks and databases which have been and are being established in the course of implementing the CBD and the FAO Global Plan of Action. In addition, developing countries can rely on an international dispute settlement mechanism for the adjudication of MTAs. This alleviates their duty to allocate resources to a national dispute settlement mechanism.

The ITPGRFA fits into an existing landscape of treaties, agreements and regimes related to conservation, access and benefit sharing and intellectual property rights. The CBD, UPOV and TRIPS determine the international context against which Parties to the ITPGRFA will have to implement its provisions. There is no legal conflict between any of these international treaties and the ITPGRFA, even though they may be considered to serve different purposes. The ITPGRFA fills a gap in existing international conservation law that was left by the CBD: the CBD was targeted at all biodiversity, which limited its usefulness for dealing with PGRFA. Neither did the CBD specifically address the issue of access to PGRFA, especially in *ex situ* conservation, nor the realisation of farmers' rights.

Even though the ITPGRFA may thus be regarded as being the most well balanced and sophisticated PGRFA-related international agreement in force, it is still too early for a definite

assessment of its assets and disadvantages. The implementation of the ITPGRFA at the national level has generally been slow so far, as many countries have made their implementation efforts dependent on the results of the further negotiation process, taking a “wait-and-see” stance towards the ITPGRFA. Furthermore, it is unclear to what extent the access and benefit sharing system under the treaty will actually be used and how much resources will be generated. Moreover, it is still unclear how the ongoing negotiations on an international regime on access and benefit-sharing which are being carried out in the framework of the CBD will influence the ITPGRFA and its functioning.



## **8. ASSESSING THE ECONOMIC IMPLICATIONS OF DIFFERENT MODELS FOR IMPLEMENTING THE REQUIREMENT TO PROTECT PLANT VARIETIES**

### **1. INTRODUCTION**

#### ***1.1. 1. The research programme***

The project proposal states, “The objective of this Workpackage is to assess the effectiveness of the regulatory measures employed by EU candidate countries and developing countries to implement Article 27.3(b) as it relates to the protection of plant varieties. The analysis treats plant variety protection as not being an end in itself but as part of a larger policy framework related to economic growth in the agricultural sector. In addition, ‘effectiveness’ is considered from multiple perspectives and not only as a requirement for compliance with international agreements.” This suggests a focus on Article 27.3(b) of the TRIPs Agreement but also requires bringing in the wider policy context of changes in and transformations of the agricultural sector. In addition to this focus, the work package also maps out two broad tasks: beginning with collating and reviewing the relevant literature and followed by country case studies.

The aim of the literature review is to critically analyse the “rich and growing literature on ‘how best to implement Article 27.3(b)’” and to study the “relevant literature on the economic impact of intellectual property rights with respect to plant genetic material”.

The first component of the review focuses on identifying the broad ‘models’ that have been presented as means to implement Article 27.3(b). This will consist of the different instruments (i.e. patents, *sui generis* or combination thereof), the nature of the scope of the rights and other key constituent elements of the architecture of the system of protection (e.g. the standards of protection, the coverage of the system, its relationship with other rights, etc.) Following on from the latter, it will also be necessary to have some – though brief – discussion of closely related issues and developments (e.g. protection of TK, Farmers’ Rights, the FAO International Treaty, etc.).

The second component of the literature revolves around the ‘implementation models’ and focuses on the economics of intellectual property in this area. The aim of the proposed documentation will be to pull out from the available literature University evidence and assessment concerning the ‘impact’ of a set of key features of the different implementation models. In terms of ‘impact’ the review will focus on market-based indicators (price of seeds, firm concentration, etc.), indicators of innovation (new varieties released) and appropriation (breeding techniques), and various structural features (nature of the seed sector, agricultural sector, etc.). The role of related regulatory systems (e.g. seed certification) will also be noted.

The case studies seek to adopt a broad template. The work on the case studies will be spread out between primary research (field-work based country case studies), analysis of primary data (economic, legal and qualitative) and secondary research; in particular, some of the case studies will be based on field work whereas other country studies will be exclusively based on secondary literature. Using the base of the literature review where (a) the models have been identified and (b) evidence of impact observed; the case studies will assess the experience of the countries and present evidence of the economic impact of protecting plant varieties. In

particular, it will focus on the impacts on the relevant interest groups (farmers, breeders – public and private, seed merchants), and on the wider economy. The following were the field-work based studies: Bulgaria, Ethiopia and Kenya. And, these are the secondary literature based studies: China, India and Turkey.

The remainder of this report summarises the main findings of the country case studies. All documents are available at the IPDEV project website, <http://www.ip4development.org/>. These documents include the background literature reviews for the law and economics of plant breeders' rights, each country case study and the final report of work package (i.e. this document).

## **2. CASE STUDY ON BULGARIA**

### **2.1. 1. Introduction**

The foreign trade balance of the Republic of Bulgaria was negative in 2004 amounting to 3 900 million BGN, and increased by 622 million BGN compared to the same period in the previous year. Foreign trade in agricultural commodities for 2004 ended with a positive trade balance amounting to just over \$247 million US. The gross added value from the agrarian sector was 2.2% and its share of added value to the economy was 10.9%. The relative share of gross value added created in the agrarian sector maintained a downward trend – from 13.4% in 2001, 12.1% in 2002, 11.6% in 2003 down to 10.9% in 2004.

According to the provisions of the Law for support of the agricultural producers, a register of agricultural producers was established and is functioning at the MAF. The registration is more of an obligation than a recommendation since it is a necessary condition for access to the financial support by State Fund Agriculture and SAPARD program. Over the period 2007-2009, around 1.8-2 billion Euro in the form of direct financing will be received in the country. In order to have access to these subsidies, the agricultural producer will have to be registered with a special form in the national register. By 19/09/2005, the registered agricultural producers, physical and legal bodies were 64 127.

The non-cultivated lands in 2004 amounted to 455 000 ha and were 7.9% of the areas with agricultural purpose. Comparing with the previous year, non-cultivated lands remained nearly the same size.

### **2.2. 2. Intellectual Property Laws and Regulations**

The new Bulgarian Law on Protection of New Plant Variety and Animal Breeds (hereinafter referred to as "Plant Variety Law") entered into force on January 4, 1997. This Law introduces a *sui generis* system of plant variety protection and brings it in accordance with the relevant international standards, in particular with the UPOV Convention and the system of Community plant variety protection (Council Regulations (EC) No. 2100/94). The subject matter of protection covers created or discovered and developed plant varieties of all botanical genera and species, including clone, line, hybrid between genera or species and root stock, irrespective of the method (artificial or natural) of their production. The full case study includes an in-depth description of the legislation wherein the close compatibility and correspondence with UPOV is apparent in key areas: the conditions for grant of protection, the scope of protection and others measures. Also included are the procedures for a grant, procedures for obtaining protection, assignment of licenses, scope of rights, limitation of scope of rights, and duration of protection. The descriptions include ministries, courts, and agencies involved in the completion of intellectual property right protection.

In March 2003, Bulgaria activated and has since continued to implement a new Plant Variety Law on seed and propagating material, which is harmonised with the EU-directives related to the production and trade of seed and propagating material, variety testing and keeping a variety register. The Minister of Agriculture and Woodlands realises fulfilment and control of these activities through its Executive agency of variety testing, sampling and seed control (ИАСАС) and National services for plant protecting (HCP3). The Law permits regulation, means of enrolment, and quality control such that the seed and propagating material is traded only if it is from the varieties enrolled in the official variety list. The list is separated into a list "A" and "B", each of which contains specific types of plants meeting requirements for

biological and economic properties. Enrolled varieties may be dealt with if they meet exception requirements (details of which are presented in the full report). In addition, the report contains a detailed listing of questions under variety data and testing. The varieties are enrolled for 20 years for fruit species and vines and 10 years for the other vegetable species. After expiry, the varieties may be enrolled for the next period if they still meet the requirements. Included in the report are conditions and requirements for the certification, production, and import/export of seed and plant material.

While the substantive laws on IP protection by and large comply with international standards, the EC Commission still sees some deficits in the field of enforcement. Reasons can be found in the insufficient capacities of administration and judiciary, and the lack of specific training in this field. Sofia Court and the Patent Office are responsible for enforcement activities. In some respects, the Sofia City Court is a special court since according to Sec. 64 Judiciary Act, it is the only city court in Bulgaria and a District Court.

### **2.3. 3. Use and Practical Aspects**

Approbation and seed grading focus on the following areas: Field inspections (approbation) of seed-producing and propagation crops intended to certify the quality of seeds and propagation material; seed and propagation material grading and issuance of certificates required for domestic and export trade; Ground control tests (zonal field tests) and laboratory tests intended to determine the authenticity and purity of tested varieties of seeds and propagation material; Control on production, storage, handling, marketing and planting of seeds and propagation material. In 2000, the government structures involved assessed 398 plant varieties for DHS (distinction, homogeneity and stability) and further 814 varieties for BEQ (bio-economic qualities) including 703 field crop varieties, 101 vegetable varieties and 10 permanent crop varieties.

The Official variety list of 2002-2003 is an objective source of information about the current economic and legal status of the new plant varieties protection as an object of intellectual property. Each plant or fruit/vegetable of the official variety is listed in the full report, along with the number of protected varieties in each list ("A" or "B"). During January 1 – July 31, 2001, 84 contracts for formal variety testing were signed: 43 with local customers, 30 with foreign customers and 11 with private variety testing laboratories.

The number of IP cases is rising. While there were 21 cases in 1995, the number had risen to more than 150 in the year 2000. This is still an insignificant number, compared to the 500 to 600 cases a judge at the Sofia City Court has to deal with annually.

### **2.4. 4. Conclusion**

Most owners of protected varieties are governmental institutes, which currently have economic difficulties and no resources for financing of new selections. Authors in the full report suggest the effective use of the protected varieties is of great importance to their survival as a scientific potential. The status of legal protection of foreign varieties in Bulgaria indicates that major private breeders do not protect their varieties with Bulgarian certificates. From the accepted 303 foreign "list A" varieties in 2004, none are protected as an object of intellectual property rights. Nevertheless, the varieties are on the Bulgarian market. From the enrolled 9 foreign varieties in the Bulgarian patent office, the owners of 8 of them refused their varieties to be accepted in the Bulgarian official list for 2004. Authors suggest this unpleasant result is due to hybridisation ("natural" protection), lack of production investment by large firms, and lack of climate information in Bulgaria.

### 3. CASE STUDY ON ETHIOPIA

#### 3.1. 1. *Introduction*

This study differs from the others in focussing mainly on a single crop: coffee. In the course of the lengthy negotiations of the FAO International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGR), adopted in November 2001, the Ethiopian government decided not to include coffee in the list, annexed to the treaty, of plants covered by the multilateral system of free germplasm flow. The rationale for this decision was that the Convention on Biological Diversity (CBD) gave the opportunity for genetic resources-rich countries to enter bilateral agreements to value their genetic resources. In 2005, the Government of Ethiopia prepared many Proclamations, Regulations and Guidelines dealing with biosafety, traditional knowledge, and plant breeders' rights, with a view to implementing the CBD, the Cartagena Protocol to the CBD, and to joining the World Trade Organization, where Ethiopia has an observer status.

Agriculture accounts for 45% of the Ethiopian GDP, 80% of total employment and 85% of exports (75% according to AfDB-OECD 2005). The total exports of Ethiopia rose from US\$ 452.3 million in the fiscal year 2001-2002, to 600.7 in 2003-2004. Coffee represents one third of total exports.

Overseas Development Aid received by Ethiopia has risen from US\$ 925 million in 2000 to US\$ 1,920 in 2003, of which on average 33% are allocated annually to humanitarian assistance, compared to 6% to agriculture and 10% to transport infrastructure. The proportion of food aid to food grain production decreased from 12.6% in 1984-85 to 7.1% during the period from 1991-92 to 1999-2000. The nature of food aid changed as well: whereas the bulk of food aid was in kind until 1994-1995, which had an adverse effect on domestic food prices and food production, it now tends to be replaced with aid in cash. However, with a population growth of 2.9% per year and the overall cereal production increasing by 1.7% per year, Ethiopia is not self-sufficient.

Under the Derg regime, the state-owned Ethiopian Seed Corporation was the sole distributor of seeds produced by itself or state farms. Although prices were kept low, farmers would rather resort to saved seeds of local varieties. The ESC was restructured and renamed as the Ethiopian Seed Enterprise (ESE) in 1993. Prices were deregulated and the private sector was allowed to participate in the production of improved seeds. Nonetheless, the market for improved seeds remains concentrated with the ESE providing more than 90% of improved seeds. The annual seed needs of Ethiopia are estimated at 140,000 tonnes, of which 86% are met by farm-saved seeds. Only 29% of grain produced is marketed. Of this, 31.4% are sold directly from producers to consumers, and 35.5% are sold to inter-regional traders.

The ESE is supervised by the Ministry of Agriculture and Rural Development. As already mentioned, its main role consists in providing improved seeds. Actually, this role is three-fold, as it entails breeding, multiplying and distributing improved seeds. These are received both from breeders and from the Ethiopian Agricultural Research Organization. ESE has one protected variety and a keen interest in intellectual property rights, in particular to protect hybrids with a view to export markets. It produces 40,000 – 50,000 quintals of hybrid maize per year, no longer in co-operation with Pioneer Hi-Bred Seeds Ethiopia. Pioneer Hi-Bred

Seeds Ethiopia now operates on its own and has registered 2-3 varieties in Ethiopia in order to multiply and sell them in this country.

### **3.2. 2. Seed Regulations**

The current variety release guidelines have been in use for over two decades. A review is under consideration. The functions of the National Variety Release Committee are:

- To approve the release of hybrids and varieties developed by governmental and private institutions, at least once per year for both the highland and the lowland crops;
- To make the necessary arrangements with foreign and local institutions to conduct quality tests such as oil content, cooking, baking or fibre quality of varieties and hybrids proposed for release;
- To register the released varieties and hybrids;
- To obtain seed of the newly released variety or hybrid from the breeder or the institution that developed it and provide it to the IBCR for long-term storage and maintenance;
- To recall and remove obsolete varieties and hybrids from the list of those eligible for seed certification when sufficient information is available;
- To give periodic review and status report to the National Seed industry Agency (now renamed NAIA).

The criteria for the release of a variety are the following are the basic UPOV ones. However, the requirement of distinctness is a blend of traditional UPOV-like distinctness criterion and of “Value in Cultivation and Use” (VCU) criterion.

The Seed Proclamation no 206/2000 deals with seed certification. The rationale for its adoption is “the need for creating a legal framework for the protection and control of the interests of users, originators, processors, wholesalers, and retailers of plant seeds.” Art. 3 of the Proclamation states that the provisions of this proclamation shall not apply to seeds produced by a farmer, and sold directly to another farmer, neither to seeds intended for other purposes than planting. The Seed Proclamation provides further that research organisations, both public and private, shall import or export varieties for research purposes only after obtaining a permit from the NAIA and where these satisfy the requirements of the Plant Quarantine Regulations.

Seeds that are genetically modified shall be imported only if the NAIA is satisfied “that these seeds or planting materials are in conformity with the laws issued regarding the importation of genetically modified plants and other pertinent directives.” Moreover, “[n]o person shall import and sell seed whose second generation seed cannot germinate or seed which has terminator gene technology.”

