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**SUMMARY ANALYSIS: LEGAL CERTAINTY FOR USERS OF GENETIC RESOURCES
UNDER EXISTING ACCESS AND BENEFIT-SHARING (ABS) LEGISLATION AND
POLICY**

Document prepared by IUCN-Canada

Note by the Executive Secretary

1. The Executive Secretary is pleased to circulate herewith, for the information of participants in the third meeting of the Ad Hoc Open-ended Working Group on Access and Benefit-sharing, document containing a summary analysis regarding legal certainty for users of genetic resources under existing access and benefit-sharing legislation and policy, prepared by IUCN-Canada as commissioned by the Secretariat of the Convention..
2. The document is being circulated in the form and the language in which it was received by the Convention Secretariat.

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**Summary Analysis:
Legal Certainty for Users of Genetic Resources
under Existing Access and Benefit-sharing (ABS) Legislation and
Policy**

IUCN-Canada¹

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Summary Analysis: Legal Certainty for Users of Genetic Resources under Existing Access and Benefit-sharing (ABS) Legislation and Policy

Introduction

This paper provides initial analysis of existing measures that have been adopted at national and regional level that provide “legal certainty” for users over the terms and conditions of access and use of genetic resources. It responds to the Conference of the Parties (COP) *Decision VII/19: Access and benefit-sharing as related to genetic resources (Article 15)*, and, more specifically, paragraph E/10(g), “[r]equesting the Executive Secretary to gather information... and undertake further analysis relating to... (g) Measures that preserve and promote legal certainty for users over the terms and conditions of access and use [of genetic resources].”

This study was based on analysis of the national and regional access and benefit-sharing measures available in the CBD Secretariat’s electronic database of provisions through which countries seek to provide legal certainty to those seeking genetic-resource access, use, and benefit-sharing. It analyses the general approaches used in existing measures in terms of legal certainty for legitimate users of those genetic resources.

I. Conceptual Background: Legal Certainty for Users of Genetic Resources

In order to address these issues briefly, this paper offers a “summary-analysis.” It does not purport to be a complete analysis, nor a compendium of existing measures, and cannot examine all elements of ‘legal certainty.’ As a first step it lists characteristics of ‘legal certainty’ that are specially relevant to ABS, and identifies indicative categories.

Taken in its broadest sense, an analysis of legal certainty for a party to a particular commercial or other instrument would encompass every aspect of law relevant to that party’s intended activity. A party would have ‘legal certainty’ regarding an instrument if he was fully aware of all relevant laws, *and certain that they were consistently and predictably in force and enforceable.*² Only after this was assured would he consider particular factors affecting his rights.³ It is neither possible nor valuable to examine this entire range of legal certainty issues in this paper. Rather, for this ABS analysis, a narrower definition of ‘legal certainty for users’ focuses on three elements:

- **Process certainty:** This kind of legal certainty encompasses
 - Establishment and empowerment of competent national authorities, specifying the rights and duties of others (landowners, communities, etc.) who may be involved.
 - Clarity regarding the procedures for applying for ABS rights;
 - Clarity regarding various deadlines for processing applications; and
 - Clarity regarding appeal of the decision by the applicant or by others.

² Typically, vague or ambiguous measures in laws and regulations are not considered “enforceable,” when court action is sought, and may not be considered practically implementable by government agencies, in the absence of a court challenge. In addition, some provisions (and entire instruments) adopted as laws do not contain the necessary provisions and powers to be enforceable (by government or by private parties.)

³ Basic principles of this approach to legislation are found in many publications. See, e.g., T.C. Hartley in *The Foundations of European Community Law* (3d ed. 1994) at 149.

- **Scope and Nature of the Grant:** This factor enhances legal certainty by clearly defining the right granted, as well as enunciating mandatory provisions and conditions that must be included within the ‘mutually agreed terms.’
- **Legitimate Expectations and Vested Rights:** This kind of legal certainty can be supported in several ways including
 - Clear and specific statutory requirements and limitations regarding subsequent challenges to the user’s activities after receiving ABS rights, and
 - A clear delimitation of the nature of government’s power to alter, cancel, repudiate, amend or suspend of an ABS right, once it has been received.

II. Methodology

In preparing this analysis, the researchers examined all of the laws submitted to the CBD, as contained in the CBD’s electronic database of ABS-related legislative measures,⁴ to locate those national or regional measures, focusing on those that (1) are currently in force or formally enacted at the time of this research,⁵ and (2) include specific implementation measures relating to access to genetic resources.⁶ Each law meeting these criteria was reviewed, and particular provisions relating to the three categories described above (process certainty, scope and nature of the grant, and expectations/vested rights) were specifically identified and studied in context of the overall law.

Naturally, complete description and analysis of each such provision cannot be redacted in a paper of a proper length for distribution in the Ad Hoc Open-ended Working Group on Access and Benefit-sharing. Rather, this summary identifies and explains specific and collective conclusions based on the examination of those laws. It offers numerous examples from the laws reviewed, but does not exhaustively list all provisions relevant to a particular point.

It is important to note that, although this summary is based solely on a desk study of nationally submitted ‘biodiversity laws,’ these laws are not the primary sources of ‘legal certainty’ in most countries. In a few countries, biodiversity legislation specifically addresses, creates or restates rights of ‘due process of law,’ administrative appeals, estoppel and other relevant legal concepts; however, these issues are more often addressed in broader governance frameworks

⁴ *CBD Database on ABS Measures*: <http://www.biodiv.org/programmes/socio-eco/benefit/measures.aspx> .

⁵ (Based on information from the CBD Database.) The database includes numerous laws that are identified as ‘draft’ many of these have existed in final draft form for upwards of 5 years, suggesting that there is a dwindling chance that they will be adopted. While these instruments were reviewed in detail and provided interesting and in some cases valuable ideas (*see, especially Guyana, (Draft) Environmental Protection Bio-Propecting Regulations 2001*, and *Philippines, Draft Guidelines for Bioprospecting Activities in the Philippines* (Joint DENR-DA-PCSD-NCIP (Final Report Draft, May 2004) and *Ecuador: Ley para la conservación y uso sustentable de la biodiversidad (Draft, 2002)*), the fact that they have not yet been enacted suggests that they may have limited value as examples. The authors were not able to independently confirm the status of all laws reviewed, but restricted this paper’s discussion to those that are listed as ‘in force’ in the Database, or included gazette numbers or other indications of formal adoption. Note: The *African Model Law* is the exception to this general operational rule, as it is not intended for enactment, but is offered as a model. Its general applicability and formal acceptance by the AU suggest that it should be reviewed in this paper.

⁶ The laws that were considered in the course of this analysis are listed in Annex A to this paper. Annex B lists laws in force from the CBD’s ABS Database which have been identified as addressing ABS, but do so only in a general way, without including any specific provisions governing the manner in which it will be implemented, or only by authorizing the development and adoption of regulations which apparently have not been adopted, as yet.

(constitutions, commercial codes, administrative codes, civil codes, licensing laws, political and civil rights instruments, framework environmental laws, etc.), which have a much greater impact on legal certainty than any of the biodiversity laws examined, and will certainly address the relevant questions with greater specificity. It would be necessary to examine a much broader context of national law in order to fully determine how legal certainty is provided regarding ABS rights.⁷

Finally, it must be noted that only about 16 of the 188 Contracting Parties to the CBD have adopted laws and procedures that actually implement their ABS responsibilities at present. Research indicates that more than 75 other Contracting Parties have attempted to do so at various times, but have dropped the attempt due to other preventing factors. Where laws exist, they may not have been in operation for long enough to provide a full understanding of their effectiveness, strengths and weaknesses. The information gleaned from the available legislation may not provide a comprehensive basis on which to address these issues. In practice, however, most countries have long experience with licensing and contract law frameworks that can provide useful templates for their country's approach to such legal certainty issues as (i) the rights of due process in commercial transactions, (ii) the protection of local communities and individuals in contracting with larger commercial entities, (iii) basic components of contractual law (prior informed consent and materially agreed terms), and (iv) the special duties, responsibilities and liabilities of government officials when giving individual applicants the rights to use national natural resources for private commercial gain.

III. Legal Certainty For Users Granted Access to Genetic Resources

The following sections will identify each of the three overall categories, explain the nature of the issue, then discuss the state of current ABS legislative measures.

A. Process Certainty

In all types of development activities, a major source of legal uncertainty for users arises from the nature of governmental permit processes. In terms of ABS implementation, legal uncertainty increases where the application process (1) is more complex, (2) takes much longer, and/or (3) requires more additional inputs and compliance than the applicant reasonably predicted at the outset of the process.

