

# **International Agreements and Processes Affecting an International Regime on Access and Benefit Sharing under the Convention on Biological Diversity**

## **Implications for its Scope and Possibilities of a Sectoral Approach**

Regine Andersen, Morten Walløe Tvedt, Ole Kristian Fauchald, Tone Winge,  
Kristin Rosendal and Peter Johan Schei





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**Abstract**

Intended as a contribution to the ongoing negotiations of an international regime on access and benefit sharing (ABS) under the Convention on Biological Diversity (CBD), this report clarifies the main interfaces with other international agreements and processes relevant for ABS, with a view to the challenges of ensuring mutual supportiveness. It provides information of importance for identifying the scope of an international ABS regime, and offers contributions to the discussion of the usefulness and possible design of a sectoral approach to ABS within the framework of an international regime.

Covered in the report are international agreements and processes pertaining to genetic resources for food and agriculture; marine areas within and beyond national jurisdiction; pathogens; traditional knowledge related to genetic resources; and intellectual property rights. For each section, the interface with ABS is identified, implications of this interface for ABS are highlighted, and options for dealing with these implications derived. The report ends with a discussion of the usefulness and possible design of a sectoral approach to ABS, concluding that there are good arguments for a broad and inclusive international regime on ABS, but that its usefulness will depend on its ability to meet the specific requirements of the various sub-categories of genetic resources.

**Key Words:** access and benefit sharing, ABS, Convention on Biological Diversity

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## Executive Summary

Intended as a contribution to the ongoing negotiations of an international regime on access and benefit sharing (ABS) under the Convention on Biological Diversity (CBD), this report clarifies the main interfaces with other international agreements and processes relevant for ABS, with a particular view to the challenge of ensuring mutual supportiveness with these established frameworks. It provides information of importance for identifying the scope of an international ABS regime, and offers contributions to the discussion of the usefulness and possible design of a sectoral approach to ABS within the framework of an international ABS regime without causing further delay in the negotiations or in subsequent implementation.

Negotiating an ABS regime with a view to mutual supportiveness with other international agreements and processes is a challenging task. The report highlights many key interfaces that must be taken into consideration. Some of these frameworks concern specific sub-categories of genetic resources, whereas others deal with access to resources in geographically defined areas. Some address the traditional knowledge attached to genetic resources, and others regulate the relevant intellectual property rights.

These various sub-sectors of genetic resources differ greatly in terms of their distinctive features and the challenges regarding their conservation and utilization. These differences have given rise to the question of whether particular sub-sectors should be included in an international regime on ABS, or should be kept outside such regulations.

- The Multilateral System of the Plant Treaty is an established and legally binding ABS system, and is therefore eligible to be kept outside an international regime on ABS. However, defining the exact scope of the material to be excluded might prove difficult. As a minimum, the material in the Multilateral System and the material already made available with the SMTA would need to be excluded. An international regime could include flexibility to enable future expansion of the Multilateral System to new species in addition to those currently listed in Annex I. In defining the scope of the material to be excluded, there are four challenges: (1) It is relevant to exclude not only Annex I material, but also all other material transferred by use of the SMTA additional to the Annex I material; (2) only the material in the public domain and under the control of the parties can be excluded, so, for instance, the material in farmers' fields is subject to an international regime; (3) there are 70 countries that are parties to the CBD and non-parties to the Plant Treaty, so it is not sufficient to refer solely to Annex I material in excluding this from the scope; (4) the MLS applies only to the specific use for food and agriculture: an international regime should address other uses of this material as well.
- The genetic resources for food and agriculture (GRFA) are many, with different distinctive features, exchange patterns and management needs. It has been debated whether GRFA should be excluded from an international regime on ABS. In any case, the specific fea-

tures and management needs of the different sub-categories of GRFA must be reflected in an international regime.

- ABS to genetic resources in the sea beyond areas of national jurisdiction has been a difficult topic for years, and international processes in other international fora have not yet resulted in agreement on solutions. If an international regime on ABS covers these resources adequately, that might solve the long-lasting dispute. The status regarding sovereignty and sovereign rights of national differs in international law for the deep sea bed, the high seas, the continental shelf, the economic zone and territorial waters. These differences must be taken into account, as they are already binding in international law. Until consensus is reached in this particular forum, the patent system remains the only legal system for establishing property rights to genetic material taken from the zones of the oceans beyond national sovereign rights. Some actors involved have vested interests in the continuation of this dispute, as that situation leaves the genetic material open. From an ABS perspective, however, it is important to seek to include these resources.
- Regulating ABS to genetic resources in the Antarctic is also difficult, due to the unclear territorial status. If these resources are not included in an international regime, that might create a loophole whereby users of genetic resources actually obtain them elsewhere but maintain that they were collected in Antarctica. This is an argument for including these resources in an international regime on ABS. In any case, the benefit-sharing side of the ABS coin needs mechanisms to validate whether the genetic resources in question are inside or outside the scope of an international regime.
- Whether pathogens should be excluded from an international regime on ABS is a complex question. There are arguments for and against the exclusion of pathogens and also suggestions that only specific uses of certain pathogens should be included. If pathogens or certain uses of pathogens are excluded, there must be clear specification of what this means. Important issues related to pathogens need to be solved, not least as regards intellectual property rights to material that is shared internationally.
- Traditional knowledge related to genetic resources is already covered in the negotiation text of an international ABS regime. As such it addresses the domestic regulation of ABS with a view to indigenous and local communities that are holders of traditional knowledge. Including provisions on traditional knowledge has additional support in several other established international frameworks.

There are good arguments for a broad and inclusive international regime on ABS. Such a regime will need to take into account the special characteristics of the various sub-categories of genetic resources. As the example of the Multilateral System under the Plant Treaty shows for PGRFA, and as the CGRFA suggests, differential solutions might be required for different sub-categories, in order to achieve the common objectives of access and benefit sharing for all genetic resources covered by the CBD.

To cover all these different sub-categories of genetic resources in one regime, and with general provisions only, might prove challenging. Negotiating a one-size-fits-all approach might result in provisions that are more general and less effective than more tailor-made solutions. Also, negotiators might seek to exclude various sub-categories of genetic resources, thereby weakening the regime. On the other hand, there is the risk that a sector-based approach could weaken an international ABS regime by splitting it up into bits and pieces. That would be the case if sub-categories of genetic resources were to be excluded from the ABS regime and referred to other international fora instead.

Differentiating among sectors within an international ABS regime under the CBD would entail having general provisions that apply for all sectors dealing with the access side and the benefit-sharing side of ABS, as well as sector-specific provisions that meet the specific features and needs of specific sub-categories of genetic resources. To be functional, user-country measures must be kept at a cross-sectoral level. They include the further specification of what is meant by ‘utilization of genetic resources’, surveillance mechanisms (like certificates and disclosure) and enforcement mechanisms for the providers of genetic resources under the jurisdiction of the user country. Importantly, they include the obligation upon users, regardless of sector, to conduct fair and equitable benefit sharing, and the obligation of the user countries to implement legislative, policy and administrative measures to ensure that benefits are shared.

A sectoral approach could be designed in various ways and through different processes. Here four different options for an international ABS regime are highlighted:

1. A regime could have general provisions which apply to all genetic resources included in its scope and not covered by specific sectoral provisions, as outlined above, and then include chapters on the relevant sub-categories of genetic resources that need specific solutions.
2. It could be designed with general provisions for all the genetic resources included in its scope, and open for the adoption of annexes on ABS to specific sub-categories of genetic resources for special regulation, based on their distinctive features. The final act of the international regime could then specify that these annexes are to be negotiated within the framework of the CBD and be presented to the next Conference of the Parties to the CBD. Alternatively, the international regime as such would prevail until sector-specific solutions could be found.
3. A regime might open for the adoption of international agreements on ABS to specific sub-categories of genetic resources developed under the auspices of other international organizations or treaties – in harmony with the CBD. This would in practice imply that these sectors were excluded from the international regime, and that the ensuing ABS regulations for these sectors were dealt with under the respective international frameworks.
4. An international ABS regime could be designed with general provisions for all the genetic resources included in its scope, and open for the adoption of annexes on ABS to specific sub-categories of genetic

resources. The COP could consider whether such annexes should be developed in cooperation with other international bodies, and could invite draft text from such bodies. This option would allow the international regime to enter into force, whereas annexes could be included in the international regime later, once they have been adopted by the decision body of the international ABS regime or the Conference of the Parties to the CBD.

Finally, it is important to keep in mind the larger context. When ABS emerged as an issue in the CBD negotiations in the late 1980s, it was much as a reaction to the development of intellectual property regimes that could deprive developing countries of rights over their resources. That issue is still not solved. How intellectual property rights are addressed in an international ABS regime may be decisive to the prospects for benefit sharing. For benefit sharing to take place there must be a legally binding system on user-country measures to safeguard the realization of this objective. A stand-alone disclosure requirement as such will not be sufficient to achieve the benefit-sharing obligations. It will have to form a part of a more complete enforcement system which can resolve the difficult technical legal issues of the cross-border use of natural resources.

## List of Acronyms and Abbreviations

ABS	access and benefit sharing
CBD	Convention on Biological Diversity
CGIAR	Consultative Group on International Agricultural Research
CGRFA	Commission on Genetic Resources for Food and Agriculture
COP	Conference of the Parties
EEZ	exclusive economic zone
FAO	Food and Agriculture Organization of the United Nations
GISN	Global Influenza Surveillance Network
GRFA	genetic resources for food and agriculture
IARCs	International Agricultural Research Centres of the CGIAR
ICC	International Chamber of Commerce
IGC/WIPO	Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore
IHR	International Health Regulations
ILO	International Labour Organization
IPRs	intellectual property rights
IPPC	International Plant Protection Convention
MAT	mutually agreed terms
MLS	Multilateral System of Access and Benefit Sharing (under the Plant Treaty)
MOSAICC	Micro-Organisms Sustainable Use and Access Regulation, International Code of Conduct of the World Federation for Culture Collections
OECD	Organization for Economic Co-operation and Development
OFFLU	OIE/FAO Network of Expertise on Avian Influenza
OIE	World Organization for Animal Health
PCT/WIPO	Patent Cooperation Treaty
PGRFA	plant genetic resources for food and agriculture
PHEIC	public health emergency of international concern
PIC	prior informed consent
Plant Treaty	the International Treaty on Plant Genetic Resources for Food and Agriculture (or ITPGRFA)
SCP/WIPO	Standing Committee on Law of the Patents
SMTA	Standard Material Transfer Agreement
SPLT	Substantive Patent Law Treaty
TK	traditional knowledge
TRIPS	Trade-Related Aspects of Intellectual Property Rights

UNCLOS	United Nations Convention on the Law of the Sea
UNDRIP	UN Declaration on the Rights of Indigenous Peoples
UNFCCC	United Nations Framework Convention on Climate Change
UNGA	United Nations General Assembly
UPOV	International Convention for the Protection of New Varieties of Plants under the Union for the Protection of New Varieties of Plants
WHA	World Health Assembly
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

## **Introduction**

This report is intended as a contribution to the ongoing negotiations of an international regime on access and benefit sharing (ABS) under the Convention on Biological Diversity (CBD). It aims at clarifying the main interfaces with other international agreements and processes relevant for ABS, in view of the challenges of ensuring consistency with these established frameworks. Furthermore, it provides information of importance for identifying the scope of an international ABS regime. And finally, it seeks to contribute to the discussion of the usefulness and possible design of a sectoral approach to ABS.

One of the important issues is the scope of an international regime on ABS. This report examines different sub-sectors covered by various international regimes, with a view to their relevance for the scope of an ABS regime and their distinct features and management needs. On this basis it outlines – in the conclusions – various options for resolving the question within the framework of an international ABS regime without causing further delay in the negotiations or subsequent implementation.

The concept of a sectoral approach emerged in the negotiations particularly through the resolution on ABS that was adopted at the 12<sup>th</sup> Session of the Commission on Genetic Resources for Food and Agriculture (CGRFA) in October 2009, and presented to the Ad Hoc Working Group on ABS in Montreal.<sup>1</sup> Here the CGRFA invites the ABS negotiators to take into account the special nature of agricultural biodiversity, in particular genetic resources for food and agriculture, their distinctive features and problems requiring distinct solutions. It further suggests that the negotiators may consider sectoral approaches which allow for differential treatment of different sectors or sub-sectors of genetic resources.

The present report covers international agreements and processes pertaining to genetic resources for food and agriculture; marine areas within and beyond national jurisdiction; pathogens; traditional knowledge related to genetic resources; and intellectual property rights. For each section, the interface with ABS is identified, implications of this interface for ABS are highlighted, and options to handle these implications derived. The report ends with a discussion of the usefulness and possible design of a sectoral approach to ABS.





## 1 Interface with the International Treaty on Plant Genetic Resources for Food and Agriculture <sup>2</sup>

While negotiators work on the details of an international regime on ABS under the CBD, a sectoral regime on ABS has already been established under the International Treaty on Plant Genetic Resources for Food and Agriculture (the Plant Treaty or ITPGRFA). The Plant Treaty, adopted in 2001 and in force since 2004, is aimed at the conservation and sustainable use of plant genetic resources for food and agriculture (PGRFA)<sup>3</sup> and the fair and equitable *sharing* of the benefits arising from the utilization of these resources, in harmony with the CBD (Art. 1). A central component of the Plant Treaty is the Multilateral System of Access and Benefit Sharing (MLS), as set out in Articles 10 to 13. Whereas the Plant Treaty as such covers all PGRFA, its MLS covers 35 food crops and 29 forage plants that are in the public domain and under the management and control of the contracting parties. These are listed in Annex I to the Plant Treaty (the Annex I crops), and include major staple crops as well as a range of other plants widely used for food and agriculture.

The MLS is relevant in the CBD-ABS context for two reasons:

1. As the only sectoral approach to ABS, it may provide lessons of relevance in discussing the usefulness and possible design of a sectoral approach to ABS under the CBD.
2. It covers a substantial part of the plant genetic resources that are relevant for a new international regime on ABS. This gives rise to the questions of how the material in the MLS should be dealt with in a new international regime on ABS and how to deal with PGRFA not included in the MLS.

