Summary Handbook for CBD Delegations:

Options and Process for the Development of an International Regime on Access and Benefit-sharing

Note: The material in this Summary Handbook is based on the research and analysis of **"the ABS Project: Law Equity and Biodiversity"** and is supported by two papers, *"Legal Analysis Regarding Options and Prerequisites for a Workable and Effective International ABS Regime under the Convention on Biodiversity,"* and *"Synthesis: The Results and Conclusions of the ABS Project's First year of Work in preparation for COP-7 and the International Regime,"* both based on a series of research, analytical and comparative papers, prepared by authors around the world, under the ABS Project.

Following COP-7, the information and experience gained in the preparation of these and other papers on the project will be integrated with deliberations and decisions on ABS, for the preparation of a formal publication on the practical and legal issues and processes for implementing ABS at the national and multinational levels. For more information on this and other work of the ABS Project, please contact the ABS Project at TYoung@elc.iucn.org or by fax at ++49-228 26 92 250 (for fastest attention, please use the words "the ABS Project" in the subject line of any e-mail or fax.) Additional information on the ABS Project can be found on the website of the IUCN Environmental Law Centre, at http://www.iucn.org/themes/law/abs01.html.

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Executive summary:

This handbook examines the following questions and issues:

I. What is an "International Regime"?

"**Regime**" means the full network of policy, legal and practical measures and tools relating to that issue. It will usually consist of a combination measures and mechanisms.

The development of an **international regime** is a process, rather than an event. Critical matters, such as the direct objectives and mechanisms that the regime will use and promote, must be decided immediately. Other activities in the creation of the regime will occur through a workplan, international negotiations or some other process.

QUESTIONS AND POINTS FOR NEGOTIATION:

A Regime is effective only when **objective-based** *with* **agreed mechanisms** *that are well understood–*

- The parties creating a regime must have a clear idea of precisely what is going to be achieve, and how. It is not enough to say that "the regime will promote equitable benefit-sharing." Rather, the specific objectives and mechanisms of the regime must be agreed. By analysing these specific objectives and comparing current conditions, the Parties can determine what kinds of provisions and authority are needed.

A regime will usually consist of a combination of **new and existing measures –**

- Although it could consist entirely of new measures, this might carry the risk of eliminating or minimising the importance of existing commitments in the CBD.

*The entire regime may be "***mandatory***" or "***voluntary***," or may have some elements of each character.*

- When speaking of contracts and agreements, an element is "mandatory" when parties to a contract must always comply with it. It is "voluntary" when they have the option to agree to something else in the contract.

*A regime may be "***binding***" or "***non-binding***" or a combination of binding and non-binding provisions.*

- It is "binding," when it can be legally enforced (in court if necessary), according to its terms.
- In essence, a "non-binding" commitment is a suggestion, or a promise to "try" to comply, within certain conditions. Although not directly enforceable in court, non-binding commitments create a "good faith" obligation. If a party has made no attempt to take such an action, the court may hold that he has violated the binding (implied) obligation of all agreements to "act in good faith."

The CBD is a "framework," enabling a broad range of collaborative activities.

- Hence a regime within this framework must
  - utilise the available tools and processes, and
  - work within the clearly agreed scope and mandate of the CBD.
- However, the development of an ABS regime under the CBD is essentially similar any process that implements policy at the national level:
  - It must, as a matter of necessity, interpret the policy language of the CBD, and make decisions about how, at a practical level, those policies can be converted into action.
  - Because the ABS regime involves trans-border transactions and transfers of genetic resources, and because the CBD does not identify or clarify any mechanism or international understandings, or create specific tools for oversight or other needed services, it will be necessary to decide what kind of tools will be best to address these needs.

II. What objectives, obligations and components already exist relevant to the development of an international ABS regime?

Primary Underlying Obligations

In discussions regarding ABS, most commentators focus on "the 3rd objective of the CBD." It is important to realise that in addition to this non-specific statement of objective, ***the CBD contains 11 separate firm COMMITMENTS of the parties, relating to ABS.*** (see Table 1)

In considering options for the Regime, **it is important not to forget the option of formally requiring all parties to comply with these express obligations**. (With regard to these obligations, the developing country Parties are far more in compliance with their obligations than are developed countries. However, at present, only about 50 developing countries have enacted or are in process of preparing legislation, and for the most part, all of these laws are focused only on addressing one of the 11 obligations. A few of these laws mention one or two others.)

Key Questions in Setting the ABS Agenda

Beyond these most important facts, it will be important to consider the following questions, to help decide how to configure the "international regime on ABS":

- ***Time:*** The ABS issues is somewhat urgent, because countries are already often finding themselves in the middle of ABS negotiations with potential bioprospectors. The COP's workplan must consider how best to *quickly* meet the most urgent needs.
- ***Approach:*** Although the Convention does not specify an approach, most of the parties have long assumed that the ABS process would be implemented by use of contracts and individual negotiations, rather than other tools.