As in all issues involving the private utilisation of natural and/or patrimonial resources, there are two kinds of concerns that must be balanced – the applicant's desire to minimise cost, complexity and time involved, and the government's desire to ensure that the grant will not create actionable concerns for affected stakeholders, and will properly protect and compensate the source countries, communities and individuals.

In any licensing or permit application process (ABS and other types), the applicant may find it necessary to invest significant time, effort and money before the government completes the permit process. If the application is denied, however, that investment may be lost. The applicant may also feel the need to begin publicising (generally or to necessary investors and partners)

⁷ This paper will use the term "ABS rights" or "ABS Agreement" to refer to the various types of grants by which users obtain access to (permission to use) genetic resources, including the full suite of access permits, licenses, other contracts or other relevant instrument or legal permissions required within a country in order to collect, study and commercially utilise genetic resources.

both its planned activities and other confidential company information in the course of that process. This, too, cannot be undone, if the permit is not granted. Usually done for commercial or business purposes, some or all of these expenditures and disclosures may also be legally required (either in direct legal provisions or as a practical matter) in the course of the permit application. Before investing time, money and reputation to obtain ABS rights, the potential user needs a high level of certainty that (1) he can ultimately satisfy the permitting agencies requirements⁸ and (2) he has a reasonable level of confidence regarding the length and expense of the process, and a basis for assessing the possibilities that unexpected requirements will later be imposed. Without this kind of certainty, the financial risks of the application process may prevent any attempt to obtain ABS rights.⁹

Conversely, however, governmental permits and permissions, once given, are often subject to rather strong protections for the user (as discussed in parts III.B and C., below.) Hence, it is essential for the government official making such a decision to make it carefully, on the basis of all relevant knowledge and information. From the perspective of the source country, an inappropriately granted permit might lead to litigation, might violate key rights or constitutional protections, or be harmful in other ways. A decision-maker would have failed in his duty if he granted the permit solely because the applicant had already invested large amounts of money. Rather, such a practice would create an incentive for companies to quickly invest an appropriate sum, as a way of ‘buying’ the decision-maker’s objectivity. This precise issue is addressed in part in *Australia: Queensland Biodiscovery Act*, which specifically notes that an application for ABS rights may be denied even where ‘a benefit-sharing agreement or approved biodiscovery plan is in force concerning the material subject of the application.’ (Art. 14(4).)

The need for this balance, of course, means that no government is capable of giving every applicant absolute legal certainty that their application will be successful. The decision maker will always need information and input (on a variety of matters from the scientific activities proposed, the nature of users, the geographic and social conditions of the target area, and other topics) and will usually require that the applicant cover the costs of obtaining it.¹⁰ A decision regarding an ABS application, however, will probably require both in-depth governmental analysis, and public participation,¹¹ before the matter can be decided. It is unavoidable that these processes will require substantial time – during which the applicant may find it necessary or expedient to spend additional money and other resources.

Clearly then “process certainty” may be best characterised as “process predictability” – a scale of predictability. The user’s willingness to apply for ABS rights will increase where the process is

⁸ The applicant does not need to be certain that his initial application satisfies those requirements. However, legal certainty is increased where he knows that he will be able remedy deficiencies. Where there is a significant chance that no approval will ever be given to an applicant in his circumstances, a potential user would be deterred from beginning any process that required the investment of time and money.

⁹ Some measures reflect this issue to a limited extent. See, e.g., *Australia: Queensland Biodiscovery Act*, which requires the government to refund the application fee in cases of denial of the application. (Art. 15(2)(b).)

¹⁰ In the CBD, this process is specifically discussed with regard to ABS, the term “Prior Informed Consent” (Article 15.5) relates to the need for the applicant to provide or ensure that the government obtains all relevant information, before it gives its consent to a request to access the country’s genetic resources.

¹¹ The CBD does not address sub-national activities such as public participation, and hence all references to participation in Article 15 relate to the involvement of the source country in the activities of the user. The manner in which each country participates (i.e., at sub-national or community level) is a matter of implementation, to be decided by that country. (See Article 5.1 of the *African Model Law*.) The Bonn Guidelines recommend public participation at the local level, with regard to all governmental decisions regarding resource and permit matters that affect the public.

more predictable, enabling him to realistically assess the risks involved. Process certainty cannot be absolute, but can be maximised. Process certainty is usually enhanced where source country ABS legislation includes measures that –

- clearly identify and empower competent national authorities (CNAs),
- clarify the role of other bodies and processes in the ABS decision, and
- provide clear guidance regarding the steps in the application process, timing and milestones, and the role of other stakeholders during the process.

In addition, countries maximise certainty where they specify (i) the bases on which the decision will be made, (ii) the manner in which it will become ‘final’ for legal purposes, (iii) the rules relating to appeals, and (iv) the nature of exemptions.

1. Identification and Empowerment of Competent National Authorities

Predictability is increased by the designation of CNAs and clarification of their roles and mandates. The user is thus able to cut down procedural time, by going immediately to the correct authorities, and to gain from them at an early point in the process, an understanding of what the procedural rules and requirements are, and (where other ABS applications have been processed in the past) an indication of the usual time and information required. Where the CNA is the primary authority regarding applications and ABS rights, it may also provide a single source of assurance regarding the status of such applications and rights.

a. Designation

Most of the laws examined contained a clear statement designating (or empowering the designation of) specific CNAs for ABS applications within the country. A clear example of a strong CNA designation is found in *CAN Decision 391*, which requires designation of a national CNA (in accordance with relevant designation procedures under national law), and delegation to the CNA of comprehensive oversight and decisional authority. *Decision 391* specifically requires that all access contracts must be executed, on behalf of the government involved, by the CNA, which must be a state agency or public institution.¹² Other examples of strong direct authorisation of CNAs include *Australia: Queensland Biodiscovery Act*, Arts. 7, 11 and 24-25; *Costa Rica: ABS Regulations*, Art. 5; *India Biological Diversity Act* (Arts. 8, 18 and 22); *Philippines: EO 247*.

In some measures, however, the CNA designation may be more equivocal. For example, in the *African Model Law* identifies the CNA as “the entity authorised by the State to supervise and watch over the implementation of one or more of the components of the present law,” but specifically notes that other agencies may be given some or all of these responsibilities, by provision in other laws. (Art. 3.3, and see Arts. 7.1-7.2.) This less-final approach to designation is common in many kinds of legislation, and in this case may arise from the fact that the ABS provisions under the *Model Law* apply to both biological resources and genetic resources.

¹² All CAN member countries have formally adopted laws implementing Decision 391, except Ecuador, which has provided a draft law dated 2001 for the CBD database of ABS Measures. It is not clear whether this latter draft is still under consideration. For examples of the various focal point/CNA mechanisms adopted by CAN countries See *Bolivia: Decision 391 Regulations*, Arts. 3 & 4 (CNA’s work to be supplemented by the input of a Technical Assessment Body); and *Peru: ABS & TK Law (2004)*.

Hence, a many different governmental bodies, officials and private persons would have at least some direct right to grant access (through, for example, selling biological resources (vegetables) in a local produce market.) Regardless of whether it has full responsibility for the application, however, the CNA is required to give prior informed consent to all access agreements. (Article 5.1.)

b. Mandate (Powers and Duties)

Several of the measures examined specifically identify some or all of the powers and duties of the CNA. The extent of such delegation of duties may vary widely as well.

In some cases, the designation is nearly pro-forma – to give the applicant a designated ‘starting point.’ This is the effect, for example, of the above-described provisions in the *African Model Law*. An opposite approach is found in *CAN Decision 391*, which endows CNAs with many specific responsibilities. The CNA is called upon to “receive, evaluate, accept or deny applications for access,” and to issue the “access resolution” that is required whenever a member country enters into an ABS arrangement. The CNAs are also charged with oversight, since it must issue and publish an administrative order when the requirements of that access contract have been fulfilled, and may be required to issue sanctions for violations of the contract. (Art. 50.1, *and see* definitions of ‘CNA,’ ‘access contract,’ and ‘access resolution’; Arts. 32, 35, 40, 43, and 47.) In addition, many other national measures (listed in Annex B) currently contain provisions authorising the future creation of regulations to develop and adopt regulatory measures that will address CNA responsibilities and operations.¹³

2. Integration with other Levels and Processes

Before examining the nature of the process, however, it is essential to consider the multiplicity of processes that must be undertaken. A key question considered by any potential applicant for ABS rights is how the basic application process integrates with other levels of ABS approval, and with other relevant governmental approvals and processes. The need for this integration was one of the most important problems identified by user corporations in the negotiation of the Bonn Guidelines (and after) – calling for ‘streamlining’ of these processes. This need can be partially answered by the designation of an ABS CNA or Focal Point. In itself, however, CNA designation does not solve the primary underlying problem – many different stakeholders, groups and offices have direct responsibilities that may be affected by an ABS agreement. Many national measures provide that, in addition to formal approval from the central government, some of the other affected parties must give their own prior informed consent, leaving a situation in which many separate PICs must be obtained. In addition to PIC, however, it may also be true that, under relevant law, the applicant will need additional permits and licenses, that are not governed by the ABS law.

