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The Nagoya Protocol on access to genetic resources and benefit sharing: User-country measures and implementation in India

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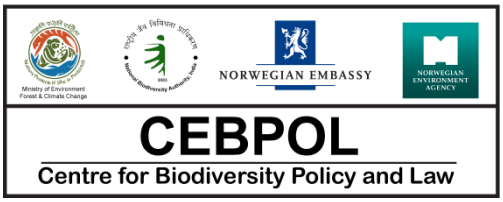

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Abstract

User-measure requirements are the cornerstone of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization developed under the Convention on Biological Diversity. These have come about as the result of hard, persistent pressure from developing countries on developed countries to take co-responsibility in making the access and benefit sharing regime functional. The degree of national implementation of the user measure requirements will thus be an important indicator of the success of the Nagoya Protocol. This report reviews these requirements and the situations as regards national implementation so far. It reviews the status and options for India in its implementation and notes some future challenges.

Key Words

Genetic resources, biological resources, biodiversity, international environmental governance and law.

Foreword / Preface / About the Report

This report is a contribution to the Centre for Biodiversity Policy and Law (CEBPOL), India. The Centre has been established in the National Biodiversity Authority (NBA), Chennai, a statutory autonomous body of the Ministry of Environment, Forests and Climate Change, responsible for implementing the Biological Diversity Act of 2002. CEBPOL is a joint project on technical and institutional cooperation between the Government of Norway and the Government of India as part of the Indian–Norwegian dialogue under the Joint Working Group on Environment.

This report has been co-authored by Christian Prip, researcher, FNI and Charlotte van't Klooster, Fellow (ABS), CEBPOL.

Contents

1 Introduction

A major reason for developing countries to push for a legally binding instrument to supplement and clarify the CBD's provisions on access to genetic resources and the fair and equitable sharing of benefits from such use (ABS) was the widespread reluctance of developed countries as users of genetic resources to support compliance with provider countries' access regulations. Thus, the Nagoya Protocol (NP) specifies various obligations for its Parties to that affect. The time has come now to implement these 'user measures' – not only as regards developed countries but on the part of all countries as potential providers and users of genetic resources. This report reviews the user-measure provisions of the NP and the situations as regards national implementation so far. It also outlines India's status in implementing these user obligations, and notes some future challenges.

2 The Convention on Biological Diversity and ABS

In many ways the Convention on Biological Diversity (CBD) is an innovative multilateral environmental agreement, but its most innovative contribution is probably its third objective: *the fair and equitable sharing of the benefits arising out of the utilization of genetic resources* and the associated provisions thereon. Based on the principle of national sovereignty and equity, the CBD establishes that benefits from using genetic resources shall be shared fairly and equitably with the provider of the resources, in return for providing access – the concept known as ABS. Such access is subject to prior informed consent (PIC) by the providing country, on mutually agreed terms (MAT) with the user (CBD Art. 15.) Although the ABS concept was developed in the context of a multilateral environmental agreement, it has since had considerable implications for international law in such diverse areas as agriculture, intellectual property rights, health and human rights (Glowka and Normand, 2013).

'Genetic resources' – biological materials of actual or potential value containing functional units of heredity[1] – are essential for a significant proportion of the world's economic activity. They are the basis for the improvement of agricultural crops and for the development of traditional medicines on which the majority of the world's population still depend. Genetic resources are used for a very wide variety of purposes, ranging from basic research to the development of products in sectors such as pharmaceuticals, agriculture, horticulture, agriculture, cosmetics and biotechnology. The combined annual global markets for the products derived from genetic resources have been estimated to be between USD 500 and 800 billion (ten Kate and Laird, 1999); at the time of the CBD negotiations, there were expectations of huge benefits to be shared, especially from pharmaceutical products derived from genetic resource compounds.

[1] 'Genetic resources' as defined in CBD Article 2.

The world's biodiversity is found mainly in the South, whereas the scientific and technological capacity to utilize its genetic resources is found mainly in the North – although this pattern is gradually changing, with some of the world's megadiverse countries also becoming emerging economies. The South saw the CBD as an opportunity to get the benefits derived from 'their' genetic resources shared, and to rectify what was seen as an unjust situation dating back to colonial times where the North created huge profits by exploiting the natural resources of the South, without returning benefits.

ABS was a controversial issue during the negotiations and remained controversial after the entry into force of the CBD in 1993. Discussions on implementing ABS provisions focused especially on how to operationalize access. Little attention was paid on how to ensure benefit sharing and compliance with provider-country access legislation. Developing countries reported many cases of alleged misappropriation of genetic resources ('biopiracy'), typically concerning inventions based on genetic resources and associated traditional knowledge (TK) that were patented without the PIC of the providing country and/or the community holding the knowledge, continuing the atmosphere of mistrust between developed and developing countries (Oberthür and Rosendal, 2014). The latter held that developed countries, as host to most of the users of genetic resources, were obliged to take measures to prevent misappropriation and to ensure that benefits were actually shared, referring to the obligations outlined in CBD Art. 15.7.[2] While the level of national implementation of ABS remained generally low, it was particularly low in terms of 'user measures'. This was due mainly to generally negative attitudes to the ABS concept on the part of many developed countries, but also to the lack of provider-country access legislation that user measures could be related to (Prip and Rosendal, 2015).

[2] Article 15.7: 'Each Contracting Party shall take legislative, administrative or policy measures, as appropriate, and in accordance with Articles 16 and 19 and, where necessary, through the financial mechanism established by Articles 20 and 21 with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Party providing such resources. Such sharing shall be upon mutually agreed terms'. The CBD includes a number of other obligations directed to users including to provide the source country with access to and transfer of technology which makes use of its genetic resources (Art. 16.3), to enable 'effective participation' in biotechnological research by (and where possibly within) developing countries, especially the source country of genetic resources (Art 19.1) and to 'promote and advance priority access on a fair and equitable basis' by source countries to the results and benefits arising from the biotechnologies based upon the source of country's genetic resources. (Art. 19.2). As noted by Tvedt and Young, 2007, CBD provisions on user obligations outnumber requirements related to access.

