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Report from the workshop Stocktaking ABS in the Nordic Countries – with a particular view to business

Morten Walløe Tvedt

FRIDTJOF NANSENS INSTITUTT
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Morten Walløe Tvedt

mwt@fni.no

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Authors
Morten Walløe Tvedt

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Abstract

This Report gives an overview over the topic raised and discussed at the workshop Stocktaking ABS in the Nordic Countries – with a particular view to business. The Nagoya Protocol to the Convention on Biological Diversity was in 2014 expected to enter into force in October 2014. The Nagoya Protocol recieved in the last moment the 50th ratificatino and into force as expected for the first COP to be held in October 2014. Since the Protocol sets standards while leaving some discretion still open for its member countries, the Nordic countries found it to be timely to explore the options for their implementation. The workshop set out to be a ground for exchaning experiences and serve as a place to discuss options among the Nordic countries. Especially, it was recognised that it was imporant to get the views of the business, the users of genetic resources, on board in these discussions.

The workshop managed to get together a broad represantation from businesses and a selection of European and global experts on ABS for open and constructive discussions on the implementation challenges and oportunities for access and use of genetic resources. The more than 50 participants called for this type of workshop anually.

This report follows the structure of the presentations and thereby the discussions at the workshop. The report has been written by the rapporteur and the content has not been checked with the presentors. Thereby, even seeking to capture the main point of the presentors, the responsibility for all the content is that of the rapporteur, and cannot be attributed to the presentors or participants to the workshop.

Key Words

Nagoya Protocol; International Treaty on Plant Genetic Resources; Access; Benefit sharing; Mutually supportive; ABS in Nordic countries; business & ABS

Foreword

This Report gives an overview over the topic raised and discussed at the workshop Stocktaking ABS in the Nordic Countries – with a particular view to business. The Nagoya Protocol to the Convention on Biological Diversity was in 2014 expected to enter into force in October 2014. The Nagoya Protocol recieved in the last moment the 50th ratificatino and into force as expected for the first COP to be held in October 2014. Since the Protocol sets standards while leaving some discretion still open for its member countries, the Nordic countries found it to be timely to explore the options for their implementation. The workshop set out to be a ground for exchaning experiences and serve as a place to discuss options among the Nordic countries. Especially, it was recognised that it was imporant to get the views of the business, the users of genetic resources, on board in these discussions.

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In 2003 the Nordic ministers met in Kalmar, Sweden, to discuss and agree on some guiding principles concerning genetic resources. The result was the report on Access and Rights to Genetic Resources in the Nordic Countries.[1] Since then, the Nordic countries have worked closely together, most conspicuously in the collaborative management of the Nordic Gene Bank, NordGen. Internationally, the landscape around genetic resources law and management has also changed since 2003. The *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity* (NP), which was adopted at the COP-XII and entered into force in October 2014, called for increased momentum in implementation.[2] The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) has gained experience in granting access to a large number of accessions a year and core topics are under review and possibly alteration.[3]

In September 2014, the Nordic Gene Bank and the Fridtjof Nansen Institute co-hosted a two-day workshop on stocktaking ABS in the Nordic Countries with a particular view to business perspectives. The main approach was to scrutinise a number of very practical questions, challenges and problems relating to the implementation of the ABS systems currently in force and working in parallel. On the agenda for this meeting were access and benefit sharing (ABS), as expressed in a legally binding manner on the 193 member countries to the Convention on Biological Diversity (CBD), the Nagoya Protocol (NP) with its increasing membership (57 in December 2014) and the International Treaty on Plant Genetic Resources on Food and Agriculture (ITPGRFA) with more than 130 members.

This report is an attempt to capture the presentations and discussions held at the workshop. These are often coupled with research-based reflections on the various topics dealt with at the workshop. The structure of this FNI Report follows the agenda at the meeting. It builds on the minutes taken by the referee (author of this report). It is not a collection of texts written by the presenters themselves and the opinions expressed herein are those of the referee alone. The accounts of the topics introduced by various persons are not intended to express their views; they are used rather as a starting point for articulating questions raised by each topic, but without referring to or seeking to provide clear solutions.

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[1] Tvedt. *A Nordic Approach to Access and Rights to Genetic Resources*. Copenhagen, The Nordic Ministry Council, 2003.

[2] *Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity* [NP], United Nations, 12 October 2014, entered into force 29 October 2010.

[3] *International Treaty on Plant Genetic Resources for Food and Agriculture* [ITPGRFA], Food and Agriculture Organization, 3 November 2001, 2400 UNTS 303, entered into force 29 June 2004.

The NordGen (Nordic Genetic Resource Centre) and FNI were very pleased to see such broad participation at the workshop, particularly of business sector representatives. It was generally acknowledged towards the end of the meeting that there was a need for a similar meeting at a later date. Again, however, this report does not necessarily reflect any consistent position regarding ABS, and it obviously does not express a uniform Nordic view on these matters.

2 Where is ABS today and where is it moving or being moved to?

The opening speech of the workshop was held by the State Secretary of the Norwegian Ministry of Climate and the Environment, Lars Andreas Lunde, and the Director of the Fridtjof Nansen Institute (FNI), Leiv Lunde. The former emphasised the need to practise ABS in a manner that made it possible for businesses utilising genetic resources to comply with it. The FNI director stressed the strong academic and applied research on biodiversity in the field of political science and law at the institute. The political attention given by the State Secretary was very well received.

2.1 ABS – challenges and potential: Oversight and forward-looking

The first presentation had a triple objective. First to provide a general overview over ABS and getting everyone reading from the same page; second, give a complete picture of the current negotiating forums and international arenas where ABS is being discussed; and third, to ask a number of difficult questions that need to be resolved if ABS is to become a functional legal and political tool for providing funds to conservation and sustainable use of genetic resources.

One overall challenge for ABS, both under CBD/NP and ITPGRFA is to create incentives for and/or binding obligations on users of genetic resources to contribute to the long-term maintenance of the resource base that genetic resources entail. One reason for the lack of incentives for businesses to share a fair and equitable part of the benefits is that there is no legally binding (or strategically justifiable) reason for sharing. From the perspective of private companies, sharing some of their surplus with others than the shareholders, without a clear legal obligation to do so, can in its most extreme form be illegal under legislation governing the responsibilities of private companies. This means that if benefit-sharing obligations are not binding and enforceable by a court of law, there is only a minimal chance that any benefits will be shared. Thus, how to make ABS binding on private and/or public legal entities is a core challenge. ITPGRFA has incorporated this experience and established a standard system for contractual obligations that are, in principle, enforceable as private contractual obligations on the companies that agree to be bound by its terms.

