The Ambiguous March to Equity

A Commentary on the Limitations of the European Union Regulation on Access and Benefit Sharing

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Editors: Berne Declaration (BD), Natural Justice and UNU-IAS
Picture Frontpage: iStock

1. Prologue

The commentary you are about to read seeks to identify and analyse the limitations of the draft EU Regulation on Access and Benefit Sharing. While it is not an exhaustive analysis of the EU Regulation, it strives to highlight the loopholes therein using the standard of equity and the spirit of the Convention on Biological Diversity and the Nagoya Protocol.

We hope that this analysis will initiate further research and discussions. It is our view, that the need of the hour is mutual coherence between the North and the South's conceptual understanding Nagoya Protocol. It is only such a coherence that will result in a coordinated implementation of the Protocol making fair and equitable sharing of benefits a reality. Though we are a long way from achieving such coherence, this commentary seeks to make a small contribution towards this goal.

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February 18th 2014

Yokohama/Zurich

Disclaimer: The views of the authors don't necessarily represent the views of the UNU-IAS.

2. Background

On the 28th of November 2013, a compromise agreement[1] was reached between the European Parliament, Council and Commission negotiators. This hard fought compromise is a draft European Union (EU) Regulation on the compliance and benefit sharing obligations in the EU for users of genetic resources and associated traditional knowledge. Through the months of October and November 2013, there were three intense trialogues between the European Parliament, Commission and Council on a proposal for a comprehensive EU Regulation on ABS. The conclusion of the third trialogue resulted in the current compromise text of the EU Regulation.

Despite the surprising lack of media coverage of this agreement, its significance cannot be overstated. It heralds an EU Regulation on Access and Benefit Sharing (ABS) that finally upholds 'user country obligations' that were incurred by the EU when the Convention on Biological Diversity (CBD) entered into force in 1993. More than twenty years after the CBD established the rights of countries and indigenous and local communities (ILCs) to determine the terms of access to their genetic resources (GR) and associated traditional knowledge (ATK) respectively,[2] the EU has got around to developing a law to protect these rights.

The trigger for this process is the Nagoya Protocol on ABS adopted by the Conference of Parties to the CBD in October 2010. The Nagoya Protocol articulates a legal framework in international law to protect the rights of countries to their GR and ILCs to their ATK as enshrined in the CBD. The draft EU regulation on ABS is currently before the European Parliament and is likely to be adopted in March 2014. It is a decisive step towards the ratification of the Nagoya Protocol by the EU.

What follows is a preliminary analysis of the compromise text of the draft EU Regulation with the aim of identifying its implications for countries and ILCs whose GR and ATK are utilized by individuals and entities in the EU.

[1] See http://www.consilium.europa.eu/documents?lang=en
[2] The abbreviations GR and ATK will be used henceforth to refer to genetic resources and associated traditional knowledge. However the full terms will be used in situations where an Article or a text is being quoted in verbatim.

3. Temporal Scope

The six years of intense negotiations towards the Nagoya Protocol resulted in a text whose silences were as significant as its words. The Nagoya Protocol is clear about measures that parties should undertake to secure legitimate rights over GR and ATK. However in order for the Protocol to be adopted, it had to allow for several strategic ambiguities. These ambiguities are intentional silences in the Protocol that provided parties with a fair amount of discretion regarding the manner in which they domestically implement their obligations under the Protocol. Perhaps it is how parties interpret these silences that is a true measure of their commitment to the spirit of the CBD and the Protocol.

The CBD, seventeen years before the Nagoya Protocol, had already established the rights of countries over GR and ILCs over ATK and the requirement to share benefits arising from their use. However in order for the Nagoya Protocol to be adopted in 2010, it needed to be silent about 'temporal scope.' Simply put, the Nagoya Protocol is ambiguous about the date from when the obligations of Parties to ensure benefit sharing by users in their jurisdiction should actually begin.

