New ABS Instruments Adapted to Genetic Resources for Food and Agriculture

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1. Context and questions to explore

The Commission on Genetic Resources for Food and Agriculture (CGRFA) has been discussing access and benefit sharing (ABS) for certain groupings of genetic resources for several years parallel to the ongoing negotiations under the Convention on Biological Diversity (CBD). The Nagoya Protocol (NP) was agreed in October 2010.[2] In July 2011, the ABS discussions under the CGRFA gained pace by the mandate to explore ABS in relation to specific sectors, *i.e*. farm animal genetic resources (AnGR), forest tree genetic resources (FGR), aquatic genetic resources (AqGR), microorganisms genetic resources (MicGR), invertebrates and ABS for plants outside the scope of the Multilateral System under the ITPGRFA. One underlying driving factor goes towards developing special instruments for genetic resources for food and agriculture (GRFA).[3] In the last meetings the discussions have concerned elements to facilitate domestic implementation of ABS to different subsectors of GRFA.

The discussion presented for the CGRFA concerning whether there is a need to develop new instruments under the Commission is based on the following rational:

- to ensure food security
- to facilitate continuous and enhanced exchange and use of GRFA
- to "maintain" global governance in the agriculture sector
- to facilitate recognition of the interrelationship between all GRFA

It seems to be a tacit assumption here that to implement the NP will lead to restricted and reduced access, and in turn constitute an obstacle to efforts to ensure food security. There is, however, little empirical evidence that a careful implementation of the NP will have this effect. The level of experience with national systems based on the NP is limited due to the short time it has been in force.

It is also not the objective of the NP to reduce access and exchange of genetic resources. Thus, domestic implementation needs to balance these needs to genetic resources while seeking

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, 29 October 2010.

3 Chiarolla, *et al*. "An Analysis of the Relationship between the Nagoya Protocol and Instruments related to Genetic Resources for Food and Agriculture and Farmers' Rights" in *The 2010 Nagoya Protocol and Access and Benefit-sharing in Perspective*. Edited by Morgera, *et al*. Leiden, Martinus Nijhoff, 2013, p. 121.

to avoid that the NP becomes an obstacle for these purposes. There is a need to discuss and better understand the gene flow and potential in exchange of genetic resources for food and agriculture outside the plant sector. In this report these questions are raised with the aim of posing the questions relevant for a country like India when managing access to genetic resources relevant for food production. This report will have a dual perspective looking at the global perspectives and seeking to include Indian situation.

A core perspective that has been left out of the CGRFA debate so far is the consequence of growing use of intellectual property rights especially in breeding methods, and concentration in ownership will lead to hyper-ownership.[4] The application of patents is particularly comprehensive in the area of micro-organisms inasmuch as the TRIPS Agreement Art 27.3 defines micro-organisms also in the agriculture area as mandatorily patentable subject matter without exception. Exactly how the patent system applies to special areas of innovation and its effect on innovation in different areas, especially in the agriculture branch, is rarely discussed in any international forum. Indeed, whenever the issue is raised in the Commission of the CGRFA, the World Intellectual Property Organisation (WIPO) is frequently held up as the right forum for these topics. Countries therefore refuse to take patent issues on the agenda of the CGRFA. But none of the forums under the WIPO discuss the consequences for specific sectors of innovation and much less on agriculture, as WIPO-discussions are mainly held at an overall and aggregated level and do not go into the special details in any sectors for innovation. When the CGRFA is discussing in detail the establishment ABS systems for single sectors, it will need to maintain a focus on patent law because the sovereign rights of countries over genetic resources are often interlinked with patents.

The link between patenting and access & benefit sharing is a topic which India hopefully maintains as a main focus in the different international arenas. This is particularly important when the topic for the discussion is to establish a common pool of resources, since a common pool is exposed to appropriation by the use of patents.

4 At the Fourteenth regular meeting in the Commission it was suggested by African country to undertake a study of intellectual property rights' effect on food production.

2. A Short Look at the History of the CGRFA for Genetic Resources

Focus on access and benefit sharing (ABS) with regard to genetic resources for food and agriculture emanated from the FAO's Commission on Genetic Resources for Food and Agriculture (CGRFA) as early as 1983. There was a call for recognizing the specific contributions of farmers to conservation and sustainable management of agricultural genetic resources using the concept of Farmers' Rights (FR).[5] The premise of those debates included that farmers and farming communities have expended effort, energy and knowledge to breed crop plants for generations and their selections have led to inclusion of unique characters to the germplasm across the world that formed a significant role in commercial breeding of crops leading to increasing food security as well as economic gain by the breeders.

The need to recognize the contributions of farmers in crop improvement was not only discussed in the context of crop genetic resources but also covered the associated traditional knowledge using better, adaptable germplasm. During the 1980s especially developed countries argued for plant genetic resources to be regarded as a special 'common heritage of mankind' under the UN Food and Agriculture Organisation (FAO).[6] This entailed an open-access system proposed for plant genetic resources. Parallel in time, patents and plant breeders' rights were increasingly securing the commercially inventions in the plant breeding field and to new plant varieties. The 'common heritage of mankind' of the 1983 International Undertaking was however abandoned by a new resolution in 1991.[7] The concept of 'common heritage of mankind' in the FAO Undertaking did not prescribe mechanisms for any benefit sharing. Due to the increasing application of IPRs, the unbinding International Undertaking in the FAO had already abandoned the view that plant genetic resources are under an open access system before the CBD explicitly reconfirmed the sovereign rights for countries.[8]

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5 Brush. "Farmers' Rights and protection of traditional agricultural knowledge" in *World Development* 9 (2007) 35, pp. 1499-1514.

6 *International Undertaking on Plant Genetic Resources*, FAO Conference, 5-23 November 1983, Resolution 8/83, entered into force 23 November 1983.

7 Plants. *Explanatory Notes on the Definitions of Variety under the 1991 Act of the UPOV Convention*, Geneva, 2010 (UPOV/EXN/VAR/1).

8 Rosendal. *The Convention on Biological Diversity and Developing Countries*. Dordrecht, Kluwer Academic, 2000

However, FAO did not agree to any specific legally binding instrument until 2001 when the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) was adopted by its member states. The ITPGRFA includes specific provisions to establish a system for multilateral access to plant genetic resources for food and agriculture and for particular purposes (MLS). Thus, under the ITPGRFA countries use their sovereign rights over plant genetic resources to make some specific accessions of them available openly and on specific terms. The MLS uses a standard material transfer agreement (SMTA) to govern the access. The SMTA establishes trigger points for benefit sharing where the basic principle is that the benefits shall flow into a global fund to benefit farmers rather than back to the individual countries. However, the manner in which this trigger point was defined, it has become clear for the Governing Body of the ITPGRFA that no or very few benefits mandatorily will be shared.[9] Therefore, a renegotiation of the SMTA is currently ongoing.