In developing the MLS, the negotiators took as their point of departure the provisions on ABS in the CBD, and developed the system according to the specific features of PGRFA.<sup>4</sup> The key features can be summarized as follows:

- PGRFA are the very basis of farming. They provide the pool from which plant traits can be found that meet the challenges of crop pests and diseases, of marginal soils, and – not least – of changing climate conditions. They are the basis of all plant breeding and are vital for spreading the risks of crop failure among smallholder farmers. PGRFA are thus crucial to present and future food security.
- All countries are interdependent on PGRFA, as all are providers and recipients of these resources.
- PGRFA are domesticated resources,<sup>5</sup> and thus depend on continued domestication for their further existence.

As a result of these specific features, the MLS was designed with a view to certain requirements: As access to PGRFA is a condition for the further domestication and thus existence of these resources, expeditious facilitation of access was a major concern to the negotiators. To ensure access, it was also important that the PGRFA that are in the MLS remain accessible, and that this material cannot be made subject to exclusive

intellectual property rights (IPRs). The MLS had to be based on a different solution to benefit sharing than that envisaged under the CBD – one focusing on custodians of PGRFA, i.e. those who conserve and sustainably use these resources, rather than on providers. This was because: (1) it is difficult to identify countries of origin (i.e. the countries entitled to provide access under the CBD) for most crops, as the crops have been developed through the exchange of seeds across borders for centuries and millennia; (2) all countries are interdependent on PGRFA, so a complicated system of transfers between providers and recipients would hamper the expeditious access to these resources; (3) rewarding only the current providers of genetic resources would not be fair to all those farmers around the world who maintain and develop crop genetic diversity which will benefit future generations.

Against this backdrop, the MLS was developed with the following features:

- The MLS is a **common pool of genetic resources**, in which all contracting parties (countries) place the genetic resources of Annex I crops that are in their public domain and under their control. Thereby the contracting parties invite all their holders of such material to include it in the MLS (Art. 11.2). In practical terms, the material remains with the holders (normally gene banks), but is accessible under the same terms and conditions as everywhere in the MLS. What makes this system multilateral is the fact that it involves a common pool of genetic resources governed by the Governing Body of the Plant Treaty, through the specific terms and conditions highlighted below. Accessions of plant genetic resources which are outside the *public domain*, such as the resources held in private collections, are not included in the MLS. Countries are to take appropriate measures to encourage these to be included, but this remains a limiting factor for the MLS.
- A **Standard Material Transfer Agreement (SMTA)** is applied for all transfers of genetic material under the MLS. This enables the expeditious transfer of PGRFA, as no negotiations are required. The SMTA was adopted by the parties to the ITPGRFA in 2006. It implies prior informed consent on mutually agreed terms among and between states in a standardized form. An increasing number of gene banks have established a web-based ‘click and wrap’ system, which allows recipients of genetic material to enter into the SMTA simply by clicking in a box at the web-site of the gene bank to confirm their acceptance of the SMTA. This makes the facilitation of access to the material more efficient, in line with Article 12.3.b, which stipulates that access shall be provided expeditiously, without the need to track individual accessions. In the first eight months of operation, almost 100,000 transfers of genetic material took place within the MLS.<sup>6</sup> Since then the number has been steadily increasing.
- **Access is provided free of charge**, or, when a fee is charged, it is not to exceed the minimum cost involved (Art. 12.3.b). All available passport data and related information are to be provided together with the material (Art. 12.3.c).

- **Intellectual property rights** are not allowed on material from the MLS, or its genetic parts and components, *in the form it is received* (Art. 12.3.d). It is, however, uncertain exactly how much the material must be modified before it is no longer regarded as being ‘in the form received’ under this Article. Whether a patent will be granted or not depends on the practice in the patent system.<sup>7</sup> If patents are granted which break with the provision of no intellectual property rights on material in the form received, one of the parties to the relevant material transfer agreement can initiate dispute settlement (see section on dispute settlement procedures below). How this will work out in practice remains to be seen, as no dispute settlement has so far been carried out. The intention of this provision (Art. 12.3.d) is to ensure that material in the MLS remains in the public domain, but how this will work in practice remains to be seen.
- **Monetary benefit sharing is fixed** in terms of shares from the sales of products developed by use of material from the Multilateral System, as set out in the SMTA. If a product resulting from the use of material from the MLS is protected by patents,<sup>8</sup> then a fixed share of the sales must be paid to the benefit-sharing mechanism. If the product is not patent-protected and is still available for use and further research and development, then benefit sharing is optional. This is meant as a further incentive to keep material from the MLS in the public domain – a point crucial for accessibility. As the MLS is still new, and crop breeding takes time, it is too early to expect to see much benefit from these provisions. It is also uncertain how much benefit the provisions will generate, as patents are used only to a limited extent for PGRFA.<sup>9</sup> Thus other forms of optional benefit sharing are taking place. For example, Norway is providing an annual contribution equivalent to 0.1 % of the total sales of seeds in the country to the benefit-sharing mechanism. It urges other countries and multinational companies to do likewise, as that would substantially improve the capacity of the benefit-sharing mechanism. Discussions continue on how to further strengthen this mechanism, as set out in Articles 13.2.d and 13.6. If an international ABS regime devises more effective benefit-sharing measures, that could influence the further development of the benefit-sharing mechanism under the MLS.
- **Non-monetary benefit sharing** is to be facilitated between the contracting parties independently of the transfers of material. This includes making available information on PGRFA; transfer of technology for the conservation and sustainable use of PGRFA; and capacity building in terms of education and training, improvement of facilities, and research cooperation for the conservation and sustainable use of PGRFA (Art. 13.2).
- **Benefits are to be shared with custodians of PGRFA**, and not with actual providers of specific material. This is an important difference between the CBD approach to ABS and the MLS. The benefits do not flow back to certain provider countries and specific providing communities, as foreseen under the CBD, but into the benefit-sharing mechanism under the MLS. From there they are distributed primarily, directly or indirectly, to farmers, especially in developing countries and countries with economies in transition, who conserve and

sustainably use PGRFA (Art. 13.3). The first disbursement of benefits from the benefit-sharing mechanism was announced at the Third Session of the ITPGRFA Governing Body in June 2009: 11 projects in developing countries were selected from a large number of applications to receive support for their contributions to the conservation and sustainable use of PGRFA. The total amount disbursed was approx. USD 500,000.<sup>10</sup>

- **A Third-Party Beneficiary of the Agreement monitors compliance with the SMTA:** The parties to the SMTA agree that the FAO, acting on behalf of the Governing Body of the Treaty and its MLS, is the Third-Party Beneficiary under the agreement. This Third-Party Beneficiary monitors compliance, has the right to initiate dispute settlement, and reports to the Governing Body of the Plant Treaty. Given the high numbers of transactions governed by the SMTA, the Third-Party Beneficiary faces great challenges in terms of monitoring compliance with the SMTA. Procedures for the operation of the Third-Party Beneficiary were adopted at the Third Session of the Governing Body as Resolution 5/2009.<sup>11</sup> A Committee is currently being established, to consist of experts from all regions, to exercise the function of the Third-Party Beneficiary.
- **A dispute settlement procedure** has been established in the SMTA for cases of non-compliance. Any of the three parties – the provider, the recipient or the Third-Party Beneficiary – may initiate dispute settlement procedures. The first step in these procedures is amicable negotiations, whereby the parties try to solve the dispute in good faith. If that does not help, mediation is the second step. For this purpose they are to select a neutral party as mediator. The last step – if nothing else could solve the conflict – is arbitration. Here the parties to the dispute must either agree on an appropriate international body to carry out the arbitration, or the dispute will be settled under the Rules of Arbitration under the International Chamber of Commerce. The result of such arbitration is legally binding.

The MLS represents a system quite different from ABS as practised under the CBD thus far. It involves a common pool of genetic resources with standardized ABS arrangements and a fixed benefit-sharing system. It is meant to provide benefits not to the providers but to the custodians of the genetic resources, so there are no procedures for PIC (prior informed consent) and MAT (mutually agreed terms) related to local communities. The introduction of the Third-Party Beneficiary represents an important difference to traditional ABS arrangements under the CBD between providers and recipients, as it aims to ensure the common interest of the MLS in each material transfer agreement.

This approach to ABS is adapted to specific needs related to the management of PGRFA. It shows how choosing a different solution to ABS for this category of genetic resources is instrumental in achieving the joint overall objective of the CBD with regard to ABS. It also highlights some components which might be considered with regard to other sectors of ABS under an international regime on ABS, if a sectoral approach is chosen. It might be useful to consider whether SMTAs adapted to the needs of specific sectors can be useful and to what extent procedures can be standardized with minimum bureaucratic effort.

The next step is to look at the exact coverage of the MLS as a basis for defining the interfaces with ABS under the CBD and their implications:

**The MLS applies to a group of genetic resources:** Basically, it covers the plants that are listed in *Annex I*. However, the boundaries are not clear. Some countries have opted to extend the use of the SMTA to material beyond the Annex I crops, and further countries are considering doing so.<sup>12</sup> The aim is to avoid different systems for different genetic resources within gene banks, which would be complicated and costly to manage. The International Agricultural Research Centres (IARCs) of the CGIAR have, according to agreements between the IARCs and the Governing Body of the Plant Treaty (Art. 15), included in the MLS the Annex I material which they hold in trust for the FAO, and which was collected after the entry into force of the ITPGRFA. In addition, they use the SMTA for all material collected prior to the entry into force of the ITPGRFA (Annex I and non-Annex I material), but it is still uncertain whether this means that the material can be regarded as included in the MLS.<sup>13</sup> Non-Annex I crops collected after the entry into force of the ITPGRFA constitute material that falls outside the scope of the MLS in the IARCs, and thus are subject to the potential regulations of an international regime on ABS under the CBD. However, the Plant Treaty enables the IARCs to use the SMTA also for this material, if the providing country agrees. Also other international organizations have included their collections in the MLS, and more material might be included in the Annex I in future, if negotiations on the contents of this list are resumed.

*Implications:*

- ⇒ PGRFA outside the MLS and those not covered by a SMTA fall under the international regulation of the CBD as regards ABS. In practice it might be difficult to draw the line between the material ‘inside’ and ‘outside’ the MLS. If the material outside is included in an international regime on ABS, it will be important to ensure that due consideration is taken of the distinctive features and the needs related to its management.
- ⇒ It is particularly important to ensure access to these resources, as their further cultivation depends precisely on such access.
- ⇒ Not only IPR systems but also the responding access regulations may themselves create disincentives for the sharing of seeds and propagating material among farmers. ABS legislation focused on benefit sharing between providers and recipients has in some cases<sup>14</sup> led to expectations among some farmers regarding potential future benefits if their crops were to be ‘discovered’ by plant breeders. As a result, they have refrained from sharing their propagating material and related knowledge with other farmers. For any ABS regime on PGRFA outside the MLS it is therefore important to consider how incentives are shaped and whether they are supportive to the continued sharing of these resources and related knowledge among farmers.

- ⇒ In addition, it is necessary to consider how to address the non-Annex I material in a way that will allow countries that apply the SMTA for the facilitation of access to non-Annex I crops to continue doing so.
- ⇒ If an international regime on ABS is to cover PGRFA outside the MLS, it is important to be aware of the possible implications for material in the IARCs not included in the MLS.

**The MLS applies only to PGRFA in the public domain and under control of the parties** to the Plant Treaty. This means that the material that is covered in public gene banks and other public *ex situ* facilities shall be included in the MLS, whereas material in the possession of private companies, other non-governmental institutions, and material in farmers' fields and in their possession, is not automatically covered. The parties to the Plant Treaty are expected to take appropriate measures to encourage natural and legal persons within their jurisdiction who hold PGRFA listed in Annex I to include this material in the MLS (Art. 11.3). As long as the material in farmers' fields is not included in the MLS, the CBD remains the international framework that applies with regard to ABS regulation.

*Implications:*

- ⇒ Whereas Annex I material in farmers' fields falls under the international regulation of ABS under the CBD, Annex I material in public and international gene banks falls under the MLS (provided that the countries are parties to the ITPGRFA). Thus, gene banks seeking to collect material for conservation and plant breeding have to follow regulations derived from the CBD – to the extent that regulations have been implemented in the country in question.
- ⇒ If Annex I material in farmers' fields is included in the international regime on ABS, the regulations should be conducive to the continued work of gene banks to conserve PGRFA for present and future generations, i.e. to collect material and ask for information about the material among local farmers. Concerning local communities and their say in deciding over the plant genetic material in their hands, they need to be made aware that such collection to a public gene bank facility is likely to make their accessions available in the MLS, complying with the PIC procedures in that country.
- ⇒ Once Annex I material has been collected from farmers' field to gene banks, it is placed in the MLS. This means that benefit-sharing arrangements beyond those of the MLS can be asserted up-front. Such arrangements could include guarantees that farmers will receive samples of their seeds from the gene bank in case of natural disasters; technology transfer through participatory selection breeding between collectors and farmers during collection work; and access to other material held in the gene bank.
- ⇒ If Annex I crops in farmers' fields are included in an international regime on ABS, it is important to ensure that the provisions do not result in disincentives to the continued sharing of these resources and related knowledge among farmers (as noted above).

**The MLS grants access only for specific uses of the material.** It covers plant genetic resources for food and agriculture, defined as ‘any genetic material of plant origin of actual or potential value for food and agriculture’ (Art. 2). Thus, ideally it shall not be possible to access material under the MLS for chemical, pharmaceutical and/or other non-food/feed industrial uses on the basis of the SMTA (Art. 12.3.a). If Annex I material under the MLS is to be accessed for such purposes, the CBD provides the relevant international framework. Intended uses of crop genetic resources in the MLS for purposes other than food and agriculture may be dealt with in the international regime on ABS.

*Implications:*

- ⇒ It is not easily proven that material obtained under the MLS has later been used for food and agriculture. Thus, there is a possibility that material from the MLS may be used for purposes beyond food and agriculture, in breach of the SMTA. That possibility constitutes a challenge to the further development of the transparency of the MLS and to the monitoring procedures of the Third-Party Beneficiary.
- ⇒ Negotiators of an international regime on ABS may wish to address in the new regime the questions of uses of PGRFA kept in the MLS other than for food and agriculture.
- ⇒ Negotiators of an international ABS regime might want to consider how to survey, detect and enforce such regulations.