To elaborate- during the Protocol negotiations, there was a lot of debate regarding retroactivity, historical debt and when obligations to benefit share could reasonably be said to begin. Some argued that the rights of countries over their genetic resources began with the General Assembly resolution 1803 (XVII) on 'permanent sovereignty over natural resources' adopted on 14 December 1962. Others held the view that it was Article 15 of the CBD that vested property rights of countries over their GR, which until then was considered the common heritage of humankind.

Be that as it may, the explicit manner in which Article 15 of the CBD outlined the requirements of prior informed consent and benefit sharing regarding use of GRs made it undeniable that benefit-sharing obligations should at least begin from the date of entry into force of the CBD *and are triggered when GR are utilized*. This was the reason Article 3 of the Nagoya Protocol that deals with scope clearly lays down that the Protocol applies to GR within the scope of Article 15 of the CBD and ATK thereto.

However the draft EU Regulation is bold in its declaration that it applies "only" to genetic resources over which States exercise sovereign rights and to traditional knowledge associated with genetic resources that are accessed after the entry into force of the Nagoya Protocol for the Union and to the benefits arising from the utilisation of such genetic resources and traditional knowledge associated with genetic resources.' (Article 2.1 of the EU Regulation)

There is an issue here regarding how we could interpret the terms access and utilization in the EU Regulations but we will come to this in the next section.

For now, it would suffice to note that the draft EU Regulation has put to rest speculation around whether the EU would require benefit sharing arising from the utilization of GR in the EU from the date of entry into force of the CBD. The EU has made it clear in its regulation that it has no intention of opening the door for that discussion and has decided to seal it once and for all.

The EU Regulation not only closes the door on accessions and utilization of GR and ATK prior to entry into force of the Nagoya Protocol for the EU, but through Article 2.1, it also eliminates the need for prior informed consent or benefit sharing on GR and ATK accessed before the entry into force of the Protocol for the EU, but utilized thereafter.

To elaborate, both the CBD and the Nagoya Protocol clearly distinguish between the act of acquiring GR and ATK (access) and their use for research and development (utilization). Therefore even if access to the GR and ATK may have occurred prior to the entry into force of the CBD (or prior to the entry into force of the Nagoya Protocol for the EU), the fact remains that the obligation to benefit share is triggered the moment that GR and ATK are utilised.

This is a critical issue on temporal scope in the EU Regulation that is worth highlighting:

The Regulation states that there is no need to comply with the laws or regulations of countries of origin or provider countries if access to the GR and ATK has occurred prior to the entry into force of the Nagoya Protocol for the EU. Accordingly there is no requirement to share benefits arising from the continuing or new utilization GR and ATK after the entry into force of the Protocol for the EU as long as the GR and ATK was accessed prior to the Protocol entering into force for the EU.

This is egregious because it not only goes against the letter and spirit of the CBD and the Nagoya Protocol but also because the domestic ABS laws and regulations of a number of provider countries have not relinquished their rights over their GR and ATK even though they may be held in ex-situ collections outside these countries. In fact these ABS laws and regulations require compliance by users and benefit sharing when their GR and ATK is utilized. In one fell swoop, the EU not only seems to have misunderstood the difference between access and utilization in the CBD and Nagoya Protocol but also put users of GR and ATK in the EU in a dangerous muddle. These users within the EU will be able to conduct activities that are at once perfectly legal in the EU but illegal in provider countries inviting criminal and civil sanctions and making them unapprehended felons.[3]

It is critical to note that we are not referring to retroactivity here as the EU argued during the Nagoya Protocol negotiations. Article 28 of the Vienna Convention on the Law of Treaties provides that a treaty shall not be applied retroactively unless its parties chose to give it that effect. Since the Nagoya Protocol is silent on this aspect, its retroactive application cannot be expected from member states and neither is this our expectation of the EU. On the contrary we are simply referring to the CBD and the Nagoya Protocol obligations to share benefits once the utilization of GR and ATK commences. And specifically, in this case we are referring to the sharing of benefits for utilization that have commenced after the entry into force of the Nagoya Protocol in the EU. This is clearly not advocating retroactivity but rather highlighting the letter and spirit of the CBD and the Nagoya Protocol that the EU has chosen to ignore.

