STUDY ON OPTIONS FOR IMPLEMENTATION OF CHECKPOINTS AND A SYSTEM FOR MONITORING THE UTILISATION OF GENETIC RESOURCES AND ITS COMPLIANCE UNDER THE NAGOYA PROTOCOL

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I. INTRODUCTION

The present study was conducted within the framework of the Cooperation Agreement between the International Union for Conservation of Nature (IUCN-Sur) and the Rey Juan Carlos University, through the UNESCO Chair for Spatial Planning and Environment. The agreement focuses on the implementation of various components of the GEF Regional Project for the "strengthening the implementation of regimes of access to genetic resources and benefit sharing (ABS) in Latin America and the Caribbean", which has been executed by the IUCN-Sur and has been implemented jointly by the UNEP office for Latin America and the Caribbean (hereinafter referred to as the "GEF-UNEP-IUCN ABS Regional Project").

The project seeks to ensure compliance with the principles of conservation, sustainability, equity and justice of the Convention on Biological Diversity (CBD) in access to genetic resources and benefit sharing; as well as in the protection of traditional knowledge associated with those resources. Its main objective is to strengthen the capacities of eight countries in Latin America and the Caribbean (Colombia, Costa Rica, Cuba, Ecuador, Guyana, Panama, Peru and Dominican Republic) to develop and/or comply with national policy and legal frameworks pertaining to the issue of ABS.

The present study, however, is not limited to the geographical scope of the countries of the project but rather aims at providing a broader practical view for the implementation of compliance measures and checkpoints of the Nagoya Protocol, although it obviously benefits from the experience and lessons learned during the execution of the Project.

The purpose of the study is to present options for the practical implementation of checkpoints and a system for monitoring the utilization of genetic resources as established in the Nagoya Protocol along with the implementation of compliance measures. This study begins by focusing briefly on the Nagoya Protocol and the importance of compliance measures and checkpoints. The following is a detailed analysis of the three basic obligations regarding compliance measures and checkpoints, as well as a discussion of the possible use of checkpoints to monitor the use of traditional knowledge and its implications. The next section elaborates on the importance of the generation of information and the role of documentation and the communication of information in this new control system for the utilization of genetic resources. Finally, based on the above analysis, a number of options for the practical implementation of these obligations will be presented.

II. THE SO-CALLED COMPLIANCE MEASURES IN THE NAGOYA PROTOCOL

The Nagoya Protocol on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising from their Utilization (ABS) of the Convention on Biological Diversity (CBD) was adopted at the tenth Conference of the Parties (COP-10) of the CBD in Nagoya (Japan) in October 2010. The Protocol develops the CBD with regard to the regulation of ABS (Article 15) and of traditional knowledge associated with genetic resources held by indigenous and local communities (Article 8j). The adoption of the Protocol brings to successful completion -both in terms of time and form- the negotiation process called for in point 42 (o) of the Plan of Implementation of the World Summit on Sustainable Development (held in Johannesburg, South Africa in September 2002), which develops and strengthens the third objective of the CBD: the fair and equitable sharing of benefits arising from the utilization of genetic resources.

The Protocol consolidates many elements that had already been included in the Bonn Guidelines (Decision VI/24 of the CBD), emphasizing in this regard the establishment –as a new legally binding obligation at international level– of prior informed consent (PIC) and the negotiation of mutually agreed terms (MAT) with indigenous and local communities for access to traditional knowledge associated with genetic resources.

Since there was no precedent at the international level, the most innovative part and therefore the most complex to implement because of its novelty and consequent lack of experience in implementation, was that related to the so-called "compliance measures". The countries supplying genetic resources had been demanding the proper implementation of Article 15.7 of the CBD, which requires all parties to the CBD to adopt measures "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." Prior to the adoption of the Nagoya Protocol, no country, provider or user of genetic resources had adopted truly effective measures of this sort, so countries providing genetic resources were alone in the control and monitoring of the use of their genetic resources. This meant that any measure, if any such measure existed, was therefore confined to the exclusive jurisdiction of the provider country. The truth is that not even provider countries had appropriate mechanisms to monitor the utilization of genetic resources in their jurisdiction, except for a few countries that had established disclosure requirements, usually voluntary in nature, within the applications for intellectual or industrial property rights. This illustrates the limited information available on the use of genetic resources (and the corresponding legal or illegal access).

With the initial scheme of Article 15 of the CBD and without the development of the measures provided for in Article 15.7 of the CBD which could monitor and control the use of genetic resources in other jurisdictions, all the focus was placed on the regulation of the access to the genetic resource. A vicious circle was thus started in jurisdictions where access to genetic resources was regulated since everything had to be controlled within their own jurisdiction, especially through access control. The overzealous access control clashes firstly with the nature of the resource itself, since it is a nearly intangible asset in the case of genetic resources, and a completely intangible one in the case of traditional knowledge associated with genetic resources. And secondly, it goes against the very reality of biotechnological chains, which nowadays are completely trans-boundary, as are many research institutes and the modus operandi of biotechnology companies.

With the introduction of a truly international system for monitoring and controlling the use of genetic resources in other jurisdictions as well as with compliance measures, the Nagoya Protocol brings new balance to the system of ABS, relieving the pressure of control which was exclusively on the country of access. The aim is to create a virtuous circle in which the information generated by monitoring the use of resources and the control exercised by the Parties on the use of the resources in turn makes for a more efficient access to genetic resources. It is therefore a new system that is capable of turning legal access to genetic resources and associated traditional knowledge into the rule rather than the exception, as it currently happens, so that a fair and equitable sharing of benefits derived from the use of such resources may become common practice.

III. THE THREE BASIC OBLIGATIONS OF THE NAGOYA PROTOCOL WITH REGARDS TO COMPLIANCE MEASURES

The great international breakthrough on the issue of ABS with the Nagoya Protocol occurs in connection with compliance measures. Compliance measures in this case refer to measures which the Parties should take to ensure that when genetic resources and traditional knowledge associated with them are utilized within their jurisdiction, they are accessed in accordance with national legislation of the provider Party, if it exists, in other words, as long as the country supplying genetic resources or traditional knowledge has regulated the matter. As discussed above, the lack of compliance measures in the Parties using genetic resources had been one of the major deficiencies associated to the international ABS regime and it is precisely what the Nagoya Protocol is called upon to solve.

Under the new heading of compliance measures there are mainly three different basic obligations of the Nagoya Protocol.

1. ENSURE THAT GENETIC RESOURCES USED IN YOUR JURISDICTION HAVE BEEN LEGALLY OBTAINED

First, according to the order of the articles of the Nagoya Protocol, there is the obligation of the Parties to adopt "appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party" (Article 15.1). In short, with this obligation the Parties commit to establishing measures to ensure that genetic resources utilized within its jurisdiction have been legally obtained, that is, in accordance with the rules on ABS of the Party from which they were obtained. Therefore, it should be highlighted that in order for these measures to be put in place they would demand an infringement of the rules of access of the provider country. It is therefore essential that Parties providing genetic resources have national access frameworks that conform at the very least to the provisions of Article 6 of the Nagoya Protocol.

The obligation provided for in Article 15.1 is an obligation of result. This means, the Protocol does not stipulate the manner in which compliance is to be achieved, but it determines an outcome: the utilization –in the Parties to the Protocol– of genetic resources and traditional knowledge associated with genetic resources legally obtained, that is, access respects and complies with legal frameworks and procedures of the Party supplying such resources. This approach, which is truly innovative at the international level because countries rarely oblige themselves to comply or at least observe the compliance of a third country regulations within their jurisdiction, contributes great flexibility for Parties to adopt measures that can best achieve this result in their jurisdiction.

The price of this flexibility is that it can lead to the adoption of rather disparate and even ineffective measures among Parties they would not attain the expected results, nor those which are required by the Protocol. It is clear that over time there will be a harmonizing, whether formal (through the Decisions of the Conference of the Parties to the Protocol or even in other forums) or informal (through the actual practice of the countries whose most efficient measures will quickly become a reference at an international level), of most of the open and flexible Protocol measures, both on access as well as on compliance. As long as such harmonization does not occur, it seems that the only mechanism for the Parties to carry out the analysis and evaluation of the effectiveness of the measures provided for in Article 15 and, therefore, achieve the expected result, shall be through a case-by-case analysis that can be conducted through the

instruments of general compliance of the measures of the Protocol provided for in Article 30. These instruments, however, remain outside the scope of this study.

This first obligation is reinforced by two other obligations listed in Article 15 itself. First, there is the obligation of the Parties to introduce measures to address situations of non-compliance with the previously mentioned principal obligation (Article 15.2). Second, there is the obligation to cooperate "as far as possible and as appropriate" with the Parties supplying the genetic resources allegedly accessed in violation of their legal frameworks for access (Article 15.3).

One way of implementing this first general obligation of Article 15 is through the establishment of the obligation of the user to exclusively use in the jurisdiction genetic resources legally obtained. This requirement can be expressed in a positive way, as in an obligation; or in a negative way, as in a prohibition (prohibiting the use in the country of genetic resources obtained illegally , for instance, without complying with the national legislation for access of the country providing the resources). The failure to comply with the obligation/prohibition should have consequences, as required by Article 15.2, which could range from a summons and a time period granted for the submission of the appropriate documentation and authentication of the genetic resource; including the imposition of sanctions; to the embargo of the resource, the interruption of the activity or the blocking of a product.