3 The Nagoya Protocol and user measures

User measures - understood here as measures to provide that genetic resources utilized within a country's jurisdiction have been accessed in accordance with the access requirements set out by the country that provides the genetic resources - were a core demand of developing countries in negotiations on the Protocol. Provisions for user measures represent a cornerstone of the Protocol, considerably expanding and reinforcing the requirements under the CBD. Article 15.1 states the a general obligation for Parties to take 'appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources have been accessed in accordance with PIC and that mutually agreed terms have been established….', if this is required by the providing country (NP Art.15.5). This obliges all parties to the NP to take measures, while leaving a margin of discretion as to whether these are to be legislative, administrative or policy measures. Since these measures are intended to provide compliance with legally binding acts required by provider countries (PIC and MAT) it would normally seem most 'appropriate, effective and proportionate' for the measures to be legislative kind – as is also the case for the limited number of user measures applied so far.

Parties are furthermore required to address non-compliance with the user measures applied (NP Art. 15.2). Again, there is flexibility as to the measures; again, it would in our view seem appropriate effective and proportional to take legislative measures. In cases of non-compliance, parties are to cooperate with the party providing genetic resources 'as far as possible and as appropriate' (NP Art. 15.3) – cooperation which in most cases would make good sense in cases of misappropriation, as the relevant information will generally be found in the country where the genetic resources are acquired and not the country where they are used.

Article 18 of the Protocol aims to facilitate settlement of disputes involving non-compliance with the terms of MAT. In most cases this will be a private, civil law contract, whereas PIC on the other hand is a public act. The Protocol encourages the inclusion of a dispute resolution clause in MAT (NP Art. 18.1) and requires that an opportunity to seek recourse be available in each country (Art. 18.2). Thirdly, it obliges countries to take measures on access to justice and the utilization of mechanisms regarding mutual recognition and enforcement of foreign judgements and arbitral awards. Countries are also to take measures to monitor and enhance transparency on the utilization of genetic resources, including through designation of one or more *checkpoints* to collect relevant information on PIC, MAT and the source and utilization of genetic resources (NP Art. 17.1). These checkpoints are to monitor that the genetic resources are accessed in a proper way in line with domestic access regulations in the provider countries, and, if specified by law, by country of origin. The checkpoints must be effective and have functions relevant to the utilization of genetic resources or to the collection of relevant information at any stage of research, development, innovation, pre-commercialization or commercialization (Art.17.1.a.iv). Situations of non-compliance with domestic ABS legislation or regulatory requirements need to be addressed by the designated checkpoints. Their function

can vary from a formal to a more substantial controlling role.[3] Checkpoints can however have a substantial controlling role when disclosure of the legal procurement of the genetic resources becomes a substantive requirement for the application or procedure (Candeira, 2014). The Nagoya Protocol does not specify this optional substantial role, but it does not prevent it either, leaving the decision up to each country.

The information gathered by checkpoints in user countries will enable monitoring by provider countries, to ensure that access was obtained legally in accordance with their own national regulatory ABS framework, and detect possible violations. The generation of information on the utilization of genetic resources via checkpoints lies at the heart of the compliance system. Possible checkpoints are presented in Table 1.

Table 1: Optional checkpoints for countries to consider (based Candeira, 2014).

Checkpoints	**Strengths**	**Weaknesses**
Institutions providing public funding to researchers	• Can control research institutions which form a crucial part of the biotechnology value chain where the initial access to the genetic resources occurs • Can prevent the use of public funds to finance research projects/activities that do not fully comply with applicable law in other countries • Formal requirement of disclosure of the legal procurements of genetic resources can easily be organized by adjusting application forms • The institutes providing public funding for research projects can convey the information to the ABS-CH directly • Control by these institutes could not only affect the institutions that receive such funding: collaborating research institutions from third countries would have a very significant external incentive for complying with their own national access legislation (ripple effect)	• They are only in contact with researchers/ institutes that do apply for funding.
Research institutions	• Can enable overviews of the research conducted at their institutes and keep track of the research outcomes e.g. by listing publications per department per year	• They are subject to funding and can therefore not control the funding
Publishing companies or bodies that publish research results based on genetic resources	• They can include the disclosure of the legal procurement of the genetic resource as one of their publishing requirements • They can communicate this information to the national authorities and the ABS-CH (optional)	• Publishing companies are private, so it is difficult to control if verification takes place, unless they do so voluntarily and are themselves committed to this task.

[3] A formal checkpoint is merely a point for collecting information relating to the disclosure of legal access to genetic resources and for transfer to third parties. It has no strong or substantial controlling role and can therefore not substantially affect the procedure or the application in question.

Patent offices	• Patent offices can include the disclosure of the legal procurement of the genetic resources, as one of their application requirements and function as a formal checkpoint (non-compliance would entail the inability to process the request until the requirement is fulfilled). • The above mentioned can be organized by changing the regulations for the inclusion of this formal element or by changing national patent application forms. • A patent office can not only function as a formal checkpoint for compiling information: it can also verify the validity of the legal procurement of the genetic resource as a substantive procedure in the case of patent application (this change requires an adjustment and its reflection in the national legislation on intellectual property rights or patents)	• They miss out products that are available on the market and do not require a patent.
Competent National Authority (CNA)	• Can be chosen as a checkpoint but its efficiency and relevance as a checkpoint needs to be proven to the ABS-CH since the responsibility of a CNA is to grant access to genetic resources and TK and benefit sharing, issue written evidence that access requirements have been met, and advise on applicable procedures and requirements for obtaining PIC and entering into MAT.	• Have no relation to the *utilization* process of genetic resources. They are not part of the 'stages of research, development, innovation, pre-commercialization nor commercialization'. • Not in contact with users gaining access of genetic resources/ TK from abroad.