  However, in 11 years this approach has not been successful. There are two options:
  - Develop the necessary legal basis for effectively interpreting, applying and enforcing ABS contracts (this does not exist, at present.)
  - Consider the use of other approaches (see page __) to replace or supplement the individual-contract approach.
- ***Existing Consistency and Focus Problems:*** Within the CBD and ***existing COP work there are some*** inherent problems that can be addressed in the regime negotiations
  - areas of apparent inconsistency, especially regarding pre-Convention specimens; and
  - lack of focus, particularly the need for a clear evaluation of levels of ABS implementation which has left ABS mandates unfocused, so that measures are recommended without considering consistency or integration.
- ***Other instruments:*** Two important efforts –
  - the International Treaty on Plant Genetic Resources, and
  - WIPO's work on ABS-related IPRs

  are important, not only for purposes of co-ordination, but also in providing lessons regarding approaches to ABS issues.
- ***Levels of Work – International, Regional (or Interest-based) and National:*** The COP should evaluate needs in terms of level.
  - "International decisions" are very costly, most difficult and time-consuming. This level should be used only where international agreement is <u>*necessary*</u>.
  - Many key decisions and actions may be better agreed by
    - smaller groups of Parties that share particular needs, or
    - regional action.

    In many cases, it is more useful for parties to work within groups with common needs, thereby improving their negotiating position, without the need for agreement from parties who will be on the "other side of the negotiating table."
  - Many key components of the ABS regime must be adopted at the national level. These are matters of national sovereignty to be addressed within the scope of national law, culture, and economy. The Bonn Guidelines focus on area of sovereignty not addressed or required in the CBD. Their scope may not cover all matters that must be part of the "global regime."

III. What options and components (approaches, tools and mechanisms) are available for the ABS Regime and how can they be utilised?

Finally, the handbook lists a number of specific options, regarding the possible nature and content of various kinds of instruments that can comprise some part (or all) of the International ABS Regime. These include action at several levels –

International Level:

- ***Overall Policy****:* Some key components of the regime will include clarification of principles and statements in the CBD as well as of primary assumptions made in the early years of the Convention. These may be addressed in several ways:
  - *A document specifically mandating that all parties comply with their existing commitments under the Convention (see table 1 on page 5).*
  - *A new instrument (protocol, annex or separate agreement) among the parties, to address the long-term failure of the CBD to make significant progress on the third objective.*
  - *A series of agreements organised on regional or interest-based lines, to address the specific implementation and mutual support needs of the parties to those instruments.*
  - *A combination of these approaches.*
- ***Implementation:*** It is clear that ABS implementation has faltered due to the lack of many key types of international consensus and guidance. Addressing this need must be a primary objective of the International Regime. In particular –
  - *The development of specific clear understandings regarding legal issues not addressed by conventional contract law (including the nature and ownership of "genetic resources" and relevant rights.)*
  - *The creation of mechanisms to enable Parties to take actions that are necessary for effective enforcement and oversight of ABS obligations (including monitoring the actions and products of user parties to ABS arrangements after the genetic resources have been removed from the source country, as well as supporting actions to ensure that user parties comply with their obligations.)*
  - *Market oversight and tools (market information, registration, certification, oversight and "fairness")*
- ***Documents and Instruments:*** *It is clear that these matters can best be addressed through a combination of instruments, including existing and new. Two key factors in deciding how to address each point will be (i) how urgent is the point (should it be adopted immediately by a fast process, or may it wait for a longer process?), and (ii) how likely is it that the document will need adjustment in future (some processes are more flexible and easier to amend than others.) The possible tools include:*
  - *COP Decisions and Guidelines provide a relatively rapid and flexible tool and a general presumption of broad acceptance.*
  - *Annex to the Convention, although frequently overlooked, this mechanism offers many potential advantages, being stronger and less equivocal but easier and thus more flexible.*
  - *Regulatory-level Protocol is also a possibility. It should be noted that the Biosafety protocol was primarily regulatory in nature, and did not create or a major new policy direction or interpretation.*
  - *Separate regulatory instruments at the regional or "shared-interest" level might address regulatory level matters, rather than (or in addition to) policy commitments.*

National Level:

- ***Actions mandated or addressed by the Convention,*** *include many matters of national sovereign discretion – that is, countries must comply with the Convention, but have full discretion regarding the specific manner in which they comply, and the governmental level at which such compliance takes effect. Among the actions that are mandated in this way are the following (see also Appendix A to this handbook) –*
  - **Facilitation of access of other Parties to genetic resources;**
  - **Obtaining, <u>at the level of national government</u>, prior informed consent to access,**
  - **Agreeing, <u>at the level of national government</u>, to the terms of the access**
  - **legislative, administrative or policy measures for** fair and equitable sharing of benefits and research results; access to technology and the results arising from biotechnologies, participation in biotechnical and scientific research, financial support, incentives and financial institutions.

- ***Other Implementation at the National and Sub-national Level.*** *It should be noted that the matters listed above relate to the intergovernmental/transboundary level of ABS. The CBD does not include any requirements regarding domestic use of genetic resources, nor of the manner in which the national framework is to be implemented within each country.*

  This includes matters of PIC and MAT. The CBD only says that the national government must provide these. It is for each party to decide how these matters will be implemented at the national level.
  - *<u>Designation and authorisation of national officials and agencies</u> ("ABS focal points", etc.)*
  - *<u>Contract Law (PIC & MAT)</u>*
  - *<u>Participation and community involvement</u>*
  - *<u>Receipt of (or distribution of governmentally received) benefit</u>*

Summary Handbook for CBD Delegations:

Options and Process for the Development of an International Regime on Access and Benefit-sharing

Tomme Rosanne Young[1]

One of the primary mandates of the delegates to the AHWG-ABS and COP-7 is to –

negotiate … an international regime to promote and safeguard the fair and equitable sharing of benefits arising out of the utilization of genetic resources.