We would also like to qualify our views by stating that we definitely do not mean here that because the EU Regulations apply only to accessions after it ratifies the Protocol, the ABS laws of provider countries or ABS agreements that predate such a ratification no longer apply. When it comes to ABS laws or regulations of provider countries, they would still bind the users of GR and ATK in the EU even if the accessions predated the EU's ratification of the Protocol. However, it is imperative to understand that the EU as per its Regulations will neither require users in its jurisdiction to comply with these laws nor will it monitor and check for its compliance.

The singular value of the Nagoya Protocol is not because it enables countries to regulate the access and use of their GR and ATK. Countries could have used their sovereign powers to do this without the Nagoya Protocol. The significance of the Protocol and the CBD is that they require countries to take measures to ensure users in their jurisdiction comply with such laws and regulations, and this makes all the difference. We make a similar qualification when it comes to private agreements amongst individuals and institutions regarding access, use and exchange of GR and ATK predating the EU's ratification of the Protocol. These agreements will continue to stand as agreements in private law and can be enforced as contracts. The draft EU Regulations would have no bearing upon such private agreements one way or another.

[3] The points here have been made previously with greater elaboration by Natural Justice and the Berne Declaration in a 2013 briefing paper when the current draft EU Regulation was still in a proposal form. The comment titled- Access or Utilisation: What Triggers User Obligations can be downloaded at http://www.evb.ch/cm_data/20130618_LA_Access-or-Utilisation.pdf

4. The Global Multilateral Benefit Sharing Mechanism

It is interesting to note here the EU Regulation's indifference to Article 10 of the Nagoya Protocol that deals with the Global Multilateral Benefit Sharing Mechanism (GMBSM). During the Nagoya Protocol negotiations, the GMBSM was advocated by the African Group and supported by the EU. It was held up as an elegant solution to the difficult problem of benefit sharing when it comes to GR and ATK that are transboundary in nature or for which it is difficult to secure prior informed consent.

The GMBSM was designed to deal with the issue of sharing benefits arising from the new and continuing uses of GR and ATK accessed before the entry into force of the Nagoya Protocol but with insufficient passport data. While Article 10 is unclear as to how the GMBSM would be set up and run, various ideas were floated by experts for its implementation in the final stages of the Nagoya Protocol negotiations and even after its adoption. What seems clear now is that the EU Regulations in their current avatar rule out any obligations among its member states regarding benefit sharing for new and continuing uses of GR and ATK after the entry into force of the Nagoya-Protocol for the EU.

5. Access - Regressive and Progressive Interpretations

As highlighted previously, the distinction between access and utilization has a pedigree that goes all the way back to the CBD. Article 15 requires the consent of states prior to accessing their GR. However the nature of access that Article 15 envisages is not just any access (for e.g. commodity trade) but access towards utilizing the GR for research and development. Article 15 goes on to require the fair and equitable sharing of benefits arising from such utilization with the State providing the GR.

The Nagoya Protocol stays true to this approach and indeed clarifies it in Article 6 by using the term '*access to genetic resources for their utilization* shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention…' Similar clarity regarding the distinction between access and utilization is provided in Articles 5.1 and 5.2 of the Nagoya Protocol that speak of benefit sharing arising from the 'utilization' and not from the 'access' of GR.

The draft EU Regulation seems to take a different tack from the Nagoya Protocol and possibly a more confusing one. It envisages access and utilization as two separate acts making it open to two possible interpretations regarding what 'access' means. The first interpretation is a regressive one and the second is progressive. We will explore both here interpretations thereby highlighting a serious ambiguity that needs to be resolved. This is critical since the EU Regulation will have to be implemented by member states and also be borne in mind by provider countries when developing and implementing their ABS laws and policy. Hence clarity at the outset will save everyone a lot of trouble in the long run.