Another core challenge for making ABS functional is the long time that elapses between the act of accessing the genetic material, the often long-term utilisation of the accessions in order to take advantage of the genetic resources, and the point at which benefits from that particular access and utilisation materialise. Access to the biological material containing the genetic material, research on the genetic resources, development and innovation, product sales and creation of benefits do not occur at the same time. Overcoming this time-gap challenge is not very easy, but it is necessary to make ABS functional.

A third challenge concerns cross-border activities, sovereignty and jurisdiction. The CBD, NP and ITPGRFA, as international treaties and conventions, are only binding on countries. The users of genetic resources, which the ABS system aims to encourage sharing the benefits, are private legal persons. Thus, there is a discrepancy between those that are obliged to follow the rules and those whose behaviour the legal systems aim at changing. The obligations for benefit sharing in one state are difficult to enforce under the jurisdiction of another. Since governments enjoy a certain level of flexibility in how they choose to implement their ABS system, the system also opens for fragmentation, with the lack of legal certainty as a consequence. Minimising such uncertainty would be an important step towards making an ABS system functional.

A fourth challenge, which is connected with the previous ones, is that the NP and ITPGRFA are both very focused on the act of access to samples where the material is found. This makes ABS a game where value is either captured at the point of time of access or it becomes *de facto* voluntary. There is also a gap in the incentives for meeting voluntary standards, since a user of genetic resources may believe that if no regulations apply at the point of bringing the accessions, it would be retroactive to capture those situations at a later stage. The time-gap challenge is closely related to this detached challenge, as a user will feel less and less obliged by the initial access contract since an increasing amount of research and development will have been mixed with the genetic material collected in another country.

This leads to a fifth challenge: There exists very limited background law on Genetic Resource (GR) and Traditional Knowledge (TK) contracts in the CBD and NP areas of ABS. Further research and development are needed on legal solutions to make access contracts and benefit sharing contracts more enforceable and functional in different court systems. Since a contract in ABS regulates research and development process where the final product is often unknown at the time of entry into the contract, the contact must foresee different factual scenarios, including grasping unexpected situations in the future. This raises a challenge with regard to the level of detail a contract should include, since neither contract law nor jurisprudence are well developed in this particular area.

ABS is far from being the only binding rule in the CBD and the more specific rules set out in the NP; various other forums and global and regional rules also regulate this issue. The International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) contains a

functional access system for accessions to specifically determined plant genetic resources for certain specific uses. The reason for negotiating the ITPGRFA was the recognition by the CBD of these outstanding matters, as is evident in the following:

> 4. Further recognizes the need to seek solutions to outstanding matters concerning plant genetic resources within the Global System for the Conservation and Sustainable Use of Plant Genetic Resources for Food and Sustainable Agriculture, in particular:
>
> (a) Access to ex-situ collections not acquired in accordance with this Convention; and
>
> (b) The question of farmers' rights.[4]

The scope of the ITPGRFA is not limited to these *ex situ* collections. The system ensuring access and exchange of plant genetic resources is widely recognized. So too are the limitations of this Standard Material Transfer Agreement (sMTA) to provide for other benefits than the access-system itself. Three meetings have been convened as an intersessional process between the meetings of the Governing Body of the ITPGRFA to examine the functionality of the Multilateral System (MLS) for ABS under the Treaty. Two questions are on the table: the expansion of the plant genetic resources covered by the MLS; and how to make the benefit sharing system more functional.

An additional challenge for ABS as a consistent global system is to draw the lines and clarify the grey zones between the general ABS system in the CBD and NP, on the one hand, and the plant genetic resources (PGR) that are mandatorily included in the MLS, on the other. The consequence of including a specific PGR in the MLS would be that the country lost its sovereign right to determine access to them. Access must necessarily be granted on the terms of the sMTA. Therefore, the terms that define the legally binding scope of the MLS and their legal interpretation will become crucial for providing legal certainty for the users. There are a number of questions that introduce a certain level of legal uncertainty concerning the legal interpretation and they need to be discussed.[5] These questions include what is meant by 'public domain' in Art. 11 of the ITPGRFA, and what is meant by the term 'in the form received' – which

[4] *Resolution 3 - The Interrelationship between the Convention on Biological Diversity and the Promotion of Sustainable Agriculture* [Nairobi Resolution 3], entered into force 22 May 1992, the Nairobi Conference for the Adoption of the Agreed Text of the Convention on Biological Diversity.

[5] Some of these grey-zone questions are discussed in Medaglia, et al. *The Interface between the Nagoya Protocol on ABS and the ITPGRFA at the International Level - Potential Issues for Consideration in Supporting Mutually Supportive Implementation at the National Level*. Lysaker, Fridtjof Nansens Institutt, 2013. (FNI Report, no. 1/2013), and these topics are discussed by Halewood, et al. "Implementing 'Mutually Supportive' Access and Benefit Sharing Mechanisms Under the Plant Treaty, Convention on Biological Diversity, and Nagoya Protocol" in *Law, Environment and Development Journal* 9 (2013) 2, which has been critised by Tvedt in Tvedt. "Access to Plant Genetic Resources – Legal Questions for Material on its Way into the Multilateral System of the Plant Treaty" in *Law, Environment and Development Journal* 11 (2015) 1and Tvedt. "Changes in the Plant Treaty – How Can Benefit Sharing Happen and the Link to Intellectual Property Rights – Assessing the Mutually Supportiveness" in *Law, Environment and Development Journal* 11 (2015) 1.

is at the heart of the definition of what cannot be legally covered by exclusive property rights.

The Commission on Plant Genetic Resources for Food and Agriculture (CGRFA) has ABS for six groupings of genetic resources on their agenda: animals; plants (beyond the Plant Treaty); forest; aquaculture; microorganisms; and invertebrates. At the first meeting of the Commission after the conclusion of the NP, ABS for these six groupings was on the agenda. There is an assumption that these groups share certain features: incremental improvements; multiple sources, and that there is no 'one GR – one product' connection; products are resources, and users can become providers.[6] In the run-up to the CGRFA in January 2015, there were ongoing consultations and discussions in technical working groups on several of these groupings. There are, however, fundamental differences between users and ways in which genetic resources are utilised by the different branches using genetic resources in these six areas for research and commercialisation. By the end of the meeting, a set of guidelines was adopted for countries to consider when implementing their domestic ABS policies and laws.[7] The statues of these guidelines and their influence on the ABS system on the national level are still to be seen.

One specialised ABS system which also came about in the year following the agreement by the different countries to adopt the NP is the *Pandemic Influenza Preparedness Framework* for the sharing of influenza viruses and access to vaccines and other benefits. This is a system based on standard agreements in private law.[8] In essence, this SMAT allows for

[6] Schloen, et al. *Access and Benefit-sharing for Food and Agriculture - Current Use and Exchange Practices, Commonalities, Differences and User Community Needs - A Report from a Multi-stakeholder Expert Dialogue*. Rome, FAO Commision on Genetic Resources on Food and Agriculture, CGRFA, 2011 no. 59).