Proclamation no 123/1995 concerning inventions, minor inventions and industrial designs excludes from patentability “[p]lant or animal varieties or essentially biological processes for the production of plants or animals.”

The Proclamation on Plant Breeders’ Rights was adopted on 3 January 2006. Members of the Rural Development and the Natural Resources and Environmental Protection Standing Committees of the House of Peoples’ Representatives considered that the proclamation would encourage farmers and pastoralists to use their genetic resources, while encouraging the private sector to release new plant varieties suitable for the varied ecosystems of Ethiopia and facilitating the use of new plant varieties released abroad. On the same day, the Proclamation

to provide for access to genetic resources and community knowledge and community rights was also endorsed. This proclamation draws on the African Unity Model Law on Rights of Communities, Farmers, Breeders, and Access to Biological Resources.

### **3.3. 3. *Focus on the coffee market***

Ethiopian germplasm constitutes the genetic base of most of arabica coffee produced in Latin America and Asia, exposing coffee production to the threat of disease outbreaks, such as the Coffee Berry Disease that wiped out an important proportion of Ethiopian coffee areas. In 1971 or the coffee leaf rust outbreak which resulted in the termination of coffee production in Sri Lanka. Maintaining this germplasm is thus paramount.

Coffee production involves over a million farming households (with land plots of 0.5 ha in average) and about 25% of the population of the country. Roughly 500,000 hectares of land are occupied by coffee, with elevations ranging from 550 to 2400m. Annual coffee production varies between 300,000-330,000 tonnes, which corresponds to an average yield of 600 kg/ha. Although Ethiopia is the first African coffee producer, it accounts for only 3% (4% in 2004) of the global coffee market.

The strategy followed by the Oromia Coffee Union seems to be the best way to promote and upgrade Ethiopian coffee, through certification and fair trade. In respect of certification, the WTO Agreement on rules of origin may have an impact.

The views of coffee brewers on this issue differ from those of coffee producers. Coffee roasters oppose a possible labelling requirement including the indication of coffee origin, as most of the time, coffee packs are the result of a blending of different coffee types, varying from year to year in order to maintain a given taste despite climate variations, even in the case of pure origins (cf. “pure Ethiopian coffee” or “pure Colombian coffee”). Two difficulties would then arise from their perspective: it would become easier for competitors to copy a popular blend if the different coffee origins and proportions thereof are clearly indicated on labels, and packaging and labelling would have to change yearly (owing to the necessity to change the respective proportions of different coffee types following the conditions of production), which would generate additional costs. In the case of “Carte Noire” coffee, which represents roughly 25% of all coffee packs sold in France, 20 different origins are present.

Rather than focusing on rules of origin and labelling requirements with their negative impact on competition, it might be preferable at the international level to push for a broadening of TRIPs Art. 23 special protection for wines and spirits by geographical indications to other products, in particular coffee, in addition to implementing domestic legislation on access and benefit-sharing.

## 4. CASE STUDY ON KENYA

### 4.1. I. Introduction

This is a study of the 'impacts' of implementing Article 27.3(b) of the TRIPs Agreement in Kenya. The study looks at how the international obligation is translated into the architecture of domestic law and analyses the economic changes that have occurred in plant breeding and the seed industry. Kenya is a useful choice as it has a 'relatively' long history with regulations in the area of plant varieties and seeds and it has been integrated into global supply chains in horticulture and floriculture. Agriculture has central significance in Kenya, not only does it support over 70% of the population but it is also a leading export earner. At the TRIPs Council, Kenya has regularly opposed the strengthening of existing obligations with respect to plant variety protection (in Article 27.3b). Consequently, studying the way in which this obligation to the TRIPs Agreement is domestically implemented can be a prism into how different domestic (and international) constituencies are handled.

### 4.2. 2. Background

Kenya is an agrarian-based economy with over 60% of the population classified as rural. Agriculture's share of the GDP is substantial, though it has fallen from nearly 40% in the 1970s to 25% in 2000. Yet, agriculture retains its importance not only as a source of livelihood (some 75% of the total labour force) but also as an export earner (about 70% of total exports). Significantly, it is small-holder agriculture that account for 75% of total agricultural production and 60% of the export-oriented horticulture and ornamental sector.

Maize is by far the leading crop of cultivation accounting for upwards of 30% of total cropped area. Production has stagnated with growth at 1.05% between 1990 and 2005. Yields have fallen from 1.76 tonnes per hectare in the 1990/94 period to 1.51 in 2000/04. Horticultural crops and flowers now account for short of 30% of the cropped area with vegetables alone accounting for 22%. Between 1974 and 2000, there has been a four-fold increase in their export value and exports are now valued at US\$167Mn. Coffee and tea together account for some 5-6% of the area. After tourism and tea, horticultural exports are the third largest export-earner; thus, displacing coffee from its position.

### Seed industry

Till recently, seed production has been the province of the parastatal Kenya Seed Company (KSC). It was endowed with a legal monopoly to grow, process and sell certified maize seed. It also had exclusive rights to the multiplication and production of varieties bred by the Kenya Agriculture Research Institute (KARI).

As part of economic reform in the early 1990s, the seed sector was opened up to the private sector. Simultaneously, the exclusive right that KSC had to KARI varieties was terminated. Many seed companies have entered the market and presently there are 55 registered seed companies.



**Table 1: Maize Seed Data**

Of the total maize seed market, it is estimated that just over 45% is commercial maize seed. Despite the opening up of the seed market, KSC continues to retain its dominating position and accounts for 86% of the maize seed market (Table 1). Other crops where commercial seed sales occur are in the various fruits and vegetables that constitute the horticultural sector and certain oilseeds (e.g. sunflower). However, this is a relatively small market as over 70% of vegetable seed is imported.

Company	Seed Volume (1000Kgs)	Seed Sales (K£ Mn)	Market Share
Kenya Seed Company	25933.97	15.00	86.49%
Western Seed Company	666.27	0.60	3.46%
Faida Seed	0.00	0.55	3.17%
Farmchem	296.19	0.30	1.71%
Pannar	430.22	0.43	2.48%
Lagrotech	5.66	0.24	1.38%
	0.00		
Total	27576.66	17.34	

Note: (1) Seed volumes based on Kephis certified seeds (2003). (2) Seed sales are estimated figures.  
Source: Ministry of Agriculture (2004)

### Plant Breeding

Plant breeding is largely a public sector activity that is centrally coordinated by KARI and implemented through a range of domestic and international public sector institutions that include the Kenya university system, the International Agricultural Research Centres (IARCs) and a host of commodity boards. KARI's research expenditures have increased from K£40Mn in 1990/91 to K£74Mn in 1997/98. There has been an increase in the share from the public exchequer (now, 52%) so as to reduce the heavy reliance on donor funding as that tends to be project driven. Yet, there has been a secular decrease in research intensity which has fallen from 2.01 in 1991/92 to 1.05 in 1997/98.

Breeding activities in maize can be analysed through the varieties released. Between 1964 and 2003 there were over 80 varieties released of which 86% were released in recent years (1994/2003) and are heavily oriented towards hybrids. Only 11 varieties were open-pollinated varieties.

#### **4.3. 3. Overview of Regulations and Laws**

Article 27.3(b) is a rare instance of intra-Quad differences, which in this case reflects the exclusion of plant varieties from patents as provisioned in the *European Patent Convention*. Consequently, the obligation allows for different legal practices and the space for imaginative law-making. Kenya has led the Africa Group at the TRIPs Council in advocating a 'no patents on life' position. Hence, the curiosity of how this Geneva rhetoric matches up with domestic law-making. Unfortunately, none of the Geneva rhetoric has filtered into the relevant domestic legislation. Moreover, the decision to accede to the 1978 Act of the *International Union for the Protection of New Varieties of Plants* (UPOV) – Kenya acceded in April 1999 – has constrained the space for legal imagination. In particular, a strong case for a cognitive lock-in to the architecture of laws established in Europe.

The *Seeds and Plant Varieties Act, 1972* provides the legal framework for plants and seeds. Provisions for PBRs were enacted through the *Seeds and Plant Varieties (Plant Breeder's Rights) Regulations, 1994* and are administered by the Plant Variety Rights Office at the Kenya Plant Health Inspectorate Service (KEPHIS). The Act establishes regulatory

framework for transactions in seeds; thus introducing provisions for the registration of seed growers and seed merchants; creating an Index of Names of Plant Varieties; and rules concerning the selling of certified and tested seeds. The seed testing and certification system is to be administered by a *Seed Regulation Committee* (the Regulation, Section 5, passim). Part VI of the Act makes provisions for a *Seeds and Plants Tribunal*. While the Committee has rarely been convened, the Tribunal was only established in September 2006.

Within Kephis is the Plant Breeders' Rights Office that administers the PBR system. In 1997, the first applications were accepted and the first grants were issued in 2003. In 1996, UPOV reviewed Kenya's law for conformity and placed accession contingent on the execution of three changes. One of these required the deletion of a test for agroecological value as part of the tests for distinctness, uniformity and stability that collectively formed the conditions for grant of protection. These amendments were made; thus, Kenya's law is very similar to the UPOV template in key features like the conditions for grant, the scope and duration of protection, exemptions from the right and provisions for stronger rights. Like in the 1978 Act of UPOV, there is no explicit exemption for farmer seed saving/exchanging. The Act in Section 20(5)(a) says that 'the sale of reproductive material of a protected variety does not imply that the breeder authorises the purchaser to produce the reproductive material that was sold to him'. However, a farmer is prohibited from selling seeds because of the requirement to obtain seed certificates.

Kenya's first national patent law was passed only in 1989: the *Industrial Property Act of 1989*. On account of obligations arising out of the TRIPs Agreement, the *Industrial Property Act, 2001* was passed. Section 26 follows a well-established routine of attempting to demarcate and differentiate juridical space that would map onto biological space in terms of 'essentially biological' and 'microbiological'. This route was pioneered in the *Strasbourg Convention* and it continues in the *European Patent Convention* and most recently in the *Trade-Related Intellectual Property Rights Agreement*. Section 26(a) states that non-patentable inventions include "plant varieties as provided for in the Seeds and Plant Varieties Act, but not parts thereof or products of biotechnological processes". This is found to be legally ambiguous as it could be argued that plant varieties not provided for can be patentable subject matter.

Overall, the legal framework is an import of the European system and demonstrates the remarkable distance between *Geneva-rhetoric* and domestic reality.

#### **4.4. 4.     *The Impacts of Implementation Models***

The economic literature on PBRs is not as theoretically sophisticated as the literature on patents; instead it tends to be empirical and case study based. With the first applications received in 1997 and grants issued in 2003 there is very little data for analysis. Additionally, the data collected was not sufficiently disaggregated. Consequently, the research seeks to map out emergent trends. In the few years of operation there have been a sizeable number of applications (Table 2). This, in a limited sense, is confirmation of confidence in the system amongst potential right-holders. Two emergent trends are noticeable: (a) resident and non-resident distribution and (b) the crop focus. While Kenyans collectively account for the largest share of applications (52%) there are leading shares held by applicants from the Netherlands (25%), Germany (16%) and Italy (10%).

**Table 2: Kenya PBR Activity, 1997-2004**

Year	Applications			Grants		
	Residents	Non-residents	Total	Residents	Non-residents	Total
1997	11	128	139	0	0	0
1998	42	33	75	0	0	0
1999	16	45	61	0	0	0
2000	24	45	69	0	0	0
2001	164	33	197	0	0	0
2002	11	27	38	0	0	0
2003	7	25	32	32	77	109
2004	16	45	61	0	41	41
<b>Total</b>	<b>291</b>	<b>381</b>	<b>672</b>	<b>32</b>	<b>118</b>	<b>150</b>
	<b>43.30%</b>	<b>56.70%</b>		<b>21.33%</b>	<b>78.67%</b>	

(a) Five grants ceased to be in force; thus total grants at the end of the year would be 36

Source: Kephis (various years), *Annual Report*; supplemented by UPOV (2005a), *Plant Variety Protection Statistics, C/39/7*.

The crop-wise distribution by nationality of applicant is one way to assess this evidence (Table 3). Even a cursory look at the table reveals a striking socio-technological division of labour between nationals and non-nationals:

- PBRs applications by residents are exclusively in cereals, industrial crops, oil crops and pulses
- Applications for PBRs by non-resident are exclusively in vegetables and ornamentals

Table 3 also shows the large share of applications in ornamentals (43%), in particular roses (37%). This corresponds with the growth of the cut-flower industry in Kenya that has also made it the largest exporter of cut-flowers to Europe. However, the particular role and impact of IPRs in this transformation remains unclear. Studying the phenomenal growth of the fresh fruit and vegetables sector, analysts have identified a number of drivers: geography and climate, demand and infrastructural spin-offs from tourism industry, effective and flexible private sector entrepreneurs, and stable, supportive policy environment. Notable in absence is any reference to Kenya's intellectual property policy or a reference to the agricultural research climate. Though PBRs have been applied for, it is clear that the industry grew with a system of informal self-regulation and has developed effective surveillance of the supply chain.

**Table 3: Crop-Wise Distribution of Applications, 1997-2004**

	<b>Residents</b>	<b>Non-residents</b>	<b>Total</b>	<b>%age Share</b>
<b>Cereals</b>				
Maize	55	0	55	8.18%
Wheat	30	0	30	4.46%
Sorghum	7	0	7	1.04%
Barley	7	0	7	1.04%
<b>Industrial Crops</b>				
Tea	33	0	33	4.91%
Pyrethrum	23	0	23	3.42%
Macadamia Nut	11	0	11	1.64%
Sugarcane	6	0	6	0.89%
<b>Oils</b>				
Rapeseed	0	14	14	2.08%
Sunflower	10	0	10	1.49%
Soybean	7	0	7	1.04%
<b>Pulses</b>				
Dry Beans	13	0	13	1.93%
Peas	0	7	7	1.04%
<b>Pasture crops</b>	10	0	10	1.49%
<b>Vegetables</b>				
French Bean	0	14	14	2.08%
Potato	4	0	4	0.60%
Cassava	2	0	2	0.30%
<b>Ornamentals</b>				
Rose	0	247	247	36.76%
Alstroemeria	0	28	28	4.17%
Limonium	6	8	14	2.08%
<b>Total Applications</b>			<b>672</b>	<b>100%</b>

*Source:* Author's calculations from Kephis data

A final theme of analysis concerns the public sector. Here, a key issue relates to the protection of varieties bred by KARI and its licensing policy. At the time of research, KARI was will debating these questions. However, strong indications of a move to use PBRs as a revenue generating exist in that the exclusive license to KSC has been terminated and applications for protection lodged. Projections of a royalty stream that contribute 8% of the operating income have been made. Caution must be sounded on this option and the projections. Effective use of PBRs requires significant investments in enforcing rights and marketing the same which may prove to be a drain on public resources. Concern about the impact of this policy on the competitive structure of the seed industry remains. Kenya has a relatively high seed-grain price ratio (4.5, compared to 1.7 in Zimbabwe) and with profits at 10-20% the market has an oligopoly structure. KARI's license policy could further aggravate this situation by hindering the entry and participation of new seed firms.

Finally, it remains to be seen whether the introduction of plant breeders' rights will actually respond to the productivity crisis in maize. Equally, is the issue of diffusion of technology in either the horticultural sector or in novel biotechnology areas.