Article 2.1 of the EU Regulation, which deals with scope, states that:

> 'This Regulation applies to genetic resources over which States exercise sovereign rights and to traditional knowledge associated with genetic resources that are accessed after the entry into force of the Nagoya Protocol for the Union. It also applies to the benefits arising from the utilization of such genetic resources and traditional knowledge associated with genetic resources'

The basis for the **regressive interpretation** would be that the draft EU Regulation uses the term 'over which States exercise sovereign rights' and avoids using other terms of art such as 'countries of origin' or 'provider countries' as used in the CBD and the Nagoya Protocol. While both the CBD and the Nagoya Protocol also use the term 'sovereign rights,' it is used in a general manner and is later clarified by the use of terms such as 'provider countries' and 'countries of origin.' But the EU's use of the term 'sovereign rights' read with other Articles in the draft Regulations seem to provide enough flexibility for ex-situ collections of GR in their jurisdiction or accessions of GR already in the EU to be interpreted as material over which the countries of origin no longer have sovereign rights.

It seems that the term 'sovereign rights' cannot be understood in the EU Regulation as it is understood in the classic sense. Provider countries or countries of origin seem to have lost their sovereign rights over their GR and ATK if they have been accessed prior to the EU ratifying the Nagoya Protocol. For e.g. a company in the EU that has accessed GR or ATK previously is not obliged to share benefits even if it embarks on the utilization of such GR or ATK after the entry into force of the Nagoya Protocol for the EU. This is made explicit in Article 2.1 of the EU Regulation irrespective of whether the laws of the provider countries still seek to exercise their sovereign rights over such GR and ATK.

But lets stop here and turn to the progressive interpretation of the draft EU Regulation.

The progressive interpretation would be that when the draft EU Regulation uses the term 'over which States exercise sovereign rights,' it would be equivalent to the terms 'countries

of origin' or 'provider countries' as used in the CBD and the Nagoya Protocol. Because a sovereign right over a GR does not end when the resource leaves the country, the country of origin would still exercise sovereign rights over its GR that could be held in ex-situ collections or privately in the EU. The draft EU Regulation then applies to all accessions from ex-situ collections or otherwise in the EU after the entry into force of the Nagoya Protocol for the EU, even if such accessions are taking place from ex-situ collections and not from within the countries of origin.

To clarify, while a reading of Article 2.1 of the EU Regulations make it incontrovertible that if a user in the EU has already accessed GR and ATK prior to the entry into force of the Nagoya Protocol for the EU, then such user can embark on new uses of the same GR and ATK even after the EU ratifies the Nagoya Protocol. The user does not have to ensure compliance with the ABS laws and regulations of provider countries for such a new use. However in our progressive interpretation we are referring to a situation where a user in the EU accesses GR and ATK from an ex-situ source after the entry into force of the Nagoya Protocol in the EU. In such a case the progressive interpretation would argue that sovereign rights of the provider countries would continue to subsist over their GR and ATK held ex-situ and since it would be a new accession, the user in the EU would need to comply with the domestic ABS laws or regulations.

We will now see how the progressive or regressive interpretation of the scope will also colour our understanding of other Articles in the draft EU Regulation dealing with 'access' and 'utilization.' Unfortunately the other articles don't do much to help clarify the correct interpretation of the scope but rather further this initial confusion.

Continuing with the **regressive interpretation**, the EU Regulations make an interesting distinction between 'access' and 'utilization'. Access is defined as 'the acquisition of genetic resources or of traditional knowledge associated with the genetic resource *in* a Party to the Nagoya Protocol' (Article 3 (4) of the EU Regulation). Nowhere in the CBD or in the Nagoya Protocol is the term '*in* a Party' used. Both the CBD and the Protocol instead use the term 'Party providing the GR.' Utilization of GR in the EU Regulations however uses the same definition as in the Nagoya Protocol. The use of this unique term '*in* a Party' in the EU Regulations seems to have a purpose.