Parties shall require users to provide the relevant information to the checkpoints, which in turn is to be provided to relevant national authorities, the Party providing PIC and the ABS Clearing House (NP Art. 17.1.a.ii and iii). The Protocol establishes an *internationally recognized certificate of compliance* (NP, Art. 17.2., 17.3) to serve as evidence that genetic resources have been acquired legally. This basically represents an elevation of the status of the access permit. Minimum information requirements for the certificate are set out in Article 17.4.

Other monitoring mechanisms in addition to the mandatory internationally recognized certificate of compliance include the sharing of information through reporting requirements, and cost-effective communication tools and systems (Kamau et al., 2010).

Besides the user-country measures to support compliance, the provisions on *traditional knowledge* associated with genetic resources are probably the most innovative. The Protocol significantly enhances the protection of the holders of traditional knowledge in international law (Buck and

Hamilton, 2011). This protection also involves user measures. In parallel and very similar to the obligations to support compliance with national access legislation, Parties shall also take measures to support compliance with PIC and MAT from indigenous and local communities (ILCs) if this is required by domestic legislation (Art. 16.1).

4 Disclosure of origin in patent applications as a user measure

One user measure with a particularly high profile throughout the negotiations of the CBD and its follow-up and later during the Nagoya Protocol negotiations (even if it is not mentioned in the Convention and the Protocol) is the disclosure of origin of genetic resources in patent and other intellectual property rights (IPR) applications.

The connection between the ABS regime and patent and other IPRs has remained a controversial issue between developed and developing countries. Reinforcing national sovereignty to genetic resources in the CBD as a backbone of the ABS regime was intended largely to counter-balance the rapid evolution in modern biotechnology with the patenting of living material at a time where questions of access to genetic resources had been moving in the direction of a 'common heritage of mankind' approach with open access. Developing countries saw patents and other IPRs as enabling commercial interests in developed countries to access 'their' genetic resources without compensation, as well as imposing a high price for 'reintroduction' of the patented products based on the resources.

The IPR development was enshrined in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), one of the pillars of the World Trade Organization (WTO) which was negotiated in parallel to the CBD negotiations but with no interconnections. Developing countries in the TRIPS Council have attempted to promote mutual supportiveness between the two regimes by introducing the obligation to disclose in patent applications the source and/or country of origin of biological resources, of associated traditional knowledge and of legal acquisition of such resources, if such resources and/or traditional knowledge are contained in an invention over which an applicant is seeking patent rights. The idea is to make transparent and subject to public scrutiny whether ABS obligations have been met, and to facilitate identification of potential cases of misappropriation at the point in time when a patent application is made (UNCTAD, 2014). Despite increasing support from developed countries, the USA in particular acted to hinder adoption of this proposal in the TRIPS Council. [4]

Developing countries also pushed for a disclosure requirement in the Nagoya Protocol. Ultimately, consensus could not be achieved, so the

[4] See BIORES article "Disclosure of origin again on the TRIPS Council agenda" reporting from a TRIPS Council meeting in 2007. http://www.ictsd.org/bridges-news/biores/news/disclosure-of-origin-again-on-the-trips-council-agenda-0

Protocol leaves it up to the Parties to decide whether or not to incorporate such a requirement in their national laws. This could be done in connection with designating patent offices as national checkpoints, in accordance with Article 17 of the Protocol.

Actually, already before the NP, several countries had introduced such disclosure requirements nationally. Among these are Belgium, Bolivia, Brazil, China, Colombia, Costa Rica, Denmark, Ecuador, Egypt, the EU, India, Norway, Peru, the Philippines, South Africa and Switzerland (Henninger, 2010). However, the provisions differ substantially in terms of binding nature, scope and consequences in case of non-fulfilment. Some countries provide only a non-binding, voluntary disclosure requirement (as is the case with the EU); some provide mandatory disclosure requirements with links to criminal sanctions, but with no effect on the validity of the patent in cases of non-compliance (e.g., Norway and Denmark); and yet others link patentability, nullity or revocation of patents with disclosure of origin (e.g., India, Brazil and South Africa). The provisions also differ as to whether they cover traditional knowledge.

It is notable that the issue of disclosure of origin has had such a prominent role in the ABS negotiations and been such a strong symbol for developing countries' demand for developed countries to take responsibility for benefit sharing and compliance. For many years it was the sole user measure to be discussed, despite its being a rather inadequate tool for ensuring compliance with PIC and MAT – particularly when disclosure has no bearing on patentability, as is the case with most developed-country disclosure requirements. As a stand-alone requirement not linked to implementation or enforceable benefit-sharing commitments, disclosure may merely serve as a mechanism for the provision of information (Tvedt and Young, 2007). Also, disclosure requirements may cover only a handful of ABS cases, as many uses of genetic resources do not invoke patents and other types of IPRs. Lastly, users acting in bad faith will always be able to conduct 'patent shopping' and then file patent applications in jurisdictions where disclosure requirements do not exist or are more lenient (UNCTAD, 2014). Still, disclosure in patent applications should be considered a useful measure for tracking compliance as it provides mutual recognition and supportiveness between two regimes that are widely perceived as conflicting.

Developing countries unsuccessfully invested huge political capital in striving for international disclosure requirements that would not seriously affect the patent system. Hence, viewing the issue through the lens of bigger developed countries like the USA, Canada and Australia, it could be argued that these countries made a tactical misjudgement by so strongly rejecting disclosure requirements. Had there been early acceptance of this concept among the developed countries, developing countries might not have insisted on an ABS Protocol which in the end came to include user-country obligations stronger than and beyond disclosure requirements.