The Plant Treaty also calls for contracting parties to establish provisions related to Farmers' Rights at national level, subject to national conditions and priorities.[10] Some few countries, such as India, have established specific legal instruments to deal with the overarching issue of breeders' and farmers' rights using *sui generic* options. Whereas an increasing number of countries are implementing the system of plant breeder' rights as established globally in the 1991 version of the UPOV system.[11] In 2015 a study was published disclosing that the implementation of UPOV-91 will be a major obstacle to the implementation of Farmers' Rights.[12]

During the discussions that led to the adoption of the ITPRGFA, and ongoing discussions at CGRFA, it was amply recognized that the definition of agriculture is larger than crop plants

9 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) 1 and 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.

10 Christinck and Tvedt. *The UPOV Convention, Farmers' Rights and Human Rights: An Integrated Assessmemt of Potentially Conflicting Legal Frameworks*. Bonn, Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ) GmbH, 2015.

11 Haugen. Legal opinion on the draft ARIPO Plant Variety Protocol (PVP) and subsequent regulations. Melville, South Africa, African Center for Biosafety, 2014.

12 Christinck and Tvedt, *The UPOV Convention, Farmers' Rights and Human Rights: An Integrated Assessmemt of Potentially Conflicting Legal Frameworks*, 2015.

and includes other genetic resources such as fish, forest species, micro-organisms and insects. However, negotiations leading to the ITPGRFA focused only on plant genetic resources and that too on the crops specifically to be designated under the MLS contained in the annex to the Treaty. Therefore, attention on genetic resources other than crop plants within the ITPGRFA and CGRFA was limited though the interest to focus on issues of access and benefit sharing related to these groups of genetic resources continued.

Parallel to the discussions within the FAO and prior to the conclusion of the ITPGRFA, countries began to focus on issues of conservation of biological diversity, its sustainable use and sharing the benefits of such uses fairly and equitably. The focus on dealing with biological diversity (biodiversity) was due to the increasing drivers contributing to the loss of biodiversity at ecosystem, species and genetic levels. The discussions to establish an international regime to deal with conservation, sustainable use and sharing of benefits priorities gained momentum during 1980 soon after the publication of the World Conservation Strategy by IUCN.[13] Interestingly, mid 1980s also saw a boom in the use of biotechnological applications and evolution of genetic manipulation technologies that successfully was changing the pharmaceutical and agricultural sectors in developed countries. This included plants and microbes accessed/sourced from biodiversity rich countries were contributing enormous economic gains. In the absence of specific legal regimes, except that of the patent systems working strongest in developed countries, developing countries recognized that unless there is an international framework, continued exploitation of biodiversity rich countries resources will continue with no benefits flowing to the providers of these resources. During the final negotiations to establish a global regime to deal with biodiversity, countries agreed to include specific provisions to deal with ABS issues. The decision was taken in the Nairobi Final Outcomes in 1990[14] and was subsequently adopted at the UN Conference on Environment and Development (UNCED, Earth Summit) in Rio de Janeiro in 1992 as the Convention on Biological Diversity (CBD).

In these negotiations biodiversity rich countries feared that national sovereign rights to their resources would be undermined subject to appropriation by intellectual property rights

13 IUCN 1980 World Conservation Strategy. IUCN, Gland.

14 https://www.cbd.int/doc/handbook/cbd-hb-09-en.pdf (accessed on 06 July 2014)

by technology rich developed countries. The focus of the ABS debates was cautious to the extent Article 15 of the CBD focusing on 'genetic resources' as defined in the CBD and not on biological diversity which is the overarching scope of the Convention. "Genetic resources" is defined in the CBD as a broader concept than what had been understood as 'plant genetic resources' in the FAO CGRFA. In 2010, a legally binding Protocol on ABS, the Nagoya Protocol on ABS (NP), was adopted by the 193 Parties to the Convention on Biological Diversity (CBD). The objective of the Nagoya Protocol is to further support implementation of Article 15 of the CBD on ensuring fairness and equity in sharing the benefits of use of genetic resources. It entered into force in 2014 and has by end of August 2017 100 states as members.

During the tenth regular session of the CGRFA in 2005, a recommendation was made that the FAO and CGRFA contribute to further work on ABS issues in order to ensure that it moves in a supportive direction of needs of agriculture considering all components of biological diversity essential for improving food and agricultural systems. In July 2011, the ABS discussions under the CGRFA gained momentum with focus on exploring ABS issues related to specific sectors of agriculture. The timing of which has raised a few questions due to this focus re-starting just after the adaption of the NP. NP Article 4(2) recognises specific instruments:

> Nothing in this Protocol shall prevent the Parties from developing and implementing other relevant international agreements, including other specialized access and benefit-sharing agreements, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.

From one perspective this wording can be seen as an invitation to start discussing sector specific instruments. According to Chiarolla et. al. (2013), there was a distinctive debate within the CGRFA towards developing 'specialized instruments' for GRFA. Developing specialized instruments bringing GRFA out of the auspices of the NP is a highly political issue in the Commission. In 2016, the Commission published 'ABS Elements' which gives certain advices to countries in their implementation of ABS and how to apply these regulations to GRFA.[15] For

15 CGRFA. ABS *Elements - Elements to Facilitate Domestic Implementation of Access and Benefit-Sharing for Different Subsectors of Genetic Resources for Food and Agriculture*. Rome, CGRFA, 2016.

the time being this is a soft legal approach since these elements are not binding on countries, but since ABS becomes functional at the national level the manner in which countries choose to implement it will decide in which directions the regime develops. There are also examples in international law where principles which started out as soft law later have been developed into more binding legal mechanisms. At the European level there are discussions going on for all the six groupings of GRFA. It is therefore foreseeable that the discussions concerning GRFA will continue for the years to come. When analyzing the rational for establishing global common pools for specific genetic resources it is pertinent to recall the particular rational for establishing the MLS which apply for plant genetic resources and not necessary for other groups of genetic resources. A common pool is also exposed for appropriation by intellectual property rights.

Fears of privatization of knowledge and resources using intellectual property protection (IPR) and ensuring benefits of use be shared with providers of resources by the users were the primary reason for ABS related debates both under the FAO and CBD. However, the instruments developed for these purposes, the ITPGRFA and NP suggest differential approaches to benefit sharing and manner of seeking prior informed consent. While the ITPGRFA calls for a standard Material Transfer Agreement, the NP calls for countries to develop appropriate contracts for access (Article 19). Benefit sharing under the ITPGRFA is decided on a formula adopted by the Governing Body of the ITPGRFA. The benefit sharing under the NP is left to countries/ communities providing access to resources to be decided and to be fleshed out in a contract with the user while the benefits accrued due to activities involving crops designated under the ITPGRFA is designated to flow into a global benefit sharing fund. Under the NP/CBD benefits shall be shared back to the custodians of biological diversity. Under the NP there is also no global fund except under situations described in Article 10 of the NP.[16]

While debates on how to deal with national implementation of the ITPGRFA and NP are

16 Article 10 of the NP read as "Parties shall consider the need for and modalities of a global multilateral benefit-sharing mechanism to address the fair and equitable 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".

ongoing, recent discussions within the CGRFA indicate the interests of countries to expand the focus on ABS issues, within the CGRFA mandate, on sets of genetic resources such as farm animal genetic resources (AnGR), forest tree genetic resources (FGR), aquatic genetic resources (AqGR), microorganism genetic resources (MiGR) and invertebrates.