NORWAY

Section 60 of Law No. 100 on the disposal of biological, geological and landscape diversity refers to genetic material from other countries. That section stipulates that the impor for utilization in Norway of genetic material from a country that requires consent for its collection or export for its use can only be carried out in accordance with such consent. The person exercising the control of such material is bound by the conditions under which consent has been granted. The State could enforce such conditions through the appropriate legal actions.

When genetic material from another country is utilized in Norway for commercial or research purposes, this material must be accompanied by information pertaining to the provider country and, if that is the case, of the prior informed consent from the country in question.

In most cases the violations will not be easily detectable in the Party in which genetic resources are used, but they will be detected through the information generated by the system, by the Parties supplying genetic resources which have broader and more complete information. For such

situations, it is essential to have clear mechanisms and fluid communication and collaboration between the Parties, as required by Article 15.3, because in most cases this will be the way to enforce compliance measures in the user Party.

2. ENSURE THAT TRADITIONAL KNOWLEDGE USED IN YOUR JURISDICTION HAS BEEN LEGALLY OBTAINED

Secondly, the Protocol establishes an identical obligation as that described above, but which refers to traditional knowledge rather than to genetic resources. This is the obligation of the Parties to implement measures to ensure that traditional knowledge associated with genetic resources utilized within its jurisdiction has been accessed in accordance with regulations or regulatory requirements of the country of access. The obligation under Article 16, just as in Article 15, requires a violation of the rules of access of the provider country. It is therefore essential that provider Parties of traditional knowledge associated with genetic resources have national access frameworks that conform to the provisions of Articles 7 and 12 of the Nagoya Protocol.

This principal obligation is once again accompanied by two obligations according to which the Parties should establish measures within their jurisdiction to address situations of non-compliance and cooperate in such situations with the countries where access to such traditional knowledge has taken place (Article 16 of the Nagoya Protocol).

Just like the obligation concerning genetic resources, this is an obligation of results, which means the Protocol does not provide for the manner in which compliance must be achieved, but rather has one outcome: the utilization –in the Parties of the Protocol– of traditional knowledge associated with genetic resources exclusively obtained through legal means. This would mean that their access has respected and enforced legal frameworks and procedures of the Party supplying such resources, which in this case means a PIC has been obtained and MAT have been negotiated with indigenous and local communities.

Parties could comply with this obligation in a manner similar to that explained in the previous section with respect to genetic resources. Perhaps in this sense it is appropriate to highlight the importance of collaboration with other Parties since, in this case, there is no international conceptual harmonization of the term traditional knowledge associated with genetic resources, as is the case with the utilization of genetic resources which is defined in the Protocol. The variability of the concept from one country to another can be very important and, therefore, bilateral cooperation will be essential to fully understanding the rules of the country of origin of the traditional knowledge in question.

In addition to the conceptual handicap when it comes to applying compliance measures in relation to traditional knowledge associated with genetic resources, it must be pointed out that, unlike the case of the use of genetic resources, the Protocol provides no mandatory system for generating information in relation to associated traditional knowledge. The lack of such an information system greatly limits the chance of detecting possible cases of illegal access to traditional knowledge and, thus, of applying the compliance measures provided for in Article 16. Point III.3.c will address this issue and propose the implementation of checkpoints both for genetic resources and for traditional knowledge associated with genetic resources.

EUROPEAN UNION (REGULATION 511/2014)

In order to comply with the provisions of Articles 15 and 16 of the Nagoya Protocol, the European Union established an obligation for the user: due diligence. Article 4 of Regulation 511/2014 of April 16, 2014 "on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union" states that:

> "1. Users shall 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.
>
> 2. Genetic resources and traditional knowledge associated with genetic resources shall only be transferred and utilized in accordance with mutually agreed terms if they are required by applicable legislation or regulatory requirements."

Paragraph 3 refers to information and documentation that must accompany the fulfillment of the above obligations. The following paragraphs of Article 4 require different considerations and exceptions to the obligation of due diligence, including the direct fulfillment of that obligation when genetic resources come from collections registered in the Union.

Regarding the penalties for non-compliance of these provisions thereof, pursuant to Article 11, they shall be established by the Member States, and they will vary considerably from one country of the European Union to another.

3. DESIGNATING AT LEAST ONE CHECKPOINT WHERE THE LEGAL PROCUREMENT OF THE GENETIC RESOURCE IS DISCLOSED

Thirdly, upon successful presentation of the first two general compliance obligations, there is the obligation of the Parties to the Protocol of designating at least one checkpoint where the legal procurement of the genetic resource must be disclosed. The purpose of this requirement is to "monitor and enhance transparency about the utilization of genetic resources" in order to "support compliance" with the obligations set out above (Article 17.1.a).

The Protocol does not establish a common or single checkpoint for all Parties, nor does it incorporate an indicative list of possible checkpoints. The list itself was present at the negotiations, but ultimately it was decided not to include it in the text of the Protocol. This indicative list referred to the competent authority in the user country; research institutions subject to public funding; publishers or entities engaged in the publication of research results related to the utilization of genetic resources; patent offices; and authorities which regulate and are responsible for granting authorization for selling products in the market. What the Protocol does in fact determine with regards to checkpoints is that they "must be effective" and "be relevant to the utilization of genetic resources, or to the collection of relevant information at, inter alia, any stage of research, development, innovation, pre-commercialization or commercialization" (Article 17.1.a.iv).

In establishing the designation, upon creation or establishment of a checkpoint, the Protocol is envisaging the increased efficacy, operability and efficiency, as well as a greater incentive for users, shall be obtained from the use of already existing procedures and mechanisms into which this disclosure requirement will be inserted.

The generation of information concerning the utilization of genetic resources becomes the heart of the compliance system, as this information will be the basis for countries providing genetic resources so they can provide a timely follow-up to the use of their genetic resources and detect possible violations. This information will be used usually by the providing countries, to activate complaint procedures and penalties in the Party where the alleged unlawfully obtained genetic resources are being utilized.

A. DISCLOSURE OF THE LEGAL PROCUREMENT OF THE GENETIC RESOURCES

The Nagoya Protocol is the first legally binding international instrument to establish a clear and structured obligation to disclose the legal procurement of the genetic resource at the checkpoint.

In addition to the requirement of designating at least one checkpoint, the Protocol in Article 17.1.a) contains various elements and requirements in relation to the disclosure of the legal procurement of genetic resources which are presented below, in a logical order and not in the order in which they appear in the Protocol. The basic obligations of the Parties regarding the disclosure of the legal procurement of the genetic resources at the checkpoint, are the following:

1. Requiring users of genetic resources to provide to the checkpoint (Art. 17.1.a.ii) with:

    a) The internationally recognized certificates of compliance (Art. 17.1.a.iii) + information pertaining the utilization of genetic resources (Art. 17.1.a.ii); or

    b) The relevant information related to the PIC, the source of the genetic resources, the establishment of mutually agreed terms and the utilization of genetic resources. (Art. 17.1.a.ii)

2. Take appropriate, effective and proportionate measures to address situations of non-compliance with point 1, for instance, when users do not provide the information required at the checkpoint. (Art. 17.1.a.iii)

3. Provide the information from point 1 to "relevant national authorities, to the Party providing prior informed consent and to the Access and Benefit-sharing Clearing-House, as appropriate".

This disclosure, as previously stated, is mandatory and the Parties must establish measures (consequences, usually penalties, although the matter could simply be addressed by not processing the application until the requirement is fulfilled) in case of non-compliance with it. Parties must transfer the information obtained by checkpoints, among others, to the CBD ABS Clearing-House (ABS-CH).

Another matter are the effects of the disclosure of the legal procurement of the genetic resources at the checkpoint. Once accepted, during the negotiation of this Article 17 of the Nagoya Protocol, the need to establish a monitoring and control in the Parties, which is therefore international, of the utilization of genetic resources, the discussions focused on the effects of disclosure and on the nature of the checkpoints. A large group of countries argued that checkpoints should be formal, and be a mere point for collection of information relating to the disclosure of legal access to genetic resources and for transfer to third parties, without having a strong or substantial control and, thus, without substantially affecting the procedure or the application in question at the checkpoint. In view of this, another also large group of countries argued that the checkpoints should exercise a substantial control over the disclosure of the legal procurement of the genetic

resources and become a substantive requirement for the application or procedure of which it was a part, for instance, of the checkpoint through which the genetic resource would pass.

As previously mentioned, the agreement reached in Article 17 requires the disclosure of the legal procurement of genetic resources and the establishment of measures in case the user does not provide this information. It is therefore a formal control. That said, the content of Article 17 does not prevent the Parties wishing to turn checkpoints substantial controls from doing so, which –as discussed later in the section on implementation options for compliance measures– can in turn facilitate compliance of the obligations of result, at least, of Article 15 and, in many cases, of Article 16.