5 Positive incentives for compliance

Even the most effective ABS regulatory means (provider- as well as user-side legislation) can never be fully enforced. Genetic-resources activities are often conducted in laboratories, making them very difficult for inspectors to control. It would therefore be a prerequisite for governments to supplement control-based compliance measures with positive incentive and motivation measures. General information to users to raise their awareness on ABS is still a key measure, although the NP has considerably increased ABS awareness compared to earlier. Professional codes of conducts, guideline standard-setting (e.g. through voluntary certification schemes) are other 'carrot' means as covered by NP Art 20 (Barber et al., 2003). An example of an international ABS standard is the one prepared by the Union for Ethical Bio Trade (UEBT) that promotes the 'Sourcing with Respect' of ingredients from biodiversity.[5] UETBT has set a positive business tone, indicating that, by providing a clearer and more level playing field, the Protocol not only creates burdens, but also opens up opportunities for companies already working towards ethical practices in their sourcing of biodiversity.[6]

Switzerland is a typical user country that has taken steps to raise awareness among its users on the ABS regime and on how to conduct their use accordingly. In 2006, the Swiss Academy of Sciences issued **'**ABS Good Practices and Model Clauses for academic research on genetic resources'[7] and in the following year the Federal Department of Economic Affairs published 'The ABS Management Tool – Best Practice Standard'.[8] An ABS standard for ex-situ collections in Switzerland has also been developed.[9]

6 ABS user measures in practice

Very little action was taken in the years after the entry into force of the CBD as regards applying national measures for users to comply with provider-country access regulations – measures relevant mainly for developed countries. This was a major reason why developing countries pushed so hard for a supplementary agreement to the CBD on ABS, and for the provisions on user/compliance measures that came with the Nagoya Protocol.

The Protocol requires all Parties to establish ABS regulatory frameworks from a provider as well as a user perspective. Hence, the Protocol is also a useful reminder that the provider–user relation is not necessarily a developing–developed country relation. *All* countries are actual or potential providers and users of genetic resources.

[5] http://ethicalbiotrade.org/
[6] UEBT briefing note on the Nagoya Protocol. http://ethicalbiotrade.org/dl/benefit-sharing/UEBT-ABS-Nagoya-Protocol.pdf
[7] http://www.iisd.org/pdf/2006/abs_swiss_abs_good_practice.pdf
[8] https://www.iisd.org/pdf/2007/abs_mt_standard.pdf
[9] http://www.indo-germanbiodiversity.com/pdf/Switzerland_Compliance.pdf

As noted, several countries have introduced disclosure requirements in patent applications. Apparently, other types of user measures in accordance with the NP have been introduced only in Europe thus far – most notably by the 28-member European Union – and little information is available on considerations of user measures in other regions. A gap analysis of the 2001 African Model Law on the Protection of the Rights of Local Communities, Farmers and Breeders and for the Regulation of Access to Biological resources in light of the NP does *not* identify the absence of user measures as a gap (Munyi et al., 2012).

Norway[10]

Norway was the first developed country to ratify the Nagoya Protocol in 2013, thereby taking the lead amongst the developed countries. It was probably also the first country to introduce user-measure legislation beyond disclosure requirements on ABS, as reflected in Norway's Patents Act (1967, amended by Act No 20. of May 2004), and its Nature Diversity Act (NDA), which entered into force in 2009. Sections 57 to 60 in the latter cover both provider and user measures in ABS legislation.

The import into Norway of genetic material from a provider state that requires PIC may take place only in accordance with such consent. According to Section 60.1, the person that has control of the material is bound by the conditions that have been set for consent and the State may enforce the conditions by bringing legal action. Section 60.2 of the NDA requires the importer of genetic material to attach information regarding the country from which the genetic material has been received; and, if PIC is required, proof of PIC. Section 60.3 further stipulates that, if the provider country is not the country of origin, the country of origin shall also be stated.

Sections 69 to 75 relates to enforcement of the provisions of the Act. Section 75 declares that any person that wilfully or through negligence contravenes the provisions including, but not limited to, Section 60, shall be liable to fines or imprisonment. So far, there have been no known cases of violation of the provisions regarding ABS.

As regards traditional knowledge, an amendment to the Nature Diversity Act was adopted by Parliament in June 2013 in order for Norway to be able to ratify the Nagoya Protocol. A New section 61a provides that the interests of indigenous peoples and local communities shall be respected when traditional knowledge associated with genetic resources held by these is accessed and utilized. The Section further provides authorization to issue a regulation stipulating that access to and utilization of traditional knowledge requires prior informed consent from the indigenous peoples or local communities holding the knowledge as well as rules on sanctions against misappropriation. Such a Regulation is currently under develop-

[10] For a more thorough review of the Norwegian legislation, see Tvedt, M.W., 2015. 'Norwegian Experiences with ABS' in: Coolsaet, B., Broggiato, A., Pitseys, J., and Dedeurwaerdere, T., (eds), *Implementing the Nagoya Protocol Comparing Access and Benefit-sharing Regimes in Europe*, Martinus Nijhoff, Leiden.

ment to meet the obligations of Articles 5.5, 7 and 16 of the Nagoya Protocol.

To track compliance with PIC and MAT, the Norwegian Patent Act has requirements for disclosure of origin in patent applications. When an invention concerns or uses biological material, 'the patent application shall include information on the country from which the inventor collected or received the material or the knowledge (the provider country). If it follows from the national law in the provider country that access to biological material or use of traditional knowledge shall be subject to prior consent, the application shall state whether such consent has been obtained' (Section 8b, Norwegian Patent Act of 2003). Moreover, any recipient of genetic material from a public collection shall refrain, in Norway or abroad, from claiming intellectual property rights to the material, unless the material has been modified in a way that results in substantial change. Similar information requirements apply to applicants for plant variety protection (Plant Breeders' Rights Act, Section 4(3)).

As is the case of similar disclosure requirements in legislation of other European countries, this duty to disclose information is without prejudice to the processing of the patent application or its validity once it has been granted. However, violation of the disclosure requirement is punishable under Norway's General Civil Penal Code, § 221.