This report provides an assessment of ongoing discussions in this regard besides analysing the ABS specific issues relevant to the debates. It also focuses on a few implementation challenges and experiences in case the scope of the debates within the CGRFA is expanded and its implications for implementation of the NP.

3. Premises for the discussions in the CGRFA–developing criteria for the analysis

Several of the premises informing the work of the CGRFA are described in the FAO Background Study paper no. 59.[17] The paper itself relies on the premise (or assumes) that access to all groups of plant, animal, aqua, forest, micro-organisms and invertebrates shares **common features**, and that these common features of relevance to access regimes are supposedly different from ABS for all other genetic resources. This paper also assumes that the Nagoya Protocol and CBD Art. 15 will create burdensome new hinders to impede the exchange of these resources. The Nagoya Protocol on ABS leaves it possible to develop special regimes for ABS.[18]

One factual description of the Study Paper for ABS to AnGR, FGR, AqGR, Mic-GR and invertebrates is that the genetic pool in all these areas is subject to *incremental improvement* rather than the making of end products. The second factual observation is that genetic resources-based products stem from *multiple sources* in such a manner as to preclude the

17 Schloen, *et al*. Access and Benefit-sharing for Genetic Resources for Food and Agriculture – Current Useand Exchange Practices, Commonalities, Differences and User Community Needs - Report from a Multi-stakeholder Expert Dialogue. Rome, CGRFA, 2011 no. 59).

18 Article 4 of the Nagoya Protocol 'Relationship with International Agreements and Instruments' and particular Art. 4.2.

a) The provisions of this Protocol shall not affect the rights and obligations of any Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity. This paragraph is not intended to create a hierarchy between this Protocol and other international instruments.

b) Nothing in this Protocol shall prevent the Parties from developing and implementing other relevant international agreements, including other specialized access and benefit-sharing agreements, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.

c) This Protocol shall be implemented in a mutually supportive manner with other international instruments relevant to this Protocol. Due regard should be paid to useful and relevant ongoing work or practices under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.

d) This Protocol is the instrument for the implementation of the access and benefit-sharing provisions of the Convention. Where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument.

identification of source country.[19] This leads to the normative arguments: first, there exists no link between a *single accession and one end product*; and second, *products are resources* for new research and development. Thus, insofar as *users can become providers* of genetic resources, it suggests a high degree of interdependence among countries in all these food relevant genetic resources. As argued by several authors,[20] it will be interesting to see how countries would argue on issues such as incremental improvements of these sub-sets of genetic resources for food security in the light of IPR regimes.

This is an adequate description for most plant breeding purposes. This recognition of the strong interdependencies between countries, and the difficulties of identifying any one country of origin for plants, were what justified the political agreement embedded in the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). The question, however, is whether this situation is adequate to the requirements of the other food and agriculture sectors.

The drivers of the ABS discussions under the CGRFA is to ensure future food security, to better facilitate exchange of genetic resources for food and agriculture, to strengthen the 'global governance' in agriculture sector and to recognize the interrelationship between all genetic resources for food and agriculture (GRFA).

This paper offers food for thought as to whether these factual descriptions are accurate and thus whether there is sufficient factual normative reason to deal with all of these groupings in a similar manner. Here some thoughts are developed along the line of exploring whether genetic resources in the sectors meet the five observations of their special features:

1. GRFA are subject to incremental improvement rather than the making of end products;
2. GRFA stem from multiple sources in a manner making it impossible to identify source country;
3. There exists no link between a single accession of GRFA and one end product;

19 Chiarolla, *et al*., "An Analysis of the Relationship between the Nagoya Protocol and Instruments related to Genetic Resources for Food and Agriculture and Farmers' Rights", 2013.

20 Sullivan. "Plant genetic resources and the law: Past, present and future" in *Plant Physiol* 135 (2004) 1 and http://www.fao.org/fileadmin/templates/wsfs/docs/expert_paper/How_to_Feed_the_World_in_2050.pdf (accessed on 9 July 2014)

4. Products are resources for new research and development meaning that there is a chain of development.
5. This means that users can become providers of GRFA.
6. In the following sections we will explore some core features of each of these groupings of GRFA and to test whether these five characteristics apply as often understood in the CGRFA.

4. Animal genetic resources

One of the main findings of a thorough study commissioned by the FAO of the Animal Genetic Resource sector which is being conducted on the basis of a broad, participatory research approach, was that the exchange paths for AnGR are very different from that of PGR.[21] There is far more exchange South–South and North to South, than from South to the North. In contrast to the plant sector, there are almost no international collections of AnGR. Private ownership to breeding material is far more common and at the time (2007) the practice of applying for patents was less intensive. From 2005 some tendencies of applying for patents to breeding techniques appeared.[22]

South-South exchanges are prominent mainly in inter-regional context such as exchange of cattle breeds in Latin America from South Asia. However, emerging interests to breed for disease resistance, climate adaptation, drought tolerance could shift the balance where the diversity rich South could contribute to the North for animal improvement programs. Such interests are already evident in countries like Australia with an interest to import native, local breeds of goat from India to improve the genetic stock for drought management.

A core difference between the animal sector and the plant sector is that the owner of the

21 Hiemstra, *et al*. *Exchange, Use and Conservation of Animal Genetic Resources*. Wageningen, Centre for Genetic Resources (Netherlands), 2006. (CGN Report, no. 2006/06). See also Pilling. *The Use and Exchange of Animal Genetic Resources for Food and Agriculture*. Agriculture, Rome, 2009.

22 Tvedt and Finckenhagen. "Scope of Process Patents in Farm Animal Breeding" in *Journal of World Intellectual Property* 11 (2008) 3.

individual animal has good practical control over semen, eggs or embryos. Often it is more specified that an animal farmer has ownership to the AnGR of his herd than is the case for a farmer growing plants. The characteristic of incremental improvements is a relevant feature to a number of animal sub-sectors, but not as relevant to commercial poultry or swine production since farmers often buy small animals for feeding and slaughter. In cattle breeding, for instance, the semen of a single bull is frequently used to inseminate thousands of females. There is no question of *multiple sources* in animal breeding as the herd books keep a close record of heritage and identify phenotypical characteristics of very specific origin over many decades. In most cases, the country of origin or even single farms and breeding line of origin is easily identified. For example, camels and ducks, despite their differences, also have clear countries of origins in common, i.e. identifiable countries for the purpose of exercising sovereign rights.