[7] CGRFA-15/15/Report.

[8] The main provisions of the SMTA are the following:
Article 4. Rights and obligations of the Provider
4.2. The Provider agrees to the onward transfer and use of the Materials, to all members of the WHO GISRS, on the same terms and conditions as those provided in Standard Material Transfer Agreement within the WHO GISRS (SMTA 1).
Article 5. Rights and obligations of the Recipient
5.2 The Recipient shall actively seek the participation of scientists to the fullest extent possible from originating laboratories and other authorized laboratories, especially those from developing countries, in scientific projects associated with research on clinical specimens and/or influenza virus from their countries and actively engage them in preparation of manuscripts for presentation and publication.
5.3 The Recipient shall appropriately acknowledge in presentations and publications, the contributions of collaborators, including laboratories/countries providing clinical specimens or influenza virus with pandemic potential or reagents, using existing scientific guidelines.
Article 6. Intellectual property rights
6.1 Neither the Provider nor the Recipient should seek to obtain any intellectual property rights (IPRs) on the Materials.
6.2 The Provider and the Recipient acknowledge that any IPRs on the Materials obtained before the date of adoption of the Framework by the World Health Assembly will not be affected by SMTA 1.
6.3 The Provider under SMTA 1 may have used technology protected by IPRs for the generation and/or modification of the Materials. Any recipient of such Materials acknowledges that such IPRs shall be respected.

certain specific uses. There is a special condition that access shall be expedient, and there shall be no intellectual property rights and certain benefit-sharing clauses. The applicability of this system is limited to particular situations. Interestingly, before the agreement on the Nagoya Protocol, the membership of the WHO found it impossible to agree on these SMTAs.

There are also discussions under the auspices of the UNCLOS and in the Antarctic Treaty meeting about if and how to regulate access and utilisation of genetic resources. The marine elements of ABS are a crucial point, as a lot of unknown and potentially interesting material lives in marine areas. ABS concerning marine genetic resources is currently being discussed. No conclusions have been reached – indeed, there is a lack of consensus as to whether there is any need of regulations in this area at all. Two recent studies by scholars at the FNI discuss the options for regulation of ABS in these areas beyond national jurisdiction.[9]

One of the main reasons for the discussions of ABS is the appropriation of genetic resources through inventions based on or related to them. Patent law is the major area for securing private, exclusive rights to inventions on genetic resources and inventions that include genetic resources. In the ABS discussion, there is clear recognition of the need to maintain the link between the intellectual property rights to bio-based innovations and the legally binding obligations in CBD Art. 15.7, NP and the ITPGRFA on the sharing of benefits arising from utilisation in a fair and equitable manner.

2.2 Global snap-shot

2.2.1 Ratification of the Nagoya Protocol

The title was initially ‘what is required and what is desired?’, but it was amended by the presenter. The Nagoya Protocol entered into force in October 2014 after the ratification by the fiftieth country having signed the NP. Various matters were dealt with at the first COP/MOP, with the Clearing House mechanisms and the measures set up for sharing and exchange of information as core topics, including the user-friendliness and functionality of the CH. The CH mechanism is currently being set up, as is the Traditional Knowledge (TK) associated with GR and the rights of local communities and indigenous people.

Another core topic at the first meeting of the NP concerned Art. 10.

> Article 10. Global Multilateral Benefit-sharing Mechanism
>
> Parties shall consider the need for and modalities of a global multi-lateral benefit-sharing mechanism to address the fair and equitable

[9] Tvedt and Jørem. “Bioprospecting in the High Seas: Regulatory Options for Benefit Sharing” in *Journal of World Intellectual Property* 16 (2013) 3-4 and Jørem and Tvedt. “Bioprospecting in the High Seas: Existing Rights and Obligations in View of a New Legal Regime for Marine Areas beyond National Jurisdiction” in *The International Journal of Marine and Coastal Law* 29 (2014).

> sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent. The benefits shared by users of genetic resources and traditional knowledge associated with genetic resources through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally.

The text of Art. 10 was not negotiated as an article in 2010, so the COP/MOP therefore needs to consider the way forward. There is a window of opportunity to discuss a viable system, and Art. 10 has been the subject of online consultations.[10]

Work is underway to prepare topics in need of further elaboration. For example, the contact group is looking at how to respond to cases of non-compliance at the COP-12. More clarity is needed on compliance. The NP includes rules on the compliance of states parties to the Protocol and their manner of implementing the obligations in CBD Art. 15 and the NP. Compliance also arises at the level of companies using genetic resources. Here the compliance question is at the level of private law, and concerns compliance by companies and other users.

Capacity building is a core topic of the NP and was also discussed by the COP/MOP.

As for specifying the definition of 'utilization of genetic resources' in greater detail, the NP allows for a certain degree of flexibility; that is, the parties may choose the check point themselves. There are several new obligations in the NP that will need to be better understood to facilitate functional implementation of the NP. Legal certainty for both the provider and user side is a central element of a functional legal system.[11] One particular challenge to achieve legal certainty is how to make the distinction between non-commercial and commercial purposes workable in a legal manner. These questions are all candidates for further elaborative work.

2.2.2 Options for enhancing the functionality of the ITPGRFA's Multilateral System of Access and Benefit-sharing

Work is ongoing in the search for options to improve the functioning of the Multilateral System of Access and Benefit-sharing of the ITPGRFA – with a particular view to increasing benefit-sharing from users of the Multilateral System

There is recognition that the agriculture sector requires a different ABS, one more closely aligned with the specificities of the plant breeding sector. One hundred and thirty nine states, including all of the Nordic countries, have agreed on this by becoming members to the Plant Treaty.

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[10] Tvedt. *A Report from the First Reflection Meeting on the Global Multilateral Benefit-Sharing Mechanism*. Lysaker, Fridtjof Nansens Institutt, 2011. (FNI Report, no. 10/2011).
[11] Tvedt and Rukundo. *Functionality of an ABS Protocol*. Lysaker, Fridtjof Nansens Institutt, 2010. (FNI Report, no. 9/2010).

There is a close connection between the CBD and the ITPGRFA. It has been said that the Treaty is in harmony with the CBD, and that the ITPGRFA is one of the pillars of the implementation of the CBD. The Treaty is a specialised system for ABS. According to NP Art. 4, the NP does not apply to the genetic material regulated by the Treaty.