Denmark[11]

In 2012 Denmark enacted its 'Act on Benefit Sharing from the Utilization of Genetic Resources' [12] as a basis for ratification of the Nagoya Protocol. The Act prohibits the use of genetic resources acquired in violation of access legislation in the provider country. Such legislation shall fulfil the conditions for access regulation, including PIC as set out in Article 6, Section 3.1, of the NP. As specified in Section 3.2, the provision applies only to provider countries that are Parties to the NP and where the Protocol has entered into force at the time of the acquisition.

A similar requirement for users of genetic resources applies to the use of traditional knowledge associated with genetic resources in violation of the provider country's legislation.

Denmark was the first developed country to adopt legislation requiring disclosure of origin in patent applications. According to the Danish provision from 2000, 'if an invention concerns or makes use of biological material of vegetable or animal origin, the patent application shall include information on the geographical origin of the material, if known'. Failure to do so does not impede the granting of a patent or validity of the

[11] For a more thorough review of the Danish legislation, see Koester, V., 2015. 'Danish Experiences with ABS' in: Coolsaet, B., Broggiato, A., Pitseys, J., and Dedeurwaerdere, T., (eds), *Implementing the Nagoya Protocol Comparing Access and Benefit-sharing Regimes in Europe*, Martinus Nijhoff, Leiden.

[12] Lov nr. 1375 af 23 december 2012 om udbyttedeling ved udnyttelse af genetiske ressourcer. (Act on benefit sharing when utilising genetic resources, not translated).

patent.[13] Breach of this provision could imply a violation of the obligation in the Danish Penal Code to provide correct information to public authorities. The disclosure requirement does not include an obligation to disclose information on traditional knowledge, however.

Denmark is a member state of the European Union. The national provisions can be regarded as a supplement to the EU Regulation (discussed below), which Denmark is bound by, but which was adopted only after the Danish Act had been adopted. Section 5 of the Act authorizes the Minister of the Environment to make further regulations on procedures and standards which could include the due diligence requirements of the EU Regulation. This could explain the absence of more detailed provisions in the Danish Act, for instance as regards reporting by users to the competent authority, checkpoints and other enforcement measures. Denmark has not yet designated checkpoints to the ABS Clearing House.

European Union (EU)

Through its Regulation No 511/2014 of 16 April 2014,[14] the European Union on behalf of its now 28 member states has implemented the Nagoya Protocol in terms of user-country measures – and such measures only. It is left to the discretion of the member states to decide if and how they, as providers, wish to regulate access to their domestic genetic resources.

Chapter II (Articles 4–11) of the regulation deals with user-compliance measures. Users of genetic resources are required to exercise *due diligence* 'to ascertain that genetic resources and traditional knowledge associated with genetic resources which they utilize have been accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements, and that benefits are fairly and equitably shared upon mutually agreed terms, in accordance with any applicable legislation or regulatory requirements' (Art. 4.1). Furthermore, the information gathered shall be transferred and utilized in accordance with MAT only if required by applicable legislation or regulatory requirements (Art. 4.2).

Users shall seek, keep and transfer to subsequent users an internationally recognized certificate of compliance together with information on the content of the MAT. If this certificate is not available, relevant information and documents with description of the genetic resources and/or traditional knowledge shall be kept about the transaction, including on PIC, MAT and the presence or absence of rights and

[13] This provision of ministerial regulation 1086 11/12 2000 replaced para 3 of the existing ministerial regulation on patents (Reg. 374 19/6 1998) (unofficial translation).
[14] REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL.
of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising out of their Utilization in the Union.

obligations pertaining to genetic resources and associated traditional knowledge in the provider country (Art. 4.3(b)).

If a user has acquired plant genetic resources for food and agriculture (PGRFA) not contained in Annex 1 of the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), and the provider country has determined that these PGRFA are under its management and control, in the public domain and subject to the terms and conditions of the standard material transfer agreement for the purposes set out under the IT, the user shall be considered to have exercised due diligence (Art. 4.4).

According to Art. 4.5, in case of insufficient information or uncertainties about legality with access and utilization, users shall obtain an access permit or equivalent, establish MAT, or discontinue utilization. If the deadlines set for providing this information are not met, utilization shall be discontinued.

The EU Commission is to establish a register of collections within the Union (Art.5). Member states shall designate competent authorities and focal points (Art. 6), and two checkpoints for monitoring compliance: when receiving research funding, and at the time of a final product developed (Art. 7). Member states shall also conduct checks on user compliance with due diligence (Art. 9), retain the records of these checks for at least five years (Art. 10), and lay down rules on penalties (Art. 11). Moreover, complementary measures shall be taken by member states, as appropriate. These may include promotion, awareness-raising and training activities, sectoral codes of conduct, model contractual clauses, guidelines and best practices (Art. 13).

The Regulation has been criticized for being too cumbersome for industry, and the plant breeding and seed industries in Germany intend to take legal action against it.[15] However, most criticism has come from the opposite side: that the Regulation is too weak to meet its normative objectives. Its temporal scope has been criticized for applying to ABS transactions only after the entry into force of the NP, thereby not supporting compliance with access legislation enacted on the basis of the CBD. Moreover, for the transactions actually covered by the Regulation, the trigger is the time of *access*, not *utilization* – thereby excluding large amounts of genetic resources and traditional knowledge acquired before the Nagoya Protocol, but still waiting to be utilized (United Nations University et al., 2014; Natural Justice and Berne Declaration, 2013). The reason stated by the EU for this temporal scope is the principle of non-retroactivity in legislation.

The Nagoya Protocol is silent on whether or not it applies to genetic resources and associated TK accessed before its entry into force, simply because this was a contentious issue on which countries could not agree.

[15] (Press release quotes from Stephanie Franck, President of the German Plant Breeders' Association (BDP (http://ipkitten.blogspot.no/2014/08/german-plant-breeders-challenge-eu.html).

However, various legal experts have held that Articles 3, 5(1), 5(2) and 5(5) call for including not only new access to genetic resources for the purpose of their utilization after the implementation of the NP, but also new and ongoing utilization carried out after that time (Natural Justice and Berne Declaration, 2013). Thus, they consider the non-retroactivity argument irrelevant. It is further argued that the (physical) access trigger would create a legal uncertainty for users that the EU is otherwise keen to do away with. This is because many national regulations of genetic resources from a provider side include utilization as a trigger, implying that utilization of a genetic resource by a European user may be considered legal in the EU but illegal in the provider country (ibid.).