The farm animal sector is marked by substantial differences *inter* and *intra* species. Commercial poultry breeding is done on the basis of other business models than those informing the tending of cattle in rural areas in developing countries. The way camels are bred by livestock keepers is very different from how ducks are bred for the production of luxury market products. Rural animal genetic resources are still clearly owned and maintained by communities and local populations and peoples. Therefore the AnGR area is rather marked by differences through its different areas, and is far from as uniform as is plant breeding and use plant genetic resources. This observation questions the usefulness of a harmonised protocol or even standardised MTA for exchange of AnGR. These considerable factual differences have legislative importance. The private enforceable ownership to the genetic material makes a common global pool of resources less adequate as a legal solution.

In animal breeding genetic uniformity is not a breeding goal. Often breeding happens where a male with particular characteristics is used to inseminate a number or female individuals. Here the AnGR is marked different from PGR since the sources of insemination is not at all multiple, but very specific. It is almost contrary to the situation with multiple sources as the source is one very specific one. The need in the plant sector for a broad access to accessions of breeding material to manage a breeding program for animals is far more specific.

Another difference is the relevance of IPRs between PGR and AnGR. For plant breeding the

plant breeders' rights in the UPOV-systems is a core manner to protect commercial breeding industry. Unlike plants, where IPR protection is possible using a *sui generis* approach, such option is absent for animal genetic resources. Similarly, like plant breeders' rights provided for under the UPOV, such options are not available for animal breeds since breeding for uniformity and distinctiveness often go against the option for animal breed improvement programs. Uniformity and distinctiveness are not objectives for animal breeding in the same manner as for plants. Animal breeding is a continuous process of improvement from one generation to the next, whereas in the plant sector breeding 'one' uniformity and distinctiveness variety is s breeding goal. Biotechnology as genetically modification of plants is often protected by patents to single genes or to the methods or techniques. For progress in breeding in the animal sector there is no parallel system for IPR protection of a certain bred or variety. Innovation in the animal sector can be protected by patents when meeting the general criteria for protection in the patent system. Till now we have seen mostly application for breeding methods and patents targeting feed, medicines or vaccines for animals rather than patents to animal genes themselves.[23] As identified by Hiemstra *et. al*., trademarks and geographical indications could potentially be used by animal breeders.[24]

In plant breeding the argument is often that the 'users can become providers' of GR. In the AnGR sector this is similar. However, often there are often contractual restrictions on the use of the GR of offspring developed by the material bought from a specialised user. In the case where the user arrives at a particularly supreme individual in the breeding process, its GR might become very valuable. The manner in which the 'user can become a provider' in animal breeding is rather an argument for a strong individual right to the new provider, rather than an argument for a multilateral system as in the MLS of the ITPGRFA. In hybrid production especially in poultry the second generation will typically not have an improved genetic combination and the product cannot easily be a resource as in the plant sector. The new provider can prevent access to the biological material in which the genetic resources

23 Ibid. and Olesen, *et al*. "Access to and Protection of Aquaculture Genetic Resources: Structures and Strategies in Norwegian Aquaculture" in *Aquaculture* 272 (2007) 1.

24 Hiemstra, *et al*., *Exchange, Use and Conservation of Animal Genetic Resources*, 2006 and Hiemstra, et al. "What's on the Menu? Options for Stregthening the Policy and Regulatory Framework for Exchange, Use and Conservation of Animal Genetic Resources" in *Animal Genetic Resources Information* 41 (2007).

are found. Pooling AnGR is therefore not an as desired option for highly industrialised animal breeding sector as for PGRFA. The current formal and informal markets for selling and exchange semen for insemination also diverges from the 'multiple sources' argument of the plant sector. In plant breeding from a number of accessions is the normal, whereas in the animal sector choosing one particular parent animal to breed a large number of females is the more frequent situation.

In the plant sector an additional argument is that it is difficult to identify the country of origin of one particular trait. This is often also not the case in the animal sector. For wild animals or those bred by local and indigenous peoples, the origin of the breeds and varieties is mostly possible to identify. For animals in the advanced breeding sector the specific genetic combination of the individuals is also a result of generations of active breeding. Thus, for both the formal and the informal sector the country of origin is far easier to identify for animal genetic resources than for plants. The soft-law instrument, The Global Plan of Action for Animal Genetic Resources and the Interlaken Declaration on Animal Genetic Resources recognize the importance of livestock keepers and their rights.

- Differences are more notable than similarities *inter* and *intra* animal species. This becomes a counter-argument to regulating all AnGR by an identical or several similar legal tools under the CGRFA. In the case of species, breeds or lines where it is possible to identify the country of origin or other place of origin, there is no rationale to detach benefit sharing, as benefit sharing in these situations can hardly be proved to run counter to food security concerns.

In the case of India, the need for regulating exchange of AnGR should be considered for the different species, sub-species and varieties. One need to analyse the particular needs of the sector before concluding on the whether there shall be one specialised system for all AnGR, they can be regulated by the general ABS system or highly individualised and tailor-made solutions are needed. One could analyse in depth what will be the consequences of simple, transparent and light structure for access, with decoupling benefit sharing from a) individual provider, and b) individual GR, as this might weaken the domestic incentives for breeding and interfere with existing ownership structures in the different branches of the animal sector.

5. Aquatic genetic resources

When it comes to the food security situation regarding aquatic genetic resources, it is very different from that of plants and even of farm animals. Only a very small percentage of food derived from marine sources has been bred or improved; estimates are around 7–8%. A series of studies of aquaculture also found the number of patents to fish genetics to be relatively low compared to plants.[25] Patents rather target disease viruses, vaccines and medicines, feed compositions and methods in aquaculture than the brood stocks themselves.

Aquaculture is a relatively recent yet fast growing sector that uses aquatic genetic resources. Aquaculture products contribute close to 50 per cent of global seafood consumption where the primary focus of the sector is to improve the existing species for enhanced commercialization and domestication of new species. Though ornamental fisheries is an emerging area of interest within this sector though it occupies relatively small portion of focus in aquaculture.

Only a very few species have been successfully bred and farmed: e.g. salmon, tilapia, carpe, oysters and shrimp being the most important. Access to AqGR improvement is dependent on sources from specific places that could be either wild populations or commercial breeders having larger breeding stock. Captive breeding is an important activity in this sector with major improvements made during the last 5 decades in terms of number of taxa bred in captivity, increasing from farming of about 72 species from 34 families to 336 species from 115 families between 1950 and 2004.[26] According to Gjedrem genetic improvement of domestic species is still nascent and account for less than 5 to 10 per cent of aquaculture production.[27] The plurality of the species makes the breeding activities generally more complex compared to the farm animal sector where less than 10 species are cultivated.

For all these species, identifying the countries of origin is far more feasible than for plants or even farm animals, simply because the history of exchange of the former is much shorter. Salmon can be identified to less than 5 countries of origin; certain subspecies of tilapia to

25 Rosendal, *et al*. "Access to and Legal Protection of Aquaculture Genetic Resources: Norwegian Perspectives" in *Journal of World Intellectual Property* 9 (2006) 4.

26 Bartley, *et al*. *The Use and Exchange of Aquatic Genetic Resources for Food and Agriculture*. Agriculture, Rome, 2009 No. 45, FAO, Rome.