This purpose becomes clear under Article 4 of the EU Regulations, which lists out the user obligations. Article 4.1 requires due diligence from users to ensure that GR and ATK are accessed in accordance with applicable ABS laws and regulations and benefits are shared as per mutually agreed terms. Article 4.1.a states that 'genetic resources and traditional knowledge associated with genetic resources shall only be transferred and utilised in accordance with mutually agreed terms if they are required by applicable legislation or regulatory requirements.'

From a regressive point of view, this reinforces our interpretation of Article 2.1 of the EU Regulation. As far as any new ex-situ access of GR and ATK from collections or through third party transfers, users in the EU do not have obligations to comply with domestic ABS laws or regulations of provider countries, if the original access of the GR and ATK happened prior to the entry into force of the Nagoya Protocol for the EU.

Such a reading also throws open the critical question of commodity trade. Commodities are normally not accessed in accordance with domestic ABS laws or regulations because utilization as understood under the Nagoya Protocol is simply not envisaged at the time of access. Would this mean that the EU Regulations would not protect GR that are accessed as commodities? Furthermore would such a Regulation result in reactions from provider countries that could adversely affect commodity trade?

Furthermore if the EU Regulations do not apply to acquisitions prior to the EU ratifying the NP, then why would users in the EU seek to acquire GR in-situ and go through the rigmarole of negotiating MAT? Instead they would acquire all the GR and ATK they need through ex-situ collections or commodity trade completely undermining the spirit of the CBD and the Nagoya Protocol.

However if we pause for a moment and switch to a **progressive interpretation** of the draft EU Regulation, then a more promising scenario emerges. The definition of access in Article 3(4) as 'the acquisition of genetic resources or of traditional knowledge associated with the genetic resource *in* a Party to the Nagoya Protocol' could be a benign one. The word 'in' could just mean that a GR could be acquired in any Party to the Nagoya Protocol even if it means from an ex-situ collection or at a supermarket within the jurisdiction of the Party.

Firm in our progressive understanding that the sovereign rights of countries of origin continue to persist over their GR exported as commodities or available in ex-situ collections we can now approach Article 4.1.a of the EU Regulation with confidence. Article 4.1.a states that 'genetic resources and traditional knowledge associated with genetic resources shall only be transferred and utilised in accordance with mutually agreed terms if they are required by applicable legislation or regulatory requirements.'

From a progressive point of view this would mean that if an ex-situ collection in the EU has GR from countries of origin whose ABS laws require that the GRs can only be utilized after prior

informed consent and negotiating mutually agreed terms, then the collection cannot transfer the GR if no such consent or terms exist. As highlighted previously, there is an interesting twist here. Whoever has accessed the GR and ATK prior to the entry into force of the Nagoya Protocol in the EU can continue to use and engage in new uses of the GR and ATK after the EU ratifies the Nagoya Protocol. Such uses can be undertaken in the EU disregarding provider country ABS laws or regulations, which may require user compliance and benefit sharing. However a progressive interpretation here would mean that new accessions of the GR and ATK (whether from ex-situ collections or through third party transfers) in any Party to the Nagoya Protocol would require compliance of ABS laws or regulations of provider countries (i.e. countries with sovereign rights over such GR and ATK).

Effectively this means that third parties cannot access and utilize the GR and ATK in the EU, even if such GR were acquired in the country of origin prior to the entry into force of the Nagoya Protocol for the EU, unless such access is in accordance with the ABS laws and regulations of countries of origin and MAT has been established. The same logic would also apply to commodities and ATK.

If the EU affirms our progressive interpretation of its draft Regulation as the correct one, then the Regulation as it stands deserves our appreciation. If on the other hand, the EU confirms the regressive interpretation, then the EU Regulations as they stand not only violate the letter and spirit of the CBD but could herald the inexorable hollowing out of the Nagoya Protocol.

6. Delegated Administration

Users of GR and ATK in the EU are obliged by Article 4 of the EU Regulations to exercise 'due diligence.' The term 'due diligence' is elaborated as seeking, keeping and transferring to subsequent users an internationally recognized certificate of compliance as well as information on MAT. Where no such certificate of compliance is available, users are required to seek, keep and transfer to subsequent users the date, place, description, source, rights and obligations, access permits and MAT relating to the GR and ATK.