**The MLS applies in a group of countries.** The MLS applies in countries that are parties to the ITPGRFA, at present 123 countries. All these are also parties to the CBD, but the latter, with its 193 contracting parties, includes 70 non-parties to the ITPGRFA.

*Implications:*

- ⇒ ABS to Annex I crops in countries that are non-parties to the ITPGRFA is not regulated by the MLS. In the 70 of these countries that are parties to the CBD, the regulation of ABS to these Annex I crops falls under the international framework of the CBD. However, material made available to these countries with an SMTA shall also continue to be available on the terms and conditions of the SMTA.
- ⇒ Whether an international regime on ABS is adopted as a protocol to the CBD or as another instrument, it is likely that some of the parties to such a regime will be non-parties to the ITPGRFA.
- ⇒ In determining the scope of an international regime on ABS under the CBD it is important to be aware of the Annex I material in the mentioned countries and consider whether it would fall under the international regulation of the new regime. If an international regime exempts Annex I material as such, these resources could fall outside all regulation for these non-parties.
- ⇒ If the material dealt with in the MLS is to be excluded from an international regime on ABS, it is important to refer to ‘material in the MLS and covered by the SMTA’<sup>15</sup> and not merely to Annex I crops. The latter would leave Annex I crops in the 70 countries that are parties to the CBD and non-parties to the Plant Treaty without international ABS regulation.

**Benefit sharing is also covered in the treaty provisions on Farmers' Rights.** The right to participate equitably in the sharing of benefits arising from the utilization of PGRFA is one of four elements of Farmers' Rights addressed in Article 9 of the Plant Treaty.<sup>16</sup> This right must be seen in conjunction with Article 13 of the Plant Treaty on benefit sharing under the MLS. However, as Article 9 is not a part of the MLS, it refers to all PGRFA, and not only material included in the MLS. That has implications for an international regime on ABS:

*Implications:*

- ⇒ An ABS regime may regulate access and benefit sharing to crop genetic resources that are outside the scope of the MLS, but still covered under the provisions on farmers' rights under the Plant Treaty. Thus there will be overlap between the provisions on benefit sharing under the provisions on farmers' rights under the Plant Treaty and the ABS regime.
- ⇒ Provisions of an international ABS regime on benefit sharing that are overlapping with farmers' rights in this regard need to take into account that access to genetic resources is a vital benefit for farmers. If the regulation of benefit sharing under the CBD results in disincentives to share seed and propagating material among farmers (as explained above), that would obstruct this most important of all benefits to farmers.

With these interfaces and implications, what *options* are available to the negotiators of an international regime on ABS? Four main options can be identified:<sup>17</sup>

*Option 1: Include all PGRFA*

It might be theoretically possible to include all PGRFA, also the material currently in the MLS. Such an option would probably impose additional restrictions on the plant genetic resources in the MLS, which in turn would interfere with the operations of the Governing Body.

*Option 2: Exclude all PGRFA*

This option would leave the PGRFA outside the scope of the MLS, offering a legal loophole in terms of international regulation of ABS. The result would be that the various countries would define the terms and conditions of access on their own, leading to many different systems and probably even greater difficulties for access to these resources than today.

*Option 3: Exclude all PGRFA in the MLS, include the rest*

This option would require extensive knowledge of the distinctive nature of these resources and their management needs, in particular as to conservation, sustainable use and Farmers' Rights in this context. A difficult technical issue under this option is how to draw the line between material in the MLS and outside it.



*Option 4: Exclude all PGRFA in the MLS and include the rest, but invite the FAO to negotiate the terms and conditions of a sectoral approach to ABS for these resources*

The negotiators of an international regime on ABS may wish to refer the further negotiations on the terms and conditions for ABS for these resources to the FAO. In that case, the general terms and conditions of the international regime would apply for ABS to these resources until the FAO had negotiated a sectoral solution. This sectoral solution could be implemented under the FAO, which would in practice mean excluding the sector from the ABS regime under the CBD. Alternatively the sectoral solution could be adopted and implemented under the international ABS regime of the CBD. An increased proliferation of negotiation fora would however involve an extra burden for developing countries.

Regardless of which of these solutions is finally chosen, one important thing to keep in mind is that the delimitation must provide legal certainty in the system. Definitions of the scope of an international regime must be formulated in a way which can be enforced legally.

## 2 Interface with the FAO Commission on Genetic Resources for Food and Agriculture

The Commission on Genetic Resources for Food and Agriculture (CGRFA) of the United Nations Food and Agriculture Organization (FAO) oversees the management of all genetic resources for food and agriculture (GRFA), although there are no legally binding international obligations except from the ITPGRFA. These include:

- plant genetic resources for food and agriculture<sup>18</sup>
- animal genetic resources for food and agriculture
- forest genetic resources for food and agriculture
- aquatic genetic resources for food and agriculture
- micro-organism genetic resources relevant for food and agriculture
- invertebrate genetic resources relevant for food and agriculture

At the 12<sup>th</sup> Regular Session of the CGRFA in October 2009, its relationship to the ongoing negotiations for an international regime on ABS under the CBD was an important agenda item. This was emphasized with a full-day special information seminar on policies and arrangements for ABS. At this seminar, a range of comprehensive background study papers commissioned by the Secretariat of the CGRFA were presented.<sup>19</sup> At its 12<sup>th</sup> Regular Session the CGRFA adopted *Resolution 1/2009: Policies and Arrangements for Access and Benefit-Sharing for Genetic Resources for Food and Agriculture*. Here the CGRFA invites the Conference of the Parties to the CBD and the Ad Hoc Open-Ended Working Group on ABS to take into account the special nature of agricultural biodiversity, in particular genetic resources for food and agriculture, their distinctive features, and problems requiring distinctive solutions. It suggests that they should consider a sectoral approach to ABS which would allow for differential treatment of the various sectors or sub-sectors of genetic resources, various types of genetic resources for food and agriculture. Furthermore it suggests that adequate flexibility should be provided in a new international regime on ABS, to acknowledge and accommodate current and future agreements relating to ABS, developed in harmony with the CBD. Close cooperation between the relevant bodies of the FAO and the CBD was encouraged.

GRFA is a diverge grouping with different distinctive features. On the other hand, there are also some generally shared features:<sup>20</sup>

- GRFA constitute the building blocks of all food production and are thus essential for achieving food security for present and future generations.
- For GRFA, diversity within species is at least as important as diversity between species.
- The diversity of GRFA provides agriculture with the means to adapt food production to changing environmental conditions, such as climate change, pests and diseases; this is vital for sustainable agriculture.

- Diversity of GRFA is the ‘insurance policy’ for most farmers in developing countries, enabling them to spread the risks of crop failure and adapt their production to changing environmental conditions.
- Massive erosion is taking place in most sub-sectors of GRFA due to policies and legal structures aimed at spreading uniform systems of production.
- GRFA are domesticated resources (except, as noted, for their wild relatives), and depend on continued domestication for their further survival.

How genetic resources are exchanged differs between sectors and species. A common concern is how these resources – to the extent possible – can be kept in the public domain, as privatization through exclusive intellectual property rights may limit the possibilities to exchange, further develop and use these resources for food production. Also the domestication of GRFA is carried out by farmers, pastoralists, fisherfolk and breeders: their continued contribution to the genetic pool depends on their legal and political space to save, use, exchange and sell their genetic material, and on cooperation among and between all stakeholders for this purpose.

Nevertheless, there are huge differences between and among the sub-sectors of GRFA. For example, the farm animal sector has distinctive features which differ substantially from the plant sector.<sup>21</sup> To establish an understanding of the interfaces between ABS in general and the special needs for each sector, it is necessary to look at the differences between the various sub-categories of GRFA with a view to ABS requirements:

**Animal genetic resources for food and agriculture** are defined in the 2007 *Global Plan of Action for Animal Genetic Resources* as animal genetic resources used in, or potentially useful for, food and agriculture. They are exchanged largely within and among countries in the South, within and among countries in the North, and from the North to the South.<sup>22</sup> There has been insignificant exchange from the South to the North, although this might change in future, due to climate change. Most animal genetic resources for food and agriculture are in the private domain, as animals carry their genetic material and transfer it to the next bred generation. Consequently, most exchange of animal genetic resources takes place according to private law agreements or contracts. For other more industrialized species as poultry and pigs, the structure of the sector is different. The feeding and raising in these two commercial branches is more similar to the plant sector where the genetically identical organisms are grown over large areas. The current state of affairs does not give rise to a demand for ABS in line with the CBD or the MLS under the Plant Treaty. The 2007 *Interlaken Declaration on Animal Genetic Resources* and *Global Plan of Action for Animal Genetic Resources* are key non-binding instruments to ensure that animal genetic resources remain available for access, exchange and benefitting.<sup>23</sup> A study commissioned by the Secretariat of the FAO prior to the Interlaken Conference to analyse the ABS needs of the farm animal sector identified several issues:<sup>24</sup>

- With importation of animal breeding material there is a need for a genetic-impact assessment to develop knowledge of whether the breeding material is adapted to the conditions where the animals live.
- Development of model contracts which could have a leveraging effect on the existing contractual practice.

Recent years have seen a tendency to apply for patents to breeding techniques in the animal sector.<sup>25</sup>

**Forest genetic resources for food and agriculture** are defined as the genetic variation between and within tree species, and, more specifically, the use and movement of forest reproductive material/germplasm (seeds, cuttings or other propagating parts of a tree) needed for regenerating natural forests and establishing plantations and agroforests.<sup>26</sup> Such forest genetic resources have been exchanged for centuries, but exchange is increasingly becoming difficult due to various forms of legal restrictions – not least, phytosanitary regulations, which differ from country to country and among types of plant material.<sup>27</sup> Such regulations reflect the perceived risk of invasiveness and diseases in the context of the exchange of forest reproductive material. There are ecological arguments for preferring native or endemic species in forestry, as trends towards increased use of exotic monocultures like eucalyptus and jatropha may have adverse implications for food security<sup>28</sup> and negative effects on biological diversity.

**Aquatic genetic resources for food and agriculture** are in this context understood as genetic resources of farmed aquatic animals for food, stock enhancement, recreation fisheries and ornamentals.<sup>29</sup> Farmed aquatic species are genetically similar to wild relatives, except from the characteristics they have been bred to develop. Whereas few of the wild forms may be endangered or threatened with extinction, the number of farmed forms is increasing. Traditional knowledge is related to wild forms, and is only to a limited extent used for farmed forms. There is little traditional knowledge about domestication in aquaculture, mainly because aquaculture also takes place by capturing and raising wild fish, not through breeding (FAO, 2009:33). The exchange patterns for aquatic genetic resources differ from those in the plant sector. Exchange here has taken other avenues, most importantly from South to South as in the cases of tilapia and catfish. In the case of salmon there is also a significant channel from North to both North and South (FAO, 2009:38). Hence the exchange has involved few ABS issues, the exception being the case of tilapia, which originates in several African countries and which has been vastly improved through breeding programmes in Asia. This has given rise to questions of both equity and ecology, as African countries would like to benefit from the improved growth in tilapia but at the same time fear contamination from domesticated fish on wild populations (Eknath and Hulata, 2009; Greer and Harvey, 2004).<sup>30</sup>

Collections of aquatic genetic resources exist in the public and, increasingly, in the private domain. In studies of how actors in the aquaculture sector perceived the balance between access to and IPR protection of aquatic genetic material, it was argued that increasingly stringent patent

legislation may limit innovation in breeding and affect the ability to provide improved breeding material on an equitable basis (Rosendal et al., 2006; Olesen et al., 2007).<sup>31</sup>

**Biodiversity of micro-organisms relevant for food and agriculture:**

Micro-organisms relevant for food and agriculture are not often domesticated, but they constitute the basis of the ecosystem on which food production depends. They include fungi and bacteria that establish mutually beneficial symbiosis with the roots of agricultural plants and the guts of ruminant livestock; nitrogen-fixing bacteria, biocontrol agents and beneficial bacteria and fungi for the degradation and recycling of organic matter in soils as well as for food and beverage processing.<sup>32</sup> They may also have pathogenic features, such as root rot diseases, and produce toxic substance, such as mycotoxin. They are made accessible through culture collections. The vast majority of these collections are in the public domain; 77% of the recipients of material from the collections are public institutions.<sup>33</sup> The majority of the collections are situated in OECD countries, and most of the collection, distribution and exchange takes place within and among these countries. Also some developing countries hold large culture collections, notably Thailand and Brazil. The MOSAICC Guidelines<sup>34</sup> cover prior informed consent on mutually agreed terms and provisions on ABS, as well as elements for material transfer agreements.<sup>35</sup> These guidelines indicate that a standard material transfer agreement to facilitate exchange across different legal systems would be a major achievement.

**Biodiversity of invertebrates relevant for food and agriculture:**

Invertebrates relevant for food and agriculture include dung beetles and earthworms, as well as pollinators, such as species of bees. Agriculture depends on their ecosystem services. Some of them are biological agents that keep pests and diseases at acceptable levels in agriculture, and as such they are vital in integrated pest management schemes for sustainable agriculture.<sup>36</sup> They are primarily living organisms, and access to these resources depends largely on collecting them from *in situ* conditions.<sup>37</sup> There is high interdependence between countries, but there is little recoverable monetary value in these genetic resources.<sup>38</sup> The guidelines used for transfer are the International Standards for Phytosanitary Measures No. 3 of the International Plant Protection Convention (IPPC). These guidelines concern the responsibility of different actors, but not the issue of ABS. Existing arrangements seem so far to ensure unrestricted access on the one hand and benefit sharing based on joint research and capacity building (i.e. non-monetary benefit sharing) on the other. This practice is seen as an important foundation for any development of ABS in the sector.<sup>39</sup>

Specific features and the distinctive problems that need to be solved differ widely among the sub-sectors of GRFA. Designing an international ABS regime to meet all these requirements is challenging. A regime that seeks to accommodate all these needs without differentiating between and among the various sub-categories of genetic resources might result in watered-down provisions. It is vital to identify the different solutions that are required for each category in order to meet the overall objectives of access and benefit sharing.

The options with regard to the scope of the international regime and the possibilities of a sectoral approach to GRFA can be outlined as follows:

*Option 1: Include all GRFA without differentiation*

This option is theoretically possible. The special features of groups of genetic resources would, however, indicate the importance of taking such needs into account.