27 Gjerdrem. *Selection and breeding programmes in aquaculture*. Dordrecht, Springer, 2005, p. 364 p.

the Congo Basin; and certain oyster varieties to identifiable places. In this setting, choosing a regulatory open access or common pool for access without connecting it to benefit sharing does not seem a very relevant approach for these countries of origin. Open access could in fact run counter to the long-term conservation of the genetic diversity *in situ*. One core question for India as a provider country would be what its national interest is in establishing a global common pool of AqGR that clearly can be traced to the country; it is not easy to identify any interest for India to establish such an common pool. For Norway, where salmon and trout are core species for fish breeding and aquaculture, establishing a global common approach would imply giving up strategic interests in developing improved breeding material that could later be sold on the global market for smolt. Similar lack of national interests for establishing a global common can be found in oysters, and other seashell species that can be produced in aquaculture or even successfully bred.

Access to improved AqGR material is highly dependent on contracts.[28] Improved AqGR is in the hands of private companies. For example in Norway, there are three companies providing improved smolt for salmon farming. Even though there is no IPR protection for the breeding lines of fish, the private ownership can to a large extent be exercised through contracts. Establishing a common pool of resources is therefore not likely to diminish the use of contracts for bred material.

In some very few cases there have been granted patents on genetically modified fish, *in casu* genetically modified salmon. Patents are more regularly used for medicines, vaccines, in the feed and the technical solutions for breeding and farming.[29] The patent to a fish virus including the vaccine developed therefrom has been highly controversial in Norway.[30] The availability of improved genetic stock with private sector will prove a hurdle in developing a multilateral system for benefit sharing detached from the individual provider. Such common pool could be most relevant for AqGR available only in public sector.

28 Rosendal, *et al*. "Balancing ABS and IPR Governance in the Aquaculture Sector" in *Global Governance of Genetic Resources*. Edited by Oberthür and Rosendal. London, Martinus Nijhoff, 2014.

29 Tvedt. "Disentangling Rights to Genetic Resources Illustrated by Aquaculture and Forest Sectors" in *Law, Environment and Development Journal* 9 (2013) 2.

30 Ibid.

The situation in AqGR can be that breeding relies on multiple sources. Here the breeding sector in aquaculture resembles more the plant sector than the animal sector. However, the clear traceability of the genetic resources to a specific country of origin makes a common pool solution less applicable for AqGR. The combination of a clearly recognizable country of origin and the control over improved AqGR are strong factual observations that will make a common pool to AqGR a difficult idea to follow and realize.

The initial CGRFA or FAO report on AqGR also discusses ornamental fish comprehensively.[31] Also here, AqGR country of origin can be identified, though it is rather doubtful whether the sovereign rights over these resources of the tropical country in question is best managed by a common pool.

Based on these observations, the rationale in favour of a multilateral common pool for the AqGR cannot be said to be strong; allowing for the general exercise of sovereign rights would seem to be an adequate solution. In addition, there are no global gene banks of AqGR that has the same need for a common pool solution like is the situation in the plant sector.

From India's perspective one could carefully assess whether it is in the aquatic breeding and farming of captured individuals interest to establish a global pool where companies from other countries should have open access to the resources. Probably, finding good solutions for affordable breeding methods in more aquatic species is more urgent than making the AqGR available in a global pool as is for plants.

6. Forest tree genetic resources

Trees has generally a longer rotation time than in the plant for food and feed production and aquatic sectors, even in the animal sector, as it generally takes many years for a tree to produce seeds. Generally, FGR can be divided in cultivated, industrialised species and wild growing tree species – each raising specific challenges for the legal regulation. Growing forests is an increasingly popular activity because of bio-fuel, reforestation and carbon capturing all

31 Agriculture, 2009.

related to climate change. Preservation and conservation of biological diversity is normally linked to primary forests. FGR is thereby an area of great importance for conservation of biological diversity along with climate change mitigation and adaptation as well as an important area for agriculture especially by plantations. Using forests for climate change mitigation and conservation of biological diversity are however often in conflict as their use will often require different forestry practices.

According to FAO, in 2005, the global forest cover accounted for 3.9 billion ha with about 271 million ha of planted forests.[32] The term 'planted forests' include commercial plantations and planted components of semi-natural forests but does not include trees outside the forests. According to Koskela et al. 2010,[33] less than 140 of the world's 50,000 or so tree species are used in commercial forestry and current breeding and improvement efforts focus even on fewer taxa. Large amounts of seed are moved through trade sector and is typically not documented or certified and no standard MTA is used except for the collection of tree germplasm from ICRAF.

In 2007, the UNFF adopted a non-legally binding instrument (NLBI) on all types of forests to promote implementation of sustainable forest management, including enhancing international cooperation. The NBLI has provisions for benefit sharing relating to the use of traditional forest knowledge but does not specifically refer to forest genetic resources.[34]

In 2009, the Nordic countries launched a project to analyze ABS issues and compare related national legislations with a view to compare regulations of ABS to discuss challenges to maintain exchange of forest genetic resources in the region. The main finding in the report was that there are differences in the legislation among the Nordic countries that can be of relevance for access and exchange of FGR from the respective countries.[35] The report also emphasized that there is a need for maintaining the open and free access approach which is

32 Lungo, *et al*. *Global planted forests thematic study: results and analysis*. Agriculture, Rome, 2006.

33 Koskela, *et al. The Use and Exchange of Forest Genetic Resources for Food and Agriculture*. Agriculture, Rome, 2009 Background Study Paper 44.

34 Ibid.

35 Tvedt. *Seeking Appropriate Legislation Regulating Access and Exclusive Rights to Forest Genetic Resources in the Nordic Region*. Lysaker, Fridtjof Nansens Institutt, 2011. (FNI Report, no. 9/2011).

currently the situation among the Nordic countries. The report also discusses the applicability for patents and plant breeders' rights in the forest tree sector. With varying legal and regulatory provisions in Nordic countries it was not possible to come up with a common ABS framework to deal with forest genetic resources though the project indicated the options to deal with linkages to approaches in the region on ABS and forest resources.[36]

Unlike genetic resources for food and agriculture that follows a path of incremental improvements, improving forest genetic resources is mostly non-incremental, time consuming and is difficult due to the biology of forest species. However, the resources are generally used for specific purposes with pre-set goals for commercialization. This aspect of use of forest genetic resources offer an easy scope to deal with ABS issues unlike genetic resources like crop plants and microbes that could have multiple uses that are often unclear at the time of prospecting and/or improvement programs. Based on the above, it could be said that forest genetic resources offer some potential to create multilateral common pools of genetic resources.

On the other hand, for forest tree GR the country of origin normally is easily determined as there has been far more limited global exchange of FGR than is the situation for plants in general. Therefore, the potential for a bilateral exchange between a provider country and a user offer a better system for their exchange and benefit sharing. Currently, there is no strong evidence for a high level of interdependence among countries when it comes to FGR. Except in rare cases where countries are situated in the same temperature zone and have been collaborating closely in forestry management, like between Norway, Sweden and Finland.