In short, in Article 17.1.a the Nagoya Protocol introduces the establishment of at least one checkpoint where the disclosure of the legal procurement of the genetic resources will be required, as an obligation of the Parties. In this disclosure, the users, and therefore the checkpoints, may encounter three different situations with respect to the documentation:

- **Internationally Recognized Certificate of Compliance (IRCC):** all genetic resources accessed after the entry into force of the Protocol in a Party state to the Protocol which requires a PIC for these genetic resources would be found under this document.
- **PIC and MAT negotiation:** all genetic resources accessed before the entry into force of the Nagoya Protocol (or after if it involves a non-Party state) in a Party state to the Protocol which requires a PIC.
- **User's Declaration of the Place of Procurement:** This would be the case for genetic resources accessed in a country, whether it is a Party to the Protocol or not, which does not require a PIC generally or in particular for the genetic resources in question.

For the system to be truly effective, it is essential that from the moment the Nagoya Protocol enters into force for that Party the checkpoints collect information on the utilization of any type of genetic resource, regardless of when their access took place, that is, whether it was before or after the entry into force of the Nagoya Protocol. Otherwise, the collection of information on genetic resources accessed only after the entry into force of the Protocol could become a mere compliance check that will have little or no use in detecting cases of non-compliance. The information must be as complete and comprehensive as possible. It must include all genetic resources in order to make it possible to detect cases of non-compliance among genetic resources presented with or without documentation, given the fact that in all the previously mentioned situations there could be cases of non-compliance. Therefore, it is one thing that information should have a very broad spectrum with very few restrictions (any type of restriction may serve as an escape for illegally accessed genetic resources) and should include all types of genetic resources. It is a different thing

whether measures provided for in Article 15 (penalties) could apply to the genetic resources accessed prior to the entry into force of the Protocol, which is a matter open to legal interpretation which goes beyond the scope of this study. The consequences in the event that a user provides false information when completing the disclosure requirement will vary from jurisdiction to jurisdiction, but in principle most jurisdictions generally provide for this type of documentary falsification situations in their administrative procedures and such provisions would have to be complied with.

B. POSSIBLE CHECKPOINTS

Although there was reference to specific checkpoints throughout the negotiations, the final agreement reflected in the text of the Nagoya Protocol does not include the determination of a mandatory checkpoint in common for all parties. It does not even include a list of possible checkpoints. This list consisted of the following check points, whose analysis is relevant for this study in view of their effectiveness and the possibilities of implementing the Protocol's compliance measures:

1. Competent National Authority in the user country;
2. Research institutions subject to public funding;
3. Publishers and entities engaged in the publication of research results related to the utilization of genetic resources;
4. Patent Offices;
5. Authorities who regulate or grant the authorization for the selling of products in the market.

However, it must be remembered that the Nagoya Protocol does stipulate that checkpoints "should be effective" and "be relevant to the utilization of genetic resources, or to the collection of relevant information at, *inter alia*, any stage of research, development, innovation, pre-commercialization or commercialization "(Article 17.1.a.iv). The possible checkpoints which are analyzed here and were part of the indicative list of the negotiating text of the Protocol, are not the only ones available, but they do reflect the importance of adequately covering the various types of utilization of genetic resources (non-commercial research and commercial use) in the various stages to which reference is made. The ideal scenario would be the designation of more than one checkpoint that allows for a good control over utilization in the different stages of the biotechnology value chain, from early research to final product commercialization (See point V.2.A).

1. Competent National Authority in the user country

During the negotiation of the Protocol, different developed countries introduced "national competent authority in the user country" in the list of possible checkpoints. The truth is that if one reviews the functions provided for in the Nagoya Protocol, principally in Article 13.2, to the competent national authority will not find any relation to this type of role, since national authorities are much more oriented towards the access to genetic resources than to the verification of the utilization of genetic resources in their jurisdiction. *A priori* it is equally difficult to envision that such competent national authorities would have any relation whatsoever with the utilization of genetic resources, in particular that they be directly related or be a part of the "stages of research, development, innovation, pre-commercialization or commercialization". This is why, the Party that chooses its designation must appropriately prove its "efficiency" and "relevance" in its notification to the ABS Clearing-House (ABS-CH), as per the minimal requirement for its designation stated in Article 17.1.a.iv for such national authorities.

EUROPEAN UNION (REGULATION 511/2014)

The European Union seems to have opted for the designation of the competent national authority in the user country as the primary and only checkpoint (at least with respect to the European Union, even though nothing prevents Member States from designating other additional checkpoints individually, in the name of the country not of the European Union). This is evidenced in Regulation 511/2014 "on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union".[1]

Article 7.3 of Regulation 511/2014 stipulates that "competent authorities shall transmit the information received on the basis of paragraphs 1 and 2 of this Article to the Access and Benefit-Sharing Clearing-House, established under Article 14.1 of the Nagoya Protocol, to the Commission and, where appropriate, to the competent national authorities referred to in Article 13.2 of the Nagoya Protocol". Paragraph 1 of Article 7 states that "The Member States and the Commission shall request all recipients of research funding involving the utilization of genetic resources and traditional knowledge associated with genetic resources to declare that they exercise due diligence in accordance with Article 4." It is not yet known exactly how that information will reach the competent national authorities nor what will be the content and usefulness of the statements of due diligence to which it refers to for the ABS-CH.

Paragraph 2 stipulates that

> 2. "At the stage of final development of a product developed via the utilization of genetic resources or traditional knowledge associated with such resources, users shall declare to the competent authorities referred to in Article 6.1 that they have

fulfilled the obligations under Article 4 and shall simultaneously submit:

a) the relevant information from the internationally-recognized certificate of compliance; or

b) the related information as referred to in Article 4.3.b.i, ii, iii, iv and v and Article 4.5, including information that mutually agreed terms were established, where applicable."

In this case, the Regulation understands that the competent authorities are those provided for in Article 6, meaning those designated by each Member State as "responsible for the application of this Regulation."

The very rule in Article 7.6 provides for the adoption, on the part of the Commission, of "implementing acts" in order to establish the procedures for the development of this article and to determine "the final stage of utilization of a product" in different sectors.

The complexity of the regulation and the necessary development of elements and concepts by the Commission, prevent the assessment –at present– of the effectiveness of this system in relation to the checkpoints and the timely generation of information. *A priori* it seems that competent authorities are far away and disconnected from the actual utilization of genetic resources and traditional knowledge, although this may vary considerably from one Member State to another and it will therefore be necessary to wait for the development and clarification of the procedures and for the designation of competent authorities in each Member State.

2. Research institutions subject to public funding

This checkpoint refers to institutions that provide public funding to institutions or research projects, rather than to research institutions which are subject to public funding. That is, the objective is to control research institutions, not for them to become the checkpoint. It means that the checkpoint for these research institutions will be those institutions which publicly funded research projects conducted by the former. The governing principle of this checkpoint is simple: that no public funds are used to finance research projects and activities that do not fully comply with applicable law in other countries. In other words, you cannot use public funds to carry out illegal activities in third countries.

The research projects of universities and research institutes are a crucial part of the biotechnology value chain and it is usually where the initial access to the genetic resource occurs. The simplest and cheapest way to integrate the principles of ABS from the beginning of the value chain is to ensure –from the user countries– that the initial access to the genetic resources is conducted correctly and legally. That is what many research institutions from different countries that have

been ahead of their regulatory frameworks have identified and done for years now. This early integration can greatly facilitate compliance for user countries in the rest of the value chain and, therefore, it might prevent important subsequent problems in which going back or trying to legalize the access to the resource can be difficult or, in some cases depending on the provider country, it may not even be possible. Therefore, establishing checkpoints for the first access with research purposes can have a very positive effect on the rest of the chain. Thus, public institutions that provide public funding for research projects are identified as an important checkpoint at this early stage. Likewise, it can be guaranteed that the provider country may take advantage of the research project in question to obtain non-monetary benefits related to technology transfer and capacity building.

According to the distinction made between formal checkpoints and substantial checkpoints, there are two basic options. The simplest option would be represented by the request, on the part of institutions which provide public funding for research projects, for the disclosure of the legal procurement of genetic resources during the implementation of the project, applicable to those projects which utilize of genetic resources. The institutions which provide public funding for research projects would convey this information to the ABS Clearing-House (ABS-CH). In order to implement this change, it would be enough to change the forms of applications for each call with the goal of incorporating this formal requirement of disclosure of the legal procurement of the genetic resource.

The most coherent and integrated option to comply with the principle stated above, however, would involve the inclusion –in public calls– of institutions for the public funding of projects for researching the compliance, on the part of applicants and raisers of funds for research, with the legal frameworks for access and the corresponding disclosure of the legal procurement of genetic resources. The consequence of non-disclosure of this legal procurement of genetic resources could be the temporary suspension of funding until any irregular situation is regularized or disclosure is appropriately complied with. In case it is not complied with, the consequence would be the withdrawal of funding as well as a requirement of total reimbursement of the funds raised. The operationalization of this change would have a greater impact since it is most likely that in order to integrate the disclosure requirement as a substantive procedure with the recently outlined consequences, it would be necessary to implement regulatory changes in financial instruments regulating these public calls.

In this case, the difference between the formal and substantive requirements and their consequences is blurred significantly to become almost null, since it is likely that access to genetic resources would be perfected in most cases during the execution of the project, so disclosure of the legal procurement of genetic resources should therefore also occur during the

execution of the project and not at the beginning, during the application, as we will later see when discussing patent offices or the authority which grants the permission to market a product. However, the difficulty would be greater for the regulatory change in the case of the substantive requirement that it would be for the formal adjustment of the forms.