*Option 2: Exclude all GRFA from an international ABS regime*

This option would provide the GRFA with a legal loophole in terms of international regulation of ABS.

*Option 3: Include all GRFA, and open up for the adoption of annexes on sub-categories*

An international regime with general provisions for all genetic resources would serve as the umbrella. It would apply to all the genetic resources covered by an international ABS regime and open up for the adoption of annexes to the regime on specific sub-categories of GRFA. Such annexes would be negotiated under the CBD. This option would require extensive knowledge of the distinctive nature of these resources and their management needs, in particular as to conservation and sustainable use.

*Option 4: Include all GRFA, but invite the FAO or other competent international fora to negotiate the terms and conditions of sectoral approaches to ABS for these resources*

The negotiators of an international regime on ABS may wish to refer the negotiations of the terms and conditions for ABS for one or more of the sectors to other international fora. In such a case, the general terms and conditions of the international regime would apply for ABS to these resources until the FAO or other competent international fora had negotiated sectoral solutions. Such solutions would be part of the international regime. Close collaboration between the CBD and the other organizations would be required.

### 3 Interface with the United Nations Convention on the Law of the Sea

The United Nations Convention on the Law of the Sea (UNCLOS) was adopted in 1982 and entered into force in 1994. It contains provisions concerning rights and obligations of states in the marine environment. Of relevance to this study are the provisions concerning the rights and obligations of states:

1. within the territorial sea (i.e. from states' baselines to 12 nautical miles)
2. in the exclusive economic zones (i.e. from the territorial sea to 200 nautical miles from state baselines),
3. on the continental shelves (i.e. from the territorial sea and to the continental margin, but at least as far as the exclusive economic zone),
4. on the high seas, and
5. on the seabed beyond the continental shelves.

The relationship between the CBD and UNCLOS is regulated in Article 22 of the CBD, which states that 'Contracting Parties shall implement this Convention with respect to the marine environment consistently with the rights and obligations of States under the law of the sea.' According to Article 4 of the CBD, obligations of a state under the CBD extend:

- a. in relation to *conservation* of marine genetic resources: to areas within the limits of its national jurisdiction, which means that the exclusive economic zone and continental shelves are included,
- b. in relation to *regulation of activities* carried out under its jurisdiction or control, including exploitation of genetic resources carried out by its nationals and ships carrying its flag: to areas beyond the limits of national jurisdiction – which means that the high seas and the exclusive economic zones and territorial seas of other states are included.

UNCLOS does not explicitly address the exploitation of 'genetic resources', but it regulates the exploitation of natural resources, which include genetic resources.

States have, according to Article 192 of UNCLOS, a general obligation to protect and preserve the marine environment. This general obligation is elaborated in obligations concerning the exclusive economic zone (in particular Art. 61), the high seas (Arts. 116 to 120), the seabed outside the continental shelves (in particular Art. 145), and more generally with a focus on pollution in Part XII of UNCLOS.

1) Within the *territorial sea*, the coastal state has full sovereignty with regard to genetic resources. Coastal states thus have the same possibility of regulating ABS within their territorial sea as they have on their land territory. The only modification is the right of innocent passage (see Articles 17 to 32 of UNCLOS), and it may prove difficult for coastal states to prevent ships claiming the right of innocent passage from collecting genetic resources.

2) Within the *exclusive economic zones (EEZs)*, coastal states have, according to Article 56 of UNCLOS, ‘sovereign rights for the purpose of exploring and exploiting, conserving and managing the natural resources, whether living or non-living, of the waters superjacent to the seabed and of the seabed and its subsoil’. Coastal states have, according to Article 77, parallel rights on the *continental shelves* that extend beyond their EEZs. Other states have the freedom of scientific research as far as such research does not conflict with the sovereign rights of coastal states. These sovereign rights of a coastal state include the freedom to regulate and authorize scientific research activities in its EEZ and on its continental shelf.

Of particular interest to *access* to genetic resources is Article 246.3 of UNCLOS:

Coastal States shall, in normal circumstances, grant their consent for marine scientific research projects by other States or competent international organizations in their exclusive economic zone or on their continental shelf to be carried out in accordance with this Convention exclusively for peaceful purposes and in order to increase scientific knowledge of the marine environment for the benefit of all mankind. To this end, coastal States shall establish rules and procedures ensuring that such consent will not be delayed or denied unreasonably.

In addition, the rights of states to carry out marine scientific research on the continental shelf beyond the EEZ is strengthened according to Article 246.6, unless the coastal state has designated the area in question as an area of direct significance for its exploration and exploitation of natural resources. To what extent access to genetic resources or even bioprospecting as an activity qualifies as ‘marine scientific research’ is an open and undecided question.

Of particular interest to *sharing of benefits* from genetic resources are the rights of both the coastal state and other states to participate in research projects (Art.249 and Art. 254 of UNCLOS), and the rights of the coastal state to be informed of research results (Art. 249). Of relevance is also Part XIV of UNCLOS, which sets out rules to promote the dissemination of benefits resulting from marine scientific research, in particular Article 244.2:

States ... shall actively promote the flow of scientific data and information and the transfer of knowledge resulting from marine scientific research, especially to developing States, as well as the strengthening of the autonomous marine scientific research capabilities of developing States through, inter alia, programmes to provide adequate education and training of their technical and scientific personnel.

There is no initiative under UNCLOS to address ABS of genetic resources within the EEZ and on the continental shelf. Against this background, the CBD ABS regime may apply to the ways in which coastal states regulate ABS in relation to marine genetic resources in these areas, provided that it does not restrict the freedom of research beyond what is allowed in Part XIII of UNCLOS, Article 246 in particular.



3) The starting point in the *areas beyond the jurisdiction of the coastal states*,<sup>40</sup> (i.e. on the high seas and on the deep seabed beyond the continental shelf) is the freedom to explore and exploit genetic resources: see Article 87 of UNCLOS. Moreover, the freedom of research is confirmed in Articles 256 and 257. The main exception is the deep seabed, where access to certain resources, defined as ‘solid, liquid or gaseous mineral resources in situ in the Area at or beneath the seabed, including polymetallic nodules’, are subject to a special regime. This regime is not directly applicable to marine genetic resources, however.

Since 2004, discussions of relevance to the ABS regime have been carried out in the Ad Hoc Open-ended Informal Working Group to study issues relating to the conservation and sustainable use of marine biological diversity beyond areas of national jurisdiction, established by the UN General Assembly (UNGA): see resolutions 59/24, 63/111 and 64/71. At its third meeting in February 2010, the Working Group adopted recommendations to be presented to the UNGA. There has been significant disagreement within the group on how to proceed with ABS-related issues. One option could be to extend the principle of the common heritage of mankind which currently applies to mineral resources of the deep seabed to cover the genetic resources there. Another option could be to extend the regime that applies to mineral resources of the deep seabed. A third option is to adopt an implementation agreement or an UNGA resolution concerning biodiversity in areas beyond national jurisdiction. It is unlikely that the Working Group or the UNGA will agree on arrangements of relevance to ABS in the foreseeable future. Moreover, some countries will probably insist that ABS in areas beyond national jurisdiction be dealt with by the Working Group under the UNGA and in the UNGA itself, and not by the CBD. Such a result would probably be to the disadvantage of the developing countries.

Any ABS regime for areas beyond national jurisdiction must respect the freedom of research and the freedom to explore and exploit genetic resources according to UNCLOS. An ABS regime could be based on the principle of the *common heritage of mankind*, as set out in Article 136 of UNCLOS. That would extend the principle (as UNCLOS does not currently apply it to genetic resources), and would mean that access to such resources would be made dependent on the existence of mechanisms to ensure benefit sharing. Applying the ABS regime to areas beyond national jurisdiction could contribute to implement the obligations under UNCLOS to

- a. ‘create favourable conditions for the conduct of marine scientific research in the marine environment’ (Art. 243),
- b. ‘promote the flow of scientific data and information and the transfer of knowledge resulting from marine scientific research, especially to developing States’ (Art. 244.2),
- c. promote ‘the establishment of general criteria and guidelines to assist States in ascertaining the nature and implications of marine scientific research’ (Art. 251),

- d. 'promote actively the development and transfer of marine science and marine technology on fair and reasonable terms and conditions' (Art. 266), and
- e. 'promote the establishment of generally accepted guidelines, criteria and standards for the transfer of marine technology' (Art. 271).

## 4 Interface with the Antarctic Treaty

The Antarctic Treaty System (ATS) is a set of agreements regulating various aspects of the area south of 60° S latitude. The main normative component of this system is the Antarctic Treaty, in effect since 1961 and of unlimited duration. It is based on three principles: the continuance of freedom of scientific investigation and cooperation (Art. 2), the dedication of Antarctica for peaceful purposes (Art. 1), and the preservation of the Antarctic environment (Art. 9(1)(f)). The system operates with three groupings of members: countries claiming a part of the area as under their sovereignty, members to the treaty system, and others. The ATS does not directly regulate rights to genetic resources as such, but bioprospecting as an activity has been on the agenda for more than 10 years. A study commissioned by the CBD Secretariat and presented to the Working Group as document WG-ABS/7/INF/3/Part.3 provides a general study on the ATS system, with discussion of the consequences of the three bracketed proposals in the working document for an international regime.

There exist no particular regulations of property rights to living organisms in the Antarctic area. As the territorial status of much of the area is disputed, applying the sovereign rights as embedded in the CBD is no simple matter. ABS as a concept in CBD consists of two main elements: access rules and benefit-sharing rules or user-country legislation. As to the point of time of access, it is difficult to see how a system for prior informed consent (PIC) could be designed for genetic resources from the Antarctic. Moreover, due to the unclear territorial status, it will not be easy to determine who is to give its PIC and who would be the counterpart for a mutually agreed term (MAT) with a bioprospector. This opens for several possible solutions for access regulation in the Antarctic:

- The CBD could address this issue. This would give rise to a question of competence between CBD and ATS.
- The COP could suggest that the ATS should develop access issues further.
- A third option would be to leave the issue of access to the future work of ATS.

Interface questions arise as to the second matter as well: the point of time of use of genetic resources. As yet the ATS system has no specific benefit-sharing requirements. There is a general principle in Article 2 of the Antarctic Treaty regarding freedom of research. Increasingly, patents are being taken out on inventions that are based on biological material from the region, but whether these commercial uses of Antarctic genetic resources shall be included or excluded from the scope of an international regime remains an open question. A difficult issue, and one that might become a possible loophole in an international regime, arises if these genetic resources are excluded from the scope. Then there will be a problem at the enforcement point of time, in separating the Antarctic genetic resources from other similar ones. If access to genetic resources is left open and no evidence can be demonstrated as to where the genetic resources have been taken from, it could be difficult to determine whether a given genetic resource really was taken from the Antarctic, or from an

area under the scope of an ABS obligation. That could create a loophole, enabling users to argue that the genetic resources they have used fall outside the scope of an international regime.

## 5 Interface with International Regimes Pertaining to Pathogens

A pathogen, or an infectious organism, is a biological agent that causes some type of disease in its host. Common pathogens are viruses, bacteria and fungi.<sup>41</sup>

Because pathogens are easily spread across borders and change rapidly, international cooperation is central to curb the damage they inflict. Human health concerns in relation to pathogens, such as the spread of pandemic influenza, are handled internationally mainly by the World Health Organization (WHO). The World Organization for Animal Health (OIE) is responsible for improving animal health globally; and the International Plant Protection Convention (IPPC) aims to protect plants by preventing the introduction and spread of pests, including pathogens. In addition, the Codex Alimentarius Commission adopts standards of relevance to human, animal and plant health issues. Negotiators of an international regime on ABS under the CBD must be aware of the processes within these organizations, especially those involving access to pathogens and benefit sharing, in order to ensure compatibility.

One important issue is whether and to what extent the CBD applies to pathogens. Some argue that interpreting the CBD to include pathogenic viruses runs contrary to its purpose, because the CBD is mainly concerned with biological resources and genetic material that people have invested their time, effort and resources in maintaining, understanding and utilizing. By contrast, pathogens are invasive organisms whose presence and spread are not due to nurturing, utilization or investment by national governments or local communities. With viruses of pandemic potential, the strategy is usually to contain and eradicate them rather than to conserve them, so it might be argued that the application of CBD principles to pathogens is inappropriate. Many pathogens are seen and treated as threats to biodiversity rather than as biological resources that need to be conserved. Those critical of applying the CBD to pathogens also point to the definition of genetic resources in the CBD and its emphasis on the actual or potential use of these resources for humanity, and the link to the conservation and sustainable use of these resources. In their view, the principle of national sovereignty is applied to achieve these goals; further, because sharing for the purpose of surveillance and vaccine development can be seen as what gives pathogens value, applying the principle of national sovereignty is not regarded as conducive to facilitating the timely and comprehensive sharing of virus samples required to improve global health governance.<sup>42</sup> When used to develop vaccines and medicines, however, pathogens are economic resources – which indicates that they are covered by the commercial aspects of ABS.

**The International Health Regulations of the WHO:** Relevant to the handling of pathogens, and important in connection with the negotiations of an international regime on ABS, are the competing interpretations of the International Health Regulations (IHR) from 2005.<sup>43</sup> The objective of these regulations is to help the international community to prevent and respond to acute public health risks that have the potential to become a

worldwide problem. The regulations are binding for 194 countries. IHR parties are required to report certain disease outbreaks and public health events to the WHO (Art. 6), and to share information concerning the events (Art. 7). There are no clear duties of countries to exchange virus samples, and opinion differs as to the extent to which duties can be inferred from the IHR in this respect.