A study from the Nordic countries discloses that patents might become more applicable in the branch of forest tree, especially patents on methods for breeding in combination with vegetative propagation.[37] The major challenge will be issues related to ownership of the material where breeders who focus on tree improvement programs are largely private sector entities. Thus, there is no established evidence that a multilateral system would prevent or

36 Ibid..

37 Myking, *et al*. "Protection of forest genetic resources by intellectual property rights – exploring possibilities and conceivable conflicts" in *Scandinavian Journal of Forest Research* (2017).

augment issues related to patenting and ownership of the material. In the Nordic case, this could be solved by a regional agreement on exchange for relevant species.

The potential to use agro-forestry based resources could offer potential for innovative product development and related benefit sharing mechanisms but national and international focus on this is limited to securing the livelihoods and local people and reducing poverty.

7. Microorganism Genetic Resources

The uses of genetic resources derived from micro-organisms cover broader categories than in the case of plants, farm animals, aquatics and forest trees. Micro-organisms can play a role in food production and agriculture as a means of biological control/crop protection, soil fertility, renewable energy, plant breeding R&D, animal health, animal nutrition and biological research into food production and other areas. Micro-organisms can also be used for their pathogenic propensities or healing properties.[38] The ways to take use of the Mic-GR and the micro-organisms themselves is thus also highly diverse. These different uses appear to call for differentiated and tailor-made solutions for each particular situation of access, rather than a one-size-fits-all solution.

What is common for these groups of uses is that *incremental improvements* happen relatively seldom. The outcome from the use of a micro-organism is an end product rather than a product that in itself can be used in further breeding. The product seldom becomes a resource on which to base new research and development. It would be more to the point to say that one or several specific micro-organisms are used to develop certain products. Therefore, assuming the general assumption of multiple sources is not accurate. When a Mic-GR is accessed, the country of origin is easily identified in most cases. Mic-GR do not have a long, history of intensive global exchange and stepwise development as in the plant sector, and such a history cannot therefore be used as an accurate description in the case of Mic-GR.

Taken together these features could be arguments against establishing common pools for Mic-GR. The normative argument to detach benefit sharing from the provider or the country of origin appears particularly weak in the case of Mic-GR since the tracing is relatively more easily done as the link between the Mic-GR and the end product is clearer, and since the origin often is identifiable. There are several existing collections which hold a large number of accessions. For these collections, it might be useful to devise a uniform set of ABS standards. The role of microbial culture collections and species in the collections in improving the agricultural production systems are immense. More than 80% of the 500 World Federations of Culture Collections (WFCC) belong to public sector entities and the remaining are semi-governmental with rare cases of private collections.[39] About 77% of the distributions from the Collections are to public sector recipients making microbial germplasm exchange largely an issue relevant to public sector like germplasm of crop plants. A large number of Collections are providing access to the genetic resources using some form of MTA though PIC is not necessarily a pre-condition for deposits. Initiatives such as the MOSAICC (Microorganisms Sustainable Use and Access Regulation International Code of Conduct) and the Microbial Commons Initiative have provided guidance on CBD compliant exchange of microbial genetic resources. Increasingly, calls for establishing a world collection of microbes under the Microbial Commons is also being made.[40]

In the absence of global guidelines and procedures to deal with ABS issues for Mic-GR, access to and sharing of benefits using microbial genetic resources have been claimed to become a concern both for the Collections and for researchers. The challenge for countries will be to agree on an ABS framework that provides legal certainty and predictability for using and exchanging the cultures which is a pre-requisite for future food security of the world. Given the nature of Collections and experiences of exchanges being made, establishing a multilateral system as the ITPGRFA does for the international collections seems a feasible option. The need to regulate these collections can, however, hardly justify of view of all Mic-GR outside these collections as covered by a common pool.

39 Dedeurwaerdere, *et al*. *The Use and Exchange of Microbal Genetic Resources for Food and Agriculture*. Agriculture, Rome, 2009.

40 Ibid.

On the user side, there is a high number of patents, often targeting naturally occurring micro-organism when isolated and in purified form. The TRIPS Agreement is clearer in requiring all member countries to make available patents as a means of IPR-protection for micro-organisms. Therefore, countries are obliged to grants patents in this area of bio-innovation with a higher density than in the plant and animal sectors since there the TRIPS Agreement has exceptions and exclusions. Because patents are applied for so intensively, countries would do well to exercise their sovereign rights to Mic-GR rather than opting for a common pool solution to create a balance between providers and users of them.

One interesting example of a patent that have importance for food security is the fish virus patent in Norway.[41] A patent was granted to one virus that causes pancreas disease in salmon. The pancreas disease has a considerable annual cost to Norwegian fish farmers. In the 1990s a virus was identified as a possible source of the symptoms of the disease. Based on samples found in Ireland, Irish researchers registered in 1995 a product patent on the virus itself that causes the disease. The Norwegian Patent Act allows for only 'inventions' to be patented. However, administrative and judicial practice has interpreted the concept of 'invention' to mean something different than the ordinary understanding of the word – the said virus was considered subject matter for an invention. Because of the principle of territoriality a patent must be granted in each country where the inventor seeks patent protection. In Europe, the European Patent Organisation (EPO) grants patents with binding effect upon all member states. Current developments indicate further European harmonisation of the patent system.[42] A core patent criterion is that the applicant must describe his invention in writing. For biological material, the written description is challenging and has been eased with the system under the Budapest Treaty.[43] Under this deposit system the patent applicants have been given

41 This example is based on Tvedt, "Disentangling Rights to Genetic Resources Illustrated by Aquaculture and Forest Sectors", 2013.

42 Tvedt. *Norsk genressursrett: rettslige betingelser for innovasjon innenfor bio- og genteknologi*. Oslo, Cappelen akademisk forlag, 2010, Tvedt. "One Worldwide Patent System: What's in It for Developing Countries?" in *Third World Quarterly* 31 (2010) 2 and Tvedt. "The Path to One Universal Patent" in *Journal of Environmental Policy and Law* 37 (2007) 4.