The EU Regulation then works on the basis that users are expected to exercise 'due diligence' and will be penalized if they don't. What is noteworthy here is that the EU Regulation is strangely light on requiring its member states to take on administrative burdens. This is done through deeming that users will normally exercise due diligence and limiting checkpoints to a declaration by user of due diligence when receiving research funding or at the final stage of product development (Article 7 of the EU Regulation). However a competent authority will not automatically check this declaration and any verification is more on a case-by-case basis. Furthermore, associations of users like sector specific industry bodies are encouraged to develop best practices for due diligence that they can self-monitor. The EC subject to these best practices meeting certain criteria can deem them as due diligence (Article 8 of the EU Regulation).

Finally, competent authorities can carry out checks that are effective, proportionate and dissuasive to detect non-compliance in accordance with periodically reviewed plan using a risk-based approach. These checks could include seeking evidence of due diligence, user declarations and spot checks. Where due diligence standards have not been met, a notice can be issued to the user to undertake remedial actions or measures (Article 9 of the EU Regulation).

To further lighten the administrative burden of member states while at the same time legalizing ex-situ collections that have hitherto not complied with provider country ABS laws, the EU Regulation creates a category of 'registered collections.' These are collections of GR that can volunteer to be registered by the EC if they use standardized procedures for the exchange and supply of samples. Such collections are also expected to provide GR to third parties with the necessary documentation and MAT, keep records of transfers, establish unique identifiers and use appropriate monitoring and tracking tools. Any user who obtains GR from such a registered collection will be deemed to have met the standards of due diligence (Article 5 of the EU Regulation).

The logic behind delegated administration in the EU Regulation is one that seeks to limit the expenditure of member states on implementing user country measures under the Nagoya Protocol. It does so by keeping check points minimal, assuming due diligence unless proven otherwise, outsourcing monitoring and tracking to registered collections and requiring user driven remedial actions in case of violations. Perhaps it also envisages that more and more users in the EU will source their GRs from registered collections due to the incentive of deemed due diligence and reduction of paper work.

What is deeply concerning is the extreme light touch approach to implementing user country measures. The light touch clearly does not meet the standards of user country compliance obligations under the Nagoya Protocol. This is because besides declarations at the research funding stage, the only other checkpoint to monitor compliance in the EU Regulation is a declaration by the user to the competent authority at the stage of final product development. This singular checkpoint does not meet the standard of Article 17.1 (a)(iv) of the Nagoya Protocol requiring effectiveness of checkpoints and their relevance to the collection of information at any stage of research, development, innovation, pre-commercialization or commercialization.

One can't help but wonder how the EU member states intend to monitor various uses ranging from privately funded research to research and development that don't lead to any final product development. What makes matters worse is the hours and days spent in developing studies, expert reports and debating the meaning and options for 'effective checkpoints' during the Nagoya Protocol negotiations seem to have had no impact on the EU Regulations. While the EU was always reticent about full disclosure regarding the use of GR and ATK in patent applications, it is surprising that EU in its Regulations has done away with all the other possible checkpoint options that were presented to ensure effective monitoring and tracking.

7. The Import Loophole

A significant loophole in the EU Regulation is one that lets off the hook certain kinds of profiteers of GR and ATK from the obligation to comply with provider country requirements. This seems perverse since users of GR and ATK within the EU are expected to comply with these requirements. However those who engage in illegal research and development of GR and ATK outside the EU and then bring the products developed outside into the EU for sale or other commercial purposes have no due diligence obligations at all.

Such a loophole exists because Article 4 of the draft EU Regulations require only due diligence from users of GR and ATK (the EU definition of utilization is the same as in the Nagoya Protocol). This leaves the gaping hole when it comes to those who utilize the GR and ATK outside the EU to avoid due diligence obligations and then bring the products for sale into the EU. The loophole is further reinforced since the only checkpoint provided by the EU for monitoring due diligence is at the final stage of product development (Article 7 of the EU Regulations) with no checkpoints at the pre-commercialization or commercialization stage (Art. 17.1. (a)(iv) of the Nagoya Protocol).