- According to one line of argument, IHR 2005 requires state parties to share biological samples like virus samples as part of the obligation to provide the WHO with accurate and detailed information about any event that might become a public health emergency of international concern (PHEIC) without preconditions, because the spread of highly pathogenic influenza viruses is considered a PHEIC. Supporters of this interpretation cite World Health Assembly (WHA) resolution 59.2 concerning the application of the International Health Regulations as supporting their case, because it ‘urges’ WHO member states ‘to disseminate to WHO collaborating centres information and relevant biological materials related to highly pathogenic avian influenza and other novel influenza strains in a timely and consistent manner’ (para. 4[4]).<sup>44</sup> It is argued that this approach is compatible with the CBD because the IHR 2005 requires sample sharing only for the purpose of risk assessment and not risk management. It would therefore still be possible for the WHO and its member states to create solutions to improve access to benefits, like vaccines, derived from this type of sample sharing.
- The second line of argument claims that the IHR does not provide a definition of ‘public health information’ as used in Articles 6 and 7. The ordinary meaning of ‘information’ covers knowledge and facts, and does not include biological samples. The use of ‘biological substances’ and similar concepts in other articles of the IHR and in earlier drafts of the text supports this interpretation, suggesting that the negotiators saw ‘public health information’ and ‘samples’ as distinct terms. It can be argued that this interpretation is compatible with the CBD as well, because deciding whether or not to share biological samples is left to the state party where the sample originated.<sup>45</sup>

Thus, the question of access to genetic resources under the IHR remains an unresolved issue in need of further clarification. The same is the case for benefit sharing related to vaccines and drugs developed as a result of access to such genetic resources.

#### **The case of access and benefit sharing related to influenza viruses:**

The WHO monitors the spread of various influenza viruses through its Global Influenza Surveillance Network (GISN). Because of discontent, especially in developing countries, with the traditional global influenza strategy, the WHO has since 2007 been engaged in a reform process on the sharing of influenza viruses and on access to vaccines and other benefits. Global influenza governance has operated in basically the same way for the past 50 years, with samples of new influenza viruses being analysed annually by WHO-collaborating laboratories before a WHO committee determines which strains are most likely to affect humans in the coming months. Manufacturers then start making vaccines against

these strains. Most of the 250–300 million doses of vaccine made each year are used to vaccinate people in developed countries, even though the new influenza viruses often originate in developing countries, primarily in Asia.<sup>46</sup> As the avian influenza spread across Asia in 2007, developing countries began to question how they were benefiting from this process. If the vaccines developed by pharmaceutical companies based on viruses shared by developing countries do not benefit these countries' own residents, why should they continue to share their virus strains?

It was this discontent with the process in general, as well as the acknowledgement by the WHO that patents had been sought on modified versions of influenza samples that had been shared through GISN, without the consent of the provider countries, that led to Indonesia's decision to withhold avian flu samples (influenza A or H5N1) from the WHO and GISN.<sup>47</sup> This controversial action created substantial controversy and alarm – especially since Indonesia had been hit hard by avian influenza, and access to its influenza strains was seen as critical to global surveillance and intervention strategies – and motivated the WHO to try to find a solution to the problem.

**The development of a WHO Framework for sharing of influenza viruses and benefits:** At the May 2007 meeting of the WHA, the issue was taken up and resolution 60.28 on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits was adopted.<sup>48</sup> This resolution urges the WHO member states to support GISN and its procedures and to ensure and promote 'transparent, fair and equitable sharing of the benefits arising from the generation of information, diagnostics, medicines, vaccines and other technologies'. The resolution also requested the Director-General to convene a working group to review, as well as propose reforms for, the influenza-sharing process within and outside GISN, and an intergovernmental meeting to consider frameworks and mechanisms to improve the timely sharing of influenza viruses with pandemic potential, and the equitable access to benefits. The Intergovernmental Meeting on Pandemic Influenza Preparedness: Sharing of Influenza Viruses and Access to Vaccines and Other Benefits (Intergovernmental Meeting) has drafted a Pandemic Influenza Preparedness Framework for the Sharing of Influenza Viruses and Access to Vaccines and other Benefits (Influenza Framework). Although most of the provisions of the Influenza Framework were agreed upon by consensus, significant areas remained unresolved when the Intergovernmental Meeting concluded its work and submitted it for the consideration of the 62nd WHA. Through a new resolution on pandemic influenza preparedness, resolution WHA62.10, the WHA in May 2009 requested the Director-General to facilitate a transparent process to finalize the remaining parts of the Influenza Framework, including the Standard Material Transfer Agreement (SMTA).<sup>49</sup>

The 63<sup>rd</sup> session of the WHA will be held in May 2010. Some discontent has surfaced regarding the handling of the H1N1 pandemic, and a member-driven process to finalize the Influenza Framework has been called for. It has been agreed that an open-ended working group would be convened in May 2010 prior to the WHA meeting; this working group should take as its point of departure the outcome of the Intergovernmental Meeting and focus on the remaining elements of the framework.<sup>50</sup>

The influenza case illustrates the divergence in views, mainly between developed and developing countries, on issues of access and benefit sharing. While the developed countries in general prefer voluntary benefit sharing without links to the sharing of viruses and are in favour of allowing patents to be claimed on material shared through the WHO and the resulting products, most developing countries stress that those entities receiving material through WHO should commit to benefit sharing through an SMTA. Further, they are against allowing these entities to take out IPRs on the shared material itself, arguing that this should be allowed on the resulting product only if it is licensed to developing countries free of royalties.

**Differing views on international agreements and their implications for pathogens:** The WHO process on the Influenza Framework is of relevance to ABS under the CBD and the finalization of the international regime. The Influenza Framework establishes several important mechanisms for ABS with regard to pathogens. To avoid confusion and overlap, these should be taken into consideration by the negotiators. Moreover, the debate surrounding Indonesia's decision to withhold virus samples and the WHO's ensuing course of action have been rooted partly in differing interpretations of the CBD as regards virus sharing, national sovereignty over pathogens and the IHR. It is stated in Article 57.1 of the IHR that the provisions of the IHR 'shall not affect the rights and obligations of any State Party deriving from other international agreements'.

When Indonesia argued that it had the right not to share H5H1 virus samples because it controlled access to such samples collected in its own territory, that no other parties could use these samples without their prior informed consent, and that use by other entities of such samples should result in benefits for Indonesia, it was drawing on the principles of the CBD.<sup>51</sup> However, this argumentation touches upon the still unresolved issue in the Montréal draft of the international regime: does the CBD apply to pathogenic viruses and other pathogens, and should these types of organisms be covered by the regime?

**Animal health, pathogens and ABS:** International cooperation to control animal pests and diseases dates back more than a century. The original multilateral agreement that formed the basis for the establishment of the World Organization for Animal Health (OIE) was signed in 1924. The mandate of the OIE extends to animals used in agriculture and aquaculture for production, breeding and/or working purposes, companion animals including 'exotic' (wild-caught and 'non-traditional') species, animals used for research, testing and/or teaching purposes, free-living wildlife; it includes the issues of their slaughter and trapping, animals used for sport, recreation and entertainment, also in circuses and zoos.<sup>52</sup> The OIE collects data concerning the status of pests and diseases and adopts standards and recommendations to assist countries in their efforts to control and combat the pests and diseases. A new system of notification and epidemiological information entered into force in 2005. It requires countries to submit information on the evolution of the disease, infection or exceptional epidemiological event and on control methods used, but it does not explicitly require countries to submit genetic materials to the OIE.<sup>53</sup> Benefit sharing in this system relates to the sharing



of knowledge concerning and assistance to improve the health situation and the effectiveness of measures taken to prevent the spread of pests and diseases.

Of particular relevance to genetic resources is the establishment of OIE Reference Laboratories and Collaborating Centres. These laboratories and centres are of great importance to the development of measures to control pests and diseases. They are encouraged to 'make every effort to share scientific knowledge and skills with laboratories in developing countries and provide relevant training in the development and implementation of rapid, robust and inexpensive diagnostic tests so that disease control programmes can be improved.' Moreover, they 'shall be encouraged to assist developing countries in designing and producing improved and inexpensive vaccines'.<sup>54</sup> There is a need to examine the effectiveness of measures taken to follow up these recommendations.

The issue of influenza control has also been addressed in the context of the OIE. At its 76<sup>th</sup> General Session in May 2008 the International Committee of the OIE adopted a resolution on the sharing of avian influenza viral material and information in support of global avian influenza prevention and control. This resolution, resolution No. XXVI, recognizes the global aspect of the avian influenza and its threat to both animal and human health, and stresses that global control strategies 'must focus on controlling the disease at the animal source'. It notes the responsibility of countries with outbreaks of the disease to share 'material and data' for the purpose of formulating global control and preparedness strategies. It recommends that OIE members with outbreaks of avian influenza share 'animal avian influenza viral material and information about avian influenza viruses' with the international scientific community through OFFLU, the joint OIE-FAO network on avian influenza. It also recommends that countries that have submitted biological material or data to IOE Reference Laboratories should be recognized in connection with any subsequent publications and other benefits arising from the use of the material.<sup>55</sup> These are merely recommendations, but they can be seen as supporting the free sharing of not only information, but biological samples as well, to enable global solutions to the problem of new influenza viruses with pandemic potential.

**Plant health, pathogens and ABS:** International cooperation to prevent the spread of plant pests and diseases was established more than a century ago, and the current multilateral framework was established in 1929. The International Plant Protection Convention (IPPC) Secretariat and its Commission on Phytosanitary Measures is located within FAO headquarters. The IPPC applies to all living plants, including wild flora, and parts thereof, including seeds and germplasm. The IPPC Secretariat collects data concerning the status of pests and diseases and adopts standards and recommendations to assist countries in their efforts to control and combat the pests and diseases. Benefit sharing in this system relates to the sharing of knowledge concerning and assistance to improve the health situation and the effectiveness of measures taken to prevent the spread of pests and diseases. The development of international standards under the IPPC began in 1992, and was closely related to the status proposed for the IPPC under the draft Agreement on the Application of Sanitary and

Phytosanitary Measure (the SPS Agreement) under the WTO Agreement. The current work programme of the IPPC focuses on the development of international standards for phytosanitary measures, the exchange of information, and capacity building and technical assistance, in particular to developing countries. The IPPC operates as a framework for regional plant protection organizations: these shall function as the coordinating bodies in the areas covered, shall participate in various activities to achieve the objectives of the IPPC, and shall gather and disseminate information.

The current version of the IPPC (1997) obliges countries, ‘to the best of their ability, [to] conduct surveillance for pests and develop and maintain adequate information on pest status in order to support categorization of pests, and for the development of appropriate phytosanitary measures. This information shall be made available to contracting parties, on request.’ (Art. VII.2(j)). Article VIII on international cooperation states that contracting parties shall cooperate in the exchange of information about pests; further, they shall cooperate ‘to the extent practicable, in providing technical and biological information necessary for pest risk analysis’.<sup>56</sup> This last paragraph has been interpreted to cover also biological samples of pathogens and other pests, including research materials, biological control organisms, germplasm banks, containment facilities and anything else that can act as a vector for the spread of plant pests. However, ‘to the extent practicable’ leaves some flexibility for the parties when determining which information to share and when deciding when to share such information. Work to encourage benefit sharing related to genetic resources is less developed under the IPPC than is the case under the OIE. There is no parallel system to the OIE Reference Laboratories and Collaborating Centres. The IPPC Secretariat provides developing countries with technical assistance, aimed primarily at improving their ability to comply with international standards.

**Pathogens in the International Regime:** As noted, the issue of pathogen inclusion in the international regime is still unresolved and the Ad Hoc Working Group on ABS needs to reach consensus on whether pathogens should be covered by the regime. The inclusion of viruses and other pathogens is still bracketed in the section on scope, and the possibility remains that ‘specific uses of pathogens’ might be listed among the types of resources to which the regime will *not* apply. For the regime to be sufficiently clear regarding pathogens, access to pathogenic material and the sharing of benefits such sharing might result in, the negotiators should consider specifying which uses of pathogens are excluded if the last phrase is kept. Because of the controversies surrounding virus sharing, a lack of clarity might affect efforts to resolve the issue in other fora. There are two strong viewpoints regarding pathogens and the international regime:

- Industry, represented by among others the International Chamber of Commerce (ICC), argues that certain pathogens and pests should be excluded from the scope of the international regime altogether. The ICC argues that those pathogens and pests that can be seen as representing only ‘threats’ to biodiversity are excluded from the scope of the CBD and should not be included in the international regime. The

ICC also holds that pathogens already subject to existing international agreements or likely to be addressed by agreements under negotiations, such as the Influenza Framework, should be excluded from the scope of the international regime. As to specific uses, the ICC suggests that only uses which are necessary to ‘detect pathogens or pests, prevent diseases caused by them, or cure the damage caused by them’ should be excluded from the regime.<sup>57</sup>

- This line of argumentation is heavily disputed by some NGOs and other stakeholders, who argue that pathogens should be included because these organisms are an integral part of biodiversity and are of crucial importance to ecosystems, and that developing vaccines for selected influenza viruses is an important use of pathogenic organisms that should trigger benefit sharing.<sup>58</sup> The wording of the definition of ‘genetic resources’ in the CBD is in support of this line of argument, as pathogens could have actual or potential value because of their genetic material.

**Implications for the ABS negotiations:** Because the Influenza Framework being developed by the WHO covers only influenza viruses, there are currently no solutions for the sharing of other pathogens of global concern or the benefits arising from the utilization of such material. Should the negotiators of the international regime seek to address this problem, it is important that any solution should be compatible with the WHO process, as well as the strategies of OIE and IPPC, and should not run counter to the need for the timely sharing of genetic material essential to pandemic risk assessments and strategies. The important differences between the approaches adopted under the WHO, the OIE and the IPPC needs to be taken into account, and may arguably be a significant argument in favour of establishing a general framework under the CBD. Any new developments concerning the WHO Influenza Framework must be taken into consideration when the regime is finalized and adopted. The following options are currently available to the negotiators of the international regime:

*Option 1: Exempt all pathogens from the scope of an international regime.*

The negotiators might choose to leave out the bracketed mention of pathogens under scope, while listing the included sectors of biodiversity. It might then be argued that the resulting international regime would not apply to pathogens, although pathogens in general would not be specifically excluded from the scope of the regime

*Option 2: Include all pathogens in the scope of an international regime.*

If pathogens are listed as a type of genetic resource to be covered by an international regime, there will be little room for interpretation regarding their status in this regard. However, it remains unclear exactly how this will affect the WHO Framework on sharing of influenza viruses, vaccines and other benefits, and the activities of the OIE Reference Laboratories and Collaborating Centres.

*Option 3: Exclude some 'specific uses of pathogens' from the scope of the international regime.*

Negotiators might choose to remove the brackets around this phrase even if pathogens in general are included. Further clarification might be needed, however, as to what this means in practice and exactly which uses are excluded.