3. Publishers or entities engaged in the publication of research results related to the use of genetic resources

Publications are another important element through which the research capacity of researchers, with public or private financing, is measured. For researchers, it is crucial to publish the results of their research, since not doing so is as if the research did not exist. Thus, publications are seen as important waypoints for researchers using genetic resources because in many cases the publication, far from being the end of a research project, becomes the beginning of another series of studies or developments.

The publications are in the hands of publishers or entities engaged in the publication of results which would in this case be identified as checkpoints. This checkpoint has the added problem that, unlike other possible checkpoints identified here, usually these entities are private companies. From this point of view it is difficult to think that a country might be able to locate this control or verification in such entities. A different thing is if these entities voluntarily included the disclosure of the legal procurement of the genetic resource among their publishing requirements and this information were communicated to the relevant national authorities and/or the ABS Clearing-House (ABS-CH). In the case of publications, there would be virtually no difference between the formal or the substantive requirement since both would entail the non-publication of the work and, in both cases, it would be difficult to rectify or invalidate the publication if, once it were published, the invalidity or inaccuracy of the information were verified.

Regarding the impacts of these two options, both have a similar impact since both cases would imply that it is a change in the policy of publishing companies that should introduce disclosure as a formal or substantive element.

4. Patent Offices

This is the classic checkpoint, one that has been discussed for a longer period of time it is where the concept of the disclosure requirement arose. There is extensive literature on the subject in relation to discussions related to this checkpoint and about their establishment both at international and national level (See HENNINGER, T., 2009).

In this sense, we could have two options for designating patent offices as checkpoints under the Protocol. On the one hand, there would be the designation of the patent office as a formal

checkpoint. In this case, along with the information and documentation that is part of the patent application, the patent offices should also collect the disclosure requirement of legal procurement of the genetic resource. As this is a formal requirement, non-compliance would typically entail the inability to process the request until the requirement is appropriately fulfilled. This could be done by changing the regulations for the inclusion of this formal element or even by changing national patent application forms. Several countries have established this as a requirement in some form or another. The new regulation in Cuba is used as an example since it is the only one that came after the adoption of the Nagoya Protocol that clearly applies both to genetic resources and traditional Cuban knowledge as well as to third countries and, therefore, incorporates the character and international vision of the Nagoya Protocol even though it may require some terminological adjustment.

CUBA

The recent regulations on intellectual property, adopted through Decree 290/2011 (of Inventions, and Industrial Designs and Models), introduced the following paragraphs into Article 26, which refers to the documentation that must accompany the application for patents:

> "j) copy of the express prior authorization for access to biological material, issued by the competent authority in accordance with applicable law in the matter, when the invention relates to such material, including genetic material and its parts or derivatives when Cuba is the country of origin or if such material is present in species which have been domesticated and cultivated in the country;
>
> k) a statement expressing that the biological material to which the invention relates has not been obtained in the Republic of Cuba, in which case the country of origin and source of the biological material and traditional knowledge associated with it must be indicated as well as the prior informed consent for access;"

This is really innovative because it not only refers to control of the access to Cuban biological material (Paragraph j) but also to the one coming from third countries (Paragraph k). In the latter case, the Decree refers not only to the biological material but also to traditional knowledge.

Likewise, Decree 291/2011 for the Protection of Plant Varieties included the following paragraphs in Article 31 concerning patent applications:

> "f) when the plant variety is derived from an initial plant material whose country of origin is the territory of the Republic of Cuba or if such material is present in

domesticated and cultivated species in the country, a copy of the document attesting the express written consent to grant access to such material or starting materials, issued by the competent authority in accordance with the current legislation on the subject; and

g) otherwise, as provided in the preceding paragraph, a statement in which it is expressed that the material which is the source of the plant variety has not been obtained in the territory of the Republic of Cuba, and that the prior informed consent for Access has been previously obtained."

The requirements of both rules are formalized so that failure to comply with the requirements, if not corrected, may result in the inability to proceed with the substantive examination, this means that the request would be understood to be abandoned, but in no case would these requirements be the cause for a refusal of the patent.

Both texts should be adjusted, if Cuba ratifies the Nagoya Protocol, to the new documentation provided for in the Nagoya Protocol, particularly the reference to an internationally recognized certificate of compliance of the genetic resource in question. At any rate, it is a good example of how to introduce this type of requirements into the regulations on intellectual property.

NORWAY (Patent Law)

In section 8B of the Norwegian Patents Act (Act No. 9 of 1967, and amended in 2004 and 2009) stipulates that inventions which relate to or use genetic material or traditional knowledge should include information on the country where the inventor obtained the material or traditional knowledge. In countries where a PIC is required for access to the material or to the knowledge, the inventor shall inform if said PIC was obtained. In case of failure to disclose the required information, the general penalties contained in the Civil Penal Code, section 166, shall apply without prejudice to the processing of the patent application or its validity once it has been granted.

The other option would be for the patent office not to be merely a formal checkpoint to compile information, but to also verify its validity and that the legal procurement the genetic resource could condition the very validity of the substantive procedure in the case of this patent. This change requires an adjustment and its reflection in the national legislation on intellectual property rights or patents. Since these are rules strongly rooted in the international regulation, it would be

ideal for these changes to be adopted at international level in order for them to be applied in all countries in a more homogeneous manner which would give greater legal security to the user. However, nothing prevents these adjustments or the integration of this element of disclosure and substantive requirements to be made directly through national legislation. This is the approach followed by the Andean Community through Decision 391 and Decision 486, although its scope is limited to the genetic resources of the countries of the Andean Community and not to all Parties to the Nagoya Protocol.

ANDEAN COMMUNITY- Decisions 391 and 486

Through the regulations of the Andean Community (namely, Decision 391 and Decision 486) the three Andean countries (Colombia, Ecuador and Peru) already have some checkpoints and compliance measures on the utilization of genetic resources and traditional knowledge associated to genetic resources held by indigenous and local communities.

Decision 391 establishes the checkpoint to be "Competent National Offices on Intellectual Property" by stipulating that these "shall require the applicant to give the registration number of the access contract and supply a copy of it as a prerequisite for granting the respective right, when they are certain or there are reasonable indications that the products or processes whose protection is being requested have been obtained or developed on the basis of genetic resources or their by-products which originated in one of the Member Countries"[1]. In fact, since it is a regional regulation, it takes an identical approach to the one the Nagoya Protocol takes almost 15 years later in applying this provision not only to national genetic resources, but also to "genetic resources or their by-products from (…) one of the Member Countries …"[1].

The Decision in question by further stipulates that "Member Countries shall not acknowledge rights, including intellectual property rights, over genetic resources, by-products or synthesized products and associated intangible components that were obtained or developed through an access activity that does not comply with the provisions of this Decision".[1] With this second part of the provision, that checkpoint would be complying with the implementation of the measures provided for in Articles 15.1, 15.2, 16.1 and 16.2 of the Nagoya Protocol, applying the penalty of refusing to grant the rights –primarily of intellectual property, although others could also be included– over the genetic resources obtained illegally.

Decision 391 also states that, in cases of default "…the Member Country affected may request nullification and bring such actions as are appropriate in countries that have

conferred rights or granted protective title documents"[1]. This clause in the Decision empowers the member country to access foreign justice in case there is a violation of its regulations on access to genetic resources. In this way, the provisions of Articles 15.3 and 16.3 of the Protocol would be complied with.

Additionally, Article 3 of Decision 486 of the Andean Community on the common Industrial Property Regime, of September 14, 2002, states that "member countries shall ensure that the protection conferred on the various forms of industrial property shall be granted in such a way as to safeguard and respect their biological and genetic heritage and also the traditional knowledge of their indigenous Afro-American or local communities. By virtue of the foregoing, the grant of patents relating to inventions developed on the basis of material derived from that heritage or knowledge shall be subject to that material having been acquired in accordance with international, community and national legal provisions".

Also, Article 26 of Decision 486 states that in the application for the patent of an invention, the interested party must submit, among other things, a copy of the access contract where the products or processes for which a patent is sought have been obtained or developed from genetic resources or products derived therefrom which come from any of the Member Countries of the Andean Community (Paragraph h). In relation to traditional knowledge, the decision stipulates a similar obligation by requiring the presentation of a copy of the document accrediting the licensing or the authorization of the use of the traditional knowledge of the indigenous Afro-American or local communities of member countries where the products or processes for which protection is sought have been obtained or developed from such knowledge of which any of the member countries is the country of origin (Paragraph i). Compliance with these articles will be checked during the evaluation process of the patent application (Article 38). In both cases, the scope of Article 26 once again does not only include the genetic resources of the country, but of all the member countries of the Andean Community and the traditional knowledge of indigenous, Afro-American and local communities living in them. It is also worth noting that this measure extends the scope of Decision 486, expressly, to traditional knowledge requiring to certify the origin and legal use of such knowledge during the patent application, while Decision 391 refers in general terms to "associated intangible components".

Finally, in Article 75, as another measure of compliance, Decision 486 stipulates that "the competent national authority shall decree the absolute invalidity of a patent at any time,

either *ex officio* or at the request of any person, where:

g) where applicable, a copy of the access contract has not been filed where the products or processes to which the patent application relates have been produced or developed with genetic resources or derived products of which any of the member countries is the country of origin;

h) where applicable, a copy of the document evidencing the licensing or authorization of the use of traditional knowledge of the indigenous Afro-American or local communities of the member countries has not been filed where the products or processes for which protection is sought have been produced or developed on the basis of such knowledge of which one of the member countries is the country of origin".