This, mandate, however is not a simple matter. Few delegates will have experience with creation of any type of "regime." This booklet provides a step-by-step guide to regime development and identifies many possible options and components of an ABS regime – providing non-legal explanations of the legal and practical issues that must be considered in applying each kind of tool. Its aim is to describe the process and tools in a non-biased way, so that all parties will be able to negotiate for the regime that best meets their needs and the objectives and obligations of the Convention.

Although COP-7 will take only the first steps in regime development, the Parties must, from the beginning, understand the full process, and the nature and effect of each kind of tool that may be included within the ABS Regime.

This handbook is divided into 3 sections:

- What is an "International Regime" in the context of ABS?
- What are its objectives, obligations and components, and which of them already exist?
- What are the options, regarding tools and mechanisms for the creation of the ABS Regime, and how can they be utilised?

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I. What is an "International Regime"?

A. Legal Regimes generally.

In general, as used in paragraph 40(o) of the WSSD Plan of Implementation, the term "regime" refers to the complex of measures and mechanisms that are used to achieve a particular objective. A "regime" (on any topic) can be thought of as the full network of policy, legal and practical measures and tools relating to that issue. It will usually consist of a combination measures and mechanisms, including some or all of the following:[2]

- Policies/Objectives
- Strategies
- Commitments and their Implementation
- Instruments
- Consultation processes
- Implementing laws and ordinances at various levels
- Defining/systemic laws and ordinances
- Social and Protective legislation
- Administrative institutions
- Private and non-governmental institutions (including certification systems)
- Regulations
- Management plans
- Action Plans
- Rules and protocols
- Market tools
- Information mechanisms
- Rewards and direct incentives
- Agreements and Understandings
- Codes
- Standards
- Licenses, permits and certificates
- Taxes and assessments
- Oversight bodies
- Enforcement provisions

CRITICAL POINTS FOR NEGOTIATION:

i. **Objective-based:** *A Regime must be designed to achieve particular, specified ends. If not, there risk is of adopting many measures that operate at random and ineffectively, where fewer coherent measures, interacting synergistically, could better achieve the objectives.*

- Part II A below identifies the particular objectives that the CBD parties have already committed themselves to, with regard to ABS.

ii. **New and existing measures:** *Although a regime may consist entirely of new measures, it will usually be comprised of some new elements, in combination with pre-existing measures (whether kept in tact or amended.)*

- It is typical, in developing a new "regime," to closely analyse all existing mandates, measures, systems and requirements that may be relevant or form a useful part of the new regime. *(A very brief analysis of current elements that may form components of the ABS Regime is contained in Part II of this booklet.)*

  On the basis of such an analysis the Parties may be better able to determine what existing measures that support their objectives, and the extent to which they are functional and effective. In developing a regime, a key concern is ensuring that the mechanisms work together appropriately – that they do not conflict or overlap, and that the elements that form part of the regime are all necessary, and interact in a way that promotes the regime's function.

  Beyond this, a regime can function only when the concepts or system is clear enough that the various mechanisms can interact without confusion. Where a regime is composed of existing components from various systems and levels of governance, it will be difficult, but important to develop clear, implementable consensus regarding the terms and systems within the regime.

[2] Primary issues relating to the role of these types of mechanisms in the ABS Regime are discussed in Part III of this paper.

iii. **Mandatory/voluntary:** *The entire regime may be "mandatory" or "voluntary," or it may have some elements of each character.* Frequently the terms "mandatory" and "voluntary" are confused with the terms "binding" and "non-binding." While there are situations in which "mandatory" and "binding" have the same effect, they are different concepts. The same is true of the terms "voluntary" and "non-binding."

A requirement is "mandatory" when every person or entity addressed by this requirement is required to comply with it. For example, a law which sets the maximum speed on highways is mandatory in that it is a requirement imposed on every person addressed – that is on every person driving a vehicle on a highway.

Similarly, a law is voluntary when a person or entity addressed by a law has a choice about whether that law will apply to him. "Voluntary standards" are an often-used example of this concept. They are created (sometimes in law) to serve two possible purposes.

- First, they may create a "safe harbour." This happens where the law is not completely clear, about what activities are legal and which are illegal. The person who can prove that he is complying with the voluntary standard is certain that he is acting legally.
- The other way that "voluntary standards" are used is where two parties to an agreement choose to adopt them as standards for that agreement. Then, depending on the terms of the agreement, they will be mandatory for the the parties to that agreement.
- In some cases, "voluntary standards" also operate as "non-binding standards" (below.)

iv. **Binding/Non-binding:** *A regime may be "binding" or "non-binding" or a combination of binding and non-binding provisions.*

The terms "binding" and "non-binding" relate to whether the particular provision (in a law or contract) is formally legally enforceable or not. A binding provision is legally enforceable by law, a non-binding provision is not.