¹³ Although a researcher in this project contacted some of these countries, he was not able to obtain any such regulations, apart from those found in the CBD database.

a. Who Gives Prior Informed Consent?

The CBD provides that prior informed consent must be obtained from the Contracting Party – that is, from the national government of the source country.¹⁴ In practice, many governments delegate elements of this responsibility to local entities and communities, for two primary reasons. First, the concept of participatory governance strongly indicates the need to involve the people in decisions granting individual rights over sovereign assets. In addition, however, local residents and other affected stakeholders are more knowledgeable about many of the potential impacts and effects of such a decision. Hence, many national measures provide that sub-nationally PIC must be sought from a variety of other persons or groups, including

- those who are ‘stakeholders’ in the genetic resources (local and traditional communities and indigenous groups), and
- those whose consent is practically necessary in order for the applicant to obtain access (for example, where access includes direct collection of samples, permission from the person or community that has the right to control entrance to or use of the land on which the collection activities are carried out.)

The manner in which this requirement is expressed is critical, and impacts the user’s ability to understand and maximise predictability of the entire process. For example, the *African Model Law*, in addition to requiring PIC from the CNA, mandates the CNA to “consult with the local communities in order to ascertain that its/their consent is sought and granted.” (Arts. 5.1, 5.3 and 7.3.)¹⁵ The *South Africa: Biodiversity Act* also places a high level of responsibility on the CNA in this regard, mandating that it ‘protect any interest of’ individual landholders or rightholders giving access to resources as well as indigenous communities whose knowledge or traditional uses are involved. (Art. 82.) Both of these provisions essentially require the CNA to serve a co-ordination and oversight function, confirmed by issuance of the ABS permit.

With regard to sub-national PIC requirements, certainty would be maximised, where legislation clearly states objective criteria, on the basis of which, the applicant can show that he has complied. On the basis of other legislative and administrative experience,¹⁶ it would appear that such criteria should include (i) the basis on which one can identify all groups and individuals that must give PIC, (ii) the procedure for notifying these persons that their input and consent has been requested, and (iii) exactly how to determine that a non-corporate group (an unincorporated community or other group of affected-but-unrelated parties) has ‘consented’ (*e.g.*, what level of participation is necessary? who may make decisions on behalf of the others where no single elected individual has the right to represent them all? whether unanimous consent is required and if not what level of agreement is needed, etc.) It may also be useful to identify an ombudsman or other official whose duty is to ensure that the relevant persons are aware of and able to fully exercise their rights.

¹⁴ It is important to keep in mind that the CBD’s ABS provisions apply to cross-border transactions only. Unlike any other part of the Convention, the provisions of Article 15 and the Convention’s third objective do not impose any obligation regarding domestic use of genetic resources in the source country, whether by governmental or other users. Although it is clear that any ABS framework must coordinate with regulation of domestic regulation of access and use of genetic resources, that coordination is not specifically addressed in the Convention.

¹⁵ Guidance on the process is not extensive, however the law notes that the applicant must “ensur[e] that women are also involved in [community] decision making process. (Art. 5.1.)

¹⁶ Land-use decisions, for example, especially those that designate rural land as a protected area, generally face the same balance of problems.

b. Integration with Other Required Permissions and Processes

Other permit requirements, and the administrative framework for integration of other officials, sectors, right-holders and affected parties into the ABS decision-making framework is also a point affecting legal certainty. In all permit processes, developers and applicants prefer a single-permit or “one-stop shop” approach. This could happen where the permit processes are completely integrated into a single permit or approval, or where the law gives one process priority over all the others. An example of this approach is found in *Australia: Queensland Biodiscovery Act*. That *Act* gives absolute priority to ABS, stating that if CNA issues ABS rights, then the applicant is not required to obtain permissions or licenses required under other laws and will not be bound by prohibitions arising under those laws. (Sec. 7.) This approach may enhance user certainty, but only where the other agencies agree that ABS permission is pre-eminent. National law typically contains a variety of licensing requirements. In some countries, several separate requirements may contain such a statement of pre-eminence, leaving the applicant in some doubt. Agencies typically agree to renounce their authority to another agency, only where the other agency’s process calls for in-depth intra-governmental consultation.

Unfortunately, complete integration or administrative pre-eminence is rarely possible due to many factors, including the distribution of authority and expertise within government. Legislation may still enhance legal certainty, by clarifying the relationship between the ABS application process and other government permissions and processes, such as:

- Customs approvals and CITES permits (for transboundary movement of samples),
- legal consents from property owners and communities (for sampling activities on private or community controlled lands),
- research permits (where controlled by permit)
- and other kinds of permits.

Co-ordination among other provisions, designations and requirements appear in several measures, some of which specifically provide that ABS decisions pre-empt the decisions of other bodies, while others specifically note that, even one who has received final ABS rights must still comply with relevant laws (*e.g.*, CITES permit requirements) as to samples collected. *See especially, Costa Rica: ABS Regulations*, Arts. 18 (integration with other permits relating to exportation of samples) and 26 (integration with law governing environmental impact assessment); *Malawi: Procedures*, Part E.4 and 5; *Australia: Queensland Biodiscovery Act*, (Arts. 24-25) (ABS rights not altered by the declaration of a protected area, or the alteration of the conservation status of particular species.)¹⁷

Assuming that national law (possibly supplemented by the negotiations of the international regime) clarifies key factors regarding the nature of ABS rights and instruments, it may be possible to be even clearer and more specific in legal documentation regarding the relationship between ABS and other processes. For example, Brazil’s CITES Permits, following on provisions from its ABS implementation measures clearly specify that

This permit does not extend to the use of biological material to access genetic information, contained in the whole or parts of plants, fungus, microorganisms or animals specimens; in substances derived from the metabolism of these living beings or from extracts obtained from live or dead specimens, occurring *in situ* conditions, including

¹⁷ The Draft *Guyana Bio-prospecting Regulations* also specifically discuss the relationship to the preparation of an Environment Impact Assessment (See Articles 10, 13 and 14).

domestic ones, or kept in *ex situ* collections, if obtained *in situ* conditions, in national territory, the continental shelf or the exclusive economic zone, aiming at prospecting for identification of components of the genetic patrimony and/or information about associated traditional knowledge with potential commercial use.¹⁸

3. Clear and Transparent Procedures

Process predictability requires that the applicant should know what steps are required in order to complete the application process, and have an idea of how those steps will proceed. Serious difficulties can arise, for both source country and user applicant, where such procedures are not clearly stated in law, or where the law leaves negotiation of an appropriate access agreement entirely to the discretion of a CNA or national ABS focal point. Often, the greatest difficulties encountered involve subsequent requests for additional information, additional public comment or other meetings, and extended deliberations.

For purposes of this paper, the specific contents of the procedures (and the particular requirements listed) need not be examined, as the nature of the requirements does not affect legal certainty, so long as the requirements are clearly stated. Clarity on these points, however, is essential, as it will enable the user to fairly evaluate his chances and costs of success. There are, however, several qualities that may increase legal certainty in measures that discuss application and approval procedures. In general legal certainty increases where relevant measures specifically identify activities and milestones, set time limits for various stages in the decision-making process, and provide a clear record of the decision and its finality. Examination of existing ABS laws provides a broad spectrum of approaches.

a. Steps in the Process

In most legislative measures reviewed, the application process is defined primarily as “prior informed consent.” There are, however, many other kinds of steps in the application process, which are necessary for a variety of reasons – especially, to maintain a record of the information and activities in the application process, and to ensure that records are complete and defensible.

The specific approach to documenting and gaining relevant consent from all required parties varies greatly among the laws examined for this paper. Some laws contain unspecific provisions, mandating and authorising the CNA to control access, but not specifying procedures. This kind of legislation may be wildly unpredictable for users and for source countries). At the other end of the spectrum are laws creating many very detailed procedures to address all contingencies and issues. While these measures may possibly be more predictable, they are frequently much more time consuming.