5. Authorities which regulate or grant authorization for the selling of products in the market

Even though the debate regarding the requirement of disclosure has revolved around patent applications, during the negotiations of the Nagoya Protocol it became apparent that these merely addresses a limited part of the utilization of genetic resources and traditional knowledge given the fact that there are numerous developments and products which do not go through the patent office before going straight to the market. This is why authorities which regulate or grant authorization for the selling of products in the market were introduced as possible checkpoints.

Once again, there are two basic options for complying with the provisions of the Nagoya Protocol. In the first place, the authorities that regulate or grant authorization for selling products in the market may include the disclosure of legal procurement of the genetic resources as a formal requirement in the process of authorization. The consequences of not providing this information may be those already established by patent offices, this is to say, the process of authorization would not move forward until the requirement of disclosure has been complied with. In case false documentation is provided, the provisions at national level for cases of forged documentation during administrative procedures should be expected. Once such information has been collected, the regulatory authority which grants the authorization would be responsible to send that information to the ABS Clearing- House (ABS-CH) and their work would end there. The introduction of such a formal requirement in principle could be realized through its incorporation into the forms, which may not require a regulatory change in many cases.

The second option would be for the authorities that regulate or grant the authorization of products for sale in the market to not only demand the disclosure of the legal procurement of the genetic

resource as a formal requirement, but as a substantive requirement of the procedure for authorizing the sale of a product on the market, so that any failure to comply on the part of the user could void the authorization for selling the final product on the market. This modification would require the change in the rules through which this disclosure requirement would be assumed to be a substantive requirement to be fulfilled by the user in order to obtain the marketing approval.

C. POSSIBLE USE OF CHECKPOINTS FOR MONITORING THE UTILIZATION OF ASSOCIATED TRADITIONAL KNOWLEDGE AND ITSIMPLICATIONS

One of the sensitive issues of Article 17.1.a and of the system for information generation of the Nagoya Protocol is that it refers exclusively to the utilization of genetic resources. Nothing is said, either in this or in any other article of the Protocol, regarding the monitoring of the utilization of traditional knowledge associated with genetic resources. This is quite a significant problem for the effectiveness of the Nagoya Protocol itself and for the new balanced and comprehensive ABS system that is intended to be consolidated internationally and with important implications at the national level. The importance of the system in generating information has been previously noted, as well as how it is located at the core of the operation of compliance measures. The information generated by the checkpoints in countries using genetic resources will enable the Parties to monitor their genetic resources and ensure that access to them was legal, that is, in accordance with its national regulatory ABS framework. Without such information on the utilization of traditional knowledge, it would be very difficult -if not impossible- to detect possible cases of non-compliance, since traditional knowledge brings about an added complexity in the fact that it may conceptually vary from one country to another. It could be said that without a system of checkpoints to collect information on the utilization of traditional knowledge associated with genetic resources to detect illegal accesses to the same will occur by chance. Thus, regardless of how good or strict the possible enforcement actions that the user country would have established under Article 16 are, they would in fact be of no consequence and would never apply. If this situation were to be evaluated by the mechanisms of general compliance of obligations in the Protocol under Article 30, it is likely they would have to consider such national measures for compliance of Article 16 as ineffective and therefore, they would have to declare the failure of the Party in question regarding its compliance with the obligations of Article 16.

CUBA

Its recent legislation on industrial property regarding both patents and the protection of new plant varieties introduced the disclosure of legal procurement, of the biological resource as well as of traditional knowledge associated with it (see point III.3.B.4).

NORWAY

Its patent law refers to both genetic material and traditional knowledge (see point III.3.B.4).

EUROPEAN UNION - Regulation 511/2014

The European Union includes the traditional knowledge associated with genetic resources both in terms of its Regulation 511/2014 "on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union", as well as in the various specific measures included in it, mainly through the obligation of due diligence and the checkpoint(s) (Articles 4 and 7) (see point III.3.B.1).

Maybe there are countries that will be able to effectively fulfill the previously mentioned obligation of results of Article 16 without generating the information that enables the monitoring of traditional knowledge by their holders; but it appears that a practical and simple way to give efficacy to the system would be to generate information for genetic resources as well as for associated traditional knowledge. As the various previous examples have illustrated, this can be achieved easily by extending any legal requirement of disclosure of the legal procurement of the genetic resource and its associated traditional knowledge. Here we must anticipate a possible inconvenience or inconsistency in the event the patents office were designated as a checkpoint at a national level in the user Party. It is probable that many countries do not have any regulation on traditional knowledge associated with genetic resources held by indigenous and local communities, especially with respect to their use. This could be a problem in patent applications since upon presenting the application and indicating that the patent is based on traditional knowledge, such information may lead the patent examiner to conclude that the substantial requirement of novelty of the patent is not met and might therefore decide not to grant it. This situation is resolved in some national regulations of intellectual property directly related to traditional knowledge of indigenous and local communities through a license or contract for the use of such knowledge, which in those cases allows the granting of the patent. In the remaining checkpoints no problem of this sort is expected and therefore the Parties may require the disclosure not only of the legal procurement of genetic resources but also of the disclosure of the legal procurement of its associated traditional knowledge.

IV. INFORMATION AS THE BASIS FOR CONTROL, TRANSPARENCY, TRACEABILITY OF THE USE OF GENETIC

RESOURCES AND ENFORCEMENT OF COMPLIANCE MEASURES

The CBD is the first legally binding instrument that explicitly recognizes the sovereignty of countries over their genetic resources and the access to them is, consequently , subject to what is provided for in national legislation; as that is where the foundations of the bilateral ABS system are. In developing the principles in Article 15 of the CBD, certain mechanisms of that bilateral negotiation have been established between the user accessing the genetic resource and the country regulating access to its genetic resources, namely the PIC and MAT. This bilateral approach has led to tremendous variety in the measures that countries introduce to regulate access. In many countries the nomenclature to refer to PIC and MAT is different while in other countries, both procedures are mixed together or have been merged into one. In some cases, the completion of the administrative proceedings concludes in a resolution of access, and in other cases, it ends in a permit or authorization. There was, therefore, a significant variability and a wide heterogeneity in relation to the documents certifying the legal access to the genetic resource. This documentary variability has not had a negative impact on the system, beyond the legal uncertainty that it might cause on users, because it was confined exclusively to the jurisdiction in which access had taken place. With the internationalization of the ABS system effected by the Nagoya Protocol, at least as far as compliance measures are concerned, and from the basis of the heterogeneity of national systems for access, it is necessary to establish some documentary homogeneity that provides legal certainty to all actors and allows for an effective and uniform monitoring of the use of resources in third countries that remain outside of the peculiar rules and documents of the country supplying the resource.

1. DOCUMENTATION AS A NECESSARY PREREQUISITE FOR MONITORING

To facilitate the monitoring of genetic resources and their utilization, the Protocol introduces an important documentation element by including the "internationally recognized certificate of compliance" (Art. 17.2), which is no more than the national compliance permit pursuant to Article 6.3.e) once it has been notified to the ABS-CH. This certificate "shall serve as evidence that the genetic resource which it covers has been accessed (…) as required by the domestic access and benefit-sharing legislation or regulatory requirements of the Party providing prior informed consent" (Art. 17.3). From the entry into force of the Nagoya Protocol this certificate becomes the reference document which accompanies and verifies the legal procurement of the resources for all those countries party to the Protocol which have regulated access to their genetic resources at a

national level. Consequently the certificate of compliance becomes the reference document that Parties in which genetic resources are utilized must ask its users.

A. THE NATIONAL ACCESS PERMIT OR ITS EQUIVALENT AND THE INTERNATIONALLY RECOGNIZED CERTIFICATE OF COMPLIANCE

Unlike other documents and actions in which the Protocol gives some flexibility to the Parties, from the entry into force of the Nagoya Protocol, the Parties which decide or have regulated access to their genetic resources shall be required to issue "a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms" (Article 6.3.e). They will also be obliged to notify the permit or equivalent to the Access and Benefit Sharing Clearing-House. "A permit or its equivalent issued in accordance with Article 6, paragraph 3 (e) and made available to the Access and Benefit-sharing Clearing-House, shall constitute an internationally recognized certificate of compliance" (Article 17.2).

The only difference between the two documents is their scope: national or international. In this case, the transition from national to international is determined by its notification to the ABS Clearing-House (ABS-CH), by way of the standard common format for electronic communication of the permit to the ABS-CH. It can be said then that the national access permit "or its equivalent" must contain at least the minimum content defined in the internationally recognized certificate of compliance. Article 17.4 stipulates that the certificate of compliance "shall contain the following minimum information when it is not confidential:

(a) Issuing authority;
(b) Date of issuance;
(c) The provider;
(d) Unique identifier of the certificate;
(e) The person or entity to whom prior informed consent was granted;
(f) Subject-matter or genetic resources covered by the certificate;
(g) Confirmation that mutually agreed terms were established;
(h) Confirmation that prior informed consent was obtained; and
(i) Commercial and/or non-commercial use."