ABS is often said to impose potentially high transaction costs on the exchange of genetic resources. Transaction costs need to be low in plant breeding. The ongoing MLS negotiation process was aimed at achieving a better balance between conditions for access and the benefit-sharing obligation. The original text of the Plant Treaty contains many political compromises, not always with logical delimitations and legal rules. The Governing Body decided to start a new process, one in which not only the access side will be dealt with, but also the benefit-sharing side. The idea is to explore the potential to expand the scope of the MLS from the 64 crops and forages covered by the MLS and to improve the mechanisms for benefit sharing. The list was agreed as a political list, and is not based on a plant breeding rationale. It has been deemed necessary to assess and review it.

The current benefit sharing system is based on two different approaches to payment embedded in Art. 6.7 and 6.11 of the SMTA respectively. These two approaches are being used as the point of departure for the discussions, with a view to establishing a system enabling a consistent and coherent sharing of benefits.[12] The aim of the ongoing work is to be presented for the next Governing Body in 2015.

2.2.3 The EU ABS regulation and the due diligence obligation for users

The EU sought in its presentation to explain the system for implementing the NP in the European Union. The EU's approach is that the CBD establishes principles. The EU is, according to the presenter, of the understanding that the CBD does not provide for user country measures. The NP is therefore the instrument for implementing the ABS. Against this background, the EU ABS regulations apply only to GR that are accessed after the entry into force of the NP, and will apply only to access in NP member countries. There is a one year transition period before these obligations enter into force for users of genetic resources in the EU. NP Art 4 and 8 list the exemptions from ABS that are allowed by the NP. The EU will treat other genetic resources in an equal manner as long as they fall within the scope of the NP.

Of the three topics, *access*, *benefit-sharing* and *compliance*, access will be addressed in national legislation and each EU country will decide their own regulations on access to their GR. Therefore, there are no provisions on access. Nor is there any article dealing with benefit-sharing; this will be left to contractual regulations between the individual user and the country where the genetic resources are collected. The regulation aims at establishing a level playing field among the 28 member countries and

[12] *Standard Material Transfer Agreement* [SMTA], ITPGRFA Governing Body, 16 June 2006, Resolution 1/2006.

maintains the focus on the compliance of users of genetic resources with the access legislation of the provider.

The crux of the obligation on the users of genetic resources is *due diligence*. This means that every user falling within the scope of the regulation is obliged to undertake *due diligence* themselves. For users obtaining the GR from a registered collection, the collection will easily be able to show whether they comply with the regulation or not. An optional tool is 'best practice', which shows more easily whether the user is part of an accredited best practice organisation. While *due diligence* is the obligation of the user it prompts the question of what *due diligence* means and implies from a practical perspective. *Due diligence* means to seek and transfer information about when the user obtained material, where the user got the material from and what the material comprises. Users must know what they are entitled to do with the material, including whether there are any special conditions forbidding the transfer of the material. The user must be in possession of this information at all times. In the case of a company failing to meet its *due diligence* obligations, if there is no PIC when required from the providing country, the company must discontinue its utilisation.

How to prove due diligence? There are different approaches to meeting the *due diligence* obligation. One is to have the international recognised certificate made from the clearing house system of the CBD. The certificate would be the easiest way to do DD. Also getting access from a registered collection is also a manner in which a user easily can meet the *due diligence* obligation. For plant genetic resources, providing that the PGR is achieved from the MLS would meet the *due diligence* obligation.

The NP requires a public law system for monitoring compliance. The EU has identified the point of time of research funding as one checkpoint at which the user must demonstrate compliance with the access legislation of the provider country. The EU also opens for random compliance checks subject to national law. The system of compliances will be linked to penalties at the national level, but the manner in which this will be organised is left to the discretion of each nation-state.

2.2.4 Initiatives for ABS under the Commission on Genetic Resources for Food and Agriculture

Initiatives to improve ABS under the Commission on Genetic Resources for Food and Agriculture – what is the current situation? Plant genetic resources was the only genetic resource area in which the Commission was engaged with respect to ABS until 2007. The 2007 meeting of the Commission expanded the scope of the mandate by including more groups of genetic resources. The CGRFA organised special ABS seminars based on the 2009 background study papers.[13] These papers document the special features and the practices of the different sectors. They were submitted to the negotiations of the NP as background study papers from the CGRFA and inf-docs at the 2010 Cali meeting. The

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Commission had to respond to the NP; it is action-oriented and the study papers were submitted to influence the negotiating parties.

The majority of the proposals from the Svalbard meeting (2011) were incorporated in the decision of the CGRFA, in which 20 features for GRFA were identified. In this long list of recommendations, the development of a matrix to illustrate what happens in each of the sectors was a core one. One challenge is to identify how the funding strategies of the different sectors could be made into an ABS system.

Members of the Commission were encouraged to report on how the GR in sectors are being exchanged, as a background to developing the framework for the sectors. Work is ongoing to establish action plans for genetic resources in each of the sectors. The draft elements aim at facilitating the domestic implementation of ABS for the different sectors by identifying what could be important for each sector. A team of technical and legal experts met in Rome in July 2014 and the report was presented to the Commission in January 2015.

The experts compiled a checklist on how countries can go about developing their own access regulations, i.e., by looking at sectors using GRFA. The CGRFA shows what the structure of the ABS measures could look like. The aim is to furnish ideas on the implementation structure for countries that are making their own national ABS system. The elements included in the first draft deal with many of factors countries need to consider when establishing their own laws. One core question concerns the difference between 'utilisation' of privately and publicly owned GRFA. The discussion in the CGRFA is very access-oriented, and not as focused on the user side of ABS or compliance with the national regulations in the provider country.

One core question for the CGRFA is how to avoid the tracking of genetic resources. Tracking genetic resources for food and agriculture is often regarded as being burdensome and complicated in agriculture. This is an interesting perspective as the NP goes in the opposite direction by establishing a system of certificates of compliance precisely to enhance the tools for tracking where the genetic resources have been used.

Many of the experts provided by the CGRFA are involved in national law-making in their home countries. There is a need to discuss the distinctive features of each of the sectors for the purpose of gaining a better understanding of the broader background of challenges to national implementation in the various sectors. Other questions to be addressed include: Can subsectors have particular legislation? Is there room and discretion to differentiate between domestic users and foreigners in the regulations? The next meeting of the CGRFA in January 2015 the Commission adpted 'Elements to facilitate domestic implementation of access and benefit-sharing for different subsections of genetic resoruces for food and agreiculture'.[14]

[14] See http://www.fao.org/nr/cgrfa/cgrfa-meetings/cgrfa-comm/fifteenth-reg/en/

2.2.5 The European gene bank community's provisions for PGR under the auspice of the international treaty

The European gene bank community's provisions for PGR under the auspices of the international treaty. The European gene bank community is handling PGR by a footnote version of the sMTA. ECPGR has 43 member countries. One of the ECPGR's main achievements is the EURISCO. Only four countries have included their accession of plants as European accessions in collections. The process of including material has been very slow.