## 5. CASE STUDY ON CHINA

### 5.1. 1. *Status of Agriculture Research*

Agriculture in China is dominated by the public sector. The main actors in the public sector are institutes under the national agricultural research system and universities. While private spending in agriculture R&D has grown rapidly since 1985, at US\$16 million (in 1995) it represents only 3% of the total agriculture research expenditure with an intensity of 0.008 of total agriculture GDP compared to the government's 0.32.

Investment in agriculture biotech has seen a rapid increase both in terms of staff and expenditure, from US\$4.2 million in 1986 to US\$56 million in 2003. Plant biotechnology research in China includes food crops including some that have received little attention elsewhere demonstrating China's concern in attaining food security. Furthermore, the emphasis in plant biotech in China has been on increasing crop yield and preventing pest outbreaks. Virtually all investment in biotech in China is from the public sector.

### 5.2. 2. *Broad Models for Implementing Art 27(3)(b)*

The 1978 UPOV Convention became effective in China from 23 April 1999. Before then, China already had Regulations on the Protection of New Varieties of Plants, which were promulgated on 20 May 1997, came into effect in October 1997 but were only implemented after UPOV became effective. Plant varieties can only be protected if they are in the published list of protected varieties. This list is determined and published by the approving authorities.

Beside PVP Regulations, plants may also be subject to patent law and other regulations. Article 25 of the Patent Law states that 'no patent right shall be granted for animal and plant varieties' however, processes used in producing animal and plant varieties may be protected under patent law. Regarding PVP, the patent law may be applied only to the *process* of producing new plant varieties rather than in the protection of the plant varieties themselves.

In addition to the novelty, distinctness, uniformity, stability and adequate denomination test, the plant variety to be protected must be in the list of protected varieties. The transfer or assignment of plant variety rights from a Chinese right holder to a foreigner requires approval by the examining and approving authorities whereas an assignment within China need be approved only when the relevant national regulations so require. In all assignment cases, a written contract between the parties shall be included in the application for assignment which is in turn published by the examining and approving authorities.

A compulsory license may be granted to exploit new plant varieties in the national or public interest. Quarantine regulations are an important aspect in the process of attaining PVRs particularly for foreign breeders wishing to export a plant variety to China for protection. China has about 15 different laws and regulations on quarantine although only about six are specific to plants. Once allowed in, plant varieties introduced into China for the first time are subject to further strict requirements.

Generally, IP enforcement in China presents an insuperable challenge evinced by the high level of activity in producing counterfeit goods. With regard to PVRs, the Regulations on the Protection of New Varieties of Plants (PVP Regulations) lay out the enforcement options and

procedures. In case of infringement of PVRs, a right holder has two options: going through the examining and approving authorities i.e. the Ministry of Agriculture and State Forestry Administration or filing a suit in court. It is reported that more than 800 PVR violation cases have been investigated with 460 cases ending up in Court. Local courts are reported to have addressed over 100 cases by April 2006.

### **5.3. 3. *Economic Impact of the Implementation Models***

In 2000, the land area dedicated to agricultural plantations amounted to 156 million hectares, of which 108 million ha were sown to food crops, 15 million ha to vegetables and fruits, and the rest to rapeseed and other oil crops, cotton, tea, etc.

The figures compiled by the International Seed Foundation in 2004 reveal the estimated size of the domestic market for seed (US\$ million) to be second largest after the United States. China is a major producer of seeds; however, it still occupies an intermediate position in the international seed trade. This can be explained by the size of domestic demand.

Figures reveal that China has been gradually focusing on horticultural crops (which sell at much higher prices than food crops, and are widely exported, especially to Japan), in particular vegetables. They also show that China has become a net importer of seeds. The shift from food crops to vegetables makes sense when one considers the relative average seed prices, which tend to be far higher for horticultural crops.

According to IFPRI, the common practice in China is for research institutes or seed development firms to outsource the multiplication of seeds to state-owned seed companies, which in turn contract with individual growers to produce commercial quantities of seeds. Thus, owing to the risks of production of higher quantities by farmers, research institutes and seed development firms are keen on resorting to plant variety protection certificates. After being multiplied, seeds are distributed to farmers mainly by research institutes, state-owned seed companies, extension agents and small traders.

The World Bank had launched in 1990 a programme aimed at introducing modern methods and equipment for producing and handling seeds. Another project run between 1996 and 2003 was concerned with the restructuring of state enterprises, the availability of credit and the use of inputs such as improved varieties. This latter project also involved the drafting of a draft seed sector policy, which was not approved as such by the Chinese government. Thus, the adoption of the Seed Law and of the Regulations on the protection of new varieties of plants was delayed compared to the initial schedule set forth by the World Bank.

In one of the first articles of the Seed Law consists in a declaration that the “State supports the protection of seed resources, and the breeding, production, and dissemination of quality seeds.” This law asserts the State sovereignty over seed resources, whether improved or found in the wild; thus, collection or felling (of trees) are prohibited, unless such activities are carried out for scientific research and provided the approval of the State Council or of local authorities has been obtained. However, the “National People’s Congress encourages and supports entities and individuals to breed and develop quality seeds.” The establishment of a reserve seed system to meet the demand in the event of calamities is contemplated in the Seed Law.

Article 14 provides for special rules for the safety assessment of genetically-modified seeds. Where the applicant is not satisfied with the decision regarding the approval of a particular

crop variety, he or she may ask for a second examination by the Examination and Approval Committee of the national or provincial departments of agriculture and forestry.

The government grants two types of licenses: seed production licenses and seed processing licenses. Producer applicants must show that they fulfil certain requirements. For seed processing licenses labels must be affixed on seed bags that indicate the seed variety, name, place of production, quality index, quarantine certificate number, licenses numbers or reference of import approval. Imported seed bags must be labelled in Chinese and show the applying quarantine certificate.

Where a seed user incurs loss due to poor seed quality, he/she is entitled to compensation by the seed supplier amounting to the seed price and the loss of profit. The seed processor can in turn ask for compensation from the seed producer or other seed processors where applicable. The parties to a dispute regarding seed use may seek intermediation, resort to arbitration or directly go to the People's Court.

In situations of emergency, where the crop seeds to be used are of lower quality than the standards set out by the national or local government, their use must be approved by the people's government above county level.

The total number of plant variety rights in force at the end of 2004 amounted to 584, just five years after the entry into force of the law. As of August 2005, 2,518 applications had been received by the Ministry of Agriculture. Whereas in 1999, one-fifth only of the domestic applicants were individuals or companies, their share has risen to 40% in 2004. The IFPRI study outlines the fact that most of the applications are concerned with hybrids, rather than open-pollinated maize and rice varieties, whereas "[a]mong the more than 190 crops for which PVP protection was sought during the past 30 years in the United States, open pollinated crops accounted for the lion's share of applications." The same study estimates that 82% of the PVP applications in China are filed by public agencies.



## 6. CASE STUDY ON INDIA

### 6.1. 1. Introduction

This is a study of the ‘impacts’ of implementing Article 27.3(b) of the TRIPs Agreement in India. The study looks at how various international obligations are translated into the architecture of domestic law and analyses the concomitant economic changes that have occurred in plant breeding and the seed industry. India is a useful choice as it a large farming community (65% of the population are dependent on agriculture), an active movement on these issues and an increasingly diverse seed industry with active (often, leading) private sector presence. At the TRIPs Council, India has regularly championed the rights of farmers and the integration of norms and principles from the Convention on Biological Diversity into obligations at the World Trade Organisation. Consequently, studying the way in which this obligation to the TRIPs Agreement is domestically implemented can be a prism into how different domestic (and international) constituencies are handled. The Report analyses the regulatory framework, focussing primarily on the *Protection of Plant Varieties and Farmers’ Right Act, 2001*. As the system is still to be operational, the economic analysis looks at the structural changes that have occurred in the plant breeding and seed industry over the last two decades.

### 6.2. 2. The legal framework

The *Protection of Plant Varieties and Farmers’ Right Act*, in specific, and the wider regulatory space concerning plant materials, in general, are driven by a complex set of principles which are not entirely compatible. At one level there are obligations to the TRIPs Agreement and at another level there are the interests of farmers and farming communities. Within these potentially competing pressures, the Act makes a serious attempt at integrating norms and principles of the Convention on Biological Diversity. This is visible in the requirement for a declaration of prior informed consent, i.e. breeding material has been lawfully acquired (section 18(1)(h), the Act). Further, there are provisions for community rights and a gene fund to make operational farmers’ rights.

In many ways the Indian legislation pioneers a path that is different and distinct from the dominant template for the protection of plant varieties as mapped out by UPOV. This is evident in the script itself. Beyond the evident absence of ‘plant breeders’ right’ in the title, the right to a breeder follows the successful registration of a variety which “shall confer an exclusive right on the breeder” (cf. section 28(1), the Act). A more substantive difference is in the conditions for registration of a variety. While adopting a similar template of ‘novelty, distinctness, uniformity and stability’, the Act differs by its requirement for ‘essential characteristics’. To explain, the requirement for distinctness requires the variety to be “clearly distinguishable by *at least one essential* characteristic from any other variety whose existence is a matter of common knowledge” (section 15(3)(b), the Act, emphasis added). ‘Essential characteristics’ is defined in Article 2 (of the Act) to encompass characteristics that “contribute to the principal features, performance or value of the plant variety”; thus substantively different from the procedural treatment of UPOV.

The scope of protection is similar to the scope offered under the 1978 Act of UPOV. The difference is its categorisation of the UPOV exemption for breeders as a ‘researchers’ right’; thus awarding it a particularly important status. However, it is in providing farmers’ rights

that the Indian law truly pioneers a different path. The following components constitute farmers' rights:

- A farmer who has bred or developed a new variety shall be entitled to registration and treatment (i.e. protection) in a manner akin to a breeder
- A farmers' variety is entitled to be registered if it fulfils all requirements
- A farmer engaged in conservation and improvement of genetic resources shall be entitled to recognition and reward from the Gene Fund
- A farmer is entitled to save, use, sow, resow, exchange, share or sell his farm produce including seed of a protected variety provided that the farmer does not sell branded seed of the variety.

There are other provisions that support farmers' rights, such as protection against innocent infringement (section 42). Farmers are protected from alleged infringement when it can be established that "at the time of such infringement [the farmer] was not aware of the existence of such right" (section 42(i), the Act).

An authority is to be set up to administer the Act. The Act also provides for various public interest measures which include a comprehensive ban on varieties that include technologies that are injurious life and health of human beings, animals or plants.

Given the historicity of the Patent Act, 1970, there is no explicit mention of biotechnology or phraseology that might allude to the attempts to demarcate the micro- from the macro-biological as pioneered in the Strasbourg Convention. However, in Section 2, where various definitions are expressed, inventions are said to mean "any new and useful [...] (i) art, process, method or manner of manufacture; [...] (ii) machine, apparatus or other article; [...] (iii) substance produced by manufacture, [...] and includes any new and useful improvement of any of them, and an alleged invention" (section 2(j), Patent Act, 1970). Chapter II sets out 'Inventions not patentable' which includes 'prophylactic processes for treatment of humans, animals or plants' and excludes 'a method of agriculture or horticulture'. Despite these provisions, case law (e.g. Agracetus transgenic cotton patent dispute of 1994) demonstrates the problems in administering this exclusion.

Following the TRIPs Agreement, the *Patent Act, 1970* underwent three revisions. In the Second amendment, a new clause, 3(j) was inserted: "plants and animals in whole or any part thereof other than micro-organism but including seeds, varieties and species and essentially biological process for production or propagation of plants and animals;". This paved the way for the *sui generis* option for the protection of plant varieties. It was in the Third amendment that Section 5 (which identified non-patentable inventions) was deleted. Now, patents on microorganisms are possible.

*Seed Market Regulations* are another sphere of regulations. The 1980s form a watershed in the transformation of the Indian seed industry. In 1983 a policy to release publicly bred varieties to the private sector was introduced. In 1987 there was a marked relaxation of industrial licensing regulations and in 1988 a new seed policy was announced. The latter allowed private sector companies to enter the industry across a range of crops and also relaxed the constraints on seed imports.

In 2004 a Seed Bill was introduced in Parliament that seeks to replace the *Seed Act, 1966*. It proposes for all varieties to be registered and meet certain prescribed minimum standards. In

establishing these standards, there are measures to back the consumer (i.e. farmer) from fraudulent seedsmen. To promote certified seeds and the certification process, it allows for self-certification. The report reviews some of the proposals and notes the concern of commentators of a lack of consistency between these provisions and those present in the *Plant Variety and Farmers' Rights Act*.

### **6.3. 3. Economic Impacts**

The seed industry has historically been the reserve of the public sector – framed by the establishment of the National Seed Corporation in 1963 and the success of the World Bank funded Tarai Seed Development Project that launched the high-yielding varieties in the 1960s. Yet, in the 1960s, small private seed companies were set up – many with technical training from the Rockefeller Foundation and the US Agency for International Development. By 1985, it is estimated that of the 420,000 metric tonnes of seed, the public sector produced 240,000 metric tonnes. The private sector has focussed on crops that have been successfully hybridised: sorghum, pearl millet, maize, cotton, sunflower, and some oilseeds. Many of the seed firms had fledgling plant breeding operations and dependent substantially on publicly bred germ plasm – and at times finished varieties. Yet, through the years, the private sector has grown in size and accounted for leading shares. One estimate indicated that hybrid seed market shares of 40% in maize, 70% in pearl millet, 90% in sorghum and over 90% in vegetables. In the early 1990s, data suggests that over 40 seed companies have turnovers valued at US\$500,000. A key large player is the Maharashtra Hybrid Company (Mahyco) valued in the 1990s at over US\$14Mn. Following the liberalisation and other policy changes in the late 1980s, the seed industry has been subject to a phase of mergers and acquisitions initiated by MNCs resulting in significant consolidation: Monsanto has acquired a 26% stake in Mahyco, Agrevo controls 100% of Proagro, Emergent Genetics has acquired 74% stake in Mahendra Hybrids and Pioneer Hybrid has a 51% stake in SPIC. More recent data would suggest a deeper level of mergers and acquisitions. Recent estimates give the (organised) private sector a 67% market share that is valued at US\$3.6Bn.

Private sector R&D spending is estimated at having doubled between 1988 and 1996. Without doubt this research is also driven by its focus on 'proprietary' hybrids – evidenced by the increasing rate of release of hybrid varieties that has accelerated. For example, of the 110 maize hybrids released between 1991/97, 93 were from the private sector. There have been substantial investments in agricultural biotechnology with the private sector investments estimated at US\$10.62Bn. This outstrips the public sector investments of US\$7.37Bn.

For some indigenous firms these structural transformations are difficult to handle. In particular, a fear of technological dependence may be appearing. This builds on their dependence on the public sector for germplasm. However, there are other firms that have entered into technological alliances or form part of the M&A activity.

The research finds the public sector in a complicated position having to confront difficult policy options. There is an opportunity to re-draw the relationship with the private sector. Equally, there are opportunities of using PBRs as an instrument for cost-recovery and revenue generation. Within this mix, a particular observation is striking. In as much as the private sector will tend to focus on hybrids, there is a strong mandate for research on OPVs and on crops and regions that will remain neglected, such as rice and wheat – the two key food crops of the country. It is clear from the Act that the public sector will seek PBRs on their varieties. Thus, the issue of how these varieties will be licensed to seed firms remains. In making its decision, the public sector should take cognition of the impact of this decision on the

competitive structure of the industry. The relatively low seed-to-grain price ratio in India is testimony to the elaborate and competent network of seed growers and seed firms. A licensing policy that compromises this network and leads to the exit of seed firms could potentially make the seed market non-competitive.