Typically, a licensing procedure involves seven general steps: (1) submission of an application; (2) initial evaluation; (3) determination/notification that the application is complete; (4) consultation; (5) public notice and participation; (6) final evaluation; (6) notification (and publication) of decision; and (7) appeal. In the case of ABS rights, additional steps may be

¹⁸ This is discussed in Bloch, F. The “Brazilian Clause” – Note on a Recent Attempt to Create Linkages Between the CBD and CITES, RECEIL, 2002. CITES COP 13 addressed many of the concerns that prompted Brazil’s inclusion of this clause, and noted the need for the negotiations of the International ABS regime to be developed in a way that clarified the crossover between ABS rights and CITES permits. See CITES Secretariat website at www.cites.org.

necessary, in drawing up the relevant documents in contractual form.¹⁹ Legal certainty is enhanced, where each of these steps is formally described in legislative measures. Several of the measures reviewed have addressed some of these steps, however in most cases, the process is controlled by a combination of CNA discretion, administrative law, and licensing and contractual practices within the country.

b. Timing and Milestones

It is indisputable that consideration of an application for ABS rights will consume a significant amount of time. The predictability of the length and nature of the time involved, however, is one of the key elements of the user's decision to apply. This timing depends on many factors. Delays may be caused by the applicant's failure to provide a complete application, by the need for additional information, by challenges from stakeholders and others, by changes of government or vacancies in key positions, and many other factors. It should be noted that strict time limits, while increasing user certainty, may also increase the chances of denial, which is required where the agency cannot be sure of all relevant factors in time to make its decision. In addition, although detailed milestones increase certainty, they may also increase the time and complication of the process.

The simplest approach to this element is to provide simply that "decisions will be made on all applications within *XX* days after they are submitted." (See, e.g., *Vanuatu: Environmental Management Act*, Art. 34. (CNA must decide applications 21 days from receipt). This kind of provision can achieve the balance between governance and certainty only where it is fully iterative – that is, when there is no restriction on the number of times an application may be resubmitted. Clearly, such a provision would result in an increase in denial of applications by officials who cannot, due to lack of information, unresolved challenges, or lack of time, confidently grant a permit or finalise its conditions and terms within the time allowed. Thus, when applied conscientiously applied, this approach will not be significantly shorter than other measures which create a more detailed process. A variant on this approach requires decision within a specified period, but allows extensions of that time for particular purposes. See, *Colombia: Scientific Investigation*, Art. 9; *Costa Rica: ABS Regulations*, Art. 10.)

Another approach is to rely on national administrative laws and other instruments governing licensing processes and governmental responsibilities, providing special 'ABS procedures and milestones, only where they vary from these general rules. See, e.g., *South Africa: Biodiversity Act*, Cap.7 Arts. 87-96 (using general procedures applicable to all environmental permits), and Cap. 6, Arts. 81 and 81 (special additional disclosure and local right-holder protection provisions for ABS permits);²⁰ *Costa Rica: Biodiversity Act*, Art. 64; Similarly, *Colombia: Scientific Investigation* incorporates ABS permits generally into the structure for obtaining all permissions for scientific research (including exportation) relating to Colombia's biodiversity.

CAN Decision 391, and the various national laws implementing it provides a fairly complete set of example of ABS-specific milestones and timeline.²¹ (Ch. II, Arts. 26(2d)-31.) Many other

¹⁹ Different expositions of the steps in acquiring ABS rights, often focus on specific components of these steps and their substantive content, rather than the step itself. See, e.g., *Costa Rica: Biodiversity Act*, Arts. 63-68 and *ABS Regulation*, Arts. 7-9.

²⁰ It should be noted that the cited elements of South African Law do not address all aspects of process certainty.

²¹ A number of the Andean Member Countries have adopted legislation implementing ABS and *Decision 391* (See, e.g., *Bolivia: Decision 391 Regulations* (Arts. 17-29); *Peru: ABS & TK Law*, *Colombia: Scientific Investigation*; and *Venezuela: Biodiversity Act*, considered in this analysis.) Although these give particular attention to the designation

laws provide time lines for some specific components of the process. *See, e.g., India Biological Diversity Act and Rules* 6 month deadline for the initial application, and 90-days for applications to apply for intellectual property rights. (Rule 14(3); *Act Art. 6(1)*); *Australia: Queensland Biodiscovery Act*, Arts. 13-14 (20-day limit on the ability of government to request additional material from the applicant) and Art. 19 (final decision must be made within 40 days following the CNA's receipt of the application); *Columbia: Scientific Research*, Arts. 6-7. Only one law reviewed (*Colombia: Scientific Investigation*) specifically allows an expedited review, in cases of environment-related emergencies. (Art. 5.)

c. Additional Requests and In-Process Stakeholder Participation

The primary factor affecting both the cost and timing of the ABS application process relates to additional requests necessitated by either

- the CNA (or other official, agency or authorised stakeholder group) discovering that it needs additional information before it can make a responsible decision, or
- formal third-party and/or stakeholder requests, comments, complaints or queries.

It is not generally possible to eliminate all possibility of additional requirements from national law, particularly in the ABS context where informational requirements depend on a constantly shifting frontier of new scientific development and discovery. However, legal certainty is enhanced where the laws specifies 'reasonable controls' on such requests, giving the applicant some level of predictability. For example, *Australia: Queensland Biodiscovery Act* empowers the CNA to ask for "any further information or document [the CNA] reasonably requires," but limits such requests to the first 20 days after the application was received. (Art. 13.)²² By contrast, in *South Africa: Biodiversity Act*, the issuing authority's power to request 'all information concerning the proposed bioprospecting and the ...resources to be used that is relevant' is not specifically limited in time. (Art. 81(2).)

d. Bases for Decision

Although the specific identified bases for the CNA's decision may not affect legal certainty, the manner in which the law specifies them can have a significant impact on certainty. Where the decision criteria are very subjective, they provide much less certainty for the user/applicant.

Greater certainty is provided where the law specifies objective criteria and specifications. In the context of ABS, however, objective decision criteria may be difficult. Many subjective factors (scientific, social and other impacts, policies and concerns) must be considered. In such cases, the applicant may have little basis for assessing the chances that his application will be approved. For example, the *Brazil: Provisional Act* states an unequivocal prohibition on 'practices that are harmful to the environment and human health and for the development of biological or chemical weapons.' (Art.5.) There remains within this provision, some room for debate over what specific practices would violate it. Laws implementing *CAN Decision 391* typically identify several

and empowerment of their country's CNA, few of the legislative measures provide significant additional detail regarding the procedures and processes. This may imply that the basic provisions of *Decision 391* govern procedural matters. In the alternative, it may simply mean that administrative procedures are sufficiently covered by other relevant national law in these countries.

²² The law does not explain what happens if the need for such information is not found until after the 20-day deadline (i.e., whether the application is automatically denied, in such cases.)

conservation-related factors (species endemism and vulnerability, impacts on human health and the environment, biosafety, etc.) as limitations of access, as well as matters of national security. (See, e.g., *Venezuela: Biodiversity Act*, Art. 75.) Similar criteria are identified in *Costa Rica: ABS Regulations*, Art. 14.

By contrast, the *India: Biodiversity Rules*’ states as bases for decision include only the criteria that “the Authority is satisfied with the merit of the application.” (Sec. 14(4).)

The *African Model Law* recognises public participation as a separate ‘final decision’ – that is, not an input into the governmental decision, but a potential veto power if the government approves. It specifically states the right of local communities to refuse access “where such access will be detrimental to the integrity of their natural or cultural heritage,” or to impose additional conditions and restrictions in certain situations (Arts. 19 and 20.) Other useful examples of legislative measures governing the bases for decision include *Australia: Queensland Biodiscovery Act* (Art. 14) (evaluation based on the objectives of the Act); *South Africa Biodiversity Act*, Art. 89(3) (requiring consistency with various national enactments); *Vanuatu Environmental Management Act* Art. 34(5) (setting some clear minimum requirements that must be confirmed before the decision can be made, as well as some subjective criteria (consistency with other acts); *Brazil: Provisional Act*, Art. 12²³

e. Clear Record of the Decision and Its Finality

Clarity regarding the final decision is usually promoted where there is a clear moment at which the decision will be considered ‘final’, and where the law describes the manner in which that decision is memorialised, recorded and communicated to the applicant. Both the CNA and the applicant have an interest in clarifying the moment of final decision. The process for communication of the decision can provide a clear means of documenting the timing of the decision, and informing the applicant and public about their options, in two ways –

- (i) making it less easy for the government to subsequently alter or ‘adjust’ the decision, and
- (ii) opening a definite statutory period for challenges to the decision, after which the decision is ‘final’ for most purposes.