Under the 2003 Kalmar Declaration, NordGen (Nordic Genetic Resource Centre) shall apply the same SMA for food and agriculture. This includes using the s-MTA for non-MLS and hobby uses. For material collected before the entry into force of the ITPGRFA, there is a footnoted version to allow for distribution of non-Annex I material on the same terms. Europe as a region has always wanted to include more than Annex I material. One difficult question when using the s-MTA for non-Annex I accessions is whether the Third Party Beneficiary (TPB) should handle non-Annex I material. One alternative could be to use the s-MTA but without using the TPB. Whether all the institutional structures supporting the implementation of the MLS would be triggered also for non-Annex I material is a fundamental question in urgent need of clarification to increase legal certainty for users of non-Annex I material.

Another core issue is the situation for PGR outside the present collections, mainly material in situ. What are the conditions for access to this material? Countries have been very slow in assigning their material to the open ABS system. In principle, these accessions are covered by the general Nagoya-based ABS legislation in the country in question, unless steps have been taken to establish specialised rules.

3 Taking stock: What is the ABS situation in the Nordic countries?

3.1 ABS in Norway – the Nature Diversity Act, Marine Resources Act and the administrative order – current status

The main acts are the Nature Diversity Act and the Marine Resources Act.[15] An assessment of compliance of current acts with the NP is ongoing. The Nature Diversity Act was amended with the addition of a new section, numbered 61A, as a step in improving harmonisation with the NP. Norway has ratified the NP.

[15] *Naturmangfoldloven / Nature Diversity Act*, Norway, LOV-2009-06-19-100 and *Havressurslova / Marine Resources Act*, Norway, LOV-2008-06-06-37.

The current situation is that access to genetic resources in Norway is free until otherwise determined by the 'King' (i.e. the government) by administrative order. Were that administrative order to be made, the government would have the authority to require parties to obtain a permit. Both the Nature Diversity Act and the Marine Resources Act give the government wide discretion to regulate access to genetic resources on land and in sea, with some particular rules for agriculture/plants. In December 2012, a written public consultation was carried out on an administrative regulation. The core feature of the draft is the permit and MAT/private contract requirement. It specifies the duty of monetary benefit sharing which includes a progressive milestone payment gross turnover. The stakeholders are generally content with the permit system, but many called for an easier, less cumbersome/time-consuming application process. The business community representatives were against the level of monetary benefit sharing and the products. The proposal was considered fair, transparent and unlikely to encumber business operations. Core questions that still need to be answered when (and if) the regulation is adopted concern the type of benefits that shall accrue to the state, when they are due and how they should be shared with Norway. According to one observer, the Norwegian draft is similar to the current proposal in Brazil.

Norway as a user country was among the first to adopt a targeted rule placing clear obligations on users of foreign genetic resources. Section 60 of the Nature Diversity Act sets conditions on the import of GR into Norway with a view to ensuring compliance with provider country regulations, and establishing rules for dealing with non-compliance.

> Section 60 (genetic material from other countries)
>
> The import for utilisation in Norway of genetic material from a state that requires consent for collection or export of such material may only take place in accordance with such consent. The person that has control of the material is bound by the conditions that have been set for consent. The state may enforce the conditions by bringing legal action on behalf of the person that set them.
>
> When genetic material from another country is utilised in Norway for research or commercial purposes, it shall be accompanied by information regarding the country from which the genetic material has been received (provider country). If national law in the provider country requires consent for the collection of biological material, it shall be accompanied by information to the effect that such consent has been obtained.
>
> If the provider country is a country other than the country of origin of the genetic material, the country of origin shall also be stated. The country of origin means the country in which the material was collected from in situ sources. If national law in the country of origin requires consent for the collection of genetic material, information as to whether such consent has been obtained shall be provided. If the information under this paragraph is not known, this shall be stated.

Section 60 leaves it to the discretion of the government to choose whether to prosecute Norwegian users of foreign genetic resources. Sections 69–75 of the Nature Diversity Act specify sanctions for non-compliance with the act as a whole and, therefore, the user country's legislation. No

prosecutions have been brought, and one might feel tempted to ask why. There are several possible explanations. It might be due to lack of awareness, lack of control, or even lack of relevant cases. No systematic investigation has been made of this matter so far.

Traditional knowledge associated with genetic resources: Amendments to the Nature Diversity Act of 10 June 2013. The king may institute a regulation of Traditional Knowledge associated with genetic resources. An interdepartmental working group will be working with a reference group to clarify questions related to TK associated with genetic resources.

Regulation of access is a complex issue and in need of resolution. There are a number of parallel questions arising in more countries. What should the fee level be? There is a common challenge to develop and designate the check-points for compliance. Plant Variety Protection offices, patent offices, Norwegian Research Council and others might be assigned in the future. If the regulation is adopted, an office must be designated as the competent national authority.

3.1.1 ABS in Finland

Finland had not ratified the NP as of September 2014 – essentially because the bill was still being drafted – and will therefore attend the next COP as an observer.

Finland will follow best practices and update the terms for collections as outlined in the EU regulation. Various ministries, stakeholders, indigenous peoples and NGOs are represented in various working groups. One of the questions these groups will address is the establishment of check points to meet the NP obligations. Finland has few endemic species. ABS legislation requires an evaluation of Finnish GR to assess whether certain GR can be excluded because they threatened by extinction. Microbes are probably the grouping of genetic resources with the most potential. Finland has never had an ABS law, so ABS will be a new area for regulation. The Finnish government aims for it to enter into force spring 2015. It is proposed that it should not be legal to import GR without permission. The selected focal point is the Finnish Environment Institute. Identification of additional check points is pending; one potential check point which has been discussed is the Finnish Research Council. The Customs Authority is willing to act as a check point, not least because it has experience of CITES. Questions have been raised as to whether the Customs Authority really is the best-suited institution to be following up ABS. The pharmaceutical and cosmetic industries are strong in Finland, but they preferred not to comment on the draft ABS law. There has been a discussion in which interest holder have expressed apprehension of multinational companies sampling and patenting the microbial material. This has triggered a discussion of the requirement to register collecting activities with the authorities, but Finland is probably not going to introduce any PIC/MAT requirement yet. It is more likely that Finland will require those involved in collecting activities with commercial intent to register whether they have been sampling from a specific area, rather than requiring a full PIC before sampling.

3.1.2 ABS in Sweden

A survey carried out in 2014 found that between 3,000 and 4,000 scientists and 60–70 institutions were using GR collected in or received from other countries/sources. Pharmaceuticals are probably the most comprehensive area in Sweden. The survey found a high degree of exchange among scientists, but a more limited collection in the field. There is little awareness of ABS among users of genetic resources. Examples of benefit sharing include collaborations with researchers in the country where the GR are being collected. Collection in two areas has been particularly important: drug-resistant malaria and antimycobact.