## **7. CASE STUDY ON TURKEY**

### **7.1. 1. Introduction**

Turkey's economy is a complex mix of modern industry and commerce along with a traditional agriculture sector that in 2004 still accounted for more than 35% of employment. The sectoral composition of the GDP in 2003 was: agriculture: 11.7%; industry: 29.8%; services: 58.5%. During the last four decades agricultural GDP grew about three times slower than the overall economy, resulting in a declining share of agriculture in GDP from 35% in 1960 to 15% in 2000. The main crops in the Turkish agriculture are wheat, rice, cotton, tea, tobacco, hazelnuts, and fruits.

Turkey's domestic seed production is not sufficient to meet the local demand, despite the privatization of the industry in the 1980s and continued government support. Turkey imported over USD 65 million of seeds in 2004 with the European Union supplying the majority of seeds to Turkey. The United States exported USD 9.1 million worth of seeds to Turkey in 2004, primarily corn, vegetable and fodder crop seeds.

The registration, control and certification facilities of seeds are executed by the Ministry of Agriculture and Rural Affairs (MAFRA), General Directorate of Control and Certification of Seeds. The official body for variety release is the Variety Release Committee. MAFRA enforces seed law. Seven official Seed Testing and Certification Stations are present in the country. Seed processing is performed by public as well as private sector entities. The seed producing organizations market their seeds through their own outlets and agencies. Seed production and marketing activities in the public and private sectors are based on a free market economy. Prices are not controlled. Trade in seed of foreign origin is subject to legal restrictions.

### **7.2. 2. Domestic law and government policy**

Turkey's application for membership of UPOV has been accepted; however the Great National Assembly of Turkey has not enacted the relevant approval code. Under Turkish law, new varieties of plants are protected by the following legal acts:

- Code on Protection of Breeder's Rights for New Plant Varieties.
- Directive on the Registration of New Plant Varieties
- Directive on Protection of Breeder's Rights for New Plant Varieties

In accordance with Decision No. 1/95 of the EC-Turkey Association Council of December 1995, Turkey has undertaken to align its domestic IP legislation with that of the European Communities. Towards this goal, the Code on Protection of Breeder's Rights for New Plant Varieties was enacted in January 2004. By this Code, the breeders are granted exclusive rights for the first time in Turkish law. Although Turkey has not been a member of UPOV yet, the Code on Protection of Breeder's Rights for New Plant Varieties is predicated on UPOV 1991. Beside the UPOV Convention, The Code numbered 5042 is also in conformity with the Acquis Communautaire. It is especially predicated on the 2100/94/EC, 1768/95/EC ve 2470/96/EC regulations of EC. The duration of protection is 25 years from the grant of the right. For trees, vines and potatoes, the said period is 30 years from the said date. When an application is complete and accurate it is entered in the register and given an application

number. The ministry examines the registration procedures in order to ensure validity of the certificate.

Accordingly, for the purposes of protecting and safeguarding agricultural production, farmers are authorized to use for new production, on their own holdings, the product of the harvest which they have obtained by planting propagating material of a protected variety, except hybrid and synthetic varieties, without infringing the legitimate rights of breeder, provided that it is not contrary to paragraph 1 of Article 14. This rule applies to a list of species.

In Decree No. 551 Relating to the Protection of Patents, plant varieties do not fall under the patent system and cannot be protected by the provisions on patents

Turkish legislation on seeds is generally compatible with EU. Sampling and laboratory analyses are done under the ISTA Rules both in Turkey and EU. The variety registration for all species are also carried out under the UPOV Rules both in Turkey and EU. Although the recent seed legislation in Turkey is adequate to the European law, a new Draft Seed Law is on the agenda of the Parliament. The main purpose of this Law is to give the private sector more control of the seed industry. According to the draft Law, an independent Turkish Seed Industry Union will be established and given a significant portion of the duties and responsibilities currently under MARA. Industry representatives expect the law to be adopted in 2006. The GOT is also developing a National Biosafety Law (NBL). The law will focus on the production, use, importation and distribution of genetically modified materials. For seeds, the Law will provide a framework on the production and marketing of transgenic seeds should be possible. Currently, the GOT does not permit planting of bio-engineered seeds. Utilization of certified seed has not developed well in Turkey, even though the GOT supports their use. However, certified seed use is expected to increase in the future in response to growing demand. The growth is expected especially for greenhouse vegetable, corn, sunflower, and fodder crop seeds.

### ***Economic Factors***

There are 128 private firms and 27 public entities that currently produce, procure, import and distribute seeds in Turkey. However, Turkey's domestic seed production is not sufficient to meet local demand especially for vegetables, fodder crops, pasture and meadow grasses, corn seeds, and seed potatoes. A private seed industry has been a relatively recent phenomenon in Turkey. Turkey became a member of the OECD certification system and International Seed Testing Association (ISTA) just a few years ago. In the past, the industry was dominated by government agencies, which even set selling prices until the 1980's when the sector was privatized and seed prices were liberalized. Local and international companies began investing in the seed sector shortly after that. The Turkish Seed Industry Association (TURK-TED) was established in 1986. The major function of TURK-TED is acting as powerful lobbying agent, contributing to the development of the sector, and assisting with the transition to the EU system. TURK-TED also assists member firms with studies on seed production, certification, storage, packaging, distribution, and variety breeding. TURK-TED currently has 75 members, which account for at least 90 percent of all private sector seed production. In 2004, privately owned firms produced either 100 percent or almost 100 percent of sunflower seeds, vegetable seeds, corn seeds, and seed potatoes. Slightly more than 50 percent of fodder crop seeds, 20 percent of cottonseeds, 15 percent of barley seeds, and 5 percent of wheat seeds were also produced by the private sector in Turkey.

The Production and Development General Directorate (TUGEM) of the Ministry of Agriculture announces a Production Programme, which sets production goals for the Turkish sector each year. The programme is established jointly with both public and private seed producers based on the country's domestic needs as well as export goals. Even though they are significantly reduced, illegal entries of expensive greenhouse vegetable seeds continue to create unfair competition against firms, which are investing in this sector.

Certified seed utilization has not developed well primarily due to the lack of the education on the part of farmers and economic situation in Turkey. Nonetheless, certified seed utilization is expected to grow in the future in response to growing demand, especially for greenhouse vegetable and corn seeds. Demand for hybrid sunflower and fodder crop seeds are also expected to increase.

Due to shortfalls in production and quality, Turkey must import most seed varieties. Corn, sunflower, cotton, vegetable, and fodder crop seeds as well as seed potatoes are the most prominent imports. Depending on supply and demand, other seed varieties may also need to be imported. The current regulation on Plant Quarantine hinders imports of seed and has created significant problems. All imported seed must be tested. Tests on imports take long time, usually about a week, because customs do not have laboratories and samples are sent to the nearest research institutes. This time is even longer, if there is a dispute on findings since reference laboratory is in Ankara. Some new laboratories at customs were set up recently and some others were planned which will hopefully alleviate the situation. Importers also need import licenses to import seed and only those firms, which are producing, procuring, and marketing seeds domestically are provided import licenses. Turkey imported approximately 27 TMT of planting seeds worth approximately USD 69 million in 2004. During the first nine months of 2005, Turkey imported approximately 25 TMT of seeds worth of approximately USD 72 million. The value of vegetable seed imports decreased from approximately USD 1.9 million in 2004 to approximately USD 1.0 million during the first nine months in 2005. Similarly, the value of fodder crop seed imports decreased from approximately USD 1.0 million in 2004 to USD 269,000 during the same period. However, the value of corn seed imports increased during the same period from approximately USD 6 million to approximately USD 6.9 million.

Turkey exported approximately 19 TMT of seeds worth approximately USD 31 million in 2004. However, Turkey exported fewer seeds, approximately 6.8 TMT worth approximately USD 19 million during the first nine months of 2005. Decreases were especially significant in corn seeds because, due to large demand, producers preferred to market their production in Turkey. On the other hand, exports of cottonseeds in 2005 are exceeding exports in 2004-second year in a row.

TIGEM is the only public entity involved in the seed trade. TIGEM imported 40 MT parent wheat seeds from France and Italy, but did not export any seeds in 2004. In 2005, TIGEM imported 20 MT of parent wheat seed from France and exported 10 MT of wheat seed to Azerbaijan.

The approach of Turkey to modern biotechnology practices is supportive as a part of its general policy on transfer and development of technology. However she wants to ensure the safety of both technology itself and its products in terms of introduction into the environment and use in consumption purposes. As stated in the report prepared by SPO (State Planning Organization), agricultural biotechnology has the highest priority among the subjects

considered for the research and development purposes. Within agricultural biotechnology plants has the highest priority.



## **9. THE PATENTS SECTION OF TRIPS: EXPLORING ITS FLEXIBILITIES TO PROMOTE BIOTECHNOLOGY CAPACITY BUILDING AND APPROPRIATE TECHNOLOGY TRANSFER**

### **Summary**

The objective of this work is to assist developing countries in designing their patent systems in order to promote biotechnology-based development. Many countries are unclear about how to tailor their patent regulations to promote their interests in the acquisition, development and application of biotechnology, and therefore how best to exploit the flexibilities of international law, especially the TRIPS Agreement. Two types of flexibility exist in Article 27.3(b) of TRIPS, which are a key focus of the present study: (i) the optional subject matter exceptions, specifically plants, animals and essential biological processes for the production of plants and animals; and (ii) the possibility to define these terms and others such as micro-organism in a variety of ways.

Existing studies are very useful in linking the importance of IPRs, especially patents, to levels of development, and answering the question of what conditions in a specific country or industrial sector are necessary to ensure that IPRs foster, rather than inhibit, domestic innovation including ‘creative imitation’ and technology transfer. One inference is that it is only after countries have accumulated indigenous capabilities with extensive science and technology infrastructure to undertake creative imitation that IPR protection becomes an important element in innovation and technology transfer.

However, few studies have focused specifically on biotechnology, and even fewer have linked biotechnological capabilities to implementation of TRIPS. This report seeks to fill this gap by focusing on relative biotechnology capabilities in different countries and linking such capability levels to a ‘menu’ of interpretative options arising from a close examination of the flexibilities of the relevant section of the TRIPS Agreement in order to achieve optimal outcomes.

We started this project with great ambition. We wanted to lay out the full range of patent subject matter options available to developing countries and give some general impressions as to the policy-related implications of selecting one particular option over another (e.g. a broad or narrow interpretation of ‘micro-organism’). We hoped also to be able to develop a reliable ranking of developing countries according to their relative capacities in biotechnology. Having fulfilled these two tasks we intended to link these relative capacities to the interpretive options so as to generate optimal biotech patent regimes for each country.

In practice this proved to be extremely difficult. The biggest challenge we faced was to find a way to objectively assess the biotechnological capacities of individual countries and then to use such an assessment to rank countries from lowest capacity at the bottom to highest capacity at the top. Unfortunately, we discovered that all of the indices devised and used so far are flawed. Therefore we adopted a more qualitative approach which sought to identify and draw inferences from general indicators of current capacity and future potential. We selected three countries which are considered to be relatively advanced, and one that is perhaps the most advanced of all developing countries in terms of biotech capacity and growth potential (India). We reckoned that if these countries have very limited capacity to innovate at the present time, then most of the developing world has minimal if any capacity at

all. And this in turn suggests that they will gain little from a biotech-friendly patent regime and may lose out overall in terms, for example, of having to pay out royalties and licensing fees that may be unaffordable. Consequently, the policy options for most developing countries as far as implementing Article 27.3(b) goes are quite simple: keep your subject matter inclusions narrow as possible and your exclusions as wide as possible. But for the most advanced developing countries, this may not be the most sensible option. While it is highly unlikely for these countries too that a US-style include everything and exclude nothing model would be at all helpful, a more nuanced calculation of where the lines should be drawn between patentable and unpatentable subject matters ought to be made. Again, this study should provide some guidance on how to do this.

National policymakers in developing countries reading this report should ask themselves if their country's biotech capacity is on the level of South Africa or Kenya, or below these countries. In such case, the TRIPS *de minimis* approach (what we call the "all exceptions option") should probably be followed. Countries which have a capacity similar to that of India should study the "some exceptions option" and then figure out how best to put that option into effect.

After a brief introduction, the report explains what we mean by biotechnology, discusses some of its commercial applications and explains why the relationship between patents and technological development, especially biotechnology, is very complex, very controversial and extremely important (Chapter 2). The following section (Chapter 3) explores and critiques the effectiveness of current methodologies available to form the basis for a ranking scheme for developing countries on relative biotechnological capacities that could offer pointers to the design of an optimal biotech patent regime. These are all highly limited if not flawed and so we present some plausible "rules of thumb" to be used as assumptions to make up for the deficiencies of these indices. We then continue with the three national case studies, which together reveal the severe lack of capacity of even the more advanced of the developing countries (Chapters 4-6). Chapter 7 comprises a detailed analysis of the language of Article 27.3(b) of TRIPS. On the basis of this analysis, Chapter 8 first casts doubt upon two matters: (i) that we yet have the tools to rank developing countries accurately; and (ii) that any more than a handful of developing countries has the ability to take advantage of patents to build up their biotech industries. More positively, though, it goes on to present the interpretative menu and discuss its applicability. We also offer some reflections on how patent policy making is conducted and ought to be conducted.

In this consolidated document we provide the introduction and the concluding section.

## **Introduction**

The overall aim of this study is to provide reliable guidance on how to design patent rules that are optimal in terms of enabling developing countries to participate in the 'biotechnology revolution' and to thereby benefit their economies and populaces. Since most countries of the world are members of the World Trade Organization, the starting point of the study is the WTO's Agreement on Trade-related Aspects of Intellectual Property Rights (TRIPS), which all members must comply with. According to Article 27.1, 'patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.'

Since biotechnology is obviously a field of technology, it is not possible to keep biotechnology out of the patent system altogether, whether or not to do so would be deemed as desirable. Nonetheless, it is important to understand that biotechnology is covered in the context of *exclusions* from patentability. Thus, Article 27.3(b) permits WTO Members to exclude from patentability:

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.

The problem is that many countries are unclear about how to tailor their patent regulations to promote their interests in the acquisition, development and application of biotechnology, and therefore how best to exploit these flexibilities.

In essence, two types of flexibility exist in Article 27.3(b). These are (i) the optional subject matter exceptions, and (ii) the possibility to define the terms in a variety of ways. Clearly, the language of this provision is complicated. But it is also subject to a wide range of interpretations, a situation that allows policymakers to implement TRIPS in a very large number of possible ways.

The challenges that subsequently arise are threefold. The first challenge is to identify all possible ways that Article 27.3(b) can be interpreted. The second is to identify the goals that governments wish to use their biotech-related patent rules to further. This must surely be based upon assessments of present biotech capacity of the country in question and of its future potential. The third is for government policymakers on the basis of such an assessment, and a decision on the goals it wishes to pursue, to select from our 'interpretational menu', as presented in our final chapter, the optimal patent rules available under Article 27.3(b).

There is little doubt that countries will meet these challenges in a variety of ways. This should not surprise us. Developing countries, least developing countries and the former socialist nations together represent an enormous diversity in terms of socio-economic conditions, levels of development, and potential. Consequently, accommodation of such diversity had to be built into the study.