- *Binding:* A provision may be automatically binding (contained in a law that states that the requirement applies, even if nothing in the contract requires it.) Other binding provisions are contractual provisions that are allowed (not prohibited by law), and that are specifically required under the contract.
- *Non-binding:* One cannot be punished for failure to comply with a non-binding provision. However, a 'non-binding provision" in an agreement or understanding is generally held to indicate a "good-will commitment" – the parties are legally expected to "use best efforts" to comply. If a party does not make such an effort, he can be accused of acting in "bad faith" in some legal systems

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B. <u>International Legal Regimes</u>:

In general, the concept of "regime" has typically been more relevant at the national (or sometimes bilateral) level, or below. Particularly in recent years, however, international law has in several instances begun to form relatively comprehensive "regimes."

Two examples (both of which have an increasing relevance to the CBD and ABS issues) are –

- the multiple-armed regime being applied under the WTO, and
- the growing body of instruments and measures toward an international regime on the protection of intellectual property (including WIPO and TRIPs.)

As these examples demonstrate, the development of an international regime is a process, rather than an event. The current work in the development of an ABS regime will almost certainly have to occur in steps. However, it is clear that an explicit commonly held view of the nature of the outcomes expected is essential, and that that consensus must be developed as early as possible in the process

C. Relationship of the International Legal Regime on ABS to the CBD

Scope and Mandate: The CBD drafters of the CBD created a "framework" convention which enable actions on the broad range of issues, using a variety of methods and mechanisms. Work within that framework, although more detailed, must operate within the CBD objectives commitments and tools.

i. *Manner of working: Up to now, the CBD has progressed under many different overarching mandates using a variety of tools*, including

- work-programmes,
- MoUs, joint workplans and other vehicles for co-ordination with other environmental agreements,
- a protocol
- guidelines and principles
- declarations

Other tools are or may be available.

ii. *Scope and mandate of work under the CBD:* In each of these documents, two primary principles were evident:

1) The work is being undertaken within the framework of the CBD, and is bounded and mandated by the CBD's scope and mandate; and
2) language in the Convention itself is clearly not intended to be the "sole and final" word on any topic, but to create a framework for more detailed work.

Documenting and Interpreting the Convention: In essence, the relationship between the CBD and the various documents listed above is very similar to the relationship at the national level between the various types and levels of policy, law and regulations that are used to address particular matters of national concern.

i. *Translating Policy into Action at the National level:* In general, the relationship between policy and implementation may be summarised as follows:

- The highest level of policy makers decide on overarching objectives and primary approaches for addressing them, including clear identification of specific issues and fields that must be addressed. At the national level, this is "national policy"
- The highest levels within the various sectors affected by the national policy examine these objectives, and develop an overall vision or outline of how these matters will be addressed in their sectors. Similar processes may happen at the level of sub-national (state, provincial, etc.) government. This is often called "sectoral policy."
- National, and sub-national law is developed based on the more specific outlines. Specific practical decisions will decide how these activities are to be achieved, what institutions or other arrangements should be created or altered, what legal authority and powers are needed, and how to protect the rights and obligations of all affected persons (not only citizens, and foreign nationals, but also government agencies and officials.)
- Below the level of law, many kinds of subsidiary legislation (regulations, orders, rules, practices and protocols, may be necessary, to clarify and implement the law, and to address particular practical problems and details.

ii. *Translating International Commitments into International, National and Sub-national Action:* The CBD's commitments can be thought of as policy at the highest level, which must be implemented through development of an ABS regime. As a consequence, using the tools available under the CBD, it is essential to take the next steps, creating the next level of understandings and policies that are necessary to support the international elements of the regime, and considering the specific needs of the Parties, including capacity-building and technical assistance, but also the possible need for international tools, such as monitoring and oversight mechanisms, in order to implement the ABS commitments and objective.

Thus, the COP's action on the development of the International Regime on ABS must, as a matter of necessity, interpret the policy language of the CBD, and make decisions about how, at a practical level, those policies can be converted into action.

Moreover, although the ABS regime involves trans-border transactions and transfers of genetic resources, the CBD does not specify or clarify any mechanisms, international understandings, or specific tools for oversight or other necessities for these transactions. It is thus necessary for the COP to decide what kind of tools will be best to address these needs.

II. What objectives, obligations and components already exist relevant to the development of an international ABS regime?

The essential prerequisite in development of an effective regime are –

- *A clear understanding of the mandate, and desired outcomes expected from that regime.*
- *An analysis of existing tools, mechanisms and systems for the ABS regime*

These activities are essential to the regime development process, and simplify the selection of regime components. In the simplest analysis, regime development can be compared to carpentry – only if the carpenter knows what he is going to create, can he know which tools to use. His artistry is in choosing the best tools and materials and finding the best way to use them, in order to complete his job most effectively, and create the best possible construction.

A. The ABS Mandate: CBD Obligations and Objectives Underlying Development of the ABS regime

Because equitable benefit-sharing is one of the three primary objectives of the CBD (and prominently mentioned in the preamble and other non-mandatory provisions found in Appendix A), it is sometimes forgotten that it is also the basis of a number of direct ***obligations*** of the Parties to the Convention. The following list demonstrates the coverage of basic obligations of the Parties, and shows that all these requirements are mandatory in nature (requiring at a minimum, that the Parties use "best efforts" to try to meet them.