According to the Swedish EPA, there are plans to draft a separate law on GR. There are a number of administrative measures pending, including whether there should be one or several competent national authorities. The proposal includes a framework law which will leave more discretion to the government. In all likelihood, access to Swedish genetic resources will not be regulated, although some form reporting requirement is on the agenda. PIC will probably not be required of, as one does not foresee large revenues from the use of genetic resources imported from Sweden. One question is whether a landowner could/should have any a say in the question of access and use of genetic resources. The government is not looking to regulate access, as natural resources are not an important political issue. Sweden is looking at ratification in 2015.

The proposed regulatory bill does not include any measures on benefit sharing. Research and development are often linked to collaboration with developing countries. Therefore, choosing to work actively with research institutions to promote collaboration, rather than passing a legal requirement on benefit sharing, would seem the most sensible strategy.

3.1.3 ABS in Denmark

Denmark does not require PIC with a process of stakeholder participation. A new act was passed by Parliament in December 2012, leading to the ratification of the NP in May 2014. The act only covers user country measures. Greenland (as a provider) has separate legislation. For the Faroe Islands there is a legal vacuum in that no legal acts have been made so far. These are the three parts of the Kingdom of Denmark. There will be a forthcoming requirement of notification when collecting GR in Denmark. The notification will act as a certificate specifying the legal status of the accessions. The act prohibits the utilisation of GR and associated TK in breach of the laws of the country in which they were accessed. The sanctions are fines or two years of imprisonment when the offence is committed wilfully or because of severe ignorance. The act equates foreigners and Danish nationals wanting to open a case for illegal use of genetic resources. Denmark will follow the EU regulation, and will establish check points in the funding of research projects and product approval procedures. The Patent Act requires the origin of the biological material included in the invention to be disclosed.

3.1.4 ABS in Iceland

There are three acts of relevance to genetic resources in Iceland. A new act was passed in 60/2013 regulating GR. There were three or four questions the new government wanted reviewed. They will probably be addressed in the new Nature Conservation Act. Act 57/1998 regulates the rights to GR in the hot springs. Agriculture is regulated under Act 151/2005, which also regulates the link to ITPGRFA. Iceland has not signed or ratified the NP.

Article 34 of Icelandic Act 57/1998 on the survey and utilisation of ground resources,, covers everything in the ground. Art. 34 was introduced late in the process and applies to bacteria etc. in geothermal areas ('This Act covers resources in the ground, at the bottom of rivers and lakes and at the bottom of the sea within netting limits ... Netting limit in this Act means a water bottom 115 metres from the shores of a lake adjacent to a property, and a sea bottom 115 metres from the low water line of a property.'), utilisation is prohibited without a license. The Icelandic Institute of Natural History is responsible for prospecting and utilisation, according to Regulation 234/1999 issued by the Ministry of Industry in consultation with the Ministry of Environment. It establishes three license types, academic licenses, research licenses and commercial licenses. The utilisation license is a separate type of license. Here a separate PIC from the landowner is required. The license does not give/transfer any property right to the outcome of activities conducted under a research license. The researcher has to log all activities and report at the end of the license period. It is an open question whether a license to use also gives a right to commercial utilisation of the material or the derivatives.

Several Icelandic genetic resources are of interest to science: thermophile bacteria, extreme thermophile bacteria, enzymes, biofuels, aqua-culture, certain activity in the plant sector. There is a high degree of collaboration among the people working on genetic resources in Iceland. Systematic work started in 1975 towards developing products for the market. A number of geothermal areas have been identified. When this was done, a company expressed an interest in collecting, and obtained a collection permit for half of the areas.

3.1.5 Traditional knowledge – where is the process in the Nordic countries? A particular view to cross-border TK

The next topic to be explored was traditional knowledge, with a view to where the process in the Nordic countries stands. The right of the indigenous peoples in the Arctic is linked to the use of the natural resources and to the use of landscapes. The normal situation is for states to have many indigenous peoples. In the four Nordic countries, however, there are only one people. The Sámi share a common language, flag, and national anthem. The total population of about 23,000 is relatively small. They all speak the Sámi language. The 1990 ILO Convention is an important tool. In Norway the Sámi are protected under section 108 of the Constitution, following an amendment in 1988.

The Sámi Parliamentary Council is linked to NP Art 11 which requires parties to consult the Sámi population on ABS questions. The Sámi should be empowered to give their free PIC and fair and equitable benefit sharing as part of the access procedures. The Nordic Sámi Convention Art. 31 has important rules on this topic. An expert group recommended that the Sámi people should decide relevant questions concerning access. Norway and the Sámi are involved in a consultation concerning the ABS area. The process was undertaken before the amendment of section 61A of the Nature Diversity Act (2013). Work is ongoing concerning traditional knowledge, the Árbediehtu Project on acquired knowledge. The main focus of the TK project is Birgejupmi which translates as survival capacity / maintenance of life / sustainability.

4 A closer look at plant genetic resources

4.1 Implementation of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) in the Nordic countries

The Nordic countries have a long tradition of cooperating in the area of plant genetic resources. The establishment of the Nordic Gene Bank (NordGen) in 1979 by the Nordic Council of Ministers was one important such step. The opening of the security storage facility on Svalbard before the security collection was made global was another important collective Nordic step. The Kalmar Declaration defines the status of the PGR in NordGen. Conservation of PGRFA depends on active use of the material. One important issue was to treat all accessions in NordGen in the similar manner; it would have been very burdensome to have different procedures according to the origin of the material. The accessions in NordGen are all covered by the same regulation. It extends to all purposes, including purposes not related to food or agriculture, and all other areas of research and development.

For non-Annex I accessions, NordGen uses a modified s-MTA, based on the s-MTA of the ITPGRFA. The FAO was designated to be the Third Party Beneficiary of s-MTA accessions. NordGen has a special set of instruments for hobby uses of PGR, i.e. not for research or development.

The functional implementation of NP and ITPGRFA depends on NordGen functioning smoothly. NordGen should not hamper cooperation among Nordic programmes. The Nordics explicitly recognise s-MTA for NordGen as sufficient documentation. The Third Party Beneficiary needs to use the information made available as the Nagoya Protocol check point.

One remaining question is how the Nordic policies address privately held PGR. It is problematic when private companies access material from the common collections, and eventually keep it in their own private collections. This constitutes a risk of privatising the collections, especially if the public collection later loses its funding and is unable to

maintain the material. It is a challenge to the openness of NordGen and the collections covered by MLS.