43 *Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure* [Budapest Treaty], WIPO, 28 April 1977, 1861 UNTS 362, entered into force 19 August 1980, as amended on 26 September 1980 (1977) [hereafter Budapest Treaty].

the possibility to rather deposit samples of the material the applicant wants patented than describing it by words. The patent then grants an exclusive right to all commercial applications of that virus deposited in accordance with the Budapest Treaty. What makes this particular patent interesting is that it not only encompasses the samples deposited, but goes further by including the phrase 'closely related strains that have similar genotypical or phenotypical characters'. The Norwegian courts rules on the detailed meaning of this, in respect of a newly developed vaccines based on the virus strain called "SAV-3" that is the one attacking Norwegian farmed salmon.[44] The matter of the case was whether the new vaccine based on this other strain of the virus was sufficiently 'closely related' to the patented virus. The conclusion of the Appellate Court of Norway was that viral strains originating in Norway which Pharmaq had used were indeed protected by the patent, despite a only 95% identity at a DNA level and despite the two strains of virus having split off from each other more than a hundred years ago. It is interesting to observe that when the Norwegian researchers (then employed at the University of Bergen) identified SAV-3, i.e. the Norwegian strain, this finding was considered sufficiently new for publication in a peer-reviewed journal. According to the judicial conclusions, however, these results fall in part within the scope of the granted patent. What is acknowledged as new in an academic setting may thus already be covered by an existing patent. In an previous article, Tvedt has concluded that:

The rationale for suggesting a global open-source and common-pool approach to Mic-GR is somewhat limited by the comprehensive possibility to patent micro-organisms as such. Looking at the fish virus patent in Norway, we can draw the conclusion that in that case,

> The lesson we can draw from this particular case is that a patent on a virus can monopolise an entire field of research on similar viri. Not only does the patent protect research that the patent applicant could foresee at the moment of application, but all research on viri causing these symptoms. The patent also prevents the making of a vaccine from similar strains found in nature that were not known to the inventors at the time. The company that takes the (until then) final step in the chain of innovation is given a twenty-year long monopoly on remedying a disease that costs Norwegian

44 Hodneland, *et al*. "New Subtype of Salmonid Alphavirus (SAV), Togaviridae, from Atlantic Salmon Salmo Salar and Rainbow Trout Oncorhynchus Mykiss in Norway" in *Dis Aquat Organ* 67 (2005) 1-2.

fish farmers dearly, and others who do research on this disease are not rewarded for their work. Taking these consequences into consideration, one may ask whether it is in the interest of fish farmers and the community as a whole to have a system where a product patent can be granted with an exclusive right to a naturally occurring virus. The specificity of the patent right shows a legal system which has a vast potential to establish well-defined objects of commercial rights, far more enforceable than those established by the Nature Diversity Act.[45]

the patent slowed down pace of innovation. One fundamental idea of ABS was to create a balance between the rights to the genetic resources in nature and intellectual property rights to inventions based on these resources. When establishing a system for open access while maintaining the possibility of granting strict and comprehensive exclusive rights even to the virus itself, then there will be an imbalance in the system. When implementing the NP applied to Mic-GR, there is a need to have a look both to the availability of material in public sector, the potential interest and opportunity to make multiple uses of the organisms in research, development and commercialization, and keep the relevance of IPR and trends in patenting of microbial-based innovation.

The Indian Biological Diversity Act, 2002 specifically regulates several aspects concerning microbes, inter alia the purpose of research, commercial utilization, transfer of research results, obtaining IPR, third party transfer and addressing non-commercial research and emergency purposes. Regulation 13 of the ABS Regulation 2014 facilitates transfer of biological resources including microbes.

8. Invertebrates – biological control agents

Biological control agents form a significant component of invertebrate genetic resources useful for the future of global food security and development even though other invertebrates such as pollinators also contribute to food security and production.[46] It is estimated that about 7,000 introductions of biological control agents involving about 2,700 species have been made

45 Tvedt, "Disentangling Rights to Genetic Resources Illustrated by Aquaculture and Forest Sectors", 2013.

with 119 countries contributing to introductions into 146 countries. Developed countries have received more species than developing countries in dealing with reducing loss to crop damage and increasing agricultural production systems.[47] It is also estimated that more than 170 species of natural enemies of pests are produced on a commercial scale and sold but about 30 species make 90 % of the market worldwide with a market of about USD 225-300 Millions.[48] The main scope in the Background study paper of the CGRFA, however, is more focused on the living invertebrates than having a clear focus on the genetic resources of them.

Given the above, the following could be key considerations on ABS issues with regard to dealing with invertebrate genetic resources. First, the market potential for such agents is rather small and is currently restricted to developed countries while developing countries in regions such as Asia and Africa are fast emerging. Given the nature of activity and the research and development involved in this sector, public sector undertakings and research institutions play a key role in the future development of accessing and using genetic resources. While many argue the non-monetary benefits should form a key component of ABS framework in this sphere, the emerging commercial interests and economic gains made by countries accessing, researching and introducing the biological control agents cannot be ignored warranting equal emphasis on monetary benefits.

Given this, the future of ABS discussions related to this set of organisms should focus on establishing formal set of guidelines for the small segment of user and provider groups on issues of access and benefit sharing. However, a key consideration that needs attention is the need for providing flexible options for access in situations of emergency and large scale destruction caused by pests that warrant flexible yet predictable use and introduction of these control agents. Such provisions are already available under Article 8 of the Nagoya Protocol.

The area of invertebrate genetic resources is the one grouping relevant for food and agricultural production that is least discussed.

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46 Cock, *et al*. *The Use and Exchange of Biological Control Agents for Food and Agriculture*. Agriculture, Rome, 2009 Background study paper No. 47.

47 Ibid.

48 Ibid.

9. Preliminary observations and discussions

9.1 Comparing the finding from the sectoral look

It is too early to conclude what the consequences of the NP will be for access to GR for food and agriculture. Countries are in the process of setting up their national systems for ABS. Countries are in process of detailing the national ABS framework processes and contents. It cannot simply be assumed that NP would impede future access to and exchange of GRFA. As to our knowledge, there has not been provided empirical evidence showing that there is a casual connection between ABS implementation and reduced exchange of GRFA. If one suspect that access to GR is reduced there is a need for exploring both increase in IPR and ABS legislation to identify the cause of any reduced effects on access.

One core observations from the discussions above is that the exchange patterns of GRFA differ vastly among and within the six groupings discussed. The manner in which these groupings of GRFA are being used also largely diverges. The extent to which intellectual property rights are applied also differ. The special needs of the different branches of food production needs to be understood and reflected into the implementation work of the countries. Therefore, it is incorrect to assume that all components of CGRFA share common features and would therefore are amenable for coverage using single common ABS framework. The extent to which there are distinctive features among and between different subsectors is an empirical question where the special national context of each country and each sector in each country must inform the legislative choices taken.

- While this is so, developing sets of specialized instruments to deal with components of genetic resources covered in this paper would add significant administrative and regulatory burden at global and national levels.
- The issue of incremental improvements to genetic resources also differs between different production systems among and within the five other groupings than plants. Whereas some species and production systems are subject to incremental improvement techniques like hybridisation illustrates different ways to gain and maintain genetic improvement. It is important not to assume that access to genetic resources always leads to development of one end product. For Mic-GR use very often leads to one end product that is not subject

to incremental improvement. For low input animal breeding in local areas the level of incremental improvement is much higher, however here the identification of owners of the genetic material is easily determined.