One of the main issues to be resolved as to pathogens and ABS is the question of access to genetic materials and the resulting vaccines and other control measures. As is the case with many of the other regimes and processes interacting with ABS and the CBD, IPRs being taken out on these materials and resulting products is one of the trends that have sparked controversy. To what degree and under what circumstances IPRs can be taken out on pathogenic material shared internationally is therefore one of the remaining issues that need to be resolved.

## **6 Interface with International Regimes Pertaining to Traditional Knowledge of Indigenous and Local Communities**

One particular intellectual asset connected to genetic resources is traditional knowledge (TK). There exists no treaty that specifically regulates traditional knowledge, but how to recognize indigenous and local communities for this knowledge and provide protection to it has been addressed in various fora.

An important ABS principle under the CBD is that access to genetic resources should be based on the prior informed consent (PIC) of the involved parties and upon mutually agreed terms (MAT). Indigenous peoples and local communities have been involved in the processes behind many of the ABS laws that have been enacted, and in specific benefit-sharing arrangements, as per Article 8j of the CBD.

In WIPO, the discussion forum Intergovernmental Committee on Genetic Resources, Traditional Knowledge and Folklore (WIPO-IGC) has been presented with 16 different policy objectives to consider, 10 general guideline principles, and 14 substantial principles, all of them connected to traditional knowledge from an intellectual property perspective. On the table for the next session of the Committee in May 2010 is a document on 'Revised provisions for the protection of traditional knowledge'.<sup>59</sup> The document was open for comment until the end of February 2010 and then revised on the basis of these comments and represented to the WIPO-IGC. This document is divided into three main parts – policy objective, general guiding principles and substantive principles – and covers such matters as overall objectives for promoting respect for TK as well as outlining more specific provisions for its protection. Work on traditional knowledge in WIPO-IGC and in the CBD about Article 8j has been carried out parallel in time, but with little overlap.

The rights of indigenous peoples have also been addressed through other international frameworks, among them ILO Convention 169 on Indigenous and Tribal Peoples and the UN Declaration on the Rights of Indigenous Peoples (UNDRIP). The ILO Convention provides that governments have the responsibility to develop, with the participation of the peoples concerned, action to protect the rights of these peoples and guarantee their integrity (Art. 2). In particular, they shall consult the people concerned with regard to legislative and administrative measures which may affect them (Art. 6); together with these people, protect and preserve the environment in the territories they inhabit (Art. 7); and safeguard their rights to their resources (Art. 15). The people concerned shall wherever possible participate in the benefits of the exploration and exploitation of natural resources, and receive fair compensation for any damages (*ibid*).

Also UNDRIP provides that indigenous peoples have the right to participate in decision making, including through their own decision-making systems (Art. 18). Any measures that might affect them are to be carried out only upon the free prior informed consent of these people (Art. 19). Indigenous peoples have the right to maintain, control, protect and

develop their traditional knowledge and genetic resources, and states shall take effective measures to protect the exercise of these rights (Art. 31). Furthermore, states shall ensure just and fair redress for the development, utilization and exploitation of natural resources and take appropriate measures to mitigate adverse environmental, economic, social, cultural and spiritual impacts (Art. 32).

In addition, Farmers' Rights as they relate to plant genetic resources for food and agriculture are addressed in the Plant Treaty. Here the protection of traditional knowledge related to these resources is one several measures suggested for the realization of Farmers' Rights (Art. 9). Protecting farmers' traditional knowledge can mean different things.<sup>60</sup> It can mean offering ownership status to farmers, with the right to act against misappropriation and decide over the use of their knowledge and related plant genetic resources (ownership approach). It can also mean protection by sharing among custodians of crop genetic resources (stewardship approach). In Norway, farmers have stressed that their traditional knowledge is about to disappear as the practitioners grow older and fewer. Protection, in their understanding, is about ensuring that the knowledge does not die out, and for that purpose the broadest possible sharing of knowledge is necessary. Some proponents of the stewardship approach note that agricultural plant varieties and related knowledge are normally shared among farming communities: Ownership' in this context is generally an alien idea among farmers, representing a profound break with traditional perceptions. In other parts of the world, misappropriation is an important issue; and in Peru, a potato catalogue has bridged the divide between the two approaches, combining the sharing of knowledge, with due recognition to the involved farmers and their knowledge – and with measures against misappropriation.<sup>61</sup> Whether a stewardship approach, an ownership approach or a combination is chosen to protecting traditional knowledge related to agro-biodiversity under the Plant Treaty, it should not provide any disincentives to the sharing of knowledge and genetic resources among farmers, nor should it contribute to genetic erosion or the loss of traditional knowledge, which would be against the intentions of the Plant Treaty.

When the negotiators of an international ABS regime under the CBD are to determine its scope, the extent to which TK should be included or excluded from the regulations must be clarified. If such an international regime is to be operational and functional in a legal sense, it will be necessary to include – or exclude – TK in a way that can be handled in a legal context. Thus, an international regime will need to develop the linkage between the definition of genetic resources as its subject matter and the TK aspects to be covered. Clarity is essential as to the object of the right, who shall be the holder of the right, whether it shall be made exclusive, and other related issues.

## 7 Interface with International Regimes on Intellectual Property Rights

### *Interface with Patent Law – WTO and WIPO*

Whereas CBD, the ITPGRFA and CGRFA are concerned with the sovereign rights of states over genetic resources in general and the management of those sovereign rights for one particular area of resources (genetic resources as subject matter for a right), intellectual property rights take a very different approach: Public authority is used to grant time-limited exclusive private rights to, in particular, companies or individuals. The patent system is historically based on national systems, with each government enjoying discretion to apply its patent law strategically to build up technical industries. Patent law has often been used to give a country-specific monopoly to the one bringing a new product or technique to the country, also when this has involved copying techniques from competing nations.<sup>62</sup> The sovereignty of nation-states has been used to grant these privileges under the jurisdiction of each one.

Today, however, the discretion of countries is limited by international harmonization treaties, the most comprehensive of which is the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) as part of World Trade Organization (WTO).<sup>63</sup> Moreover, various nations work together under regional systems for shared systems for granting patents and harmonization.<sup>64</sup> In these regional offices (except for one), the grant of a patent is decided outside the national sphere. In fact, it is supranational rather than international: the power to grant patents rests outside the control of any one particular nation-state. It is the organization that grants the patent. The patent granted by that organization becomes legally binding for everyone in each member country. This is relevant for ABS in general, and Africa in particular, since OAPI and ARIPO form the institutional basis for granting patents also in the field of patents to biologically-based inventions.

Two major changes in patent law constitute main interfaces between ABS and patent law. First, there are the changes in the practice of the *industrialized* countries in granting patents to inventions based on biological material. This dimension becomes relevant for ABS because inventions connected to genetic resources and traditional knowledge are being patented in the industrialized countries – and this may happen almost without any transfer of benefits to the developing countries. As a result, the first generation of ABS measures emanated in provider countries, generally in the South. In an effort to ensure that benefit sharing would take place as foreseen, comprehensive procedures for access to genetic materials were established in some countries.

The second dimension concerns the *international* level, when the standards from the industrialized countries were made global in scope. This is relevant for ABS in a less direct manner, since ABS is primarily an international tool for ensuring the distribution of benefits back to the one that provided the genetic material. International patent law could be ABS-relevant if it included means to give force to an international regime, but as yet there has been a lack of political consensus on this point. There-

fore, the most relevant interface for an international regime is how to establish mechanisms or obligations that can capture ABS-relevant benefits from the patent systems and channel them back to the providing country.

The disclosure of information connected to patent application to ensure benefit sharing has been presented as a crucial element for ensuring compliance with the ABS/CBD. Disclosure is intended as a mechanism whereby the patent applicant is obliged to give relevant information about various aspects relevant to the invention. Disclosure provisions have been suggested for the TRIPS Agreement,<sup>65</sup> under the Patent Cooperation Treaty (PCT/WIPO),<sup>66</sup> and have been discussed in the Intergovernmental Committee on Genetic Resources Traditional Knowledge and Folklore (IGC/ WIPO).<sup>67</sup> Despite the massive attention accorded to disclosure requirements in political negotiations as well as by academics, there is little to indicate that a stand-alone disclosure requirement in the IPR legislation would solve the problems related to benefit sharing.<sup>68</sup> Merely requiring information does not necessarily lead to any benefits being shared – say, from a private company in an industrialized country to a developing country.<sup>69</sup> This is also an underlying assumption in the more extensive proposal about a detailed disclosure requirement made by Brazil and others to the TRIPS Council.<sup>70</sup> The discussion of disclosure in WTO-TRIPS has been halted. The IGC/WIPO suffers from considerable disagreement and has made little headway in negotiating any binding text in the area of genetic resources.

As a stand-alone disclosure requirement is not likely to ensure benefit sharing under the CBD, an international regime must as an important interface address disclosure within a more complete context. It must be recognized as being only one small part of the solution.

Many difficult issues will need to be clarified for a disclosure obligation to be effective. One crucial point is to establish the link between *genetic resources* accessed and the obligation to disclose. If this is not specified, the obligation will not provide clarity as to when patent applicants are obliged to disclose information and when they are not under such an obligation. The proposal from Brazil and others for a new Article 29bis in the TRIPS Agreement includes wording about this linkage: ‘When the subject matter of a patent application is derived from or developed with biological resources and/or associated traditional knowledge, [...]’. This refers both to *derived from* and *developed with* as the trigger point for when information must be disclosed. The suggested draft Article 29bis refers to a broader subject matter: biological material or traditional knowledge. The term ‘derived from’ indicates that the origin should be disclosed with *all* innovation derived from biological material. The term ‘derived’ indicates a fairly close linkage between the biological material and the patented invention. The term ‘developed with’ broadens the scope somewhat, indicating the possibility of a more distant link between the biological material or TK and the invention. An international regime will need to be quite specific on this issue.

The application of IPRs, the attempts to regulate access and the lack of benefits shared – all point up the importance of establishing user-country



measures to ensure benefit sharing in order to balance the responsibilities for ABS between users/IPR-owners and providers/ custodians of GR.

The truly important interface between ABS and patent law concerns the changes in practice in recent decades. Especially five mechanisms in patent law are crucial in this respect:

- the narrowing down of the legal exemption from patent protection;<sup>71</sup>
- the definition of what is recognized as *prior art* (already known before the patent application);<sup>72</sup>
- the practice of the novelty criterion;<sup>73</sup>
- the practice of the inventiveness criterion; and
- the acceptance of the deposit of biological material replacing the complete written disclosure.<sup>74</sup>

The content of these five issues is not yet harmonized globally. Global rules regulating these standards would affect how to safeguard the public domain for research and development as well as the rights under ABS. Their more detailed potential to interfere with ABS has been explained elsewhere, and the scope of this report does not allow a more thorough explanation.<sup>75</sup> The strong call for full harmonization has been on the table of the specialized body of WIPO for patent law harmonization, the Standing Committee on the Law of Patents (SCP), for a good while.<sup>76</sup> The most recent meeting of the SCP-WIPO when harmonization of these and other substantive patent law issues was discussed was in 2005. There exists a draft Substantive Patent Law Treaty (SPLT), a draft Regulation under this draft treaty and draft implementing rules to them. Beyond doubt, if the draft SPLT with the supplementing rules had been binding they would have a broad and profound interface with ABS.<sup>77</sup> Indeed, four of these five issues were the ones that the developing countries insisted that the SCP-WIPO should negotiate first.<sup>78</sup> However, under the new agenda of the SCP from 2008, harmonization of these issues is not on the table as negotiable text.<sup>79</sup> Currently the SCP-WIPO is focusing on more academic studies of selected patent law issues, with a much lighter form than text-based negotiations.<sup>80</sup>

As the international patent system has showed a very limited willingness to include mechanisms to ensure that the obligations in CBD Article 15 are met and enforced, an international regime will need to take a more active approach to the interface between the commercial use of genetic resources subject to patent rights and ABS.

In this context there is a need for an international regime to take clear measures on the user side of the ABS coin. User-country legislation should emplace clear obligations on the one using genetic resources. That could be implemented as an obligation in the legislation to have information about the origin and legal provenance of the genetic resources available to all users – including, of course, the providing country and the country of origin. It could mean clear obligations that, for any use of genetic resources to be legal, the user must be able to document that a scheme for benefit sharing has been established.

One particularly important interface issue is when access regulations attempts to regulate the applicability of patent law. This is sought done in ITPGRFA Article 12.3.d where, as mentioned in section 1 above, material from the MLS, or its genetic parts and components, *in the form it is received* shall not be patented. This is binding upon the user of the MLS if the material is accessed under the SMTA of the ITPGRFA. An open question is how much the material must be modified before it is no longer regarded as being ‘in the form received’. This is a matter of interpretation of the SMTA. However, this contractual restriction cannot ensure that the patent system is not used for granting exclusive time-limited rights to the said material. Whether a patent is granted or not depends on the practice in the patent system, and not on the interpretation of the ITPGRFA. In the patent system, the consideration is not whether the material is in the form received or not – it is a question of whether the invention is *novel* and sufficiently *inventive*. These considerations in patent law are not identical with the restriction according to the ITPGRFA. To challenge a patent, legal procedures must be taken under the patent system and in the courts of the country where it is granted. A resolution from the dispute settlement system under the SMTA is not recognised as to have effects for the validity of the patent. This establishes a potentially difficult situation where a patent holder is in breach with the SMTA but still is the holder of a patent to the invention based on the plant genetic material.

*Interfaces with the intellectual property right of the plant breeder to plant varieties – UPOV*

The specialized IPR system for the plant sector, the International Convention for the Protection of New Varieties of Plants under the Union for the Protection of New Varieties of Plants (UPOV), grants time-limited rights to new plant varieties.<sup>81</sup> These plant breeders’ rights affect the accessibility of plant genetic resources, since each granted right establishes an exclusive right to a specific protected ‘plant variety’, and that has consequences for the exchange and use of it in further breeding and in growing crops. There are different versions of the UPOV treaty, as the UPOV convention has been revised four times. Currently the version of UPOV-78 and that of 1991 are in use. There are important differences between them: UPOV-91 establishes the most stringent right, whereas UPOV-78 opens for country discretion in its implementation and grants more flexibility for plant breeders to use already protected material.