4.1.1 Nordgen: Collections in the MLS – what is the situation for material on its way into the collection?

One unresolved issue concerns material in transit in NordGen, that is, material which is not yet in the 'public domain' and not covered by the MLS. Many landraces in the Nordic countries have been lost, and it is costly to conserve wild relatives because of the regeneration process. The mandate of NordGen is to look after plants of Nordic origin or of Nordic relevance. There was a time when all the gene banks held identical collections. This led to redundancy. However, the common Nordic collection made gene banks more effective. NordGen has an online ordering system. FAO's global plan of action and strategic action plans are important documents for NordGen. The Kalmar Declaration provides important guidance for the activity at NordGen. Some questions remain to be answered and clarified, however.

There is a potential to include the national cloning archives in the MLS. There are a number of questions connected to material on its way to the collection. Does it belong to different countries while in transit or in a collection? Does the country which deposited the material retain any rights in the material? What is the legal position of the farmer sharing accessions with the Nordic Gene Bank? Does the farmer retain any rights to the accessions or material he shares? What happens to non-annex I and research and development in non-food and non-agriculture? The Nordic countries need to clarify status and whether the material becomes part of the MLS.

What happens if a country withdraws and does not want to exercise its sovereign rights over GR through the common Nordic approach and apply the s-MTA beyond its mandatory scope? This is an additional open question. Access on the terms of s-MTA is stricter than if the PGR remained unregulated. Applying s-MTA beyond its mandatory scope counts therefore as a stricter regulation than if these genetic resources are unregulated. Regulation, however, might provide greater legal certainty, more secure access, enhance exchange and stimulate use.

4.1.2 Plant breeders organisations and seed organisations: Importance of breeders privilege and access to genetic variation seen from plant breeders actual situation

Plant breeding is a core activity for the purpose of bringing new varieties to the market. One of the presentations offered a review of the plant breeding. It is crucial to have access to variation in plant breeding. There are large differences among breeding companies. Some cover the whole value chain and others only provide a more specialised service for other breeders. Large integrated companies do not have the same need to participate in the MLS since they already hold large collections.

The EU regulation of ABS is perceived as a constraint on the use of the breeders' exception under the UPOV Conventions. A court case is

pending the core question of which is whether the EU ABS Regulation can be upheld or whether it is in conflict with the breeders' exception under the UPOV Conventions. It is not easy to understand at first glance how EU's implementation of the NP is hindering plant breeding. One argument was that the NP removes the public domain from plant breeding. Another is that since sovereign rights last longer than an intellectual property rights (20 years) there is no time specification in the NP or the CBD. One question that came up was whether a variety protected by a PVP falls outside the scope of the CBD.

5 Private sector and involvement in ABS – user contribution or payment? Practical examples of bio-innovative value creation in the Nordic countries

5.1 Private sector and involvement in ABS – User contribution or payment? Practical examples of bio-innovative value creation in the Nordic countries

In Section 5 the private sector perspectives on genetic resources and ABS is discussed.

5.1.1 How does enzyme technology relate to ABS?

Enzymes have been used for thousands of years. In 1917, patent was granted to a *yeast* to Carlsberg, the laboratory at Carlsberg and to Chr Hansen. Other relevant enzymes are industrial, and such that produce insulin and trypsin. The question is with whom business shall share benefit, the person bringing the enzyme to their attention or the elephant hosting the isolated enzyme. The product is based on a microbe residing in the elephant. Enzymes are found in nature.

Few countries have legislation or clear instructions about where to go to obtain a permit. Previously, Novo did the collection work itself. There is a company in Thailand that collects enzymes, for example. Now, however, the company farms out contracts to small companies that do the collection. These companies are providing something the customer is looking for when setting up the assays that will be used in the innovation. The country of origin provides the plant, but not the enzyme. Novo looks after the microbes. Testing must be done on thousands of candidates before finding one that is suitable for use as a product. Production strain and product approval are a time-consuming process. The research process in the company is costly and takes time; still, the source country has provided a plastic bag of soil. There is a difference between nature's diversity and artificial diversity. Mankind can create diversity in the laboratories. There is an ongoing molecular evolution, where millions of microorganisms are being produced. However, innovation always needs natural diversity. Is there a need to go to Greenland or Finland? It is so cheap nowadays to sequence a DNA, the scientist sequence a whole

genome, not only a single gene. Sequencing the whole genome (rather than the gene) is the fastest and cheapest option. Based on sequencing, one can search the databases and look for useful enzymes. The industry is able today to synthesise the gene, and this is getting cheaper as well.

Everything we put through professional screening is connected to a PIC. The biotechnology branch assumes there is no retroactivity in the CBD/NP for samples collected. The industry knows where the material came from, and that it was collected legally under the laws applicable at the time.

Now are we at a crossroads, the NP is in force and some countries have legislation like the EU Regulation. EU member states have yet to introduce legislation at the national level. The enzyme industry does not have to go abroad to find diversity, it is often right outside the door. Take a soil sample from the grounds of the FNI and you might find something interesting. If sampling is being conducted on interesting sites, volcanoes and suchlike, the company will enter into an agreement with the relevant country.

ABS is not about inventions. ABS is not a new set of patent criteria. ABS cannot act retroactivity, regulating the past on the basis of new rules. There is a need to increase the level of legal certainty. The industry is still in a limbo. The industry needs clear rules. In Denmark industry has to notify the government when we go bioprospecting. Research and development in different countries is regulated by different rules. For example, access in the US is mostly open, but you have to steer clear of national parks and private land. Companies need the authorities to give them clear signals. At the moment, we only have the EU regulations. We need regulations that are more specific and detailed to give legal certainty. The regulations were based on consultations and discussions. The industry is looking forward to clarification best practices and registered collections.

5.1.2 Aquatic Genetic Resources, value creation and ABS

Norwegian salmon breeding is a story of success based on the strategic use of genetic resources. Forty years of systematic breeding has gone on in Norway, using genetic material sourced from 40 rivers in the country. The Bred salmon yield about four times more fish meat than un-bred material. In the salmon breeding sector, IPRs are relatively new. All the strains that are used in breeding currently are privately owned by private companies now.

At the global scale, around 10 per cent of farmed fish have been bred systematically. This means that in the aquatic sector, there is a huge potential to increase value creation. Fish breeding is biotechnology, but there is no drive towards GMO in the sector in Norway. There were a discussion on whether the use of IPRs would increase the income of the breeding sector, but the industry maintains that information sharing remains a valid strategy for them. It is difficult to keep records and track of where the improved material is being used.

5.1.3 Access to viral genetic material – illustrated with the pancreas disease case

In the pharmaceutical industry, the challenge is to find the pathogen that leads to the disease; to identify the virus and turn it into a vaccine. This includes a level of testing. Testing is largely fundamental science. In this process you have to survey the variation in the virus. You need to search the broadest or most meta-genetic material, whichever is the most characteristic. When Vibryosis was introduced to the market, salmon production rose, and the use of antibiotics exploded. When the vaccines were introduce, the use of anti-bacterial agents dropped. Efficacious vaccines can solve the problems of bacterial diseases.