- The assumption that providers can become users and vice versa cannot hold good for all situations and in all contexts with regard to ABS issues. Experience has shown that the normative relationship between provider and users of GR should be assessed based the resource(s) and its intended use.
- The role of IPR coverage for each group of genetic resources is different. Again this depends heavily on the branch, the actors driving the developments forward and how the value in the genetic resources becomes manifest in each of these groupings. The manner in which IPRs are applied to bio-inventions also affects how the benefits sharing system could and should be designed. The role of IPR protection using trademarks and geographical indications in dealing with CGRFA still needs to be assessed in a systematic manner. It is time to address this specific issue in the context of existing and emerging national and global IPR regimes.[49]
- There might be a need to accommodate the special needs of GRFA in national regulations of access, exchange and benefit sharing along with the tendencies in the use of patents in the field of innovation.
- While decoupling of benefit sharing from individual users and resources is suggested in the current debates, one has to be careful about contextualizing this issue. In the absence of this, the principle of sovereign rights could be undermined along with eroding the contractual obligations related to benefit sharing. Discussions on this issue need nuanced approaches in a manner such approach be used for specific purposes and situations (such as epidemics and emergency situations. For India addressed in Regulation 13, ABS Guidelines November 2014). The current experiences from the plant sector and the fact that no benefits have been shared from users according to the SMTA of the MLS entails a warning and a signal for new developments in international law.[50] The on-going

49 Blakeney. Trends in intellectual property rights related to genetic resources for food and agriculture. Agriculture, Rome, 2011.

50 Tvedt, "Changes in the Plant Treaty – How Can Benefit Sharing Happen and the Link to Intellectual Property Rights – Assessing the Mutually Supportiveness", 2015 and Tvedt, "Access to Plant Genetic Resources – Legal Questions for Material on its Way into the Multilateral System of the Plant Treaty", 2015.

renegotiating of the SMTA needs to reformulate the trigger points for benefit sharing and needs to be made more of a contract that can be enforced in a case of non-compliance. If benefits are to be detached from the individual transaction and provider for other sectors than plants, then such a system must be much more specific and legally potent than is the situation for the SMTA of the MLS.

- While the idea of maintaining GRFA in a common pool is a reasonable one to enhance future food security in the world, answers need to be found on how to reduce and/or stop private appropriation of these common pool resources. These two topics need to be developed in tandem.
- While NP is a generic framework to deal with ABS issues, there might be a need for more flexible approaches to deal with ABS issues for GRFA. Clarity is needed about issues such as flexibility for whom and the kind of flexibility needed since such provisions are already found in the NP (Article 4, 8 and 19).
- Care should be taken not to negotiate yet another set of ABS provisions/instruments at this moment, emptying the options for implementing the NP. Rather, efforts should be made at country level to develop or redesign flexible ABS mechanisms that address the concerns related to GRFA. This can reduce costs, time and ensure that the global community does not continue 'forum shopping'.

9.2 A balancing act and keeping sufficient flexibility

These groupings of GR, it is argued, should be kept in a common pool and access should be flexible. When flexibility is used as a normative argument in the CGRFA, we need to look at how we can maintain a balance in the systems between flexibility regarding access and exchange, on the one hand, and in relationship to patents, on the other. If flexibility is only provided for on the one side of this balance, food security and conservation could be put at risk. Strong and broad patent rights can slow down innovation pace as we saw in the salmon virus case from Norway. They can also lead to monopolisation in a field of innovation for food production; this might have effect on the level of food production in the world. The idea of maintaining genetic resources in a common pool is one worth of exploring further. Main obstacle to its achievement is the private appropriation of the resources in intellectual

property rights (patents and others), in mergers and acquisitions, in the concentration of power in the various fields of food production.

- ABS in the CBD and NP can be interpreted as a counterbalance to the increasing private appropriation of genetic resources. By changing the scope of which groups of genetic resources are governed by the CBD and NP principles of mutually agreed terms and prior informed consent, it should be possible to alter the balance with regard to other legal systems which create exclusive rights in the area. Therefore, decisions of the CGRFA should be informed by a closer empirical consideration and a more nuanced factual background considering the use of patents in the fields. The indicators from AnGR, AqGR and Mic-GR looked at here present a much more detailed and nuanced picture than that described by Study Paper no. 59. The aim is not to draw any firm conclusions on whether these rules are applicable and how to articulate them – we need more cross-disciplinary research and expert discussions on GRFA, patent law and general ABS-law if the decisions are to have a solid empirical basis.
- When discussing flexibility it is a need for clarifying for whom this flexibility should be provided. The kind of flexibility in ABS that GRFA requires needs to be further explored. The Nagoya Protocol on ABS Article 19 addresses sectoral options and establishes a clear role for model contractual clauses for different types of ABS-situations, and states that:

  1. Each Party shall encourage, as appropriate, the development, update and use of sectoral and cross-sectoral model contractual clauses for mutually agreed terms.

  2. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall periodically take stock of the use of sectoral and cross-sectoral model contractual clauses.

- One way forward for both India and for the next COPs to the CBD and MOP to the NP could be to explore more in details how these embedded flexibilities in the NP can be used to ensure continuous access and exchange of GRFA. While these options are worth pursuing, they cannot be argued in vacuum given the critical role of nature of resource, holding and ownership of the resource, type of use, potential for commercial utilization, risks of privatization of resource using IPR regimes and accrual of benefits to the country and communities.

Minimizing the regulatory burden and increasing the compliance canvas form key to success ABS measures at national level. There is a great advantage for an ABS-system that any complexity in the system is backed up with a good institutional system for handling ABS contracts. In an ABS contract there is seldom possible to apply a 'one size fit all' approach. This also implies that there is a need for tailor-making the ABS contracts to the groupings of GRFA.

Experiences from countries such as India could provide guidance to deal with development of specific contractual clauses for sectors of genetic resources as foreseen in NP Article 19 and 20. Focus on specificities associated with the management principles of various sectors of genetic resources, the related issues of IPRs, the role of public and private sector in holding the germplasm, institutional and oversight mechanisms to deal with compliance all form the essential pre-requisites for successful implementation of ABS provisions at country level.

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About CEBPOL

Government of India in collaboration with the Norwegian Government has established "Centre for Biodiversity Policy and Law (CEBPOL)" at the National Biodiversity Authority (NBA), an autonomous and statutory body of the Ministry of Environment Forest and Climate Change towards strengthening of expertise in Biodiversity Policy and Law in India. This programme is executed by the NBA in collaboration with Norwegian Environment Agency through the Royal Norwegian Embassy, New Delhi, India.

The Centre aims to provide advice and support to the Government of India and Norway on Biodiversity Policy and Law related issues including complex negotiations on Access and Benefit Sharing and Traditional knowledge as well as governance issues relating to biodiversity at the National and International level. The Centre proposes to help NBA in the effective implementation of International agreements on conservation, sustainable use and the associated access and benefit sharing components of it.

CEBPOL is set up as a specialized Centre of Excellence in Biodiversity Policy and Law to network, organize and consolidate expertise on issues of Biodiversity Policy and Law in India and Norway. The Centre, located at NBA, would function as an independent think tank on Biodiversity Policy and Law. In addition, CEBPOL aims to contribute to the effective implementation of the Biological Diversity Act 2002 and Rules 2004.

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