Countries members to the WTO and the TRIPS agreement have discretion to exempt plants from patent protection (TRIPS Art 27.3.b) – however, they are obliged to grant a particular *sui generis* protection to *plant variety* as subject matter (TRIPS Art 27.3.b). The *sui generis* alternative in the TRIPS is not linked to any particular treaty, even though there was already an international treaty open for signature – UPOV-78 – providing one example of a *sui generis* system at the time of negotiations. Therefore, no obligation can be identified under the TRIPS Agreement for countries to apply plant-variety protection legislation according to UPOV or to become UPOV members.

One particular interface issue between UPOV-91 and ABS concerns the manner of defining ‘novelty’ under the UPOV-91 system. ‘Novelty’, according to Article 6 and Article 1(iv), refers to either a newly bred or

‘discovered and developed’ plant variety. The baseline for this assessment is not only what has been published previously, but also whether the plant variety has been previously offered for sale in a commercial farming system in the form of seeds or propagating material. This implies that non-commercial farming systems are not guaranteed that breeding material which has been in non-commercial use will not be included under a new plant-variety right. If such non-commercial material is described in a new manner, it can meet the criteria for being subject to a new property right. Thereby the definition of novelty becomes an important element for the interface between ABS and plant breeders’ rights.

A granted right according to UPOV-91 also reduces the right of farmers to exchange seeds among themselves. In such cases, the farmers growing the new, protected, seeds step out of the community for seed exchange. And that reduces the number of farmers participating in the local exchange system.

The UPOV does not require any particular system for benefit sharing. One specific link to ABS could be to establish an obligation whereby a plant variety right-holder must distribute a part of the benefits arising from the plant variety back to the Plant Treaty benefit-sharing system, or for genetic resources falling under an international regime to this benefit-sharing system. The SMTA under the MLS of the Plant Treaty includes an optional benefit-sharing clause if the plant variety is commercialized; this optional system is relevant for the UPOV. For material not under the scope of Plant Treaty, the benefits need to be shared with that relevant provider. The problems of solving the interface issue between the UPOV and an international regime also give rise to enforcement challenges similar to those described under the patent system. Also here the international aspects of use and enforcement become relevant issues.



## 8 Conclusions

Negotiating ABS with a view to mutual supportiveness with other international agreements and processes is a challenging task. This report has highlighted many key interfaces that must be taken into consideration if a new international regime is to be mutually supportive with already established international commitments. Some of these frameworks deal with particular sub-categories of genetic resources, whereas others deal with access to resources in geographically defined areas. Some address the traditional knowledge attached to genetic resources, and others regulate intellectual property rights that are relevant to appropriate these resources. The options for the negotiators of an international ABS regime with regard to each of these international regimes and processes have been highlighted in the respective sections of this report. Here we will focus on implications for the discussion of the scope of an international regime to take into account the special needs of each grouping of genetic resources.

There are great differences between and among various sub-sectors of genetic resources in terms of their distinctive features and the challenges regarding their conservation and utilization. These differences have given rise to the question of whether particular sub-sectors should be included in an international regime on ABS, or should be kept outside such regulations.

- The Multilateral System of the Plant Treaty is already an established and legally binding ABS system, and is therefore eligible to be kept outside an international regime on ABS. However, it might be challenging to define the exact scope of the material to be excluded. As a minimum, the material in the Multilateral System and the material that is already made available with the SMTA need to be excluded. An international regime could include flexibility to enable future expansion of the Multilateral System to new species in addition to those currently listed in Annex I. In defining the scope of the material to be excluded, there are four challenges: (1) Not only Annex I material is relevant to exclude, but also all other material transferred by use of the SMTA that are additional to the Annex I material; (2) only the material in the public domain and under the control of the parties can be excluded, so, for instance, the material in farmers' fields are subject to an international regime; (3) there are 70 countries that are parties to the CBD and non-parties to the Plant Treaty, so it is not sufficient to refer solely to Annex I material if excluding this from the scope; (4) the MLS applies only for the specific use for food and agriculture: an international regime should address other uses of this material.
- The genetic resources for food and agriculture are manifold, with very different distinctive features, exchange patterns and management needs, despite some commonalities. There have been discussions as to whether GRFA should be excluded from an international regime on ABS. The core message here is that the specific features and management needs of the different sub-categories of GRFA must be reflected in an international regime.

- ABS to genetic resources in the sea beyond areas of national jurisdiction has been a difficult topic for years, and international processes in other international fora have so far not resulted in agreement on solutions. If an international regime on ABS covers these resources adequately, it might solve the long-lasting dispute. The status regarding sovereignty and sovereign rights of national differs in international law for the deep sea bed, the high seas, the continental shelf, the economic zone and territorial waters. These differences must be taken into account, as they are already binding in international law. In the period until consensus is reached in this particular forum, the patent system remains the only legal system for establishing property rights to genetic material taken from the zones of the oceans beyond national sovereign rights. It is in the interest of various actors that the dispute should continue, as this leaves the genetic material open. From an ABS perspective, it is important to seek to include these resources.
- Regulating ABS to genetic resources in the Antarctic is also a difficult task, due to the unclear territorial status. However, if these resources are not included in an international regime, that might create a loophole whereby users of genetic resources actually obtain them elsewhere but argue that they were collected in Antarctica. This is an argument for including these resources in an international regime on ABS. In any case, the benefit-sharing side of the ABS coin needs mechanisms to validate whether the said genetic resources are inside or outside the scope of an international regime.
- Whether pathogens should be excluded from an international regime on ABS is a difficult question. There are arguments for and against the exclusion of pathogens and also suggestions that only specific uses of certain pathogens should be included. If pathogens or certain uses of pathogens are excluded, clear specification of what this means is vital. In any case there are important issues related to pathogens that need to be solved, not least as regards intellectual property rights to material that is shared internationally.
- Traditional knowledge related to genetic resources is already covered in the negotiation text of an international ABS regime, and as such it addresses the domestic regulation of ABS with a view to indigenous and local communities that are holders of traditional knowledge. Including provisions on traditional knowledge has additional support in several other international frameworks.

As we see, there are good arguments for a broad and inclusive international regime on ABS. It will need to take into account the special characteristics of the different sub-categories of genetic resources. As the example of the Multilateral System under the Plant Treaty shows for PGRFA, and as the CGRFA suggests, differential solutions might be required for different sub-categories, in order to reach the common objectives of access and benefit sharing for all genetic resources covered by the CBD.

To cover all these different sub-categories of genetic resources in one regime, and with general provisions only, might prove a challenging task.

Seeking to negotiate a one-size-fits-all approach might lead to provisions that are more general and less effective than more tailor-made solutions. Also there is the possibility that negotiators will seek to exclude various sub-categories of genetic resources, thereby weakening the regime. On the other hand, there is the fear that a sector-based approach could weaken an international ABS regime from another angle, by splitting it up into bits and pieces. That would be the case if sub-categories of genetic resources were to be excluded from the ABS regime and referred to other international fora instead.

To include differentiations among sectors within an international ABS regime under the CBD would entail having general provisions that apply for all sectors dealing with the access side and the benefit-sharing side of ABS, and sector-specific provisions that meet the specific features and needs of specific sub-categories of genetic resources. A central item for the general provisions is user-country measures, which must be kept at a cross-sectoral level to achieve functionality. These include the further specification of what is meant by 'utilization of genetic resources', surveillance mechanisms (like certificates and disclosure) and enforcement mechanisms for the providers of genetic resources under the jurisdiction of the user country. In particular they include the obligation upon users, regardless of the sector in which they operate, to conduct fair and equitable benefit sharing, and obligation of the user countries to implement legislative, policy and administrative measures to ensure that benefits are shared.

A sectoral approach could be designed in various ways and through different processes. Here four different options are highlighted and discussed:

1. An international ABS regime could have general provisions which apply to all genetic resources that are included in its scope and that are not covered by specific sectoral provisions, as outlined above, and then include chapters on the relevant sub-categories of genetic resources that need specific solutions.
2. An international ABS regime could be designed with general provisions for all the genetic resources that are included in its scope, and open for the adoption of annexes on ABS to specific sub-categories of genetic resources for special regulation of them, based on their distinctive features. The final act of the international regime could then set out that these annexes shall be negotiated within the framework of the CBD and be presented to the next Conference of the Parties to the CBD. Alternatively, the international regime as such would prevail until sector-specific solutions could be found.
3. An international regime might open for the adoption of international agreements on ABS to specific sub-categories of genetic resources developed under the auspices of other international organisations or treaties – in harmony with the CBD. This would in practice imply that these sectors were excluded from the international regime, and that the ensuing ABS regulations for these sectors were dealt with under the respective international frameworks.

4. An international ABS regime could be designed with general provisions for all the genetic resources that are included in its scope, and open for the adoption of annexes on ABS to specific sub-categories of genetic resources. Under this option, the COP could consider whether such annexes should be developed in cooperation with other international bodies, and it could invite draft text from such bodies. This option would allow the international regime to enter into force, whereas annexes could be included in the international regime when adopted by the decision body of the international ABS regime or the Conference of the Parties to the CBD.

In any case, it is important to keep in mind the larger context when designing an international regime on ABS. When ABS emerged as an issue in the negotiations of the CBD in the late 1980s, it was much as a reaction to the development of intellectual property regimes that could deprive developing countries of rights over their resources. That issue is still not solved. The way in which intellectual property rights are addressed in an international ABS regime may be decisive to the prospects for benefit sharing. Whether benefit sharing will take place depends on the possibility of establishing a legally binding system on user-country measures which can safeguard the realization of this objective. An important observation is that a stand-alone disclosure requirement will not be sufficient to achieve the benefit-sharing obligations. It will have to form a part of a more complete enforcement system which can resolve the difficult technical legal issues of the cross-border use of natural resources.

## Notes

<sup>1</sup> CGRFA-12/09/Report, Appendix B.

<sup>2</sup> This section is based on Regine Andersen (2008): *Governing Agrobiodiversity – Plant Genetics and Developing Countries* (Aldershot: Ashgate), and on findings from the Farmers' Rights Project ([www.farmersrights.org](http://www.farmersrights.org)) as presented in Regine Andersen (2009): *Information paper on Farmers' Rights submitted by the Fridtjof Nansen Institute, Norway, based on the Farmers' Rights Project*. Information paper for the Third Session of the Governing Body of the Plant Treaty (IT/GB-3/09/Inf. 6 Add. 3). Some of the interfaces are also dealt with in Jane Bulmer (2009): *Study on the Relationship Between and International Regime on Access and Benefit-Sharing and Other International Instruments and Forums that Govern Genetic Resources. The International Treaty on Plant Genetic Resources for Food and Agriculture and the Food and Agriculture Organisations' Commission on Genetic Resources*. Information paper for the Seventh Meeting of the Ad Hoc Open-Ended Working Group on ABS. UNEP/CBD/WG-ABS/7/Inf/3/Part.1. I am grateful to Grethe Evjen, head of the Norwegian delegation to the Plant Treaty, for valuable comments.

<sup>3</sup> PGRFA are defined as 'any genetic material of plant origin of actual or potential value for food and agriculture (Art. 2).

<sup>4</sup> For more information of the negotiations that led to the Plant Treaty and the difficult political challenges encountered along the way, see Andersen (2008), pp. 87–115.

<sup>5</sup> Except for their wild relatives.



<sup>6</sup> Report by the Secretary of the Plant Treaty to the Second Session of the Governing Body in 2007: IT/GB-2/07/5, p. 3

<sup>7</sup> Further details regarding this interface are provided in section 7.

<sup>8</sup> The Plant Treaty does not prohibit intellectual property rights on products developed on the basis of material received from the MLS – only on material from the MLS in the form received.

<sup>9</sup> Plant breeders' rights are most frequently used to ensure intellectual property rights, as further elaborated below.

<sup>10</sup> Information sheet from the Secretariat, available at: [ftp://ftp.fao.org/ag/agp/planttreaty/news/news0009\\_en.pdf](ftp://ftp.fao.org/ag/agp/planttreaty/news/news0009_en.pdf)

<sup>11</sup> See Report from the Third Session of the Governing Body of the Plant Treaty, IT/GB-3/09/Report, at <ftp://ftp.fao.org/ag/agp/planttreaty/gb3/gb3repe.pdf>, pp. 28–30.

<sup>12</sup> As pointed out by Bulmer (2009), p. 4.

<sup>13</sup> According to information from the head of the Norwegian Delegation to the Plant Treaty, Grethe Evjen, in a note to Regine Andersen, 17 February 2010.

<sup>14</sup> Regine Andersen (2005): The Farmers' Rights Project – Background Study 2: Results from an International Stakeholder Survey on Farmers' Rights. FNI report 9/2005 (Lysaker, Norway: The Fridtjof Nansen Institute)

<sup>15</sup> An explicit reference to material covered by the SMTA would be useful to remove uncertainties regarding exactly what is included in the MLS; note the first point in this list: 'MLS applies to a group of genetic resources'.

<sup>16</sup> For more information on Farmers' Rights and the contents of these four elements, see [www.farmersrights.org](http://www.farmersrights.org).

<sup>17</sup> The first two of these options have been described by Bulmer (2009), pp. 12–15.

<sup>18</sup> Although the Plant Treaty is the most important instrument in terms of the conservation and sustainable use of PGRFA, and ABS in this context, the CGRFA still holds responsibility for the implementation of the 1996 Global Plan of Action for the Conservation and the Sustainable Utilization of PGRFA and the production of the report on the State of the World's Plant Genetic Resources for Food and Agriculture.

<sup>19</sup> Studies on food security and ABS for GRFA; the impact of climate change on countries interdependence on GRFA; trends in intellectual property rights related to GRFA; and studies on the use and exchange of animal genetic resources, forest genetic resources, aquatic genetic resources, microbial genetic resources and biological control agents for food and agriculture. All papers are available at: <http://www.fao.org/nr/cgrfa/cgrfa-meetings/cgrfa-comm/twelfth-reg/en/>

<sup>20</sup> This list is based on the CGRFA Resolution 1/2009 on ABS referred to above; on Andersen (2008): *Governing Agrobiodiversity* (see above); and on G. S. Nijar, G. P. Fern, L. Y. Harn, and C. H. Yun (2009): *Framework Study on Food Security and Access and Benefit-Sharing for Genetic Resources for Food and Agriculture*, CGRFA Background Study Paper No. 42 (Rome: FAO).