It has also been criticized that the EU Regulation includes no means for structural monitoring and tracing of compliance. User declarations will not be made public, and providers will depend on accidental discovery of use and commercialization (Godt, 2015). Moreover, it has been argued that the Regulation should have adopted a more integrative approach whereby ABS measures were included within existing procedures along the development chain. Godt (2015) argues that a better implementation approach on the part of the EU would involve 'the integration of the duty to disclose information about ABS compliance into existing procedures in which genetic resources and products based or derived from genetic resources are accessed, stored analysed, developed, and make their way up to market commercialization *coupled* with general rules which allow providers to seek judicial redress.' Not only would this ease the administrative burden of users and the state alike, it would also improve transparency of the flow of genetic resources and associated traditional knowledge (Coolsaet, 2015).

Finally, the limited attention and the approach in the Regulation to traditional knowledge associated with genetic resources have been criticized. Referring to the lack of an internationally agreed definition of traditional knowledge, the Regulation states that traditional knowledge associated with genetic resources is to be defined in mutually agreed terms (EU Regulation No 511/2014, Recital 20). This approach *de facto* excludes traditional knowledge accessed *without* a benefit-sharing agreement (Tobin, 2014).

Switzerland

From a user perspective, Switzerland employs genetic resources mainly through private-sector businesses and scientific research institutions – in the pharmaceutical sector (including biotechnology), the food, cosmetic and flavour industries, as well as in agriculture (Kraus and Rüssli, 2011). All these sectors are interested in good and clear access to genetic-resources procedures. Also before the NP, several stakeholders were active in developing measures to comply with the ABS provisions from the CBD. This led to new collaboration between the industry and developing countries and the development of various best practice guidelines and recommendations made e.g. by the Swiss Academy of Sciences (SCNAT) for academic research on genetic resources. As noted, Switzerland is advanced in introducing voluntary guidelines, standards,

codes of conducts, best practices etc. for users.[16] Swiss implementation of the NP therefore consists of a mixture of non-legally binding measures and practices and legally binding ABS measures.

In 2008, Switzerland introduced a requirement in its Federal Act on Patents for Inventions on disclosure of the source of genetic resources and associated traditional knowledge used in inventions which are the object of a patent application. According to Article 49a of this Act, an application must contain this information to which the inventor or patent applicant had access, provided that the invention is directly based on this. If the source is unknown to the inventor or patent applicant, the applicant must confirm this in writing. The source to be indicated will generally be the country providing the genetic resources (Kraus et al., 2011). If this information is missing, a deadline will be set for the applicant to supply the information; if the information is still missing when the deadline expires, the patent will not be granted. Anyone providing false information under Article 49a is liable to a fine of up to 100,000 Swiss Francs (Art. 81a(1)). Courts may also order the publication of the judgment (Art. 81a(2)).

With its ratification of the NP, Switzerland amended its Federal Act on the Provision of Nature and Cultural Heritage with a new section 3c dealing with genetic resources. Very similar to the EU, the Swiss legislation introduces a requirement providing that whoever – according to the NP – utilizes genetic resources and associated traditional knowledge, or whoever directly benefits from their utilization, shall apply due diligence appropriate to the circumstances to ensure that access to these resources has taken place lawfully and that benefits arising out of their utilization are shared fairly and equitably (Art. 23 n.1).

Access is considered lawful if it has taken place in accordance with the domestic regulatory requirements on ABS of the Party to the NP that has provided the resource or the knowledge, respectively (Art. 23 n.4). If it is found that the due diligence requirement has not been complied with, the user shall ensure that this is fulfilled at a later stage, or must renounce use of the genetic resources in question (Art. 23 n.5). The Federal Government will provide additional regulations at the Ordinance level concerning the information to be recorded and, where appropriate, to be passed on to future users, in compliance with the due diligence requirement (Art.23 n.6).

Compliance with due diligence must be notified to the competent authority before market authorization has been obtained or, if such authorization is not required, before the commercialization of products developed on the basis of utilized genetic resources (Art. 23o.1). The above-mentioned also applies to traditional knowledge of indigenous and local communities associated with genetic resources, if this traditional

[16] Presentation by Marco D'Alessandro, National Swiss Focal Point for the Nagoya Protocol, Federal office for the Environment, Switzerland at CBD COP 11 side event in 2012.
(https://www.cbd.int/abs/side-events/cop-11/switzerland-en.pdf)

knowledge is not already freely available to the public (Art. 23p). One or more checkpoints shall be designated.

As in the EU, the due diligence requirement does not apply if access to genetic resources has taken place before the NP enters into force (Art. 25.d).

Checkpoints

To date, four country parties have notified the designation of checkpoints to the ABS Clearing House: Belarus, Peru, South Africa and Switzerland.[17]

Concluding remarks on user measures and checkpoints in practice

The above presents basically two models of user measure legislation as inspiration for the many countries that do not have such measures in place as required by the Nagoya Protocol:

a) A *result-based* direct requirement of users to comply with provider-country legislation, as in Norway and Denmark, with little specification as to which measures users should take to achieve this result.

b) A *conduct-based* due diligence requirement, as in the EU and Switzerland, aimed at supporting user compliance with provider-country PIC and MAT obligations, specifying minimum steps to be taken, but leaving a margin of user flexibility on how to act and with no direct legal obligation for users to comply with access regulations in provider countries.