This kind of legal certainty often depends more on general national laws regarding government contracts and regulatory decision-making.

i. Evidence of “Final Decision”

The manner in which the decision is made and documented can affect legal certainty. Options may vary from a simple decision (written in a file or noted on the application) at one extreme, to a formally adopted legislative decision at the other. Plainly, a more formal and public decision may offer greater legal certainty (by decreasing the possibility of casual alteration), but it may

²³ Another possibility is demonstrated by the *Guyana (Draft) Bio-Prospecting Regulations*, which give broad latitude of discretion to the decision-maker. The agency is directly called upon to approve only those applications in which, “the environmental or social impact of the research are not detrimental, the terms for benefit-sharing are in keeping with national development goals.” Some of the listed factors in this decision include several relatively concrete matters (Environment Impact Assessment, public comments, and the need to protect certain species from over-exploitation.) Others give broad discretion – e.g., “preservation of the character of the environment, including indigenous or local communities.” (Art. 15(1).)

also increase the level of public knowledge, and possibly of controversy, surrounding the decision.

CAN Decision 391 addresses the finality issue, by specifically including formal public procedures to memorialise all ABS decisions in a written statement, which must be reflected in a governmental instrument (“resolution”), adopted and published at the time the access contract is completed. (Arts. 1 and 16) By contrast, the *African Model Law* provides somewhat less documentation to help establish or clarify the moment of the final decision, although it does require that all access permits to be confirmed in a signed written agreement, between the CNA, the concerned local community and the applicant or collector. (Arts. 7.2 and 7.3.) The issuance of this approval operates as a final governmental statement that all requirements under the legislation have been met, including that the concerned local community has been consulted by the prospective users and that its consent was in fact granted (Arts. 5.3 and 10). Most measures reviewed stated that a written instrument at least is required. (See, e.g., *India Biodiversity Rules* 14(5), 19(6), *et passim*; *Australia: Queensland Biodiscovery Act* (Art. 15); *South Africa: Biodiversity Act*, Art. 88(5); *Vanuatu Environmental Management Act* Art. 34(5).)

ii. Communicating the “Final Decision”

The method by which the decision is communicated, may increase certainty, both directly (communication with the applicant), and indirectly, by ensuring that all relevant stakeholders are made aware of the decision, and thus have only a limited period during which they may challenge the decision. Of course, in many countries, these matters are covered by other laws (those addressing administrative, licensing, and interpretation law, for example). However, in some of the laws examined, special provisions address communications of ABS rights decisions. A detailed communication mechanism is found in *CAN Decision 391* which specifically requires that a formal Resolution be issued, and then be published together with an extract of the contract. The *Decision* specifically states, that “[a]s of that moment, the access shall be considered to have been granted.” (Art. 38) (See also *Costa Rica: Biodiversity Act*, Art 62 and *ABS Regulations* Arts. 13 and 15, which specifically notes that publication of such dispositions should be undertaken for the benefit of third-parties.) Slightly less specific, the *India Biodiversity Rules* require the Authority to take steps to “widely publicize the approvals granted, through print or electronic media and shall periodically monitor compliance of conditions on which the approval was accorded.” (Arts. 14(10), and see 19(4), 20(4), *et passim*.)

iii. Record of Decision

The record-keeping process can be useful, as a way of minimising appeals, and by providing a clear roadmap for the applicant, if he wishes to revise and resubmit his application. This process also sets a clear record for challengers who may later seek to appeal or overturn the decision (*see* Part III, below.) The record-keeping process increases legal certainty by ensuring that the full range of information supplied by the applicant are considered in the decision. It provides government with a way of proving that they have complied with legal requirements, and gives the applicant a basis for confirming and ensuring this consideration. Often, the record-keeping responsibilities of government agencies are covered by other national law, however, some ABS laws specify them.

While most ABS measures require the keeping of substantive records regarding scientific developments from the access itself, (*see, e.g., Brazil: Provisional Act*, Art. 8 (III) (IV)) few

require records of the application process. *See, e.g., CAN Decision 391*, Art. 18, and see Arts. 6, 19 and 21 (CNA must maintain a public file,²⁴ preserving a broad selection of relevant documents, communications and instruments, including the CNA's final resolutions.) *See also South Africa: Biodiversity Act, Arts. 94-96.*

f. Appeals

The possibility of an appeal after the completion of the application/decision process necessarily injects a note of uncertainty for users. However, it is generally felt that administrative processes operate most effectively and predictably when they include a full right of public oversight, including by giving both the applicant and the affected stakeholders some power to challenge the decision. User certainty is increased where appeal rights and time limits are clearly specified in legislation, and where the bases and standards on which an appeal will be decided are clearly stated.

A rather detailed provision for appeals to the Magistrates Court by 'dissatisfied persons' is contained in *Australia: Queensland Biodiscovery Act* (Arts. 103-106). The *African Model Law's* provision for appeals focuses only on the appeal by the applicant or permit-holder in the case of the disapproval or cancellation of his permit. (Art. 68.) Such appeal shall be "through appropriate administrative channels" with recourse to the courts only "after exhaustion of all administrative remedies." A similar appeal right is granted to those who challenge the approval of a permit. (*See Brazil Provisional Act*, Art. 11, Para.1)

g. Exemptions

Legislative measures providing for exemptions from the need to obtain an ABS right may also be sources of uncertainty, in some cases. Where an exemption is not clearly defined, the user relying on it may later find himself charged with legal violation. In many cases, exemptions may depend on terms that are subject to interpretation – without clarity, the user may not know whether it is better incur the expense and difficulty of applying or to simply rely on the possibility of exemption.²⁵ User certainty is increased where exemptions are specific and objective, and/or where the law provides an avenue for confirming the applicability of specific exemptions, in cases of doubt.

For example, the *India Biodiversity Act*, includes exceptions for "local people... who have been practicing indigenous medicine" (Art. 7.) and another authorising the central government to exempt "any items, including biological resources normally traded as commodities." (Sec. 40.) These exemptions are to be clarified in regulations, to minimise uncertainty in the user. In another exemption, however, the same act provides a different and potentially more certain basis for resolving doubts. The Act exempts "collaborative research projects involving an exchange of biological resources and related information between institutions," on the basis of *inter alia*, approval by the Central Government. (Arts. 3, 4, and 5(3).) This approval provision may operate

²⁴ That file is open to consultation by any person. of completed applications. (Art. 6.)

²⁵ The consequences of misconception of a stated exemption may be dire. As provided in *Brazil: Provisional Act* at any time that an agreement that is found to relate to genetic resources, and to be undertaken in violation of the *Act*, that agreement will be 'null and void, without any legal standing.' (Art. 29 Sole.) *See also, Costa Rica: ABS Regulations*, Art. 28, full legal sanctions applicable to those who access genetic resources without permission.

in a way that resolves all doubts, if the approval is conditioned on governmental oversight of policy conformance.

To some extent, the scope of an exemption will often depend on interpretation of primary ABS concepts, such as ‘genetic resources’, as discussed in the following section.

B. Scope and Nature of the Grant

The second broad category of legal certainty issues revolves around the question of what, precisely, is granted in the ABS Agreement, and how that grant may be limited or controlled in normal operations. These matters must necessarily be addressed in binding legal provisions, if the user is to have certainty regarding the rights he has obtained. Even where the law calls for separate negotiation of an “ABS Contract” or other legal instrument, legal certainty (as well as many other factors²⁶) is enhanced where legislative measures give reliable information regarding critical issues, including:

- What rights may be granted;
- What rights may not be granted;
- What limitations must always be imposed;
- What rights and limitations may be granted or imposed in the discretion of the authority.

The participants in development of the Bonn Guidelines noted an essential need for clear and simple contractual provisions. The most efficient way to provide such simplicity is through legislative measures that clearly and comprehensibly describe the rights and duties granted by the ABS decision. This will ensure that courts, agencies, officials and members of the public share a clear common understanding of the nature of the right granted and/or the user’s contingent duties and performances, including, and how it is applied, protected, transferred, or otherwise used. This will provide improved user certainty indirectly by giving relevant officials confidence that their ‘simplified’ contract language will not result in negative or unexpected decisions, if the contracts are construed by a court or other expert.

1. The Nature of the Right Granted

One of the key requirements of user certainty is that the user and the granting agency or source should share a mutual understanding of the exact nature of the basic right that is granted by the ABS Agreement. In this context, certainty is primarily dependent on the clarity of the grant instrument and of the legislative measures describing the rights that are transferred.