<sup>21</sup> Hiemstra et al. (2006): Exchange, Use and Conservation of Animal Genetic Resources Policy and regulatory options (S.J. Hiemstra, A.G. Drucker, M.W. Tvedt, N. Louwaars, J.K. Oldenbroek, K. Awgichew, S. Abegaz Kebede, P.N. Bhat & A. da Silva Mariante) Study commissioned by the FAO for the first meeting on Farm Animal Genetic Resources, in Interlaken.

<sup>22</sup> Hiemstra et al. (2006) and D. Pilling (2009): *The Use and Exchange of Animal Genetic Resources for Food and Agriculture*, CGRFA Background Study Paper No. 43 (Rome: FAO), p. 42

<sup>23</sup> Pilling (2009), p. 43.

<sup>24</sup> Hiemstra et al. (2006) and Tvedt (2007).

- <sup>25</sup> Tvedt (2007): 'Patenting in the Field of Animal Breeding and Farm Animal Genetic Resources', *Acta Agriculturae Scand Section A*, vol.57: 105–120.
- <sup>26</sup> J. Koskela, B. Vinceti et al. (2009): *The Use and Exchange of Forest Genetic Resources for Food and Agriculture*, CGRFA Background Study Paper No. 44 (Rome: FAO), p. 2
- <sup>27</sup> *Ibid*, p. 41.
- <sup>28</sup> FAO (2009): *State of the World's Forests*. FAO, Rome, p.8.
- <sup>29</sup> Based on D. M. Bartley and J. A. H. Benzie et al. (2009): *The Use and Exchange of Aquatic Genetic Resources for Food and Agriculture*, CGRFA Background Study Paper No. 45 (Rome: FAO)
- <sup>30</sup> Ambekar E. Eknath and Gideon Hulata (2009): 'Use and Exchange of Genetic Resources of Nile Tilapia (*Oreochromis niloticus*)', *Reviews in Aquaculture*, vol. 1, pp. 197–213; David Greer and Brian Harvey (2004): *Blue Genes. Sharing and Conserving the World's Aquatic Genetic Resources*. Earthscan: London.
- <sup>31</sup> G.Kristin Rosendal, Ingrid Olesen, Hans B.Bentsen, Morten Walløe Tvedt, Martin Bryde (2006): 'Access to and Legal Protection of Aquaculture Genetic Resources – Norwegian perspectives', *Journal of World Intellectual Property*, vol. 9, no. 4, pp. 392–412 ; Ingrid Olesen, G. Kristin Rosendal, Hans B. Bentsen, Morten Walløe Tvedt and Martin Bryde (2007): 'Access to and Protection of Aquaculture Genetic Resources – Strategies and Regulations', *Aquaculture*, vol. 272, Supplement 1, 2007, pp. S47–S61.
- <sup>32</sup> T. Dedeurwaerdere, M. Iglesias et al. (2009): *The Use and Exchange of Microbial Genetic Resources for Food and Agriculture*, CGRFA Background Study Paper No. 46 (Rome: FAO), pp. 13 and 14.
- <sup>33</sup> *Ibid*, p. 7.
- <sup>34</sup> Micro-organisms Sustainable Use and Access Regulation International Code of Conduct of the World Federation for Culture Collections.
- <sup>35</sup> *Ibid*, p. 56.
- <sup>36</sup> M. J. W. Cock, J. C. vanLenteren, et al. (2009): *The Use and Exchange of Biological Control Agents for Food and Agriculture*, CGRFA Background Study Paper No. 47 (Rome: FAO), p. 9.
- <sup>37</sup> *Ibid*, p. 24.
- <sup>38</sup> *Ibid*, p. 38
- <sup>39</sup> *Ibid*, p. 34.
- <sup>40</sup> For a study more detailed on these issues, but not updated to include the most recent developments, see Sam Johnston, 'Study on the Relationship Between an International Regime on Access and Benefit Sharing and Other International Instruments and Forums that Govern the Use of Genetic Resources. The Antarctic Treaty System (ATS) and the United Nations Convention on the Law of the Sea (UNCLOS)', February 2009, Information paper to the Seventh Meeting of the Ad Hoc Open-ended Working Group Meeting on ABS, UNEP/CBD/WG-ABS/INF/3/Part.3.
- <sup>41</sup> The term is also sometimes used to refer to non-living and non-infectious agents of disease, such as chemicals. However, only the types of pathogens that might be seen as part of biodiversity are relevant to our discussion here.
- <sup>42</sup> David P.Fidler (2008): 'Influenza Virus Samples, International Law, and Global Health Diplomacy', *Emerging Infectious Diseases*, vol. 14, no.1; and Endang R. Sedyaningsih, Siti Isfandari, Triono Soendoro and Siti Fadilah Supari (2008): 'Towards Mutual Trust, Transparency and Equity in Virus Sharing Mechanism: The Avian Influenza Case of Indonesia' *Annals Academy of Medicine*, vol. 37: 482–88: [www.annals.edu.sg/pdf/37VolNo6Jun2008/V37N6p482.pdf](http://www.annals.edu.sg/pdf/37VolNo6Jun2008/V37N6p482.pdf)
- <sup>43</sup> International Health Regulations (IHR) 2005: [http://whqlibdoc.who.int/publications/2008/9789241580410\\_eng.pdf](http://whqlibdoc.who.int/publications/2008/9789241580410_eng.pdf)

<sup>44</sup> [http://apps.who.int/gb/ebwha/pdf\\_files/WHA59-REC1/e/Resolutions-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA59-REC1/e/Resolutions-en.pdf)

<sup>45</sup> Fidler (2008)

<sup>46</sup> Laurie Garrett and David P. Fidler (2007): 'Sharing H5N1 Viruses to Stop a Global Influenza Pandemic', *PLoS Medicine*, vol. 4, no.11: 330

<sup>47</sup> Fidler (2008)

<sup>48</sup> Resolution WHA60.28: [http://apps.who.int/gb/ebwha/pdf\\_files/WHA60/A60\\_R28-en.pdf](http://apps.who.int/gb/ebwha/pdf_files/WHA60/A60_R28-en.pdf)

<sup>49</sup> WHO (2009): 'Pandemic influenza preparedness: sharing of influenza viruses and access to vaccines and other benefits – Outcome of the process to finalize remaining elements under the pandemic influenza preparedness framework for the sharing of influenza viruses and access to vaccines and other benefits', report from the Secretariat. Executive Board, 126<sup>th</sup> Session, Provisional agenda item 4.2, EB126/4, 10 December 2009

<sup>50</sup> Third World Network (2010): 'WHO: Virus-Benefit Sharing Working Group set up, pandemic flu response to be reviewed', TWN Info Service on Health Issues, 27 January 2010: [www.twinside.org.sg/title2/health.info/2010/health20100103.htm](http://www.twinside.org.sg/title2/health.info/2010/health20100103.htm)

<sup>51</sup> Fidler (2008)

<sup>52</sup> See Resolution No. XIV, Adopted by the International Committee of the OIE on 29 May 2002.

<sup>53</sup> See Resolution No. XXXI, Adopted by the International Committee of the OIE on 27 May 2004.

<sup>54</sup> See Resolution No. XXI, Adopted by the International Committee of the OIE on 30 May 2002.

<sup>55</sup> Final Report of the 76<sup>th</sup> General Session of the OIE, Resolution No. XXVI (p. 159): [www.oie.int/downld/SG/2008/A\\_RF\\_2008\\_webpub.pdf](http://www.oie.int/downld/SG/2008/A_RF_2008_webpub.pdf)

<sup>56</sup> IPPC (2005): New Revised Text of the International Plant Protection Convention: [www.ippc.int/ippctypo3\\_test/index.php?id=1110485&L=0](http://www.ippc.int/ippctypo3_test/index.php?id=1110485&L=0)

<sup>57</sup> ICC (2009): 'Pathogens and the International Regime on Access and Benefit-Sharing', Document No. 450/1051 – 11 September 2009: [www.iccwbo.org/policy/ip/index.html?id=2480](http://www.iccwbo.org/policy/ip/index.html?id=2480)

<sup>58</sup> Chee Yoke Ling, François Meienberg and Christine von Weizsäcker (2009): "'Pathogenic" Organisms: In or Out of the International Regime', (Paris, 2 March 2009): [www.evb.ch/en/p25015616.html](http://www.evb.ch/en/p25015616.html)

<sup>59</sup> WIPO document WIPO/GRTKF/IC/16/5 Prov.

<sup>60</sup> Regine Andersen (2006): *Realising Farmers' Rights under the International Treaty on Plant Genetic Resources for Food and Agriculture, Summary of Findings from the Farmers' Rights Project (Phase 1)*. FNI Report 11/2006 (Lysaker, Norway: The Fridtjof Nansen Institute)

<sup>61</sup> The International Potato Centre and La Federación Departamental de Comunidades Campesinas (2006): *Catálogo de Variedades de Papa Nativa de Huancavelica, Peru* (Lima: The International Potato Centre and La Federación Departamental de Comunidades Campesinas) More information in Regine Andersen and Tone Winge (2008): *The Farmers' Rights Project – Background Study 7: Success Stories from the Realization of Farmers' Rights Related to Plant Genetic Resources for Food and Agriculture*. FNI Report 4/2008 (Lysaker, Norway: The Fridtjof Nansen Institute). The story can be accessed online: [www.farmersrights.org/bestpractices/success\\_tk\\_1.html](http://www.farmersrights.org/bestpractices/success_tk_1.html)

<sup>62</sup> This parallels what the developing countries have been calling for in the 'technology transfer' discussion: the opportunity to draw on the research and development of others to promote their own development.

<sup>63</sup> TRIPS became international law together with the entry into force of the WTO in 1995.

<sup>64</sup> The African Intellectual Property Organization (Organisation Africaine de la Propriété Intellectuelle) unites 16 francophone African countries. It came into force with the revision of the Bangui Agreement of 2 March 1977 ([www.oapi.wipo.net](http://www.oapi.wipo.net)). The African Regional Intellectual Property Organization entered into force with the Lusaka Agreement adapted on 9 December 1976 ([www.aripo.org](http://www.aripo.org)) and unites 16 African countries. The Eurasian Patent Organization entered into force on 12 August 1995 ([www.eapo.org](http://www.eapo.org)). The European Patent Convention was signed in 1973 and entered into force in 1977. It grants patents with direct binding effect under the jurisdiction of 36 European countries ([www.epo.int](http://www.epo.int)).

<sup>65</sup> See e.g. Jorge Medaglia Cabrera (2009): 'Study on the relationship between the ABS International Regime and other international instruments which govern the use of genetic resources: The World Trade Organization (WTO); the World Intellectual Property Rights Organization (WIPO); and the International Union for the Protection of New Varieties of Plants (UPOV).' UNEP/CBD/WG-ABS/7/INF/3/Part.2, paragraphs 5–16, 19, 32–33, 36, 55–56 and 60, where this topic receives considerable attention.

<sup>66</sup> PCT (Washington DC, 1970), amended in 1979 and modified in 1984 and 2001 (PCT Union); by 2008 it had 139 country members.

<sup>67</sup> The IGC/WIPO is a forum for discussing issues relevant to *genetic resources* and intellectual property rights, established as a reaction to the proposal from Colombia to include disclosure requirements into the general patent discussion in the WIPO.

<sup>68</sup> Cabrera (2009); Morten Walløe Tvedt and Tomme Young (2007), *Beyond Access: Exploring Implementation of the Fair and Equitable Sharing Commitment in the CBD*. Gland, Switzerland: IUCN, pp. 48–49 and 184; Tvedt (2006), 'Elements for Legislation in User Countries to Meet the Fair and Equitable Benefit-sharing Commitment', *Journal of World Intellectual Property*, vol. 9, no. 2: pp. 189–212. See also Tomme R. Young and Morten Walløe Tvedt (2009): *Balancing Building Blocks for a Functional ABS System*, FNI Report 7/2009. Lysaker, Norway: The Fridtjof Nansen Institute.

<sup>69</sup> Tvedt 2006, pp. 189–212.

<sup>70</sup> The following documents are those of greatest relevance to the work in the WTO and TRIPS Council regarding disclosure: WT/GC/W/564/Rev.2, TN/C/W/41/Rev.2, IP/C/W/474 and WT/GC/W/564/Rev.2/Add.2, TN/C/W/41/Rev.2/Add.2, IP/C/W/474/Add.2. Note that these documents appear with variable numbering.

<sup>71</sup> Article 27.3.b of the TRIPS Agreement narrowed down the discretion of countries to exclude areas of innovation from patent protection. In addition, regional agreements close this, depending on their text. The connection is that by allowing parts of a DNA molecule to be patented, a gene or an allele the material accessed under the CBD cannot be exempted *en bloc* from patent protection. This enables the material accessed to be included under a patent right, regardless of whether the material was gained in line with the rules of the providing country.

<sup>72</sup> There exist cases disregarding the deposit in a gene bank from being sufficient to be included as qualifying as *prior art*. There is no connection between rules implementing or applying the sovereign rights to genetic resources and the prior art in WIPO, or in regional or national patent systems.

<sup>73</sup> How 'novelty' is interpreted and practised has an important interface with ABS. If a low threshold is practised, this permits genetic resources already accessible, but not described, to be included in a patent claim.

<sup>74</sup> The Budapest Treaty opens for depositing biological material in lieu of enabling disclosure if the patent applicant does not manage to describe his invention in a manner sufficient to meet the requirement.

<sup>75</sup> Morten Walløe Tvedt (2005), 'How Will a Substantive Patent Law Treaty Affect the Public Domain for Genetic Resources and Biological Material?', *Journal of World Intellectual Property*, vol. 8, no. 3: 311–344.

<sup>76</sup> Tvedt 2005; see also WIPO/SCP/5/2 from 2001.

<sup>77</sup> Tvedt 2005, pp. 341–343.

<sup>78</sup> Document WIPO/SCP/11/3.

<sup>79</sup> Document WIPO/SCP/12/4 rev.

<sup>80</sup> Document WIPO/SCP/14/2 – document WIPO/SCP/14/6.

<sup>81</sup> The various UPOV conventions have in total 68 member states.

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