A few clarifications and disclaimers are in order. First, patents are one among several legal and policy measures to promote local innovation and technology transfer and may not be the most important.

Second, patent subject matter scope decision are not the only way to balance interests of all stakeholders and secure the best interests of the public. Patent systems should strike a balance so that the economic rights of inventors are sufficient to encourage invention, innovation and the dissemination of useful technical information, but not so excessive as to unduly hinder competition, stifle follow-on invention, or harm the public. Various measures are available to ensure that this balance is struck as optimally as possible. These may include:

- 1) Subject matter exceptions, such as those that may be applied to drugs, software programs, business methods, plants and animals, whether or not the standard patentability criteria can be met
- 2) Limitations to rights, such as compulsory licensing, government use provisions, research exemption and the 'bolar' (regulatory review) exemption
- 3) The patent examination, which is supposed to ensure that what is disclosed is enabling, and what is claimed does not extend beyond what is disclosed
- 4) Local working requirements
- 5) Pre- and post-grant opposition procedures
- 6) Morality/ ordre public objections
- 7) Competition law

This study only deals with the first of these. This might seem to make the study rather limited in terms of what it can achieve. However, biotech patenting subject matter flexibility is extremely broad in TRIPS and since implementation of this part of TRIPS continues to be under review at the TRIPS Council, producing evidence based policy guidance as to how developing countries may take advantage of the flexibilities is both necessary and timely, if not long overdue.

One might add here that the existence, quality and size of the wider legal infrastructure, including patent practitioners, trained examiners, and well functioning courts is essential to make any patent system work. A balanced patent system in theory cannot become an optimal patent system in practice without these. But dealing with this issue falls beyond the scope of the study.

Third, this study takes no position on specific biotechnological applications that some might endorse while others would deem them to be dangerous, immoral or otherwise inappropriate. Neither does it insist that countries should prioritise biotechnology-related research and development over other fields of technology or industrial sectors. But we do accept that biotechnology has lots of potential and ought to be promoted, and that in any case WTO members are required to make patents available for at least some biotechnological inventions. Nonetheless, we do not take it as axiomatic that what is good for the biotechnology industry is good for the public.

This study provides some useful guidelines on how to design optimal patent regimes for biotechnology within the confines of what TRIPS allows. That is about as far as we are able to go. But at the very least, our research shows how complicated it is to achieve efficient patent regimes especially in new fields of technology, and highlights the failure of policymaking generally to take into account the complexities. Another inference of the present study is that technical assistance providers and others claiming to be authorities on how to design biotech patent regimes sensitive to the specificities of individual countries should be urged to provide convincing objective evidence for their prescriptions.

### **Towards optimal pro-biotech patent regimes**

#### ***So can we rank developing countries according to their biotechnological capacities?***

Are we capable of measuring and thereby ranking the biotechnological capacities of different developing countries so as to determine the most efficient way countries should take advantage of the flexibilities of Article 27.3(b) of TRIPS? Earlier discussion particularly in

Chapter 3 would suggest that this is a difficult thing to do since no 100% reliable schemas or indices have yet been devised, certainly not the ones we reviewed earlier which comprise all of the well-known ones. Needless to say perhaps, such a task is possible but requires further research.

The three developing countries that we looked at are widely acknowledged to be among the more advanced developing countries in terms of biotech capacity and potential, especially India. Indeed, India's biotech sector stands apart from almost every other developing country in its size and potential. Yet even here, the ability of India's commercial biotechnology sector to take advantage of the patent system is still quite limited at this time.

As for attracting FDI, India is becoming more successful with life science corporations setting up research and development facilities in the country. Since India's patent system is still considered by many transnational corporations to be inadequate, the existence of a large number of well-qualified and inexpensive-to-hire Indians able to do the research and the enormous growth potential of such a high-population market are likely to be far more significant factors than the patent regime however it may be designed. That is not to say that a more expansive patent regime would not necessarily spur accelerated biotech research-oriented FDI. We have no evidence to counter such a scenario, and therefore cannot rule it out. Nonetheless the growth of such investment has so far not been directly influenced by changes to the patent regime and has more to do with the relative cheapness of doing high quality research in India compared to Europe and North America.

### *The implementation menu*

Regulating biotechnology, a new, complex, expensive, research-intensive and rapidly advancing field presents particular challenges for developing country policymakers. If they lack a clear idea of how – and even whether – biotechnology can benefit their economies and improve the lives of their citizens, they are in no position to design a patent system to promote welfare-enhancing biotechnological innovation. Moreover, many of these countries have no biotechnology industries to speak of, and there is every reason to be highly sceptical that such businesses will spring up just because life-forms and micro- and non-biological processes can be patented. And yet, they have obligations under international IP law to provide patent protection for at least some types of biotechnological invention. What is a developing country government to do?

On the basis of what we have covered so far, we present three different ways to implement Article 27.3(b). Option 1 (Table 1) we call the 'no exceptions option'. This more or less reflects US practice and is unlikely to be optimal for any developing country.

**Table 1: Biotech patenting in TRIPS: the ‘no exceptions option’**

<b>Provide</b>
Microorganisms (broadly defined)
Animals and plants (including plant varieties by patents and an effective <i>sui generis</i> system) and their parts including seeds, somatic cells, gametes, cells, genes
Non-biological processes
Essentially micro- and macro biological processes
Plant varieties also (either by patents or by or by any combination thereof)

Option 2 (Table 2) is the ‘all exceptions option’ which incorporates all of the exceptions while construing the terminology widely or narrowly so that what must be provided is the absolute minimum that is legally acceptable and scientifically reasonable, while as much subject matter as possible is kept outside the patent system.

**Table 2: Biotech patenting in TRIPS: the ‘all exceptions option’**

<b>Provide</b>	<b>Exclude</b>
Microorganisms (narrowly defined, e.g. unicellular organisms in the range of $10^{-5}$ m maximum size.)	Whole animals and plants (including plant varieties) and their parts including seeds, somatic cells, gametes, genes and gene products
Microbiological processes that are specific to microorganisms	Essentially biological processes for the production of plants or animals (even with substantial human intervention)
Non-biological processes	
Plant varieties (only by an effective <i>sui generis</i> system, e.g. modelled on UPOV 1988)	

Option 3 (Table 3) is the ‘some exceptions option’. It is not really a single option and the table below aims merely to provide some examples of exclusions and interpretations. Between Options 1 and Options 2 lie a whole range of possibilities between the two extremes, and the table provides just a few of these.

**Table 3: Biotech patenting in TRIPS: the ‘some exceptions option’**

Provide	Exclude
Microorganisms (narrowly defined)	Whole animals and plants
Microbiological processes found in microorganisms that are found in larger organisms too.	Essentially biological processes for the production of plants or animals
Non-biological processes	
Plant varieties (only by an effective <i>sui generis</i> system, e.g. modelled on UPOV 1988 or 1991)	
Genes (as chemicals with specified function)	

In this study we have been sceptical about the methods available for assessing the biotechnological capacities of developing countries, and explained why calling for more research in this area and, one hopes, making the case this is vitally important. However our survey of three relatively advanced developing countries highlighted that in this recent and rapidly advancing field of technology most if not all of the developing world lags far behind countries like the United States, Japan and such European countries as the UK, Germany and France. Therefore, and taking into account the work of researchers like Lall and Kim, for the overwhelming majority of developing countries the all exceptions option is for the time being the most rational basis for biotech related patent rulemaking. However for the most advanced of the developing countries which are beginning to innovate and seek to develop their inventions either alone or in collaboration with foreign corporations, some elements of option 2 may now be desirable.

***From policytaking to policymaking***

Historical evidence shows that well designed IPR systems can benefit national economies just as poorly designed ones can harm them. But how does one go about designing and negotiating an appropriate IPR system or fine-tuning an existing one? The economic and social impact of IPR reform is very hard to predict reliably, especially in the long-term. This is particularly the case for developing countries. This is a real handicap in the present situation where countries

are pressured to negotiate and implement new multilateral trade rules, bilateral or regional free trade or investment agreements, and to respond to powerful stakeholder groups – often foreign ones – demanding changes to national regimes that may not serve the interests of their citizens and other domestic stakeholders. Such difficulties in measuring impacts make it difficult for governments and their representatives to know what negotiating position to adopt on IP, how best to handle complex trade issue-linkage bargains, and how far they should accommodate the demands of international business interests clamouring for change to domestic IP rules.

As with other areas of business regulation, IP policymaking and negotiation position formation is, or at least should be, a matter for *national* decision making involving the collaboration of all *national* stakeholders including owners, users and the public. Foreign interests should not be ignored but government business regulation is about what is good for the national economy and the country's citizens. Good policymaking cannot be based solely on the implementation of obligations accepted in multilateral treaties or regional or bilateral trade agreements. Unfortunately, policymaking often seems to be done in this way, which is to say that *policytaking* is the norm rather than *policymaking*. What we have here are political and technical challenges. So as to better overcome the challenges, and as Workpackage 4 of the IPDEV project on technical assistance provision concludes, technical assistance providers themselves have much to learn. In the present context, they and others claiming to be authorities on how to design biotech patent regimes sensitive to the specificities of individual countries must provide convincing objective evidence for their prescriptions. And recipient countries must of course demand such evidence.



## **10. DISCLOSURE OF ORIGIN IN IPR APPLICATIONS: OPTIONS AND PERSPECTIVES OF USERS AND PROVIDERS OF GENETIC RESOURCES**

### **1. BACKGROUND**

In recent years, there has been growing concern among biodiverse countries about misappropriation of genetic resources (GRs) under their sovereignty. In particular, these countries are concerned about intellectual property rights (IPRs) being granted for inventions based on these resources and their subsequent commercial exploitation by foreign companies and scientists, without any benefits returning to them. This has led to calls for reform of the intellectual property system. The introduction of disclosure requirements (DRs) into patent law has been proposed as one important measure to help countries maintain sovereign control over their resources. Proponents of this measure suggest that it will achieve this through increasing transparency within the patent system and by facilitating monitoring of the use of genetic resources. However, many remain unconvinced about the feasibility of implementing such requirements and their effectiveness in preventing misappropriation of resources.

Such requirements have already been introduced by a number of countries, and proposals are also being discussed for the introduction of international legislation on this issue. Indeed, DRs have become an important issue within international negotiations on trade and the environment, with ongoing debate within the Conference of the Parties to the Convention on Biological Diversity (CBD), World Trade Organisation (WTO) and the World Intellectual Property Organisation (WIPO).

With respect to the CBD, negotiations are underway on an international regime on access and benefit-sharing (ABS). Many countries consider that DRs should be an integral part of such a regime, in order to monitor the use of GRs or additionally, to enforce ABS requirements. Consequently, they have been one focus of debate within recent negotiations. The current draft text on the development of an international ABS regime includes extensive references to this measure – although the fact that these are all bracketed reflects the divergence of opinion on this issue.

In the WTO, DRs are being debated as part of the Doha round of trade negotiations. These negotiations are at a crucial phase, with the pressure on to conclude them by the end of 2006 to avoid collapse of this round of talks. DRs are on the agenda in discussions over the relationship between the TRIPS Agreement and the CBD. Developing countries are pushing for amendment of the TRIPS Agreement, which they regard as necessary to ensure mutual supportiveness of these agreements. However, a number of countries do not think that there is any conflict, and are opposed to dealing with issues linked to the CBD within this forum.

DRs are also being discussed in WIPO, where reform of the Patent Cooperation Treaty has been proposed to allow for DRs in international patent applications, and they are being considered as part of the discussions over further international harmonisation of the patent system, under the draft Substantive Patent Law Treaty (SPLT). Debate on the issue of DRs within WIPO seems likely to increase in momentum with the opening of discussions on the establishment of a development agenda for this organisation.

## **2. INTRODUCTION TO PROJECT**

### ***PROJECT AIMS, METHODS AND DATA SOURCES***

This project was aimed at evaluating the effectiveness, feasibility, and acceptance of current and proposed national mechanisms for disclosure requirements within patent applications. The project also sought to assess the prospects for harmonisation of these measures within the European Union.

The research began with a review of the existing legislation on disclosure, and a report was produced describing the state of the art of national and regional measures. This enabled the identification of countries for further analysis. The research focused on European experiences, but also examined the cases of a number of biodiverse countries. This was done to gain the perspective of those countries that are primarily the providers of genetic resources.

A questionnaire survey was undertaken during the summer of 2005. The questionnaires sought to determine experiences with the existing legislation, opinions of the potential impact of implementing DRs more widely, either within Europe or internationally, and views on alternative or additional measures aimed at facilitating fair and equitable access and benefit-sharing. The questions asked in the survey are listed in appendix I.

The questionnaires were sent to government officials, NGOs, academics, patent attorneys and industry representatives. The survey focused on the six countries within Europe in which DRs have been introduced or proposed. Questionnaires were also sent out more widely within Europe, as well as to representatives from the USA, New Zealand and a number of biodiverse, developing countries.

A total of 368 questionnaires were sent out, and these elicited 74 responses, including 16 participants representing developing countries. The distribution of responses by sector is shown in table 1. (The full list of organisations and countries represented in the survey is shown in appendix II.)

Follow-up interviews were undertaken during October – November 2005. A total of 18 interviews were conducted in Belgium, Denmark, Norway and Sweden. These were with government representatives as well as some members of industry and academia.

#### **8. Table 1: Breakdown of participants in the questionnaire survey**

Sector	Number of responses	
	Total:	Developing Country:
Private sector (industry)	20	0
Private sector (attorneys)	5	2
Government	10	2
Patent offices	9	2
Academic institutes / NGOs	30	10
	74	16

A two-day workshop was held at Chatham House on 9-10<sup>th</sup> February 2006, for further discussion and analysis of the research findings and to consider their policy implications. The workshop included 40 participants from throughout Europe (Belgium, Denmark, Germany, Netherlands, Norway, Switzerland, UK) and also further afield, including Canada, Colombia, Japan, Peru, South Africa and the USA. The organisations represented are listed in appendix III. The meeting was held under the Chatham House Rule, to facilitate frank and open discussions.

The workshop was organised around a series of parallel working groups. The groups, each focussing on slightly different areas, addressed the following questions:

- What impact will DRs have on patent attorneys and patent offices?
- What should be the consequences of non-compliance with disclosure requirements?
- What link is needed between an invention and the genetic resource / traditional knowledge in order for disclosure to be triggered?
- What definitions and terminology should be used?
- What should the extent of disclosure requirements be? Should disclosure be required of: geographical origin or of source; evidence of PIC; evidence of benefit-sharing?
- Should disclosure be required for traditional knowledge?
- Should there be further harmonisation of DRs within European patent legislation?
- What additional measures could be taken to enhance the effectiveness of disclosure requirements?
- What alternative measures or areas of legislation could be developed within Europe?

### **3. RESULTS**

#### **3a. CURRENT LEGISLATION AND EXPERIENCES OF IMPLEMENTATION.**

##### **THE IMPLEMENTATION OF DRS IN EUROPE**

The implementation of national legislation on DRs by European countries was prompted by the adoption of the EU Biotechnology Directive in 1998. Under this Directive, disclosure of the geographical origin of biological material is encouraged. Recital 27 states that:

“Whereas if an invention is based on biological material of plant or animal origin or if it uses such material, the patent application should, where appropriate, include information on the geographical origin of such material, if known; whereas this is without prejudice to the processing of patent applications or the validity of rights arising from granted patents.”