In this connection, it is interesting to note that none of the measures examined describes or considers ABS rights from the perspective of the user (*i.e.*, by stating, in effect “the grant of ABS rights entitles the user to undertake the following: XXX.”) In general, the nature of the positive right granted by the ABS decision is expressed in terms of limits (geographical boundaries, specific numbers of samples, etc.) Apart from these, the nature of the grant is somewhat determinable by considering the activities that are strictly prohibited unless an ABS right is

²⁶ Governments and government officials generally prefer clearer and more specifically limited laws and legislative instructions, as this provides a barrier against requests for special treatment, and also gives them protection against claims that, by signing or approving such agreement, they have violated their fiduciary duties – become bio-pirates themselves.

obtained. (See, e.g., *Philippines: EO 247* (Art. 2); *Vanuatu: Environmental Management Act* (Art. 32); *India: Biodiversity Act* (Arts. 3(1), 19.) These provisions do not specify that the issuance of any ABS right will automatically allow the user to engage in the full range of prohibited activities, however. Hence, the particular scope of the ABS right is typically a matter of individual contract negotiation (and often not memorialised there either.)

A critical element of user certainty in the context of the nature of the right granted relates to the question of whether additional permits or permissions will be necessary at later stages in the process of accessing and utilising the genetic resources. For example, under the *India Biodiversity Act*, the initial permission received does not convey permission to obtain intellectual property rights for any invention based on research or information on a biological resource obtained from India. Hence, a second approval from the CNA will be required at this point (contemporaneously with the IPR application.) (Art. 6(1); and see *Rules 18 and 19*.) A number of other laws also require additional negotiations after the initial grant of ABS rights (See *Venezuela: Biodiversity Act*, Arts. 79-83; *Colombia: Scientific Investigation*, Arts. 16-17, 21; *Australia: Queensland Biodiscovery Act*, Arts. 36-40 (procedural provisions in addressing other instruments (ABS plan and contracts) that must be negotiated separately from the application for the initial ABS right); *African Model Law*, Art. 13.1.)

To some extent, the question of what is granted underlies many recent well-publicised controversies over ABS, such as where a user has obtained biological samples through conventional means (at a vegetable market) and then indicated an intent to utilise its genetic resources (genetic or biochemical properties) in less conventional ways. This issue is complicated by basic questions currently troubling ABS implementation and the current negotiations. Specifically, uncertainties may be tied to the current lack of clarity regarding whether and how ‘genetic resources’ differ from ‘biological resources.’²⁷ Although it is clear that the convention perceives ‘genetic resources’ to be different from (possibly a subset of) biological resources, it has so far proven difficult or impossible to describe this difference with ‘legislative clarity’ – needed in order to apply the CBD through national legislation.

- In some countries and measures, the lack of certainty is preserved in national legislation, thereby making it difficult for any potential user to know if he plans to ‘utilise a genetic resource’ (an activity that requires ABS compliance), or simply to use a biological resources (already governed by other law) See, e.g., *Vanuatu: Environmental Management* (incorporating the CBD definitions verbatim, without additional legislative provision.)
- In a few countries, to avoid these uncertainties, the law focuses instead on the use of ‘biological resources.’ (See, e.g., the *African Model Law* (Art. 3, *et seq.*); *South Africa Biodiversity Act* (Art. 1 (definitions of ‘bioprospecting’ and ‘indigenous biological resource,’²⁸ and Arts 80-86).) This choice can lead to significant uncertainty – because commercial development and other transactions involving *biological* resources (in

²⁷ The question of the distinction between ‘genetic resources’ and ‘biological resources,’ and the impact of that distinction on effective ABS implementation is being addressed by other work under CBD COP Decision VII/19. In the months since COP VII, this issue has been examined by experts in a number of ways. Some critical papers on this issue can be found at www.canmexworkshop.com.

²⁸ The South African act focuses primarily on ‘indigenous biological resources’ – a term that includes ‘genetic material.’ It contains a special definition of the term, “genetic resource”—“any genetic material or the genetic potential and characteristics of any species.” (Art. 1) That term, however, does not appear anywhere in the *Act’s* ABS provisions (Cap. 6) or in its definitions of the terms that are used in those sections (‘bioprospecting’, ‘indigenous biological resource’ and ‘genetic material.’)

vegetable markets for example) may not, as a practical matter, be subject to ABS requirements. User certainty will only be enhanced where a consistent rule identifies the dividing line between transactions that are covered and those that are not.

A few measures recognise genetic resources to be something different from biological resources (that they are genetic and/or biochemical information, for example, or a right to engage in a specific use), but still control movement and use of those resources by controlling the movement and use of biological material. (See, e.g., *Brazil: Provisional Act*, Art. 8; *Malawi: Environmental Management Act*, Art. 36.) Here also, some mechanism for exempting conventional trade in biological materials may become necessary, and difficult to integrate into a consistent legislative framework.

Finally, it should be noted that many of the laws examined require the user to share all information acquired through the access and analytical processes relating to resources collected under the ABS rights. (See, e.g., *Colombia: Scientific Investigation*, Art. 23.) Although, in itself, this does not affect intellectual property rights acquired by the user (so long as they are consistent with relevant ABS measures), it may have the impact of compromising the user's ability to protect its un-patented research as a 'trade secret.' Here also, interests on both sides suggest that such requirements and needs will continue to come into conflict. Hence legal certainty is maximised when the nature and extent of these requirements is clearly specified in relevant law.

2. Clarity on Mutually Agreed Terms – the Users Obligations

Mutually Agreed Terms (MAT) are a primary mechanism by which the ABS instrument imposes duties on the user. 'Mutually-agreed terms' is generally an identical concept to 'clear contractual provisions' – a prerequisite of any binding instrument. In the context of ABS, MAT has a slightly different implication, however, suggesting a combination of legislative terms, license provisions and conditions, and individually negotiated elements. The clearer and more definite national legislative measures (and the mandate regarding license provisions and conditions) are, the greater will be the user's certainty of the exact nature of the responsibilities that he must comply with in order to maintain and use these rights is a critical element of legal certainty. This type of legal certainty is usually expressed legislatively by listing several provisions that are mandatory (to be applied to all ABS rights within a given category), conditions that must be considered and specifically negotiated in the ABS rights and contract, optional provisions (that may be applied at the CNA's discretion, and provisions that are not permitted.

Apart from certain very basic limitations, for example, the *African Model Law* does not clarify the contents of the grant, noting only that all conditions agreed by the CNA must be incorporated in the written permit. (Art. 10.) *CAN Decision 391* includes a fairly detailed list of the sort of conditions that the applications for access and access contracts must include. (Art. 17.) This list generally emphasises the applicant's duties and responsibilities (both in the application and in the subsequent access and use of the material). The *Decision* specifically notes that 'ancillary contracts' relating to sourcing – i.e., contracts with the owner of land from which the samples will be collected, or with *ex-situ* collections to be tapped – must be considered and protected in the same way, only if they are signed by the legal owner of the physical resource from which the genetic material will be taken, etc. (Art. 41.)

3. Restrictions on Transfer and other Rights

One range of issues that may affect user certainty, but which has not been addressed in most existing ABS measures, relates to the possibility that the successful applicant will subsequently transfer his ABS rights, and the procedures by which such transfer may be undertaken. Under *Australia: Queensland Biodiscovery Act*, it appears that the holder of ABS rights is not allowed to transfer those rights, even in the case that he transfers physical samples collected in accordance with those rights. (Arts. 31.) In *India: Biodiversity Act* a separate approval from the CAN will be required for any transfer of “the results of any research relating to any biological resources occurring in or obtained from India” (Arts. 4, 20; and see *Rule 16*.) It is not clear in other legislation (where no statement about transfer is included) whether the ABS rights (or information and other matters derived under them) are transferable.

C. Legitimate Expectations and Vested Rights

The third area of user certainty in ABS includes perhaps the most publicised limitation on user certainty -- the possibility that, even after he has obtained an ABS Agreement, the user may find his right rescinded or changed. Possible avenues for such retroactive change may include

- legal challenges to the issuance of the ABS Agreement,
- new information or concerns on the part of the government, or
- claims that the user is not in compliance with the agreement.

These concerns are critical to user certainty, given that they affect the user’s expectations. From some point (usually at the expiration of the appeal period following issuance of the final decision) the user needs to have sufficient confidence in his ABS rights that it will invest significant time and effort in them.

One critical element of user certainty in the case of any such revision or rescission is the right to know of, participate in or provide input into the governmental decisional process regarding alteration of his ABS rights. The following discussion is broken into analysis of changes, based on whether they are motivated by third-party action, user violation, or response to the country’s environmental and other needs. Relevant to all three categories, it should be noted that only two of the measures examined specifically discuss procedures for giving the holder notice and opportunity to participate in consideration of the alteration. See, *Australia: Queensland Biodiscovery Act*, Arts. 21-22; and *Costa Rica: ABS Regulations Art.16*.