TABLE 1: ABS-RELATED COMMITMENTS IN THE CBD

When they ratified the convention, Contracting Party agreed to take the following actions[3]:

… create conditions to facilitate access to genetic resources for environmentally sound uses by other Contracting Parties and not to impose restrictions that run counter to the objectives of this Convention. (Art. 15.2.)
… develop and carry out scientific research based on genetic resources provided by other Contracting Parties with the full participation of, and where possible in, such Contracting Parties. (Art. 15.6.)
… take legislative, administrative or policy 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 resources with the Contracting Party providing such resources. (Art. 15.7.)
… take legislative, administrative or policy measures... ***with the aim that ... developing countries, which provide genetic resources, are provided access to and transfer of technology which makes use of those resources***..., including technology protected by patents and other intellectual property rights. (Art. 16.3.)
… take legislative, administrative or policy measures... to provide for the effective participation in biotechnological research activities by those Contracting Parties, especially developing countries, which provide the genetic resources for such research, and where feasible in such Contracting Parties. (Art. 19.1.)
… fairly and equitably share … the results of research, development arising from the commercial and other utilisation of genetic resources with the Contracting Party providing such resources. (Art. 15.7)
… take all practicable measures to promote and advance priority access on a fair and equitable basis by Contracting Parties, especially developing countries, to the results and benefits arising from biotechnologies based upon genetic resources provided by those Contracting Parties. (Art. 19.2.)
… ***provide,*** in accordance with its capabilities, ***financial support and incentives in respect of those national activities which are intended to achieve the objectives of this Convention***. (Art. 20.1.)
… (developed country Parties) ***provide***, and developing country Parties ***avail themselves of, financial resources related to the implementation of this Convention through bilateral, regional and other multilateral channels.*** (Art. 20.3.)
… ***facilitate the exchange of information,*** from all publicly available sources…, taking into account the special needs of developing countries…. Such exchange of information shall ***where feasible, include repatriation of information (***Art. 17.1&2)
… ***consider strengthening existing financial institutions to provide financial resources*** *for the conservation and sustainable use of biological diversity*. (Art. 21.4.)

[3] The listed requirements from articles 15 and 16 call upon the party to "endeavour to" take the actions listed. This "endeavour" language creates a requirement of "good faith" – suggesting that all parties must make all reasonable efforts to implement these obligations, but shall not be considered to be failing if, after those efforts, the obligations are not satisfied.

CRITICAL POINTS FOR NEGOTIATION:

i. ***The Protocol Question:*** *One question that will probably be asked in these negotiations is whether there is a need for a separate binding instrument on ABS (an "ABS Protocol.") That question must necessarily begin by examining the obligations already in force.*[4] *The Parties must determine whether these obligations would be sufficient to support a functional ABS process, if all Parties adhered to them. If so, then the bigger question arises – What advantage will a new instrument give, and why do we feel that the Parties will implement it, if they have not implemented existing measures?*

NOTE: It is a basic principle of international law that Conventions like the CBD bind and create obligations only for their Country Parties. They must then adopt legislation binding on subnational governmental levels, entities and individuals under their respective jurisdiction and control, as a way of implementing their obligations. The final responsibility for implementation (or failure of legislative measures to achieve the Convention's objectives) rests on the Contracting Party governments, and not on the individuals or sub-national levels to whom the government devolved implementation responsibility.

- The ABS Project's legislative review processes suggest that only about 50 of the CBD's 188 Contracting Parties have adopted measures partially implementing the direct "access" and "benefit sharing" obligations, and nearly all of these are developing countries in which "use of genetic resources" has not been systematically regulated, due to the fact that no significant in-country use has been conducted or expected.

  Virtually no country has adopted measures to address the "use" side of the process, or to tie-in key elements such as research and development, technology transfer and financial support .

- It should also be noted that many "provider" obligations are not well or effectively addressed in legislation, and that research and facilitation are not entirely one-way.

- The mention of "patents and intellectual property rights," and the general expectation that most of genetic resource collection would be undertaken by private entities, individuals, educational and research institutions, has obscured the fact that the obligations of the Convention are binding on Party governments, all of which accepted the above-listed obligations under the CBD with regard to encouraging and providing incentives for transfers of benefits, information and technology, few of which have been formally addressed,

Another important point relevant to this question is whether the improvements one is expecting from a protocol will be worth the time that would be lost in creating one, Based on recent experience, the process should be expected to consume several years. The actual negotiations that led to the creation of the Cartagena Protocol on Biosafety began well before the adoption of the CBD in Rio in 1992, and the Protocol was adopted in 2000 and entered into force in 2003. Other recent international protocols have had similar experiences.