Activities like this could be fairly common in the EU in the context of multinational companies. For example, a multinational pharmaceutical company could engage in research and product development of GR and ATK in its laboratories in the US and it will have no due diligence obligations under the EU Regulations, even if the said product is marketed and sold in the EU. Through this loophole the EU Regulation ironically pushes research and development activities away from Europe into jurisdictions that have no due diligence obligations and may also result in unfair competition negatively impacting honest European companies conducting their research in Europe

It is hard to imagine how the drafters of the EU regulation overlooked this serious lacuna despite the obvious fact that various companies marketing products in the EU also engage in research and development of GR and ATK outside the territories of EU member states. In fact it is standard practice in intellectual property law to take into account situations where a protected good is produced in a country where the protection does not apply, but then is imported to country where the protection does apply. Without a protection like this, the intellectual property system would break down. Why the drafters of the EU Regulation didn't deem it fit to extend a similar protection to the rights of countries and ILCs over their resources and knowledge is difficult to understand. What is obvious is that if the obligations to share benefits can so easily be circumvented, no benefits are likely to be shared.

8. The Plant Treaty

Another puzzling aspect of the EU Regulation is the liberties that it takes with genetic resources relating to crops and forages. The EU Regulation seems breathtakingly laissez-faire when it comes to implementing its obligations under Article 4 of the Nagoya Protocol. Article 4 exempts Parties to the Protocol from their obligations when it comes to implementing another specialized international ABS instrument that is consistent with the objectives of the CBD and the Protocol. The countries negotiating the Nagoya Protocol specifically had the International Treaty on Plant Genetic Resources for Food and Agriculture (Plant Treaty) when they agreed on this exemption.

The EU Regulation in its Article 2a deems due diligence for users acquiring plant genetic resources for food and agriculture (PGRFA) from other Parties to the Nagoya Protocol who have decided that the non Annex 1 PGRFA under their management and control and in the public domain can be accessed as per a standard material transfer agreement (SMTA). While provider countries who are Parties to the Plant Treaty are busy developing ABS frameworks that bring their non Annex 1 PGRFA firmly under the Nagoya Protocol, the EU has decided to unilaterally give the right to decide benefit-sharing mechanisms over such PGRFA to countries who have the PGRFA under their management and control (and not to the countries of origin as foreseen in Art. 15 of the CBD).

There is a nuance here that must be grasped to understand the implication of this hand over. Article 2a of the EU Regulation for the first time uses the term 'management and control' when it comes to PGRFA and not other terms of art like 'sovereign rights', 'provider countries' or 'countries of origin.' The draft EU Regulations seem to assume that the sovereign right of a provider country ends when the PGRFA is under the management and control of another country.

In law, the EU Regulation creates the possibility for users of PGRFA in the EU to legally access non-Annex 1 PGRFA from collections in countries that may not be countries of origin and thereby bypass the ABS requirements of countries of origin. On reading Article 2a of the EU Regulation, one is left with fundamental legal question of how the EU can give away something that it clearly does not own. This especially so when Article 10 of the Plant Treaty establishes the sovereign rights of countries over their PGRFA and establishes the Multilateral System only for Annex 1 crops and forages and not for all PGRFA.

9. Traditional Knowledge Associated with Genetic Resources

While the traditional knowledge associated with genetic resources or associated traditional knowledge (ATK) for short has now become a term of art, it wasn't always the case. ATK was originally described in Article 8j of the CBD as 'knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity.'

Through the various negotiations in the run up to the Nagoya Protocol including a dedicated expert group meeting on ATK[4] in 2009, this term of art has now been established.

The draft EU Regulations in its Article 3.8 goes on to define ATK as 'traditional knowledge held by an indigenous or local community that is relevant for the utilization of genetic resources and that is as such described in the mutually agreed terms applying to the utilization of genetic resources.'