Concerning model a, an important difference between Danish and Norwegian legislation should be noted: The Danish Act's prohibition of the use of genetic resources that are acquired in violation of access legislation in the provider country does not necessarily imply a prohibition against breach of the *terms* set for permitting access.[18] In contrast, the Norwegian legislation makes it clear that the person with control of the genetic material is bound by the conditions that have been

[17] CBD Secretariat, the Access and Benefit-Sharing Clearing House https://absch.cbd.int/search/national-records/CPBelarus has designated the National Coordination Centre on Access to Genetic Resources and Benefit-Sharing as a checkpoint, which is also one of its two existing competent national authorities; and Peru has designated its National Commission Against Bio-piracy (La Comisión Nacional para la Protección al Acceso a la Diversidad Biológica Peruana y a los Conocimientos Colectivos de los Pueblos Indígenas, Comisión Nacional contra la Biopiratería) and the National Institute for the Defence of Competition and the Protection of Intellectual Property **(**Dirección de Invenciones y Nuevas Tecnologías (DIN) del Instituto Nacional de Defensa de la Competencia y de la Protección de la Propiedad Intelectual, INDECOPI) as checkpoints. In 2014 Switzerland designated two checkpoints: the Swiss Federal Institute of Intellectual Property, responsible for implementation of the disclosure of source requirement for GR and/or TK in patent applications; and the Federal Office for the Environment (FOEN).

[18] This limitation is specifically mentioned in the Explanatory Notes to the Danish Act (Lovforslag nr. L 70 Folketinget 2012-13. Forslag til Lov om udbyttedeling ved anvendelse af genetiske resourcer, p. 5.)
http://www.ft.dk/RIpdf/samling/20121/lovforslag/L70/20121_L70_som_fremsat.pdf

set for consent. Another difference is that Norway prohibits the *import* of illegal material, whereas Denmark prohibits the *use* of illegally acquired genetic resources and/or traditional knowledge. It seems unlikely that this difference would have any real impact. Genetic resources will always be imported for some kind of utilization, a term broadly defined in the NP[19]. Lastly, Norwegian (but not Danish) legislation provides that the state can enforce the conditions by bringing legal action.

It should be pointed out that the apparent inadequacies in the Danish legislation may be rectified by means of the provisions of the national Act which empowers the Minister to issue further regulations on procedures and standards and which include implementation of the EU Regulation. When this is carried out, Danish legislation on user measures will actually be able to combine models a and b.

Regarding the *temporal scope*, Norway's legislation is special because it was adopted prior to the NP, thereby covering the acquisition of genetic material both before and after the entry into force of the NP; other countries' legislation applies only to the latter. The legislation of EU and Switzerland explicitly provides that *access* to the genetic resources and not the *use* is the trigger for its application. As noted, legal scholars have criticized this for being in violation of the NP. The Danish Act (§§ 3 and 4) refers to genetic resources and traditional knowledge that have been 'acquired' in violation of access legislation enacted by NP Parties in pursuance thereof; and hereby the temporal scope and the trigger for application appear similar to the EU and Swiss legislation.

Checkpoints have been installed in no more than four countries, only one of which (Switzerland) has introduced wider user-country measures. The effectiveness of the checkpoints will need to be evaluated at a later stage.

A general discussion on pros and cons of the models of user measure legislation is provided below.

7 User measures in India

With its rich biodiversity, India has been playing an important role for bioprospectors as a provider country. In response to the extensive use of its biodiversity, India enacted an advanced regulatory framework for ABS in 2002, at a time when very few countries had introduced such frameworks. India's Biological Diversity Act (2002) was developed through an extensive and intensive consultation process initiated in 1994. The Act aims primarily at the regulation of access to Indian biological resources and associated traditional knowledge so as to ensure the equitable sharing of benefits arising out of their use, in accordance with the provisions of Article 15 of the CBD. To implement the various, mostly access related, provisions of the BD Act, the National

[19] NP Article 2(c): *"Utilization of genetic resources" means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention.*

Biodiversity Authority (NBA) was established in India under Section 8(1) of the BD Act.[20]

Although India is well known as a provider country, it is also a user of genetic resources and associated TK obtained from abroad. A broad range of users in India – academic and other non-commercial researchers, but also commercial companies from various sectors of industry – use genetic resources and/or associated traditional knowledge obtained from outside Indian jurisdiction for research, development and commercialization purposes. These users must comply with domestic legislation on access and benefit sharing in the country where the material is obtained. Like other mainly-provider countries (as well as many mainly-user countries), before the adoption of the NP, India paid limited attention to its citizens and companies using genetic resources from other countries, or to India's role in supporting compliance with these countries' access regulations.

In order to determine user measures for compliance with the NP, the Indian Centre for Biodiversity Policy and Law (CEBPOL) is in the process of identifying Indian users of foreign genetic resources within the various sectors. This provides a starting point for determining appropriate measures to ensure that users enter into ABS agreements with providers according to the domestic legislation of the provider country. Thus it is also important that countries which provide Indian users with genetic resources have their regulatory ABS frameworks in place.

Patent applicants (users) are in India already obliged to disclose the source and geographic origin of biological material in their applications, as a condition for patent being granted.[21] This is an important user measure for monitoring and enhancing transparency on the utilization of India's biological resources. However, as discussed above, a disclosure requirement is not in itself sufficient to establish an effective national system to support compliance with other countries' access requirements for genetic resources and traditional knowledge in accordance with NP Articles 15 and 16. These provisions require more direct and tangible measures, to which disclosure could be viewed as a support measure. Moreover, outreach measures are being developed to raise awareness about the ABS regime among Indian users, in line with Article 21 of the NP.

Finally, India is currently in the process of designating effective checkpoints to cover the various stages of the biotechnology value chain, from early research to final product commercialization. Institutes involved in granting approval or monitoring research in which biological resources are involved could be essential checkpoints to establish, in addition to the authorities involved in granting patent applications and the authorities granting the sales of products. The latter can play an important role at the end of the biotechnology chain, since patent offices can cover

[20] The Act and the issues of access and benefit sharing of biological resources and governance have been discussed in further detail by Rana (2012, 2014) and Narayanan & Pisupati (2015).
[21] Patents Act 1970, Chapter III.10.4d.ii.D

only products for which patents have been applied for. Research institutes are not favoured as checkpoints in India, because they employ the users of genetic resources and traditional knowledge, and are subject to research funding. No decision has been made so far on checkpoints.