The inclusion of a reference to DRs in the Directive was first proposed by Denmark. It was the subject of some debate and negotiation between the European member states, and due to the reservations of a number of countries the paragraph on DRs was included in the Directive's Preamble rather than in the main text. This means that it does not create a legally enforceable obligation, and indeed, when implementing the Directive, not all countries adopted legislation on this issue. Just five countries have done so to date (Belgium, Denmark, Germany, Norway and Sweden), and one other (Switzerland) has draft legislation, currently being considered by its parliament. (See appendix IV for details of the national legislation.)

The decision of these countries to adopt DRs was influenced by a range of factors. For example, the Danish Government was keen to implement such legislation because it had been proactive on this issue within Europe. Also significant was the fact that the national debates on disclosure were part of a wider consultation on implementing the EU Directive. The Directive was very controversial in some of the countries, mainly because it formalised the patenting of life-forms. This was the case in Norway, where the Directive met with considerable opposition, and so the introduction of DRs was, in part, a means of appeasing those opposed to it.

During the national debates, voices were raised both in support of and opposed to DRs. Those stakeholders who were more supportive of DRs tended to be those who were involved with environmental or development issues – these included NGOs, some academics and also certain government departments. Typically, they were motivated by the wish to promote the aims of the CBD, and also to support developing countries on this issue, many of whom are strong proponents of DRs.

Industry and those government departments dealing with trade and industry or economic affairs were more sceptical, concerned as to the potential impact of DRs on the biotechnology industry, and on research and development activities. There was particular concern within a number of government departments as to the impact of such legislation on smaller companies, as it is they who tend to apply for national patents rather than going through the international system. Questions were also raised as to the effectiveness of this measure in dealing with ABS issues, and furthermore, whether such issues were in fact best dealt with by the IP system. (These concerns remain for many, as is considered in more detail below.)

It was reported that during the process of these national debates there was some convergence of views and a more informed debate developed. For example, initially, many of those coming from within the patent and industry sector did not recognise any link between the IP system and ABS issues. Rather, the latter was regarded as being completely alien to IPRs, and so DRs were considered inappropriate to the patent system. While there is still debate as to whether ABS issues are best addressed through the IP system, there has been some acceptance of the links between these two areas, and a growing awareness of the need to address these issues within the IP system. On the opposite side, among the proponents of DRs there has been greater recognition of some of the problems which need to be addressed if more wide-ranging DRs are to be introduced, for example, the need for clarification of terminology and definitions (see later for further consideration of this issue). In fact a couple of participants reported that they had changed their view, no longer supporting a requirement that would be linked to patent validity, but favouring a formal requirement on the basis that this would be more feasible and widely acceptable.

However, in none of the countries was the adoption of DRs highly controversial. This was perhaps because of the recognition that these national requirements would have a limited impact because of their narrow scope – they only affect national patent applications which are a small proportion of the total applications made. Indeed, in all six countries the adoption of national DRs was regarded, to a large degree, as a means of showing political support for this issue, rather than actually having a significant impact on improving ABS. Thus, they were adopted in part in order to show support for developing countries on this issue and also as a potentially valuable first step towards the elaboration of such a requirement at the international level.

## **The approaches adopted**

The particular approaches to DRs that were adopted by these countries reflected the concerns and balance of interests within each of the countries. For this reason, and also because of differences in their legal framework, there was some variation in the legislation adopted.

In the five countries which have implemented legislation, disclosure is only required for applications involving genetic resources and not for those which have utilised TK. This was because of concerns over the difficulties of defining the concept "TK", and so it was thought that such a requirement would not be workable. In Switzerland this was regarded as less problematic, and was felt to be outweighed by the argument that disclosure of TK would be a useful measure to allow the providers of such knowledge to trace its use, and in particular, to facilitate searches for prior art. Therefore, its draft law requires disclosure for inventions based on either genetic resources or TK related to genetic resources.

Regarding the information that is to be disclosed, Belgium, Denmark, Germany and Sweden all followed the EU Directive, requiring disclosure of the geographical origin. Switzerland's draft legislation uses slightly different terminology, requiring declaration of "source" rather than origin. The term "source", as it is defined in the Swiss proposal, is a broader concept than that of origin and was employed in order to deal with those situations in which the origin was unknown. Thus, source is defined as the entity that is competent to grant access to the genetic resources, or to participate in the sharing of benefits arising from their utilisation. Applicants would be required to declare the "primary source" (in other words, the origin), which may be the country or community providing the genetic resources, or if this is unknown, to disclose the "secondary source", for example a gene bank or botanic garden.

Norway introduced a more extensive requirement, reflecting the high degree of political support here for this measure. Disclosure is required of the providing country and also of the country of origin, if this is different. Furthermore, information on whether PIC has been sought is also required (although not evidence of the PIC itself), if this is required by the providing country or country of origin. This information must be declared with respect to the providing country, but for the country of origin the option exists to state that it is not known whether PIC is required.

Disclosure of PIC was apparently considered in Sweden and Denmark, as well as in Switzerland's draft legislation. However, this was not adopted because of concerns over the feasibility of such a measure, given the patchy nature of national access legislation in many source countries. In addition, it was argued in Switzerland that disclosure of PIC is not necessary since disclosure of the source is sufficient to achieve the objectives of this measure – for Switzerland, these include enhancing transparency, assisting in prior art searches and improving trust in the patent system.

None of the countries introduced a DR for evidence of fair and equitable ABS. This was either simply not considered (the case in Belgium and Denmark) or it was not thought to be feasible (in Norway and Switzerland). The problems of feasibility that were highlighted were the subjective nature of determining what is "fair and equitable", and also the fact that patent applicants would not be able to provide evidence of benefit-sharing because the commercial benefits would not yet be known.

The other area in which the national legislation on DRs varies is in relation to the consequences of non-disclosure. During the debates on this issue, some proponents of disclosure argued for strict DRs, i.e. affecting the validity of patents. Such strict requirements were not adopted by any of the countries, largely due to concerns that this could create legal uncertainty, a critical issue for industry. In addition, concerns were expressed that substantive requirements would be in conflict with TRIPS (although this is debatable). It was for this reason that Norway and Denmark took the route of criminal sanctions. In both these countries, non-compliance would not affect the handling of a patent application nor the validity of a granted patent. However, penalties could be imposed under their penal codes, since these include an obligation to provide correct information to a public authority. This would allow for the imposition of a fine or a prison sentence.

In Sweden there was also concern over the compatibility of a mandatory requirement with TRIPS. However, the approach taken in Norway and Denmark was not an option here because the Swedish civil code does not enable prosecution in the case of a false declaration being made within a patent application. Therefore, Sweden decided to introduce a voluntary requirement, with no sanctions for non-compliance.

In Belgium, a novel approach to disclosure had initially been considered, it being proposed that non-compliance with a DR would be contrary to the concept of *ordre public* and morality, on the basis that in such a case the invention would have been developed in breach of the CBD. However, this was not adopted, apparently because the legislation never made it through parliament due to changes in government. Instead, Belgium introduced a simple formal requirement. Under this legislation, non-compliance could, in theory, result in a patent application not being processed, although this would seem an unlikely event given that the patent office does not check compliance. If a patent has been granted, then criminal sanctions could be sought through the courts for wrongful disclosure, and this could result in a fine or payment of damages. Switzerland has proposed a similar measure. Under its draft law, failure to comply would result in rejection of the patent application, while wrongful declaration could be prosecuted *ex officio*, and the applicant would be liable to a fine of up to 100,000 Swiss Francs. In such cases, the draft law also allows for the judge to order publication of the ruling – the intention behind this being that this would function as an incentive for compliance.

## **IMPACT OF DR LEGISLATION**

### Europe

In the five countries where DRs have been implemented, these measures have had limited impact. This is in part because they have not been in place very long. Denmark was the first to introduce DRs, amending its legislation in 2000. In Norway and Sweden DRs were introduced in 2004, and in Belgium and Germany this took place in 2005.

Another reason for the limited impact of these requirements is that they only refer to national patent applications. Consequently, a very small number of patent applications are affected by this legislation. The Norwegian office estimated that about 20% of all patent applications that they receive are national. Similarly, the Swedish office estimated that national applications accounted for 25% of all biotechnology related applications (of which there are about 300 a year), although most of these go on to be filed through the EPO and are discontinued at the national level.

Indeed, to overcome this problem, the draft Swiss legislation would also apply to international applications.

Only the Norwegian patent office had data on the number of applications in which disclosure had been made. They had received three such applications, but only one of these is still active – one having been withdrawn and a second shelved.

None of the other patent offices kept records of applications where disclosure had been made, but they all estimated that there had been few, if any. In Denmark, no applications in which disclosure had been made could be recalled, and it was thought likely that there had not been any. In the 6 months since implementation of Belgium's disclosure requirement (from May to October 2005) a quick survey of patent applications found that there had been just six national applications concerning pharmaceuticals, although it was unknown whether these used biological matter.

This pattern is mirrored in the responses from the private sector, in which only two companies (out of 20 respondents) reported having been asked to comply with a disclosure requirement. This is perhaps a reflection of the fact that nearly all the respondents from the private sector were from large companies, and they tend to make patent applications through the international or European systems rather than applying for national patents.

Thus, it would seem that these requirements have had barely any impact on patent applicants. However, in Norway it was reported that the implementation of DR legislation did create some uncertainty among patent applicants as to when disclosure would be triggered. The patent office received a number of enquiries about this, as well as some queries about the national ABS legislation of other countries.

The impact of DRs on the work of patent offices has also been minimal. The offices of Belgium, Denmark, Norway and Sweden all reported that the introduction of DRs had not impacted significantly on their work. This is not surprising, given the small number of applications and the fact that none of them check on whether disclosure should have been made, nor whether the information provided is correct. One additional task reported was that being undertaken by the Belgian patent office during October 2005 to adapt the patent application form. This was being amended to include a question on whether an invention has been developed from biological matter. In none of the other countries had this been done, and so there is no specific question for applicants to answer or forms to fill out.

#### Developing countries – Brazil, Colombia, Costa Rica, Peru.

Experiences of implementing legislation on DRs in Brazil, Colombia, Costa Rica and Peru were reported on in the survey questionnaires. With the exception of Costa Rica, all these countries had experienced severe problems of implementation.

In 2001, Brazil introduced a Provisional Measure requiring patent applicants to disclose the origin of any genetic material or associated traditional knowledge used in an invention (Article 31, Provisional Measure No. 2.186-16 of August 23, 2001). However, this requirement has not taken effect. This is because of legal uncertainty over how it should be enforced, since the rules to implement this measure have not been developed.

DRs were not thought to pose a problem for the functioning of Brazil's patent office, since the office does not have a large backlog of patents and it is currently planning to increase the number of patent examiners. Furthermore, biotechnology patents represent a small percentage of the applications. More significantly, it was noted that any checks on compliance would probably be undertaken by a separate institute, that responsible for ABS, and so any problems of monitoring and enforcement would fall on this institute.

Difficulties with implementing the legislation were also reported from Colombia. As a member of the Andean Community, disclosure in Colombia is required as outlined under Community Decision 486 (Common Intellectual Property Regime, December 2000). This requires that applications for patents disclose the access contract and evidence of PIC for genetic resources or TK. The legal framework regarding access to genetic resources is outlined in Decision 391 (Common Regime on Access to Genetic Resources, July 1996). However, because of difficulties in implementing this Decision, the access system is very complex and unclear, and to date there has only been one access agreement granted. The complexities of the system also resulted in one case in which an applicant for a Colombian patent did not comply with the requirement to file an access agreement. Such an agreement had apparently not been obtained by the applicant because of the difficulties of doing so, although this was subsequently rectified through a provisional permit being granted, allowing processing of the patent.

In Peru, another member of the Andean Community, implementation of the Community Decisions has also proven problematic. Here, the rules to implement the disclosure requirement have not been implemented, and consequently, this measure has yet to be utilised within Peru.

In Costa Rica, there have also been no cases of disclosure. However, this is not because of implementation problems, but rather, because of the narrow applicability of the disclosure requirement. Patent applications involving biodiversity or TK need to be accompanied by a certificate of origin, but this only applies if the resources or knowledge are from Costa Rica and not if they originate from any other territory.

The legislation of all the developing countries considered here only applies to genetic resources from within their own territory – that of the Andean community only refers to GRs from its member states, and the Brazilian legislation to GRs from its national territory. Therefore, even when effectively implemented, these measures will be limited in their scope. This raises questions as to the effectiveness of such legislation as a measure to facilitate ABS, as discussed in further detail below.

#### WHAT CAN BE LEARNT FROM EXPERIENCES OF IMPLEMENTING DRS?

The previous sections highlighted that existing national DRs have had little impact, either on patent applicants or on the work of patent offices. While this means that experiences of this legislation are limited, there are some lessons that can be learnt.

One important issue, noted within Europe, was the lack of information on patent applications in which disclosure had been made. One objective that has been identified for DRs is to enhance the transparency of the patent system. However, the existing legislation has done little to achieve this. The European patent offices do not monitor applications in which



disclosure has been made. Furthermore, although the patents are made available online, there is no means to search for those in which disclosure has been made. This would make it difficult for a third party, for example the provider of a resource, to search for any relevant applications. If DRs are to be effective as a transparency measure, then a system needs to be established to monitor these applications and to make this information easily accessible.

Another lesson that can be drawn from these experiences, and in particular those from the developing countries, is that such legislation needs to be carefully designed if it is to be effective. While it is relatively easy to amend patent legislation to require disclosure, it is quite another matter to ensure that it is usable, either for patent applicants or patent officials. For example, patent officials in Brazil, uncertain as to how to enforce the DR legislation, have called for further rules to clarify this. In Colombia, the problems of utilisation lie with patent applicants, because of the difficulties of complying with the country's access legislation. This latter example illustrates a potential problem with proposals in which disclosure of an access agreement or other form of PIC is required. A concern of many, and in particular those from industry, is that such requirements could prove impossible to comply with since many countries do not have such legislation, or alternatively their institutional arrangements are so complex that it is difficult to ensure that the correct procedure has been followed.

The final point to highlight is the narrow scope of these measures. This undermines their effectiveness as a tool to prevent resource misappropriation or to facilitate ABS because they could easily be circumvented. As explained above, they are of limited scope because they only apply to national patent applications – a problem that would be resolved if an international DR were introduced, and this is one of the arguments used to justify such proposals. In the case of the developing countries, their legislation is even more narrowly applicable, since disclosure is only required for applications that utilise national or regional genetic resources. For example, disclosure would not be required for patent applications in Costa Rica if Brazilian genetic resources had been used, or vice versa. Costa Rica took this approach in order to avoid the question of how to deal with resources that come from countries in which no access legislation has been implemented. This problem remains, but it could perhaps be better addressed by including a clause stating that disclosure of PIC is only needed where this is a requirement in the country of origin – as implemented by Norway.

It was acknowledged by many that the legislation of the developing countries could have been better designed, and that the shortcomings were largely due to the limited experience of designing such legislation among policy makers. This would suggest that these national measures have been of some value in building expertise. Indeed, one important reason given by both the European and developing countries for introducing these national measures was that they would provide useful models for the design of such legislation, and so provide valuable experience for the implementation of an international requirement.