While the first part of the definition is standard, it is the second part of the definition that limits the understanding of ATK to its description in the mutually agreed terms that is concerning. This is because it leaves the understanding of ATK open to speculation and hence interpretation that could go against the interests of the ILCs providing access to it. For one, it would be near impossible to think of all the possible potential uses and hence definitions of ATK at the time of negotiating the mutually agreed terms. In the San Hoodia case for example the Council for Scientific and Industrial Research (CSIR) in South Africa argued that their patent which was based on the appetite suppressant qualities of the Hoodia plant was inventive and not based on the direct application of the San ATK that was already publicly available. The CSIR took such a position based on the nuance that while the San used it quell hunger, they were using the knowledge to suppress appetite amongst people who were prone to overeating.

The Hoodia example is an interesting case in point to show that it may be impossible to anticipate in advance all the possible descriptions of ATK in the mutually agreed terms. Moreover to restrict the rights of ILCs to their ATK, once they have entered into an ABS agreement, only to the description of the ATK in the agreement, leaves it open to abuse and hair splitting. It is clear that the rights of ILCs to their ATK is protected in the draft EU Regulations in Article 4 which requires compliance with domestic ABS laws and regulations. Hence as long as the domestic ABS laws and regulations requires prior informed consent and mutually agreed terms of the concerned ILCs when using the community's ATK, all users in the EU should comply with it.

But this still does not help vitiate the concern that arises when the EU Regulation limits its protection to ATK not as how the domestic ABS laws and regulations understand it, but as it is described in the mutually agreed terms. If anything, the EU's definition of ATK adds more confusion than clarity and increases the possibility of violation of rights of the most vulnerable communities through some crafty drafting of mutually agreed terms which don't specifically mention the ATK which will later be used in the research and development.

It could be that the EU's definition seeks to provide clarity on what ATK means in a particular context especially when there could be multiple ways of understanding it. However, it is precisely because of this that a definition on what constitutes 'utilization of ATK' would have solved this problem. The EU could have developed a conceptual or a descriptive definition of what constitutes 'utilization of ATK' providing some flexibility to regulators to interpret whether ATK is being utilized or not on a case-by-case basis. This is exactly what the EU has done with respect to GR. When it comes to GR, the EU Regulations not only define it but also define what constitutes 'utilization of GR.' It is puzzling as to why the EU Regulations don't follow a similar approach when it comes to ATK- an approach that would have resulted in an elegant solution to the EU's concerns about the diverse understandings of ATK.

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[4] https://www.cbd.int/doc/?meeting=ABSGTLE-03

10. Conclusion

The draft EU Regulation is a step towards the EU and its member states finally implementing their obligations under the CBD and the Nagoya Protocol. However leaving aside speculation regarding whether ambiguities in the EU Regulations are intentional, its narrow scope and confusing drafting clearly exempt an important part of access and uses of GR and ATK and lay it open to regressive interpretations.

Furthermore the light touch approach to administration, outsourcing of monitoring and tracking to non-state entities who are themselves suppliers of GR and loopholes regarding products developed abroad considerably weaken it. Moreover, the draft EU Regulations takes unjustifiable liberties with non-Annex 1 PGRFA that tantamount to violation of the Nagoya Protocol.

While we are aware that there is no possibility of amendment when the EU Parliament votes to adopt the Regulations in March this year, we would hope that the EU would remedy these limitations through implementation acts and revisions at a later stage. We would further urge the EU member states to move in the direction of a progressive interpretation of the EU Regulations at the level of national implementation. More could also be done by the EU and its member states to clarify and tighten its draft Regulation in a review process.

Finally, it is critical that the incoherence amongst countries regarding the interpretation and implementation of the Nagoya Protocol is addressed at an international level at the first Conference of Parties to the Nagoya Protocol. A lack of an implementation strategy that is coordinated and internationally coherent and an overuse of the ambiguities in the Protocol could pave the way for disaster and irreparably undermine the third objective of the CBD.