8 Discussion

Which measures are feasible for India? One consideration to be taken into account is what type of user measures India, as a typical provider country, would like to see from a typical user country to support compliance with the Indian regulatory system. Together with other megadiverse countries, India urged a strong user-measure focus for the NP, to emphasize the neglected responsibility of typical user countries to make the ABS regime functional. Such considerations would point in the direction of introducing a straightforward prohibition of the *import* and *use* of genetic resources acquired in violation of the provider country's access legislation (model *a*, like Norway and Denmark). This should include an obligation for users to comply with the conditions set by the provider country for granting access and an opportunity for providers to seek judicial redress in India, as in Norway (but not Denmark).

Such a general 'model *a*' prohibition could well be combined with model *b* (due diligence, as applied by the EU and Switzerland) by introducing a certain conduct for users, either as legally binding or through voluntary – possibly sector-specific – codes of conduct, guidelines, a consulting service or other types of awareness-raising in line with NP Articles 20 and 21. There are lessons to be learned particularly from Switzerland, which has played a vital role in developing awareness-raising and capacity-development activities.

A dialogue with the users of various sectors is essential, to clarify which legal and other measures India should take within the legal obligations of the NP. Preparations for these dialogues are being taken as of this writing.

Further steps to be undertaken in the near future:

- *Cooperation with countries where Indian users have violated domestic ABS legislation (NP Art. 15.3 and 16.3).*
- *Requirement to users on which information to provide to checkpoints (NP Art.17.1).*
- *Encouraging users (and providers) to include provisions in MAT on dispute resolution (NP Art. 18.1).*
- *Ensuring opportunities to seek recourse in case of disputes arising from MAT (NP Art. 18.2.)*
- *Ensuring access to justice and the utilization of mechanisms regarding mutual recognition of and enforcement of foreign judgments and arbitral awards (NP Art. 18.3).*

9 Conclusions

User-measure requirements are the cornerstone of the Nagoya Protocol. They have come about as the result of hard, persistent pressure from developing countries on developed countries to take co-responsibility in making the ABS regime functional. The degree of national implementation of Articles 15 to 18 will be an important indicator of the success of the NP.

As to the implementing steps already taken in this regard, special attention should be paid to the EU ABS Regulation: it covers 28 countries, some which are considered among the biggest user countries in the world. It may be questioned whether this piece of legislation is adequate for meeting its objective of providing compliance on the part of users of regulatory requirements on access and benefit-sharing in provider countries. The Regulation stipulates that access, not utilization, is what triggers the compliance requirements by users – in contrast to many ABS legal systems in provider countries, under which any new use of genetic resources triggers ABS obligations. Thereby, the Regulation excludes genetic resources accessed but not used before the NP entry into force. Its due diligence requirements are intended to be monitored only moderately by the competent authorities, and the requirements are not linked to existing procedures along the genetic resources development chain. Furthermore, the issue of traditional knowledge is barely addressed by the EU ABS Regulation.

The inadequacies in the legislation applying to such a massive constituency of users may strike back and obstruct objectives of the ABS regime which the EU has fought for: legal clarity, and facilitated access. In itself, the inconsistency between the temporal scope of the EU ABS Regulation and legislation in many provider countries creates legal uncertainty. The rather weak conduct-based user obligations in the EU Regulation may lead to renewed mistrust on the part of typical provider countries towards typical user countries as regards the sincerity of their intentions of supporting compliance. As in the early days of ABS negotiations, developing countries might introduce protectionist legislation that would make access difficult, rather than serving as an incentive for bioprospecting and beneficial partnerships between providers and users.

On that basis, NP country parties would seem better advised to apply the ‘Norwegian approach’ – a straightforward obligation for users to access/use the material only in conformity with the ABS requirements of the provider country. Such a general requirement could be accompanied by further requirements or codes of conduct by users to ascertain that the acquisition is legally in order.

An obvious first priority for many developing countries is establishing a legal and administrative framework to regulate access to genetic resources from the provider side. Many of them probably have yet to consider whether and how to enact user measures. However, all parties are required to introduce the user measures outlined in Articles 15 to 18, and for good reasons. All countries are providers as well as users of

genetic resources – this is becoming increasingly true in today's globalized world with growing volumes of transactions between countries. Introducing user measures in developing countries could also serve to put pressure on those developed countries that may still be lagging behind.

As a pioneer country in terms of provider-country measures, India has already implemented the NP from that side. It is now on its way to becoming a pioneer as a developing country introducing user measures as well. This, it is to be hoped, will contribute to a more balanced system for access to genetic resources and benefit sharing – in India and worldwide.

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About CEBPOL

CEBPOL is a joint programme on technical and institutional cooperation between the Government of Norway and the Government of India as part of the Indian–Norwegian dialogue under the Joint Working Group on Environment.

CEBPOL is intended as a centre of excellence focused on biodiversity policy and law, catering to the needs of national and international rule-making and subsequent implementation on biodiversity issues. Its objectives are as follows:

1) to provide professional support, advice and expertise to the Governments of India and Norway on a sustained basis on matters relating to biodiversity policies and laws at the national level, as well as in international negotiations relating to biodiversity in multilateral forums;

2) to develop professional expertise in biodiversity-related policies and laws, *inter alia* by encouraging research, development and training in matters relating to the Convention on Biological Diversity, as well as its interface with other multilateral environment agreements and UN bodies;

3) to develop and implement an array of capacity-building programmes through multidisciplinary research and customized training programmes for a wide range of stakeholders, focusing on human resource development;

4) to facilitate interactive information sharing through web conferencing, web seminars and virtual meetings involving relevant research centers and environmental law associations in India, Norway and other countries where such expertise is available;

5) to help to develop India as a regional and international resource centre for biodiversity policy and law, through the provision of training and human resource development.

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