The national access permit or its equivalent, as the source document in which the internationally recognized certificate of compliance is based, must therefore contain at least the above items, provided these do not contain confidential information (Article 14.2 .c). The national access permit or its equivalent may contain more information, beyond that which is reflected in the elements of the internationally recognized compliance certificate. This information may appear in

the certificate, in the sections referred to in the electronic communication document of the permit sent to the ABS-CH that provides a section to reflect any additional information that the issuing Party might deem necessary.

It is clear that the international part of the system, and in particular the ABS Clearing-House (ABS-CH), do not expect to contain confidential information. The Parties who are responsible for communicating and notifying about the national permit or its equivalent to the ABS-CH are ultimately responsible to ensure that such documentation does not contain confidential information. In that sense, the apparent technical difficulty in introducing in Article 17.4 the reference pertaining to confidentiality when collecting information that will be a part of the internationally recognized internationally recognized compliance certificate, stands out in the standard common format for electronic communication of the permit to the ABS-CH, at least in its version of June 2014. On the one hand, the minimum content of the certificate as outlined by Article 17.4 itself must be insured in order to maintain the minimum content and documentary homogeneity required by any international certification system. Moreover, it should reflect the possibility that in some cases, a particular field may not be completed because the information cannot be conveyed by the Party due to it being confidential. The provisional way in which this reference to confidentiality has been integrated into the draft communication document to the ABS-CH (version June 2014) has determined a number of elements *a priori*, contained in Article 17.4, in which on occasion there might be confidential information. These elements are, namely: (c) the provider; (e) the person or entity to whom prior informed consent was given; (f) subject-matter or genetic resources covered by the certificate; (i) the commercial and/or non-commercial use. This technical consideration seems to stray away from what was agreed in the Protocol and, therefore, should perhaps be revised or otherwise resolved in a manner which does not predetermine any given elements of a certificate.

The minimum content of the internationally recognized certificate of compliance reflects a clear understanding of the Parties about the fact that it simply conveys information regarding the administrative and public procedure, which is contained in the national access permit or its equivalent and that the only reference to private and confidential elements (mutually agreed terms or contracts) is determined by a simple mention of their negotiation and existence, without going into any detail about them. Therefore, there is no doubt that, as a general rule, the minimum fields that the certificate must contain are all the elements stipulated in Article 17.4. The exception will be if in any one of these elements, the Parties find information which cannot be disclosed due to its confidential nature, probably due to another horizontal regulation that grants protection to certain information in the country. That is why, while all elements of Article 17.4 must be completed by the Parties, in the exceptional case confidential information were present, this

would be determined by each Party and such confidentiality could affect any of the elements therein. It is, therefore, arguable to have chosen that only some predetermined elements in the document may contain confidential information, which might appear to predispose Parties to interpret these elements as discretional and choose not to communicate the corresponding information. The system should address this matter from a technical point of view so that the information for all minimal elements contained in Article 17.4 is required and, at the same time, to allow Parties to justify their inability to communicate the contents of any of these elements in exceptional cases because the information is protected or confidential.

The possible elimination of certain fields in the certificate might in some cases imply a decrease in the effectiveness of the document and, ultimately, the effectiveness of compliance measures. It should be highlighted that the Party which is most negatively impacted by any limitation on the minimum information of the certificate is, in fact, the country issuing a national permit or its equivalent, which is why it is recommendable to limit this type of situations to those strictly determined by their national legislation.

2. THE ABS CLEARING-HOUSE AND MONITORING THE USE OF GENETIC RESOURCES

The Nagoya Protocol defines, perhaps tangentially, the ABS-CH as the central and focal point of the new system for exchanging information and monitoring the utilization of genetic resources and traditional knowledge associated with genetic resources. On one hand, it is the mechanism that transforms the national access permit, provided for in Article 6.3.e of the Protocol (whose issuance is mandatory for the Parties who choose to regulate access to their genetic resources), into an internationally recognized certificate of compliance simply by notifying of its existence. On the other hand, it is responsible for receiving the information obtained by the checkpoints on the utilization of genetic resources and associated traditional knowledge in their jurisdiction and transferring that information to those directly concerned. With all of this, the ABS-CH becomes the main reference mechanism providing information and transparency to the utilization of genetic resources to which provider and user countries, as well as others, should go for any information on any genetic resource or associated traditional knowledge, and information about countries that have granted permits regarding such knowledge, as well as information about the countries where it is being utilized and its uses.

A. CHECKPOINT COMMUNIQUÉ

Another important element at the core of the system in terms of the generation of information is the information flow that all the Parties to the Protocol must generate in connection to the

utilization of genetic resources (and traditional knowledge associated with genetic resources) within their jurisdiction. As discussed earlier, in this regard the Parties are required to establish at least one checkpoint to which the user is required to disclose the legal procurement of the genetic resource (*disclosure requirement*).

This information, collected by the various checkpoints, must be transferred to the ABS Clearing-House as provided in Article 17.1. In order to facilitate this information transfer from the checkpoint to the ABS Clearing-House, the CBD Secretariat –in the development of the pilot phase of this center– works with a standard document for the electronic communication of the document information called "checkpoint communiqué". In this document, the national authority or checkpoint of the Party in which the genetic resource are being utilized communicates the information obtained regarding the utilization of genetic resources or associated traditional knowledge. That information can be reduced in many cases to the country of utilization, the identification number of the internationally recognized certificate of compliance, the source of procurement, the genetic resource in question and the type of use. Once the ABS-CH receives this information it automatically communicates it electronically to the national authority of the user country, to the focal point and to the competent national authority of the country providing the genetic resource. It is important to point out that, once received by the Clearing-House (ABS-CH), the information is not only communicated but it is available to any interested party through the ABS-CH itself. This facilitates full transparency of the system and makes it possible for anyone interested to spot any potential failures to comply that could be hidden such as access in countries which have open access.

The verification and checking of the information received is up to the Party which is most interested in ensuring that their genetic resources and associated traditional knowledge have been obtained and are being used in accordance with the law: the country providing the genetic resource. This tracking task, which is not explicitly specified in the Protocol, must be clearly identified as a task with its respective competencies and entrusted to the National Focal Point, the competent national authorities or an institution created specifically to perform that function, as has been the case in Peru through the creation of the National anti-Biopiracy Commission created by Law 28216 on Protection of Access to Peruvian Biological Diversity and the Collective Knowledge of Indigenous Peoples of April 30, 2004 (See V.1.B). From the institutional point of view, it would be ideal for compliance to be as close as possible to the access, but if this were not possible or if it were located in independent institutions, then the important thing would be to ensure proper integration and coherence of the system. Institutions for the monitoring of compliance and the legal utilization of genetic resources and traditional knowledge subject to terms will be very useful for detecting faults and shortcomings of their own access system.

In this new international system of information on the utilization of genetic resources, information should not come solely from the checkpoints at a national level, but also from other international, public or private mechanisms and initiatives which should also establish instruments that will provide information to the system.

The generation of information is essential, and in both cases the information originates in and returns to the providing country in most situations. Certainly the role of user countries is crucial when it comes to generating timely information and properly complying with their obligations under the Protocol by requiring users to disclose information in the appropriate checkpoints pertaining to the utilization of genetic resources, and communicate that information to the ABS-CH. This allows the provider country to appropriately monitor the utilization of its genetic resources and detect possible non-compliance cases, particularly involving compliance with its legal framework for access, but also including the fulfillment of the mutually agreed terms (MAT) agreements signed in legal accesses (in this case, the procedures provided for non-compliance in Articles 15 and 16 would not apply. Instead, actions should be taken as stipulated in the procedures for implementation of Article 18).

In cases of non-compliance with national access frameworks, the procedures for cooperation between the Parties under Articles 15.3 and 16.3 –for genetic resources and traditional knowledge respectively– will be crucial for both the provider Party, which will normally be the one to detect and prove the failure to comply with its national ABS framework, as well as for the user Party. These procedures should facilitate the bilateral exchange of information between national authorities that will help to confirm and prove the specific breach of national frameworks of the provider Party to the Party in whose jurisdiction the infringing user is located. Thus, the user Party may activate the specific sanctions at a national level pursuant to Articles 15.2 and 16.2.

In situations of confirmed non-compliance, user Parties may first compel the user to remedy the situation in the provider country (proceed, if possible, to legalize such genetic resources) and, if legal access to the genetic resource or traditional knowledge is not proven within a reasonable time, they might proceed to establish the sanctions. Additionally, in the interest of a correct and full compliance with the obligations under articles 15.1 and 16.1, they may include the prohibition of use of the genetic resources or traditional knowledge concerned in such jurisdiction, among other sanctions. However, in the latter situation (when establishing sanctions and the prohibition of use of resources in the user Party) compliance with the main objective of the Protocol would not be achieved, since the provider Party would not be participating in any way in the benefits arising from the utilization of the genetic resources. This result confirms the importance of establishing procedures for the legalization or regularization of genetic resources or traditional

knowledge obtained without complying with the legal ABS framework of Parties supplying genetic resources which have conditioned access to their genetic resources to a PIC.

These procedures could establish surcharges or sanctions to penalize the illegally procurement of genetic resources and to undoubtedly encourage legal access from the beginning and not after the occurrence. In this case we must also take into account that the provider Party will be in a much better position to negotiate than it would initially have, since the benefits of use are much more concrete and real and users have more at stake at that moment when faced with the possibility that their product may be completely blocked and they may not obtain neither benefits nor a return that covers the significant investment they have had to make in developing their product. The impossibility of legalizing the genetic resources would mean not complying with the third objective of the Nagoya Protocol, since the fair and equitable sharing of benefits arising from the utilization of the genetic resources would not be guaranteed.