Finally, it should be remembered that Protocol is a negotiation process. In the end, the document that is created may be no more comprehensive than the current CBD provisions on ABS. This too is demonstrated by comparing CBD Article 19.3 (which includes "safe handling and use" within a much broader list of issues to be addressed by the biosafety protocol) with the Cartagena Protocol.

ii. ***International Needs and Measures: The "Contractual Approach" to ABS Implementation.*** Although it does not say so explicitly, the Convention seems to presume that individual "ABS Arrangements" (contracts, licenses, permits, etc.) will be the primary mechanism through which ABS will be undertaken. *IF THE ABS REGIME CONTINUES TO FOLLOW THIS APPROACH, IT WILL BE NECESSARY TO EXAMINE THE FUNCTIONING OF RELEVANT CONTRACTUAL PRINCIPLES AND RULES AND PROCESSES GOVERNING TRANSACTIONS IN INTANGIBLE PROPERTY, TO DETERMINE WHAT ADJUSTMENTS, MECHANISMS AND CLARIFICATIONS ARE NEEDED SO THAT THEY CAN BE UTILISED IN THE ABS CONTEXT.*

[4] In addition to these specific obligations, a number of other CBD provisions and obligations are less directly focused on the ABS issue, but still are essential components of the overall regime. These are included in Appendix A to this paper.

Altering the Overall Approach: It is possible within the Convention to reconsider the decision to rely solely on individual contracts as the mechanism for implementing the ABS obligations.[5]

Since the adoption of the Convention, there has been a general *assumption* that ABS would be implemented by contracts, under national law, however in 11 years this approach has not been effective. Accordingly, before determining the specific mechanisms and tools that will build an effective ABS Regime, there is a basic question that must be answered:

> *Should the ABS regime continue to rely only on national-based contracting and ownership mechanisms as its primary mechanism?*

In this connection, the Parties may consider a variety of possible overall approaches, including,

- maintain the current approach, and address the problems and gaps with new instruments or other mechanisms;
- create an internationally agreed contract-based mechanism;
- limit the ability to enter into ABS Arrangements, so that ABS contracts will be possible only where the user entity is governed by (and/or operating in) countries have adopted user legislation or met other requirements;
- closely track all genetic resources taken pursuant to ABS Arrangements, so that benefit-sharing can be based on ***use*** rather than solely on contractual provisions and enforcement ;
- adopt one or a series of completely non-binding and voluntary mechanisms and integrating them into the laws and practices of all countries in such a way that they function as direct, dependable incentives to make commercial, institutional and individual users recognise strong reasons why they should use it; or
- derive "benefit-sharing" from all activities based on naturally occurring genetic resources (regardless of where the user claims they have been acquired.)

[5] The Convention's text focuses on national contractual regulatory environments, but does not specifically require them, nor say that they cannot be assisted by a new regime. While it is clear that the Convention's drafters assumed that existing legal conditions were sufficient to support the creation of ABS mechanisms, the Convention does not require the use of such conditions. Rather, it calls on the Parties to

- "Create …",
- "take legislative and policy measures for…"
- "develop and carry out…" and
- "provide…."

various conditions and ***outcomes***, rather than specifying a particular mechanism that must be used.

Retaining the "Individual Contract" Approach: Need for clarification at the international level. One of the most important underlying causes of the failure of ABS processes to operate well, on an international basis relates to the lack of a regulatory level of clarity regarding the nature of ABS concepts, including key matters of coverage and legal authority. Currently, national/regional implementation of ABS relies primarily on the convention's definitions and provisions. But these definitions in an international policy document are not clear enough and do not create the level common understanding needed for a functional practical, implementable and enforceable international regime. Yet contract law (the basis for ABS implementation) can only operate on the basis of such common understandings.[6]

COP-6 decided that the crucial work of clarifying definitions should be addressed in COP-7. Two examples show why "policy" definitions alone do not support practical contracts:

- ***Genetic resources***: Three CBD definitions are critical to determining what a 'genetic resource' is for purposes of applying the ABS regime –
  - *'Biological resources' includes genetic resources, organisms or parts thereof, populations, or any other biotic component of ecosystems with actual or potential use or value to humanity.*
  - *'Genetic material' means any material of plant, animal, microbial or other origin containing functional units of heredity.*
  - *'Genetic resources' means genetic material of actual or potential value.*

  As written, there is little difference among the three, since all plant, animal, microbial and other living or formerly living matter contains 'functional units of heredity' (DNA and/or other proteins that have an apparent role in genetic/heredity processes), and there is no way to determine now which genes may someday have value. Any plant, animal, microbe, or part thereof could be considered a 'genetic resource.'

  However, a close reading of the entire Convention suggests that–

  - the term "biological resources" refers to any specimen of a plant, animal, microbe, etc. (or any part), used in traditional ways, (harvesting, extraction and conventional purposes).
  - the terms "genetic material" and "genetic resources," as used in the CBD, refer to either –
    i. the genetic "code" or unique genetically defined characteristics of species, or
    ii. the ***use*** of samples: *i.e.,* particular analysis and utilisation of their DNA, genes, and other genetic components.

  Thus, a "genetic resource" is not a type of material, but a type of use – the sampling and commercial application of genetic information and related biochemical properties. This kind of distinction between 'biological resources' and 'genetic resources' is clearly what the Convention envisions, but needs to be stated in legislation and other instruments, so that it can be applied in implementation and enforcement of the ABS process.