1. Third-party impacts on the ABS Agreement

Few ABS laws specifically include provisions giving affected citizens or others the right to formally challenge an ABS Agreement after it has become final and the basic procedural limitations period on appeal have expired. (This suggests that third party rights are probably addressed in other laws in the country.) However, several laws do give some right to affected parties to challenge later government decisions, including licenses, permits, agreements and other exercise of administrative powers. One example of this is found in the *African Model Law*, which specifically mentions the right of local communities to impose additional conditions and restrictions in certain situations (Arts. 19 and 20.) Since the *Model Law*, does not place any procedural or time limits on these rights, this provision may authorise withdrawal or further conditioning of local assent *after* the permit has been granted. This is balanced by a provision

which spells out rights of appeal in the case of post-issuance cancellation of the permit. (Art. 68.)

The concept of good governance would seem to require that the public, particularly affected stakeholders, must be given full rights to challenge individual actions that do not appear to have been properly made and to ensure that the government meets its obligation of protecting its citizens and obtaining suitable return when it grants or sells the countries rights or resources to a single user. National legislation cannot be expected to eliminate or abridge these rights in the cause of increasing user certainty. Rather, it must promote certainty through clear and specific statutory requirements and limitations regarding the bases on which stakeholders may subsequently challenge the user's activities after receiving ABS rights or seek rescission of those rights. In addition, interested parties presumably have the right to report apparent violations to the government, and expect formal enforcement, as discussed below.

2. Claims of Non-compliance

A user that fails to comply with the terms and conditions of his ABS rights, typically risks the loss or cancellation of those rights. This result of non-compliance may be based on other law, which may explain why these provisions are not always included explicitly in ABS measures. User certainty in such cases is increased where legal measures clarify what kinds of violations can result in revocation of the ABS rights, whether and when the overseeing agency must first give notice and an opportunity to correct the fault, whether the process of addressing non-compliance is administrative only (or may involve the courts), whether there is an appeal from such decisions, and other information.

In a number of countries, ABS measures specifically discuss the responsibilities of the CNA to oversee and monitor the user's activities under the ABS Agreement, and address possible sanctions. *CAN Decision 391* provides a short list of the bases for sanctions against users (including, *inter alia* Arts. 22-26, 46, and 47). This is not, apparently, an exhaustive list. The CNA appears to be charged with oversight, since it must issue an administrative order when the requirements of that access contract have been fulfilled, and may be required to issue sanctions for violations of the contract. (Art. 50.1, *and see* definitions of 'competent national authority,' 'access contract,' and 'access resolution'; Arts. 32, 35, 40, 43, and 47.)

Under the *Brazil: Provisional Act*, in the event of any violation of 'relevant legal provisions,' the penalties include suspension or cancellation of the ABS rights, as well as seizures, embargos on sales and other activities, and even the loss of the right to contract with any public agency for up to five years. (Art. 30.) Since the *Act* does not set a formal application process and procedure, and since in many cases, the ABS rights appear to be granted by private landholders and others, it would appear that the individual ABS contracts, licenses, etc., may be considered "other relevant legal provisions" for these purposes. *See also Colombia: Scientific Investigation*, Art. 22.

In the *Model Law* the possibility of cancellation for noncompliance is addressed in several provisions. For example, "[a]ny access carried out without the prior consent of the State and the local indigenous community will be deemed invalid by the authorities." (Art. 5.2). Similarly, the CNA is authorized to "withdraw consent and repossess the written permit" (after consulting with the consult the "concerned local community") in cases of, *inter alia* violation of the access legislation; failure to comply with agreed terms or conditions." (Art. 14(1)(i) and (ii), and 14(2).)

Similar provisions are found in *India Biological Diversity Rules* (Art. 15 (1) (i)-(iii).) (revocation where the CNA reasonably believes that the user was in violation of relevant law, rules or ‘the conditions on which the approval was granted’); *Australia: Queensland Biodiscovery Act* (Art. 20) (discovery of violation or failure to report as required, or that the original application was incorrect or misleading); *South Africa: Biodiversity Act* Art. 93 (and see Arts 94-96 regarding appeals from such decisions); *Costa Rica: ABS Regulations*, Arts. 20, 27.

In a few instances, although the measures discuss possible sanctions in the event of violation, they do not include any specific mention of rescission as a sanction. In the *Malawi: Procedures*, for example, sanctions for violation include “fine, imprisonment or both,” but not suspension or termination of the ABS rights. (Part G.2.) (As noted below, however, the *Procedures* include a more general power of the CNA to alter or withdraw the rights without cause.)

3. Government Rescission or Alteration For Other Causes – the Loss of a ‘Vested Right’

Governmental powers of rescission or alteration of the ABS rights, after they have been granted obviously have a very direct impact on legal certainty. The user generally expects that at some point, the ABS rights granted to him will be legally protected, and thereafter cannot be rescinded or altered, retroactively, except for cause or in specific exceptional, legally defined circumstances. From the source country’s perspective, however, some power to reconsider the grant may be necessary for a variety of reasons, including changes (developments) in scientific understanding, conditions conservation status, and other factors.

This kind of legal certainty can be supported by

- clear and specific procedures and notice requirements applicable any time a governmental agency considers changing an existing permit;
- clear statement of the permissible bases that can underlie a governmental decision to alter, cancel, or suspend of an ABS right, once it has been received; and
- determination whether, in any situation, the right-holder will be entitled to compensation, for alteration amounting to “taking” a vested right²⁹ of the holder .

A strong statement of government’s right to alter ABS rights it has granted is found in *Brazil’s Provisional Act*, providing that such alteration may occur “at any moment, in the light of scientific evidence denoting the risk of serious and irreparable damage to biological diversity, arising from activities carried out in the terms of this Provisional Act, the Government...shall determine measures intended to prevent such damage and may even stop the activity.” (Art. 6.) Similar provisions other laws, state that justifications must be given, alluding to general law of the country. See, e.g., *Nicaragua: General Environmental Law*, Art. 58.

In *CAN Decision 391*, the source country’s sovereign ability to penalise violations in the exercise of ABS rights is specifically recognized, and includes the ‘temporary or definitive closing-down of establishments and disqualification of the violator from applying for new access.’ (Art. 47).

²⁹ In general, a ‘vested right’ is an ‘entitlement.’ One may operate under general law allowing particular activities, incurring the risk that the law will be changed, resulting in the cancellation of that general right. However, some kinds of activities may be the subject of ‘vested rights.’ This means that, if one takes appropriate steps (licensing, installing improvements, etc.), he will acquire a right that is similar to a property right. Even if the government repeals the relevant laws (so that no other person can acquire such a right, the rights of a holder who has already vested will not be taken away by this action, without compensation as a ‘taking’ of property.

Although the *Decision* specifically considers genetic resources to be a property right, it provides that the penalties will apply without any requirement of compensation. A separate provision specifically states that contracts, even if signed by the CNA, may be nullified if it is later found that the right was granted in violation of required procedures. (Art. 39) The *Decision* does not limit the right to challenge a contract on these grounds, although such a limitation may already apply through existing administrative law of the Member Countries.

A broader approach is found in the *African Model Law* appearing to authorize rescission or cancellation “in cases of... overriding public interest”; or “for the protection of the environment and biological diversity,” (Art. 14(1) (iii) and (iv), and 14(2).) The effect of this provision in decreasing certainty is balanced by a provision which clearly spells out rights of appeal in the case of post-issuance cancellation of the permit. (Art. 68.)

The CNA is also authorised to adopt specific legislation or other instruments regarding general conservation-based and health-and-welfare-based restrictions on access. (Art. 15.) As written, these provisions suggest that the adoption of such legislation may impact earlier acquired ABS rights.

In *Malawi: Procedures*, the CNA specifically “reserves the right to withdraw any certification without notice or giving reasons to the [holder of an ABS right].” (Part G.1.)

India’s Biological Diversity Act specifies that relevant activities under pre-enactment ABS agreements may be considered void, to the extent that they are inconsistent with the act. (Art. 5(2).) As to ABS rights concluded since the Act entered into force, the CNA is authorised to revoke ABS rights on account of overriding public interest or for protection of environment and conservation of biological diversity; (*India Biological Diversity Rules* Art. 15 (1)(iv).) In the exercise of these provisions, the government is required to *inter alia* “assess the damage [to the environment], if any, caused by the ABS activities, and take steps to recover the damage.” (Art. 15(2).) In addition, a somewhat ambiguous provision gives the CNA the right “if it deems necessary... shall take the steps to restrict or prohibit the request for access to biological resources” where it would affect endangered and rare taxa, create “the possibility of genetic erosion, or have negative environmental social or political impacts. (Art. 16.)³⁰ These provisions do not require assessment or compensation relating to the taking of the user’s vested right.