V. PRACTICAL OPTIONS FOR IMPLEMENTATION

1. PROVIDER PARTIES

A. NATIONAL ACCESS PERMIT AND ITS NOTIFICATION TO THE ABS CLEARING-HOUSE (ABS-CH)

This study is focused mainly on checkpoints and compliance measures that must be put in place in user countries, but it is worth noting that the effectiveness of the whole process depends on various elements of the Party regulating access to their genetic resources. In fact, the first essential requirement for the enforcement of compliance measures in Parties where genetic resources or traditional knowledge associated with them are being utilized, is that there has been a violation of the national ABS framework of a Party to the Protocol. Therefore, the first indispensable condition is the existence of access regulations as provided in Article 6 of the Nagoya Protocol in the Party providing the genetic resources.

Additionally, for the monitoring and detection of an improper use of genetic resources or traditional knowledge there should be a minimum documentary basis that allows for such monitoring and detection of breaches. The documentary novelty introduced by the Nagoya Protocol in order to facilitate this exchange of information and detect possible breaches is the national access permit or its equivalent which, once notified to the ABS-CH, becomes the internationally recognized certificate of compliance. Both the issuance of the national access permit (Article 6.3.e) and its notification to the ABS-CH (Articles 6.3.e, 14.2.c and 17.2) are

obligations of the Party giving the PIC and it is, therefore, important that such obligations are met successfully due to their relevance in generating legal security and to ensure the rest of the obligations that depend on such information.

B. INSTITUTION FOR MONITORING THE UTILIZATION OF GENETIC RESOURCES AND TRADITIONAL KNOWLEDGE

This matter is not reflected directly in the Nagoya Protocol but stems from the compliance system that it introduces. At the heart of the new system lies the generation of information regarding the utilization of genetic resources. In some cases (probably the least and the most flagrant manifest non-compliance, depending at any rate on the action taken by user Parties), such information will produce an *ex officio* action by the user Party. However, in most cases the information will simply be generated by the user Party without it being verified or proven in essence. The analysis and verification is expected to be carried out by the Party with more interest and more direct information about it, that is, the Party providing the genetic resource or traditional knowledge associated with genetic resources. It is therefore imperative that the Parties regulating access to their genetic resources and associated traditional knowledge have one or more institutions – depending on the administrative setup of the country and especially on the institutions that grant access– which have the competence and capacity to properly keep track of the information generated by the system. In sum, a national institution capable of monitoring the legal utilization of their genetic resources and traditional knowledge throughout the world and effectively ensuring the participation of the country in the benefits derived from their utilization. Monitoring this information will enable contact with third Parties where an alleged misuse of resources is happening in order for them to enforce the national compliance measures implemented at national level.

C. INTRODUCTION OF REGULARIZATION SYSTEMS

Most of the national ABS frameworks prior to the Nagoya Protocol had to solve the whole question and issues on ABS in their own jurisdiction without external help from third countries. This created a vicious circle, mentioned at the beginning of this study, in which almost all the focus and control was on access to genetic resources. Any illegal access normally provided for the inability to request new access or conduct research in the country. Some of these national access systems introduced periods of regularization of genetic resources, which have typically had limited success, with the added problem that these periods have already expired. This in turn has left a number of important genetic resources accessed prior to the entry into force of the Protocol in a condition of permanent illegality.

The problem with this approach is that typically the national access systems did not provide for the regularization of genetic resources obtained in violation of the procedure. Additionally, the approach had some logic when everything had to be resolved at the national level. However, now that the system introduces other compliance systems and measures at the international level, national systems could introduce regularization measures, since not having them could lead to outcomes which are very far from the goals that the Protocol intends to achieve, in particular that of ensuring fair and equitable sharing of benefits arising from the utilization of genetic resources and traditional knowledge associated with providers.

If the system works appropriately, it should become a relatively common situation that country A (who has regulated access to its genetic resources) detects the use in country B of a genetic resource obtained illegally in country A –especially at the beginning, while the turnaround in the trend makes regulated access the norm and illegal access the exception. Country A communicates the situation and provides information to country B for it to enforce national compliance measures. If the system of country B is really effective, it is likely that the user of the genetic resource will be unable to use the resource in country B until it certifies that it has been obtained legally (it is also likely that the user will receive a sanction from country B, which will only benefit country B if it is a monetary sanction). In that case, it is most probable that the user will attempt to return to country A to regularize or legalize the genetic resource in question. The application of many of the current national access frameworks would prevent such adjustment and, in the attempt to legalize, the user would not get any response or would simply be subject to various sanctions in country A. Sanctions that the user would not comply with except in the case it continued operating in country A.

In the new scenario and international system promoted by the Nagoya Protocol, it would be advisable for the Parties that regulate access to their genetic resources to establish procedures for the legalization of illegally obtained genetic resources, for example, in breach of the national ABS framework. Such regularization or legalization would result in very favorable trading conditions for the provider country since, at that moment, it will have much more real and concrete information on the use of the genetic resource which will in turn facilitate their participation in the benefits, effectively ensuring Protocol objectives.

In short, second generation or post-Nagoya national ABS frameworks should consider the incorporation of legalization mechanisms for genetic resources and/or traditional knowledge associated with genetic resources with a view to achieving the main objective of the Nagoya Protocol: the sharing of benefits arising from the utilization of genetic resources and/or traditional knowledge.

2. ALL THE PARTIES (AS USERS)

A. CHOICE OF CHECKPOINTS AND THEIR CHARACTER (FORMAL OR SUBSTANTIAL)

During the study, an analysis of the obligations of the Parties to the Protocol (of all Parties in this case) regarding the so-called compliance measures and checkpoints has been carried out. The heart of the Protocol for this section lies in the generation of relevant, timely and consistent/comparable information. The protocol is extremely flexible as to the appointment of checkpoints simply determining the obligation to establish a checkpoint.

However, the analysis conducted of paragraph III.3.b, revealed that it would be ideal to have at least two checkpoints. The first would be in the first stage of utilization: research. This would already ensure legal access to a great part of the genetic resources that make up the biotechnology chain, as well as a good initial integration of both the principles of ABS in the research sector and the non-monetary benefits of access (technology transfer, training, etc.). In this sense, although the study has analyzed the two checkpoints related to research (public funds for research and publications) it is considered that the verification conducted through public research funds can be much more effective, transparent and consistent with the premise of not allowing public funds to be used in the conduction of illegal activities in third countries. It is important to emphasize the crucial ripple effect that this measure could have given that such control would not only directly affect the institutions that receive such funding, but it would also affect those collaborating research institutions from third countries that would have a very significant external incentive to comply with their own national access legislation, which is unfortunately not the case in many situations nowadays. The control in publications would involve some uncertainty and difficulty in the control by private institutions and it also seems that it would not have the results and the multiplier effect of the previously mentioned measure.

The other checkpoint should cover the final part of the biotechnology chain closest to the introduction of the final product into the market and therefore the closest to obtaining monetary benefits. In this sense, patent offices and product marketing have been considered. For years, the patent office has been the main demand of many countries in terms of disclosure requirements. However, coverage is partial: not all biotechnology products are based on a patent, whereas truly operational patents end products which are sold in the market. Therefore, a priori, if one had to choose, it would seem that the marketing of products would have a wider and more effective coverage than that of the patent office.

In view of this, it should be noted that although application procedures for patents or intellectual property are national, they are much more internationally harmonized than authorization procedures for selling products nationwide, which vary considerably from one country to another. Choosing patents over product marketing would have the advantage of such requirement providing greater ease for international harmonization.

The introduction of a checkpoint in research and one closer to commercialization would result in a balanced and effective approach of the system aimed at ensuring legal access and, therefore, participation in both non-monetary and monetary benefits.

The checkpoints described above have two main strengths over other checkpoints. First of all, they are checkpoints already in existence, which is an option the Protocol explicitly points out. This represents a cost saving by integrating the disclosure requirement for users into existing procedures. Therefore, they facilitate the verification of compliance in a simple manner, while another type of application is being processed.

The second strength of the integration into existing checkpoints, is the improvement in compliance since users have a direct interest in the correct processing of their disclosure requirement because it directly associates the correct fulfillment of the requirement of disclosure to the procedure in which it has been inserted. This is reinforced by the fact that a breach of the disclosure requirement, even if it is a formal verification, will usually be accompanied by the suspension of the request until it meets the previously mentioned requirement, which is a great incentive to comply. Furthermore, in some countries it may be the case that checkpoints are not merely formal but rather constitute the primary measure of compliance pursuant to Articles 15 and 16 and, therefore, the disclosure requirement is a substantive requirement of the procedure in which it is inserted. In the latter case, the non-compliance, the provision of incorrect information the subsequent verification that the genetic resource has not been obtained legally in the country of access could, at any given time, entail the invalidation of the substantive procedure in which it is inserted (public funding, publication, patent or product marketing). These are extremely serious and burdensome consequences for the user that exponentially encourage the proper execution of legal access to genetic resources.