An additional reason given for implementing these measures was to build political support for this measure – an objective both of the developing countries and some of these European countries. Thus, it was suggested that this would demonstrate that there exists the political will within these countries to progress on this issue. Within Europe, an additional motivation for introducing this legislation was to show support for developing countries. According to some, this latter motivation was not simply out of a desire to implement the goals of the CBD, but also the hope of gaining concessions from developing countries in international negotiations, in particular within the WTO.

It is difficult to determine what impact the introduction of this legislation has had on debates over disclosure, and in particular, whether it has enabled any progress to be made at the international level. Some felt that the European approach was too weak to satisfy many developing countries, implying that it would have had a limited impact on negotiations. At the national level, it was reported that more informed debates have developed within Europe, which suggests that implementation of these measures has resulted in a better understanding of the issue within these countries. However, whether there is greater consensus is debatable, as is considered further below.

### 3b. CURRENT VIEWS ON DRS AMONG STAKEHOLDERS

#### ***OVERVIEW OF STAKEHOLDERS' OPINIONS***

Participants in this research represented a wide range of viewpoints, from those opposed to any form of disclosure requirement to those advocating strict measures. Although opinions cannot be divided neatly by sector, some general patterns did emerge.

The various stakeholders concerned with this issue include those from government, industry, research institutes, NGOs and indigenous and local communities. The latter were not represented in this survey, but there were a number of participants who had been working with communities on these issues.

From within government, participants came from a number of departments and ministries with diverse responsibilities and priorities, and so their responses were correspondingly varied. Those concerned with international affairs, the environment and development issues tended to support DRs. The most common reason given for this position was that DRs would improve the transparency of the IP system, and so facilitate monitoring of resource use. In addition, the wish to support the goals of the CBD was frequently cited, as was the desire to show support for developing countries. The political value of this measure was widely acknowledged, in particular, in negotiations with the WTO.

Those departments concerned with industry and economic affairs were more sceptical, highlighting the potential negative impact of these requirements on research and development activities. Patent offices, which fall under the responsibility of these ministries, also tended to be less in favour of DRs, concerned as to their impact on the functioning of the patent system.

Representatives of the private sector were, without exception opposed to DRs, at least if these were mandatory. They included industry representatives, mainly from pharmaceutical firms but also the seed industry, and patent attorneys. The survey responses received from this sector were among the most detailed, reflecting the high level of concern about this issue. Most industry respondents were from large companies. Of the smaller companies approached, there seemed to be less awareness of this issue. Many of the small companies contacted did not respond, and of the few that did, a common response was that they did not know about this issue and that their company did not have IPR expertise because they used outside patent lawyers.

A number of the private sector respondents from within Europe felt that their views had not been fully taken into account in developing the European position on this issue. It was suggested that this issue was being used politically as a negotiating tool, for example, in

negotiations over geographical indications within the WTO. There was concern that an international DR was being promoted within Europe for this reason, and not because of any evidence that it would help to achieve ABS objectives and without a full consideration of its potential impact on research and development activities.

The responses from the research and NGO sector included wide-ranging views, from those opposed to DRs to those advocating an international, mandatory requirement. A particular concern within the academic community was that research should not be overly restricted, or hindered. Several respondents felt that concerns about access rights and benefit-sharing have resulted in too great a shift away from an environment in which knowledge and expertise can be freely shared, and that this is to the detriment of research and scientific understanding. Calls were made to re-focus on the objectives for which these measures are supposed to have been developed, which include not only equitable benefit sharing but also facilitating the sustainable utilisation of resources.

The need for compromise was also highlighted. It was suggested that “hardliners”, opposed to any form of DR, risk undermining the credibility of the patent system, and that without trust, the functioning of the IP system and research activities would both be hindered. On the opposite side, it was thought that proponents of disclosure need to recognise that DRs could serve to discourage research and development activities, particularly within industry, which would reduce the opportunities for benefit-sharing.

The developing country respondents came from a wide range of backgrounds and countries. Therefore, not surprisingly, there was no single "developing country view". However, developing country respondents did tend to be more supportive of DR proposals, and emphasised the concerns of indigenous and local communities. Another issue that was highlighted was the lack of trust in the IP system within many developing countries, which is seen as serving the interests of developed countries and of the private sector. Therefore, DRs were regarded as one measure that could help to increase the legitimacy of the IP system.

Having highlighted the differences in views between the various stakeholders, it should be noted that there was also some common ground. One area of agreement was that DRs will not be able to stop all cases of resource misappropriation, even though, at times, DRs seem to have been advocated as the solution to this entire problem. Even if effective legislation can be developed, DRs will only apply to a relatively small proportion of the uses of genetic resources – that for which patents are applied for. Therefore, this measure can only make a small contribution towards facilitating fair and equitable ABS. Other measures are also crucial, for example, clear and workable national ABS legislation, which was regarded as a priority by all sectors. The need for capacity building in many developing countries was also highlighted by many respondents. This was seen as crucial both at the national level – to develop and implement legislation and to build expertise and institutional strengths – and also at the community level, for example, to provide training in negotiation and legal skills.

Another point on which there was general agreement is that both the existing and proposed legislation on DRs still requires further elaboration of terminology and definitions. This lack of clarity creates legal uncertainty for patent applicants, particularly if disclosure is linked to patent validity. As is considered further below, such a situation could be detrimental to all – acting as a deterrent to research and development, and hindering the generation of benefits.

The various perspectives are considered in more detail in the following sections. These are organised according to the questions presented in the questionnaire survey, but opinions expressed during the interviews and workshop have also been incorporated.

## **RESPONSES TO THE SURVEY QUESTIONS**

What advantages or disadvantages can you identify, or do you foresee, in implementing disclosure requirements?

### **ADVANTAGES:**

Among the proponents of DRs, the main argument used to support the introduction of this measure was that it would facilitate fair and equitable ABS, one of the objectives of the CBD. It was held that this would be achieved through improving the transparency of the patent system. Thus, information on the geographic origin of a genetic resource, or of PIC, would facilitate the monitoring of resource use, particularly by the source countries. It was also suggested that the introduction of DRs could act as an incentive for countries to introduce ABS legislation. Relatively few countries have enacted such legislation, and this is a major hindrance to ensuring fair and equitable access and benefit sharing.

A further potential benefit highlighted for this measure was that it could help to increase awareness of CBD issues. This was still felt to be low, particularly in some parts of the research community. The need for greater awareness of environmental conservation and ABS issues within the “IPR world” was also highlighted, although it was felt that there had been some positive changes in recent years – in fact, partly as a result of the debate over this issue.

An additional argument used in favour of a DR was that such a measure could enhance the patent system through helping to improve the quality of granted patents. Thus, disclosure of origin would facilitate the examination of inventorship, prior art and patentability. This was felt to be particularly relevant when TK had been used in an invention, as it would help to direct searches for prior art.

Such an outcome would also help to increase the legitimacy of the IP system. Within many developing countries, the IP system is regarded with a high degree of suspicion, and is seen as operating largely in the interests of western business concerns. Through improving the quality of patents, and also through giving greater recognition to developing country concerns, DRs were felt by many to be of value in enhancing the reputation of the IP system.

This could also help to enhance confidence between the providers and end users of genetic material, and so create an environment more conducive to the establishment of access and research agreements. Thus, such legislation would increase trust among the owners of genetic resources or TK, who would then be more willing to allow utilisation of these resources. It could also encourage relaxation of access regimes, for example, systems could be established whereby nationals of those countries with such requirements are given better access to resources. In fact, this was one of the few possible advantages identified by private sector respondents, although they did regard this outcome as somewhat tentative.

Finally, an additional benefit of DRs that was mentioned was that this measure could be useful for improving understanding of how genetic resources are being used and commercialised. This would depend on there being a system for compiling or registering the information, which does not currently exist.

#### DISADVANTAGES:

A number of possible disadvantages of DRs were identified by respondents. Not surprisingly most of these came from those respondents who are not in favour of DRs, but there was also recognition of some of the potential problems among their advocates.

One of the main concerns was the feasibility of such measures, with a significant number of respondents doubting whether it would in fact be possible to comply with them. This point was made both for requirements to disclose geographical origin and for disclosure of evidence of PIC. In the former case, it was highlighted that it is often difficult to determine the origin of a resource, for example, in cases in which a resource comes from an *ex situ* collection (e.g. a botanic garden or the compound library of a pharmaceutical company), and was collected many years ago. The need for clarification as to whether disclosure would refer to resources collected prior to implementation of the CBD was seen as a priority for any new legislation. Disclosure of PIC was felt by many to be even more problematic given that many countries do not have ABS legislation in place, and in some cases, the procedure to obtain access is complex and unclear – as was highlighted in the case of Colombia earlier in this report.

A further problem relates to the link between a resource and an invention that would trigger disclosure since current and proposed legislation only vaguely defines this. It was highlighted that the complexity of many research processes and the length of research chains mean that it would often be difficult to know when disclosure was required, or to determine the information for the original resource. The existing legislation refers to the link between an invention and genetic resource in the following ways:

- concerns or makes use of biological material (Denmark);
- a process or product obtained using samples of components of the genetic heritage (Brazil);
- obtained or developed from genetic resources (Andean Community);
- innovations involving components of biodiversity (Costa Rica);
- to which the inventor or the applicant has had access, if the invention is directly based on the resource (Switzerland – draft legislation).

Respondents commented that it is unclear how such terminology relates to real research processes and products. For example, would disclosure be required for the use of a product if it was several generations away from the original genetic resource, or for a synthetic compound derived from lead compounds discovered in nature?

The lack of clarity over terminology and definitions in legislation was of particular concern to industry, who felt that it would create great legal uncertainty. This would particularly be the case if DRs were linked to patent validity, for example, it was suggested that such legislation could be exploited by competitors to challenge patents in order to gain free access to the invention. Therefore, there was concern that such legislation would be detrimental to those companies or researchers who were trying to operate legally and ethically. This could serve to discourage compliance, and so, have the opposite effect of the desired objective of increasing transparency.

It could also be a significant burden to companies – both because of the difficulties of complying and also because there could be delays in the processing of patent applications. A couple of respondents suggested that the public research community would be particularly disadvantaged, since they would face all the potential costs of such a system, but few advantages, as they do not usually pursue their activities for commercial purposes.

As well as being detrimental to patent applicants, it was suggested that such legal uncertainty would be a disadvantage to the source countries of genetic resources. Firstly, it would make challenges to patents very difficult to uphold in a court, or at best, would make the outcome of any legal case unpredictable. Therefore, this would be a risky strategy for those wishing to go down this route. Secondly, it would act as a deterrent to research and development activities. Ultimately, this would mean that fewer benefits would be generated from the utilisation of genetic resources. A number of respondents suggested that there had already been a shift away from the use of genetic resources, both within the industry and research sectors, because of the complexities of the ABS system in many countries and concerns about possible legal disputes.

These concerns were most strongly expressed by those from within the private sector, but were also noted by academics and those from within government. Government representatives were particularly concerned that national or regional requirements could place domestic interests at a competitive disadvantage, and hinder research and development within these jurisdictions. They were also concerned at the potential impact on the patent system, and prioritised the need for a smoothly running and efficient system.

This was one reason why more extensive requirements were not supported by many in government, and in particular, those from some patent offices. It was suggested that proposals for disclosure of PIC could place too great a workload on patent examiners because this would require them to examine “problems outside of the patent system”, and which they were not qualified to assess – for example, the access legislation of another country. It was also argued that such a requirement would not improve the patent system in any way (or no more so than disclosure of geographic origin could), for example, through helping in searches for prior art. More fundamentally, it was held that this was an area that should be dealt with outside the patent system. This latter view was held by a number of lawyers, who argued that it is wrong in principal to try to deal with ABS issues within the IPR system, since these are foreign to patent law. It was commented that patents should be a tool to encourage innovation, rather than an enforcement tool, and as such, patent law is inappropriate to police ABS – as one respondent stated “patents are certificates of inventive behaviour, and not certificates of good behaviour”.

The purported benefits of DRs for the ABS system were also called into question. It was highlighted that patents represent a very small proportion of the use of genetic resources, and that there are many circumstances in which patents are not sought. For example, in certain sectors, such as those of cosmetics, natural remedies and plant breeding, patents are only used to a limited extent. Consequently, the suggestion that DRs could help to monitor the commercial use of genetic resources and prevent resource misappropriation was disputed.

It was also felt by a number of respondents that DRs would not be effective in policing the use of genetic resources nor in facilitating benefit-sharing. Any workable system for disclosure would have to rely to a certain degree on good faith, because of the need to allow for the various situations in which disclosure could not be made (for example, for resources

collected prior to the CBD, or where no ABS legislation was in place in the source country). This flexibility could therefore be exploited by unscrupulous applicants. Furthermore, if DRs affected the validity of a patent, the loss of patent rights would probably result in no benefits accruing to the source of the genetic resources or TK in question.

It was noted that DRs are unlikely to result in significant benefits returning to the providers of genetic resources or TK, and that expectations of “green-gold” will probably be unfulfilled. It could also be difficult to establish ownership of resources, and thus, to whom benefits should be returned. For example, many genetic resources are found in more than one country, and TK may be shared by a number of communities or peoples. In fact, any benefits could be outweighed by the costs of implementing such a system, for example, because of the need to introduce new legislation, establish monitoring institutions, train staff, etc. This would be particularly acute in developing countries. Many of these countries lack the expertise and institutional capacity to implement the necessary legislation. Furthermore, there is often insufficient capacity to monitor patent applications and resource use, this requiring a high degree of co-ordination between authorities as well as new institutional arrangements. Indeed, a number of respondents expressed concern that DRs could lead to a complex, bureaucratic and inefficient system. Thus, there was considerable doubt as to whether this measure would bring any net benefits.

What measures, if any, do you think should be taken at the European or international level in relation to disclosure requirements?

Among the respondents from within Europe, there was no appetite for greater harmonisation at the European level. However, it was thought that it would be preferable to address this issue at the European rather than national level, as the latter approach would result in increased divergence between countries. Such a situation could create legal loopholes and greater uncertainty. A couple of respondents did support the introduction of an EU-wide mandatory requirement, but they viewed this as a useful first step towards the development of an international system rather than an end in itself.

In the discussions during the workshop, when asked if any possible benefits of European harmonisation could be foreseen, it was suggested that this could enable better evaluation of the consequences of imposing such a measure. In addition, it was thought by some that a European-wide DR could improve trade relations between Europe and other countries, namely those which are the *demandeurs* on this issue. However, it was also commented that this would probably only be the case if a mandatory requirement were introduced – a suggestion that met with strong opposition from those from within the private sector. Due to their doubts about the feasibility of such a measure, they believed that this would in fact place European business at a competitive disadvantage.

Further harmonisation at the European level could be achieved either through passing a new directive, or by amending the European Patent Convention (EPC). If harmonisation was to be followed, it was felt that the latter approach would make more sense since this would mean that European patents would also be affected rather than just national patents. However, this step was not being advocated by any of the participants – the private sector was opposed to additional European legislation on this issue, while the proponents of DRs felt that there was not much to be gained from further harmonisation at this level, but that this issue should be pursued at the international level.

Similarly, within the developing countries, an international solution was regarded as the best way forward on this issue, since it was felt that an international measure would be most effective in preventing resource misappropriation.