Under *Australia: Queensland Biodiscovery Act*, ABS rights may be altered without compensation to the holder, where necessary due to an emergency or natural disaster, but alteration is not allowed where the area covered by the agreement later becomes a protected area, or where the conservation status of an affected species is changed to a higher level of concern. (Arts. 20 and 24.) The Act also sets out detailed procedures for giving the holder notice and opportunity to participate in consideration of the alteration. (Arts. 21-22.)

IV. Summary Conclusion

There are many ways in which source country ABS measures may enhance legal certainty for those who obtain rights to utilise genetic resources. These measures cannot give absolute or near-absolute certainty, however, given that governments must balance the user’s desire for

³⁰ This provision is somewhat unclear. The language “take the steps to restrict or prohibit the request for access” suggests that this provision applies only prior to decision on ABS applications. Placement and other factors, however, suggest that it might apply after approval.

certainty against their sovereign obligations – to protect their rights and interests, and to ensure that the State or other holders of its collective and sovereign rights in genetic resources are properly compensated by individuals seeking permission to utilise those rights and resources for private benefit.

This need for balance, coupled with principles of good governance suggest that it will not be possible to simply assure users that their rights will be protected. Thus, the best way to enhance user certainty appear to be through clarity, including clarification of key elements of the application process, such as –

- the rights and duties of Competent National Authorities;
- the relationship between ABS application and other approvals and processes;
- milestones and the timing of the various steps in the process;
- the extent to which the CNA may request additional information and performances;
- the bases on which the decision will be made;
- rights of appeal; and
- the objective factors that will determine whether an applicant is exempt from the need to obtain ABS permits.

Once the right is obtained, certainty is increased where the law rather definitely explains to the user both the positive rights granted and the terms, conditions and limitations on which those rights are contingent. Perhaps the most important way to maximise certainty is to clarify the legal status of the rights granted – whether it is a property right or vested interest. A user can determine what it can legitimately expect, whether it is worth his investment, and what procedures and protections of law apply.

In sum, the concept of ‘user certainty’ does not require complete assurance that the user may do anything it chooses. Rather, certainty involves clearer information about the rules and processes that apply, and clear understanding about what the user may expect.

ANNEX A: List of Laws Considered in this Analysis

These laws are available from the CBD, "Database on ABS Measures" located online at <http://www.biodiv.org/programmes/socio-eco/benefit/measures.aspx>.

Regional Instruments:

"African Model Law" – *African Union Model Legislation for the Protection of the Right of Local Communities, Farmers and Breeders, and for the Regulation of Access to Biological Resources*, formally endorsed by all African Union States.

"CAN Decision 391" – *Comunidad Andina Decision 391: Régimen Común sobre Acceso a los Recursos Genéticos* (adopted 2 July 1996) Note: Quotations in this Paper from this decision are taken from the English translation provided by the Comunidad Andina, rather than direct translation.

National Instruments

"Australia: Queensland Biodiscovery Act" *Queensland Biodiscovery Act 2004* (N° 19/2004)

"Bolivia: Decision 391 Regulations" *Reglamento de Decisión 391...* (N° 2012/1997)

"Brazil: Provisional Act" *Provisional Act N° 2,186-16* (August 23, 2001).

"Colombia: Scientific Investigation" *Decreto por el cual reglamenta la investigación científica sobre diversidad biológica* (N° 309/2000) (Refers to regulations on ABS, not found in the CBD database. Art. 15. Note: this Decree specifically refers in detail, operative language, to specific provisions of other laws (including N° 13/1990, N° 165/1994, 99/1993), codes (Administrative Code) decrees (including 302/2003 (modified)) and other legal instruments (Unified National Parks Administration), which are not available on the CBD Database, and which were not reviewed for purposes of this paper.

"Costa Rica: Biodiversity Act" *Ley de Biodiversidad* (N° 7788, 1998)

"Costa Rica: ABS Regulations" *Normas Generales para el Acceso a los Elementos y Recursos Genéticos y Bioquímicos de la Biodiversidad* (Decreto N° 31 514, 2003)

"India: Biodiversity Act" *The Biological Diversity Act, 2002* (N° 18 of 2003)

"India: Biodiversity Rules" *Biological Diversity Rules 2004* (GSR 261 E, published April 25, 2004, India Gazette, Extraordinary, Part II, Section 3, subsection (i))

"Malawi: Environmental Management" *Environmental Management Act (1996)* (N° 23/1996)

"Malawi: Procedures" *Procedures and Guidelines for Access and Collection of Genetic Resources in Malawi*

"Nicaragua: General Environmental and Natural Resource Law" *Ley general del medio ambiente y los recursos naturales* (N° 217/1996) Arts. 54-71 (some provisions adopted. Other procedures, regulatory measures and process to be set by regulation (Arts. 64 and 70).)

"Peru: ABS & TK Law (2004)" *Ley de protección al acceso a la diversidad biológica peruana y los conocimientos colectivos de los pueblos indígenas* (N° 28216 (2004))

"Peru: Conservation Law (1997)" *Ley sobre las conservación y aprovechamiento sostenible de la diversidad biológica* (N° 26839) (1997)

"Philippines: EO247" *Executive Order N° 247 Prescribing Guidelines and Establishing a Regulatory Framework for the Prospecting of Biological and Genetic Resources, Their By-products and Derivatives, for Scientific and Commercial Purposes and for other Purposes* (1995)

"Philippines: Joint Implementing Rules" *Joint Implementing Rules and Regulations pursuant to Republic Act N° 9147* (Admin. Order No. 01/2004) Art. 14-15

"Philippines: Wildlife Act" *Wildlife Resources Conservation and Protection Act* (N° 9147/2001) Art. 14-15

“South Africa: Biodiversity Act” *National Environmental Management: Biodiversity Act 2004* (N° 10/2004)
Arts. 1, 80-96

“Vanuatu: Environmental Management” *Environmental Management and Conservation Act* (N° 12/2002)

“Venezuela: Biodiversity Act” *Ley de diversidad biologica* (2000)

ANNEX B: National Legal Measures Containing General Provisions on ABS

- Australia: *Environmental Protection and Biodiversity Conservation Act of 1999* (N° 91/1999) Art. 301 (This omnibus (443-page) conservation law was not studied in detail. From initial examination, it appeared that only Article 301 was directly relevant to ABS.)
- Bulgaria: *Biological Diversity Act* (State Gazette N° 77/9-08-2002) *see* Art. 66, and Arts. 61-65.
- Camaroon: *Loi portant loi-cadre relative à la gestion de l'environnement* (N° 96/12,1996) *see* Art. 65
- Cuba: *Ley del Medio Ambiente* (N° 81/1997, Gaz7, p47) (regulations to be developed per Arts. 87(c) and 88(n).)
- Kenya: *Environmental Management and Coordination Act* (N° 8 of 1999) *see* Art. 53
- Mexico: *General Law of Ecological Balance and Environmental Protection* (Gazetted 28 Jan 1988, as amended 7 January 2000 (provided to the CBD Database in English.), regulations ("mechanisms") to be developed per Art. 87 bis.
- Panama: *Ley General de Ambiente de la Republica de Panama (No. 41)* Generally addressing natural resources and their use and development
- "Peru: Conservation Regulations" *Reglamento de la Ley Sobre la Consevación y Aprovechamiento Sostenible de la Diversidad Biológica* (Regulations under Law 26839, adopted by Decreto Supremo N° 068-2001-PCM) *see* Tercera Disposición (calls for the adoption of ABS regulations within 30 days of the publication of these regulations.)
- "Peru: Indigenous Knowledge Law (2004)" *Ley de protección al acceso a la diversidad biológica peruana y los conocimientos colectivos de los pueblos indígenas* (Ley N° 28215) (2004) (This law is directed at **traditional knowledge** related to access to **biological** resources. As such it is only indirectly relevant to ABS.)
- "Peru: Indigenous Knowledge Protection Procedures Law (2002)" *Ley que Establece el Régimen de Protección de los Conocimientos Colectivos de los Pueblos Indígenas Vinculados a los recursos biológicos* (Ley N° 27811 (2002)) The authors have not attempted to address the relationship between this law (which remains in the CBD database) and *Peru: Indigenous Knowledge Law* (2004).
- Portugal: *Decree-Law N° 118/2002 (April 20, 2002)* Calling for the establishment of (but not establishing or setting formal procedures for) a mechanism for the legal registration of "local varieties," and "plant material of agrarian, agroforest and landscape interest" as well as "spontaneously occurring autochthonous material"
- Uganda: *National Environment Statute* (N° 4/1995) Art. 45 Calling for the development of regulations addressing ABS