Establishing checkpoints not directly related to the biotechnology value chain, such as the competent authority for access or compliance, a priori seems to move away from the value chain and direct incentives that have been discussed above. They also demand a significant degree of coordination with the procedures which are related but do not actually get inserted. This poses the question of how the competent authority will know a user has requested public funding (or a patent, or the marketing of its product) and has not submitted the appropriate documentation in a

timely manner. That authority will only know if it establishes mechanisms for coordination with the authorities carrying out such procedures, for example, by asking for information to those who could be directly processing the paperwork and verification.

This system does not only place a greater administrative burden on said authority, which is alien to the procedures in which the user is asked to provide information, but it also lacks any of the aforementioned incentives for the user, since these are parallel and disconnected instances, beyond the possible monetary sanctions, with extremely limited effectiveness in the face of a possible breach of the disclosure requirement.

B. Establishing Procedures for Cooperation with other Parties of the Protocol and Effective Measures related to Compliance

The generation of relevant and timely information on the utilization of genetic resources is the heart of the new system, but the information in itself does not generate compliance. It is essential that when a breach is detected on the basis of the information generated, there be suitable measures to solve this kind of situations.

In a few cases, it might happen that the Party that detects the breach, is in fact the Party where the genetic resource or traditional knowledge associated with genetic resources are being utilized. In these cases, the Party shall apply the measures provided directly in their jurisdiction to comply with Articles 15 and 16. However, in most cases, the detection of breaches will come from the Party whose genetic resources have been accessed, and who has more information and control, as well as a greater interest in having its national legislation enforced. In such cases, the Party that detected the illegal access by a user who is in the user Party, needs to contact the user Party with the aim of getting the latter to enforce appropriate compliance measures on its user. The procedures of communication and cooperation provided for in Articles 15.3 and 16.3 are, therefore, indispensable for the operability and effectiveness of the system in general.

Once the breach of a user has been verified by the Party where the utilization of genetic resources or traditional knowledge is being conducted, it is essential to adopt the measures provided for in Articles 15.1 and 15.2, 16.1 and 16.2. This is to say that the user Party shall ensure that the

genetic resources and/or traditional knowledge utilized in their jurisdiction have been accessed in accordance with the national access framework of the Party providing the resource, and it shall implement effective and proportionate measures to address situations of non-compliance. In this sense, the most effective and proportional measure would seem to be the enforcement of sanctions and the impossibility of using those resources until they have been legalized.

SUMMARY AND GRAPH OF THE OBLIGATIONS AND INFORMATION FLOW RELATED TO COMPLIANCE MEASURES

STAGE 1- PARTY TO THE NAGOYA PROTOCOL WHO HAS REGULATED ACCESS TO ITS GENETIC RESOURCES

1- Application for access to genetic resources –the applicant obtains PIC– obtains a national access permit or its equivalent at the end of the process (Art. 6, particularly 6.3.e)
2- National competent authority notifies the access permit –through an electronic communication– to the ABS Clearing-House (ABS-CH) (Art. 6.3.e) (Art. 17.4)
3- The ABS-CH issues the Internationally Recognized Certificate of Compliance (IRCC) (Art. 17.2 and 17.4)

STAGE 2- PARTY TO THE NAGOYA PROTOCOL WHERE THE GENETIC RESOURCES ARE BEING USED (ALL PARTIES):

1- Obligation to require disclosure of the legal procurement of the genetic resource by the user at designated checkpoints (through the IRCC, the PIC, or via a statement regarding the place of collection) along with information, in all cases, on the utilization of the genetic resources (Art. 17.1.a).
2- Measures in case the user does not provide the required information (penalties, inability to process application, etc.). (Art. 17.1.a.ii)

2bis- In cases where the checkpoint exercises a substantial control, a detected breach of compliance would substantively affect the application in question.

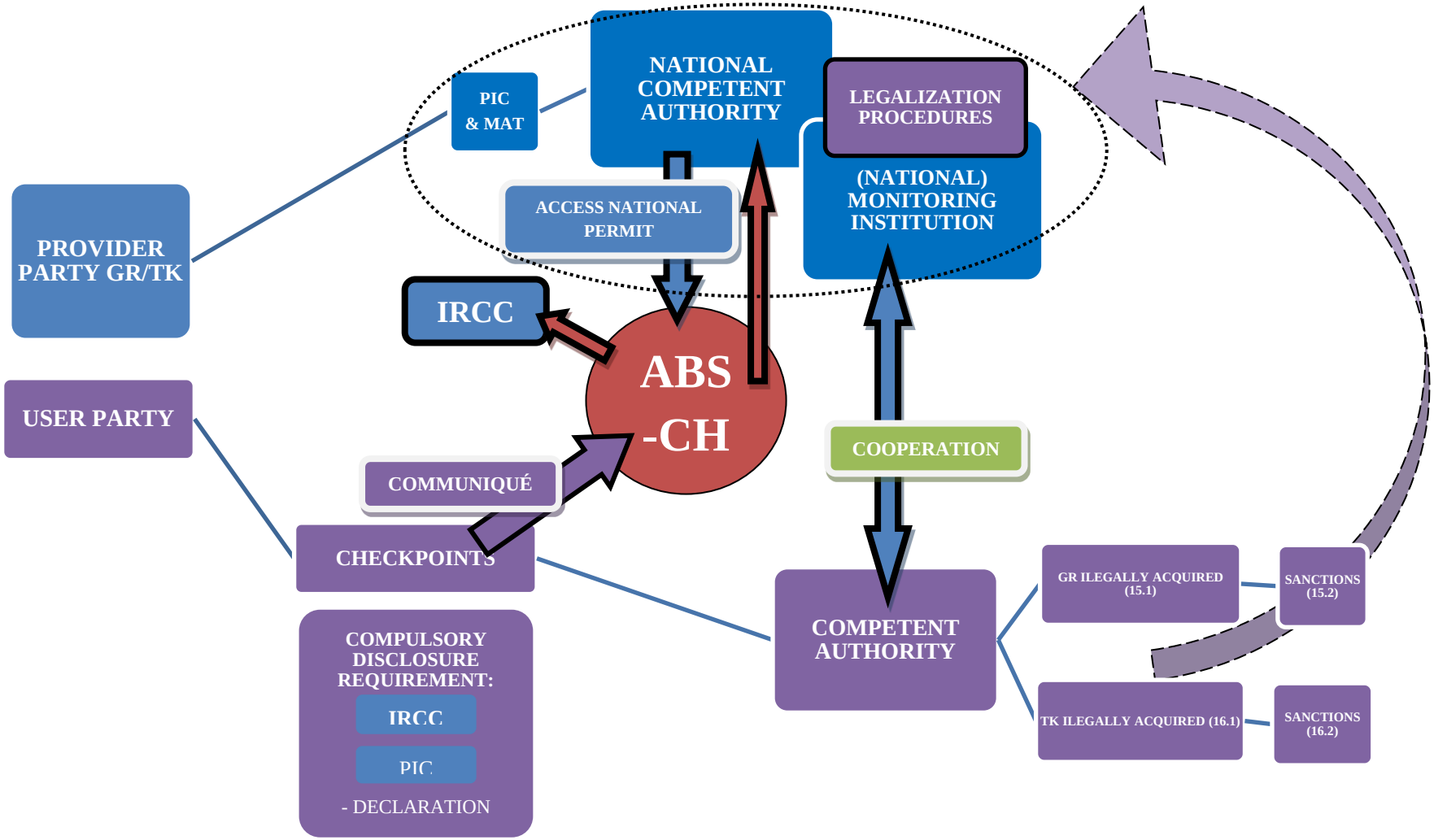
3- The checkpoint communicates said information to the ABS-CH via its *checkpoint communiqué* which is and electronic communication document.
4- The ABS-CH sends a copy of that information to the Party that has granted the PIC or the country of access to the genetic resource, and to the competent

authority designated by the country in which the checkpoint is located.

STAGE 3- IN CASE BREACHES OF THE REGULATIONS OF ACCESS ARE DETECTED (*)

1- The process of cooperation with the country in which the genetic resource has been utilized is activated (by the Party providing the resource or automatically by the user Party).
2- Once the breach has been proven, measures must be enforced by the user Party of the genetic resource with regards to the user (sanctions, prohibition of use, etc.) (These may be at the checkpoint –see Point 2bis of Stage 2– and might substantively affect the application, for example, by impeding a patent, marketing, research fundraising, etc.)
3- User must legalize the genetic resource and traditional knowledge in the provider Party (user should return, if the provider Party allows it, to the Stage 1 procedure or to a similar procedure)

(*) NOTE OF CLARIFICATION: These procedures could also reveal breaches of the mutually agreed terms, although such breaches would not be covered by said procedures but by those stipulated in Article 18 of the Nagoya Protocol, which leaves them out of the scope of this study.


PROVIDER PARTY GR/TK
USER PARTY
PIC & MAT
NATIONAL COMPETENT AUTHORITY
ACCESS NATIONAL PERMIT
IRCC
ABS -CH
COMMUNIQUÉ
CHECKPOINTS
COMPULSORY DISCLOSURE REQUIREMENT:
IRCC
PIC
- DECLARATION
LEGALIZATION PROCEDURES
(NATIONAL) MONITORING INSTITUTION
COOPERATION
COMPETENT AUTHORITY
GR ILEGALLY ACQUIRED (15.1)
SANCTIONS (15.2)
TK ILEGALLY ACQUIRED (16.1)
SANCTIONS (16.2)

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