In pancreas disease (PD), the true reservoir of the virus is not the salmon, but another organism. Perhaps it comes from insects, and sometimes jumps over to salmon. The origin of the virus is not known. It was isolated by a veterinary institution in Northern Ireland, patented, then sold to Intervet, who sold it to Merck. Merck produces vaccines, but also uses the patent to prevent other companies from developing vaccines against the same disease. The PD case illustrates more patent questions than questions related to ABS, since the PD virus's place in the Norwegian common pool of resources has never been legally tested in court.

5.1.4 International gene flow of animal genetic resources and ABS implications

There are significant differences between animal and plant breeding. It is not easy to apply the DUS criteria to animals as it is to plants. The DUS criteria are for the protection of new plant varieties. The new variety must be novel, distinct, uniform and stable to be eligible to a plant variety protection right. In the animal sector, genetic variety is mainly found in the breeding population. Large public gene banks for animal genetic material are uncommon. And live farm animals and their genetic material are usually own by private individuals or entities. This affects the application of the ABS rules for the most intensively bred species in the animal sector. Exchange is not the same as it is for plants, and is mainly governed by private law contracts.[16] There are also large differences among the breeds of animals used in food production and between the different species used in the production of food. The biology and breeding methods determine the manner in which access and benefit sharing are implemented and function.

5.1.5 Managing the expectations – ITPGRFA from a business breeder perspective

It is important to manage expectations to benefit sharing. The private sector does not understand the rationale of the NP and benefit sharing. It

[16] Hiemstra, et al. *Exchange, Use and Conservation of Animal Genetic Resources*. Wageningen, Centre for Genetic Resources (Netherlands), 2006. (CGN Report, no. 2006/06).

was asked whether NP is a convention of equity. It is difficult, moreover, to identify the country of origin of food plants. Where does a plant variety come from originally? And who is paying whom when the material is not originally from the region? Sugarcane is moved from the Pacific through the Middle East. Brazil is earning a great deal from sugarcane. What is the value? The grass in your parking lot has no value. Knowledge has value. When knowledge of the plant increases, so does the plant's value.

The modern plant breeding sector uses modern varieties; it does not go back in time to old landraces or gene banks. Only if you don't find material in your local gene bank would you go back to nature. The pedigrees of a modern variety are complex because they have a multitude of ancestors. Since each contributes only a tiny piece, it is difficult to put a value on any particular ancestor.

Companies' negotiation power falls considerably after completing research and development. For that reason, the industry opposes a two-step model for access and benefit sharing.

What can you expect from benefit sharing, when you have a lot of crossing of different plant accessions? The EU focuses on compliance. Should companies be obliged to conduct *due diligence* on genetic resources that are in the public domain? The private sector does not normally assume responsibility for undertaking a process of *due diligence* on material that is in the public domain. The cut-off point (temporal scope of the obligations) is the present, but what happens in the future? There needs to be a level playing field and the differences between companies can be significant.

Do private companies have a responsibility to conserve biodiversity? Companies develop new varieties, and are already adding to the gene pool. Businesses also support the collection of new material on occasion. But the responsibility of maintaining biological diversity should not be carried by the business sector.

5.1.6 Lessons from Down Under – experiences from the Australian case[17]

Australian ABS legislation is advanced and pioneering in giving national effect to the third objective of the CBD with mandatory permits for all biodiscovery and mandatory benefit sharing agreements for biodiscovery with a commercial intent. Nevertheless, under Commonwealth legislation there is still only one biodiscovery case involving commercial benefit sharing. This is spite of persistent interest in biodiscovery.

One lesson is the need for improving the dynamic element in ABS contracts, also building in a clearer trigger point for when the obligations

[17] This section is the introduction from the FNI Report, Prip, et al. *The Australian ABS Framework - A Model Case for Bioprospecting?* Lysaker, Fridtjof Nansens Institutt, 2014. (FNI Report, no. 1/2014).

to share are actualised and to reverse the burden of tracking and follow-up to the user rather than leaving it to the provider. If a rich country like Australia lacks sufficient resources to follow the future development based on its material, this speaks volumes for poor provider countries. Linking the ABS and IPR legislation through disclosure of the source of biological resources in patent applications can be an appropriate legal measure to track compliance. Also, the statutory declaration in Commonwealth legislation is a legal instrument that could bind the user to Australian criminal law, although this holds a more limited prospect for following and tracking genetic material if it is transferred to third parties. This indicates that building on general legal instruments for making the ABS regime work is a fruitful way forward.

Australia played an important role in the negotiations leading to the Nagoya Protocol (NP), and its legislation inspired some of the Protocol's provisions. On that basis, and being a megadiverse country with extensive ABS experience and wide support by the biodiscovery stakeholders to the NP, it would seem obvious and in the interest of the country to become a party to the NP. The outside world would also benefit from Australia being a party because Australia has learned many ABS lessons to be shared with other parties of which many will not have come nearly as far in their ABS experience. Among others, there are lessons about drawing up an effective regulatory system, but also about legal challenges for federal nations with mixed jurisdictions between the federal and state level. These lessons concern partnerships between public academic institutions and the private sector with great benefits for both parties, as well as difficulties in distinguishing scientific from commercial biodiscovery and defining roles.

5.1.7 ABS Capacity Building Initiative

Norway, Germany, Denmark and the EU support the global capacity building initiative for implementation of ABS. The FNI is working closely with other partners in assisting analyses and capacity building. Joint efforts involve Brazil, India, South Africa and a number of other countries on sharing and exchanging lessons learned in ABS implementation under this umbrella. The FNI has the last six years contributed to the ABS Capacity Building Initiative providing research and competence building in Africa and the Pacific.

6 Summing up the discussions

Repeatedly during the discussions, the question of IPRs comes up in the context of ABS. There was a lot of focus on the business perspectives towards ABS. The relationship between the ITPGRFA and the NP/CBD also merited attention. The discussions in the Commission on Genetic Resources for Food and Agriculture (CGRFA) and the next meeting in January 2015 were a topic of discussion.

There was general recognition of the need for a continuous meeting place where different groups of users of genetic resources, policy makers and lawyers working in the field could come together. Some wanted a similar workshop to be held annually. The Fridtjof Nansen Institute and NordGen offered their services as possible co-hosts of such a meeting and would absolutely pursue the idea.

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Fridtjof Nansens vei 17, P.O. Box 326, NO-1326 Lysaker, Norway
Phone: (47) 67 11 19 00 – Fax: (47) 67 11 19 10 – E-mail: post@fni.no
Website: www.fni.no