Among the proponents of an international DR, there was general support for the approach outlined in the EU proposal, under which disclosure of the country of origin would be required. Many felt that disclosure of origin would be sufficient to promote ABS, arguing that such information would allow source countries to check whether their access legislation had been complied with and if PIC had been obtained. However, some felt that a more extensive requirement, with disclosure of evidence of PIC, would be necessary for this measure to be effective in encouraging compliance with ABS legislation. In a few cases, evidence of benefit-sharing was called for. However, most felt that this would not be feasible because of the subjective nature of determining whether benefit-sharing is fair and equitable, and also the difficulties in many cases of establishing who should receive these benefits.

The question was also raised as to whether disclosure of the country of origin or of provider country would be better. The former would be more difficult to comply with in many cases, but it was noted that this could be useful in controlling the use of intermediaries to access resources.

The question of whether disclosure should be required for inventions concerning TK, rather than just those based on genetic resources, was not considered in detail. Most respondents supported this in theory, but recognised that it would be difficult to implement in practice because of the lack of an internationally recognised definition for TK. Therefore, it was generally felt that this was not currently workable.

Opinions varied widely as to whether there should be sanctions for non-compliance, and if so, what form these should take. Options for sanctions against non-compliance include:

- Patent invalidity;
- Unenforceability of a patent;
- Transfer of rights of a patent;
- Imposition of benefit sharing arrangements;
- Criminal sanctions (e.g. as in Norway, Denmark and Switzerland's draft legislation);
- Halting patent processing;
- No sanctions.

Participants from within the private sector generally felt that there should not be any sanctions because of the potential difficulties of complying with these requirements, but many other respondents thought that some sort of sanctions were needed if this measure is to be effective as a tool to encourage compliance with ABS legislation. However, it was also noted that the fear of adverse publicity could be an effective spur to compliance, just as much as any direct legal consequences.

There was strong opposition from many to a requirement that was linked with patent validity, because it was felt that this could create too much legal uncertainty, and could hinder the utilisation of genetic resources and generation of benefits (as highlighted earlier). This was a particular concern of the private sector, but the feasibility of such a strict requirement was also questioned more widely. The transfer of patent rights and imposition of benefit-sharing both met with more support and it was felt that these options should be explored in greater detail.



If an international DR were to be introduced, then clarification of the terminology and the development of workable definitions were highlighted as crucial – particularly by the private sector. However the difficulties of reaching international consensus on DRs were also highlighted, particularly if disclosure was a substantive requirement, since the compatibility of this approach with international law is contentious.

Do you think any other measures should be taken at the European or international level, either as an alternative to, or in addition to, disclosure requirements in order to facilitate fair and equitable access and benefit-sharing?

It was widely recognised among the respondents that DRs alone will not be able to solve the problem of resource misappropriation – there was the feeling that they had come to be regarded as a panacea by some. It was highlighted that, in order to improve ABS, a range of measures needs to be implemented. DRs could be one such measure but opinions varied as to the significance of their role in this.

In order to improve the effectiveness of DRs, a notification system for applications in which disclosure had been made was widely considered a priority. This was not only regarded as a measure that should be introduced in the case of an international DR being implemented, but a step that should be taken immediately. It was felt that this would enhance the effectiveness of existing measures, through improving transparency, and also enabling monitoring of their impact – something that is not currently taking place. Such a system could be established under the CBD’s CHM. Its role could be limited to informing countries that their resources had been used, or it could also take on a more ambitious role, facilitating exchange agreements between the providers and users of resources. Either way, this would require the identification of competent agencies in source countries, and a significant increase in institutional capacity.

The implementation of national ABS legislation was generally regarded as the most important step that could be taken to enhance ABS. Relatively few countries have implemented such legislation to date and it was felt by many that improving this situation should be a priority. The private sector in particular highlighted the importance of “robust but user-friendly” ABS legislation, as well as the need to identify national focal points so that it is clear who should be contacted to obtain access and user rights. It was felt that focusing on this area would be far more effective in promoting ABS than the wider implementation of DRs, because this would cover all material being transferred and not just that for which patent applications are made. It would also improve predictability for the users of resources, for example, through clarifying the appropriate legislation and the systems through which approval for access should be obtained.

Some participants suggested that a two-tiered system could be established for access legislation, with a non-restrictive licensing policy for non-commercial research and a restrictive policy for commercial users of resources. A suggestion was also made for establishing a system for registering *bona fide* research organisations within source countries. Foreign parties who wished to access resources within this country would then have to collaborate with one of these organisations.

To facilitate enforcement of ABS regulations, the need for some kind of international legal framework was highlighted, to address the problem of how legal redress can be sought in foreign jurisdictions, and to overcome some of the inequities in power and access to legal measures. An alternative proposal was for the amendment of the national laws of user countries to regulate the activities of their citizens, for example, to ensure their compliance with international and source country ABS and TK protection measures.

A system of certificates of origin or of legal provenance was regarded as a valuable measure by many, particularly among developing country respondents. If an international certificate was developed, this could make a DR for evidence of legal access (i.e. PIC) more workable since it would provide a standard system of proof, overcoming the problem of variable national legislation. It was highlighted that, as with DRs, the lack of ABS legislation in many countries is problematic for such a measure, and also that the points at which a certificate would be required would need to be clarified. However, it was generally considered that there should be further exploration of this measure.

In the absence of ABS legislation, the need for good commercial practices was highlighted, including the use of MTAs. Codes of conduct for both industry and researchers were regarded as a useful step, and the need for industry to deal with 'black sheep' was highlighted, for example, through excluding them from trade associations. The code of conduct being developed for the use of micro-organisms (MOSAICC) was mentioned as a possible model, as well as those developed by industry, for example, the guidelines produced for members of the Biotechnology Industry Organization (BIO). The need for further awareness raising and education about CBD obligations among small firms and some sectors of the research community was also highlighted.

The establishment of a fund to compensate countries of origin when a resource comes from more than one country was proposed by a number of participants. An international industry fund for ABS development in provider countries was one suggestion, and the system being developed under FAO's ITPGRFA was regarded as a potentially useful model for this. It was also highlighted that benefits could be shared in other ways, for example, through companies providing training and building capacity in source countries.

With respect to all these possible measures, the need for capacity building measures was emphasized – both within government and civil society. To ensure the effective implementation of ABS procedures and legislation, capacity building is needed within patent offices, customs and immigration, ABS institutions and more widely within many government institutions. Within civil society, it was suggested that public understanding of the IPR system should be improved, in particular among indigenous and traditional communities, and that expertise among such communities to negotiate ABS agreements needed to be developed. This was an area which it was felt should be a priority for European countries, and that this could be one of the most valuable means of enabling progress on ABS within developing countries.

The need to deal with the particular issues and problems faced by local and indigenous peoples was emphasized by a number of respondents. It was highlighted that the rights of communities to their traditional territories, practices and knowledge need to be guaranteed to ensure that they are able to act as custodians of genetic resources and TK. The need for further work on the issue of PIC was also noted, for example, to consider the mechanisms available for enforcement and also to develop effective mechanisms for the restitution of the

rights of communities. Training of communities in negotiating skills and legal education, to help them to establish fair access agreements, was also prioritised.

Finally, it was commented that there is a need to follow through on the technology transfer commitments made in both the CBD and TRIPS, and that this should be part of a bigger, broader understanding of benefit sharing, which can help to provide support for maintaining biodiversity and viable rural livelihoods.

#### **4. CONCLUSIONS**

The aims of this project were to assess the effectiveness, feasibility, and acceptance of newly proposed and established national legislation on DRs, and also, to assess the prospects of harmonisation of these measures within the European Union.

##### **Effectiveness**

Assessing effectiveness depends on what the objectives of DRs are. There is no consensus on this – even among the participants in this research, a wide range of objectives were identified. These included: supporting the CBD's objectives, including the facilitation of access to genetic resources; enhancing fair and equitable benefit-sharing; improving transparency of the patent system; preventing misappropriation of genetic resources; enhancing the patent system through facilitating searches for prior art; improving the equity of the patent system; protecting rights over genetic resources or TK; enabling tracking of resource use; promoting confidence in the patent system.

It is very difficult to determine whether DRs have actually had an influence in these areas, either negative or positive. The fact that there have been so few patent applications in which disclosure has been made suggests that these measures have had little direct impact on these goals – indeed, with just three known applications in which disclosure was made within Europe, and only one from the developing countries surveyed, this measure will have had very little impact on any of the proposed objectives of this measure.

The limited impact of these measures is in part due to the narrow scope of this legislation, which applies only to national patent applications. The fact that many of these DRs are voluntary, or are effectively so (given that there is no checking or monitoring of the applications), also limits their role, for example, in monitoring resource use or preventing resource misappropriation. In addition, the fact that no notification system has been established means that little progress has been made in enhancing the transparency of the patent system.

However, these measures may have had a more subtle influence. The national consultations on disclosure have apparently raised awareness of the CBD and ABS issues among researchers and industry, and this process may have helped to promote fair and equitable ABS. Implementation of these measures may also have been of value in helping to build expertise among policy makers. As highlighted above, some lessons have been learnt in the developing countries as to how such legislation could be designed.

## **Feasibility**

Questions have been raised as to the feasibility of DRs both with respect to the ability of patent applicants to comply and of patent offices to check compliance, particularly with requirements to meet the PIC legislation of other countries. None of these national experiences can shed much light on this because of the narrow scope of these measures and the fact that compliance is not checked. Therefore, to date, they have not been much of a burden, either for applicants or patent offices.

Within Europe, no problems of feasibility were reported. Among the developing countries, difficulties of complying with the legislation were encountered in Colombia, while in Brazil, lack of clarity of the legislation has meant that the patent office has not yet utilised this measure. These limited experiences underline the need for well thought-out legislation. This would be crucial if an international, mandatory requirement were introduced.

Another aspect of feasibility is the cost of implementing such legislation and of establishing systems to monitor and enforce compliance. This could be considerable, particularly in developing countries where expertise and institutional capacity is often limited. The transaction costs of this measure need further analysis to assess whether these might in fact outweigh any possible benefits.

## **Acceptance**

It was reported during the survey that a more informed debate has developed within Europe since this measure was first proposed, and it seems that there has been a narrowing of the gap between the proponents and detractors of this measure. For example, the proponents of DRs recognise some of the potential problems with this measure, and conversely, its opponents acknowledge the need to address ABS issues.

However, this gap has not disappeared, and there remain fundamental differences in the perspectives of the various stakeholders, with no consensus on many areas. Among the sceptics, concerns remain as to the feasibility of this measure, for example, how the link between a resource and invention could be meaningfully defined, whether resources could be tracked through research processes and commercial exchanges, and whether there would be too high a level of legal uncertainty created, which could ultimately undermine the objective of facilitating ABS.

If this measure is to gain wider acceptance, particularly among potential patent applicants (i.e. the industry and research sectors), the question of whether workable definitions can be developed needs to be explored.

## **Assessing the Prospects of Harmonisation**

The second question examined in this research project was the issue of harmonisation within Europe. The general consensus was that there was little to be gained from this. Rather, it was felt that this issue should be dealt with at the international level, if at all. This would create a level playing field for both the users and providers of genetic resources, and would be more effective in tracking resource use.

## WAYS FORWARD

Although a more informed debate on disclosure requirements has developed in recent years, it would seem that these discussions have not moved forward significantly. One hindrance has been the fact that there has been little practical experience of implementing such legislation and so arguments continue to be based on theoretical scenarios. In spite of this limited experience, this study has been able to identify a number of key areas which warrant further exploration. These areas, listed below, provide a means of making progress on this issue.

- **Clarification of terms and definitions:** Clarification of the terms and definitions used in DR legislation was recognised by all as a priority, to allow a better assessment of the feasibility of complying with such requirements and a clear definition of their scope.

Policy makers need to work with those involved in research to develop workable definitions, and in particular, to explore how to define the link between a resource and invention that would trigger disclosure. Clearer definition of the link between a genetic resource and end product would enable clarification of the range and duration of obligations that may be associated with such resources.

Those involved in research and industry also need to determine whether a workable system could be established for tracking genetic resources. This would enable assessment of the feasibility of complying with DRs. Furthermore, regardless of whether DRs were introduced, such a system could be of value in monitoring the use of GRs and improving transparency within the sector.

- **Determining the objectives of DRs:** A wide range of objectives have been proposed for DRs. Clarification of these is required, as this would help in determining how such legislation could best be designed in order to achieve these ends.

A crucial question is whether DRs should simply be a transparency measure, aimed at facilitating enforcement of ABS legislation in other areas of legislation, or alternatively, a means to enforce ABS compliance and prevent the granting of "bad patents". In other words, what role should the patent system play in facilitating ABS?

The proponents of this measure need to clarify its objectives. This should include an assessment of what objectives could realistically be attained through introducing DRs, and a consideration of whether there are any alternative, and more efficient, means of achieving these goals.

- **Exploration of other options within the patent system:** The debate on DR legislation has often been very narrow, for example, discussion of possible sanctions for non-compliance with this measure has focused on imposing fines or making a patent invalid. Alternatives, such as enforced benefit sharing or the transfer of patent rights, have received less attention. However, these options could hold greater potential for enhancing ABS, and they met with wider support from the participants in this research.

Discussions of how to enhance the patent system and ensure that it promotes equity have also been overly narrow, with most attention being given to DRs. However, the effectiveness of this measure remains unproven, and other measures could be just as valuable, if not more so, in achieving these goals. Therefore, other options within the patent system also need to be explored. For example, the provisions on *ordre public* and morality or the doctrine of unclean hands could perhaps be utilised to prevent the enforcement of patents if these are based on illegally obtained resources.

Those within the IP world need to explore other means of improving the patent system, to enhance the quality of patents and to ensure that it promotes, rather than undermines, equity. This would be an important step in enhancing the reputation of the IP system and restoring trust.

- **Exploration of alternatives to DRs outside the IP system:** The limitations of DRs as a means to enhance ABS were widely recognised, by both the advocates and dissenters of this measure. DRs can only deal with a small part of the problem of resource misappropriation, and so a range of other measures is also needed.

The implementation of workable national ABS legislation is probably the most effective way of preventing resource misappropriation and facilitating ABS. Therefore, policy makers and national governments need to prioritise this. In particular, higher priority needs to be given to implementing effective national legislation in many developing countries, where it was suggested that the slow progress at this level reflects a “divorce of the positions at the national and international level”. A key role for Europe in this area is capacity building, and greater effort is needed to provide training and build expertise.

Other measures could also play an important role, for example, certificates of origin and systems to track genetic resources. One priority area should be developing an international system to facilitate legal enforcement of ABS regulations. These measures need further exploration, with input from all stakeholders – including the providers of resources (whether these are local communities or national governments) and end-users (who may be academics, public research institutes or private companies).

An important step for the users of resources is to monitor and control activities within their own sector. For example, codes of conduct and the establishment of model contracts need to be more widely implemented as they would help to build awareness and expertise of ABS issues, and would also improve trust among the providers of resources.

This study highlighted the fact that there remain fundamental differences between the various stakeholders on this issue. However, it was also apparent that the complexities and potential problems of DRs are widely recognised by both the supporters and dissenters of this mechanism. Such a balanced view needs to be communicated to the policy makers, as there exists a feeling that they have tended to give precedence to political issues over practical matters.

Although opinions varied widely as to the need for, and benefits of, DRs, it was acknowledged that this issue seems unlikely to go away because of its high profile within

international negotiations. Therefore, all parties need to continue to engage in the debate. Furthermore, this debate needs to be based on practical questions such as costs, definitions and terminology, and the capacity of institutions and personnel. Only in this way will a solution be found which is workable and effective.