  At the same time, the above clarification is at the heart of many difficulties encountered in attempting to implement ABS obligations and objectives. In essence, it is clear that, ***the same material, specimen or sample would be treated differently in the ABS system, depending on how it will be used.***

  ABS measures and controls in provider-based contractual ABS Arrangements would be legally effective, then, only where the governments and providers have the ability to know, oversee and control the uses that are made of the resources. However, in the case of ABS, provider government's involvement occurs at the "front end" – the ABS process *requires negotiation of contracts and other actions before any use has been made.* By the time the resource is used, the samples are usually outside of the jurisdiction of the agencies that conducted the negotiation and signed the contracts. Most source countries cannot know how the resource is being used, and cannot enforce permits and contracts against a bioprospector who violates his restrictions or commitments after he has left the source country.

  Even user countries currently find enforcement difficult, since government involvement in research and development processes does not usually involve a level of oversight that would enable them to know

[6] More discussion of the specific problems with applying normal pre-CBD contract and property law to transactions involving genetic resources is found in Chishakwe, N. & Young, T., *Access to Genetic Resources, and Sharing the Benefits of their Use:International and Sub-regional Issues*, another document of the ABS Project, currently available in discussion draft form for the ABS meeting.

or determine the nature of processes and of the genetic and other material that comprise the products.

- ***Ownership issues:*** Although there are many issues that need to be addressed regarding the ownership of genetic resources, One of the most difficult relates to the fact that GR are treated in three different ways under the CBD and under most national laws:
  - *Physically owned property:* Genetic resources are treated as physical substances over which a landowner may assert possessory rights. This means that when the user obtains physical "access" to the resources, and the right to bio-prospect, that right is often negotiated with a specific property-owner or community, and will relate to the taking of specific samples or working within a specific area.
  - *Generic Nationally-owned property:* Genetic resources are often treated as the sovereign property of the country that provides access, at the time that the user negotiates the ABS agreement. This means that, when the user and the provider government enter into an ABS agreement, the government may be asked to promise not to give similar rights in the same species to other bioprospectors, even though obtained from the lands of a different landowner or community.
  - *Internationally patentable property:* Genetic resources are treated as internationally patent-able information, when the user obtains a patent for his work with them. This means that the user may now limit the use of the particular GR, even by source-countries that are not party to any agreement with the user.

The problems inherent in this inconsistency can be illustrated by a simple story: Suppose that five people co-write a song. They all agree that any of the five may, if he chooses, sell the song to anyone (multiple ownership.) Then one of the five sells the "exclusive rights" to the song for a large sum, and does not share his profits with the others. The buyer then copyrights the song, based on his "exclusive rights." At this point, the buyer can claim that it is the only owner with a continuing right to sell the song. He is protected against any other claim, including from the other four original co-writers. None of the others can ever sell the song again.

Realistically, for the international regime to function as a legally consistent and rational processes, it must find a way to rationalise these ownership issues. It must ***either***

1. recognise single ownership through the entire process (in which case the buyer could not patent the resource against any countries that do not share in benefits); ***or***
2. consider the GR to be an international resource from the beginning (in which case benefits from GR should compensate all countries which possess that resource).

Mandatory exceptions and "loopholes": *It will be essential in choosing the overall approach to consider the primary exceptions that are negotiated within the Convention.*

The most important of these is the exception for pre-Convention specimens. For many decades, many institutions (botanical gardens, herbaria, zoos and similar collections) around the world (but particularly in developed countries) engaged in the systematic collection of biological examples. These collections have engaged in many trades and transfers around the country, and in some cases, at least, do not maintain detailed records regarding the origin of specimens received through these lateral trades, nor, in some cases do they keep detailed records of the recipients to which they send samples.

As a consequence, unless some very detailed records and agreements involving the pre-existing samples held in collections prior to the Convention, the existence of such collections can be thought of as a major "loophole" that could prevent the full effective implementation of mandatory requirements in the ABS Regime or in individual ABS Arrangements, unless a way can be found to address these issues.

Focusing on "Outcomes": *In selecting an approach, as well as in selecting the tools that are necessary or helpful in the ABS Regime, it is important to have a clear idea of the outcomes that the Regime should bring about.*

- There are a variety of possible outcomes to consider, including the following:
  - Increasing protection for developing countries and certainty of payments;
  - Increasing the number of transactions,
  - Maximising opportunities to develop new uses of genetic resources (for health, food security, and other purposes.
  - Enabling ABS Arrangements to be concluded quickly,
  - Maximising the value received by developing countries,
  - Increasing the Parties' confidence that their legal rights and interests are not being lost through undue haste in concluding transactions,
  - Increasing factual knowledge of the value of ABS Arrangements,
  - Creating additional incentives for conservation and sustainable use,
  - Enabling oversight to increase ABS compliance,
  - Maximising the distribution of technology and information,
  - Increasing equity among all countries.
- Some of these outcomes may not be completely mutually achievable. For example, many solutions that increase the certainty of payments, may decrease the value received in transactions. For this reason, ***it will also be important to <u>prioritise</u> these and other outcomes, so that a proper balance can be achieved.***

Need for international consensus: *It may not be sufficient or effective for each country and its courts to develop the necessary definitions, contractual principles, and other understandings individually. With regard to the international transactions of ABS,[7] a broad range of different national understandings would probably not be an improvement over the current system in which no specific clear interpretations exists anywhere. National development, if it happens, will occur through the three conventional mechanisms by which countries interpret legal and policy matters for purposes of practical application:*

(1) ***Express, intentional development*** – this occurs where a country creates its own particular definitions and interpretations in specific law or formal regulatory processes'

(2) ***Judicial interpretation*** – this occurs where a document or transaction "goes wrong," and the courts are called to interpret. If there is no clear common international understanding, each country's courts will interpret differently. This may lead to inconsistent results, since, in most cases, the ABS arrangement is negotiated under the law of the provider country, but any claim against the user entity for violation of that agreement will probably have to be brought in the courts of the country in which the resources are used.

(3) ***National Legislation, Regulation or provision in the ABS Arrangement*** – there is a need to be very clear about the exact national interpretation that will apply to the ABS Arrangement, in national legislation or in specific provisions of the ABS Arrangement. However, since no clear understanding of these issues has developed at the international level, and owing to their legitimate desire to ensure that all courts will apply the proper interpretation, provider countries feel that they must address this issue individually. The result is that national ABS legislation or procedures are either (a) very long, and in some cases rather complex – often requiring several levels of oversight and "double-checking" to ensure that the country's rights are properly protected, or (b) very

[7] It is important to remember that the CBD's ABS regime applies only to international transactions – that is, to situations in which the "user" comes from and is regulated by one country (the "user country"), and the genetic resource is found in another country (the "source country"), and provided either by that country directly, or by agreement with a individual or community regulated by the source country. Thus, for ABS purposes, there is always a "user country" and a "source country." (It remains true that a country may be the "user country" in one instance and the "source country" in another, but the incidences of this are rare. Some countries that are "users" of genetic resources may find useful genetic resources within their own country, but they remain primarily (or exclusively) "user countries" for purposes of ABS.)

unspecific, merely parroting the Convention or language from other national legislation, without addressing the relevant practical and legal needs involved in creating a functioning, enforceable legal document. Either way, in order to protect their rights, source countries have no choice but lengthy and detailed negotiations and processes.

*A **clear internationally recognised interpretation of the key points of law** identified in this paper would serve as the bases for protecting the source countries in the event of a problem. The lack of such a basis is one of the primary underlying reasons that national procedures are often complicated, inflexible, and take a lot of time to complete (the concerns expressed by bioprospectors and other users (see e.g. CBD COP Decision V-26), and responded to in the "Bonn Guidelines.")*

It is not reasonable to expect countries to eliminate their complex and protective procedures, until they can have some confidence that their interests can be reasonably protected under accepted principles of law and contract. Until then, source countries are correct to be concerned that "streamlining" their regulatory system may result in unintended consequences that compromise their national interests and the interests of their citizens.

The solution? If the international system develops and generally accepts relevant common understandings, the countries may be able to simplify and streamline their laws, based on the assurance that common provisions and understandings will protect their interests, providing some assurance that courts in other countries will interpret their ABS Arrangements in a consistent and rational way.

iii. Other Instruments and Tools: *Apart from the specific obligations described above, there have been only three formal attempts to develop any part of the relevant and necessary international measures on ABS. One of these, the Bonn Guidelines, is focused on matters of national sovereignty, and discussed below. The others are:*

- **The International Treaty on Plant Genetic Resources for Food and Agriculture -- Addressing the special issues of food and hunger**:[8] When it enters into force, the ITPGRFA will create a mechanism for transfer of the genetic resources for varieties of a specific list of basic "food and agriculture" species. In essence, ITPGRFA's approach is to identify the genetic resources that are most commonly being freely traded around the world now – the basic food product varieties (beans, rice, bananas, etc.) and create a mechanism for integrating and rationalising the current systems of handling those trades, organised and approached in a way that will allow it to integrate into the developing ABS regime. It recognises that there are different uses and different benefits, as well as different needs, with regard to these food related transfers.

  It is a particular important agreement, offering a concrete example of a different way to approach ABS – by separating out one part of the overall concept (in this case a specific list of commonly traded agricultural varieties), and dealing with it in a separate but integrate-able manner. This suggests that the possibility of separate, linked solutions to other key ABS issues.

- **The International IPR processes – Guidance on the creation and protection of rights in GR**: Currently, many ongoing initiatives and processes, including in the World Intellectual Property Organisation (WIPO) and the WTO's work on Trade-Related aspects of Intellectual Property (TRIPs), are examining the question of intellectual property rights as it relates to genetic resources, ABS and traditional knowledge. Although this work is highly relevant to the ABS regime, it is also a source of significant concerns, as described above that will be resolved through a longer process.

  In addition, it should be noted that the IPR concepts and issues that affect genetic resources and ABS relate to only a small part of the larger and more complex issues of IPR and Traditional Knowledge. It may be useful to address and resolve the separate set of ABS-related IPR issues first, leaving the TK issues to be addressed in an overall manner that integrates with the ABS IPR decisions.

[8] IUCN (through the ABS Project, funded by BMZ), in partnership with FAO and IPGRI is in the process of preparing a Guide to the International Treaty on Plant Genetic Resources, written by G. Moore and W. Tymoski. It is expected to be available in English, Spanish and French, in March, 2004.

iv. National Needs and Measures: *In creating a workplan for development of the ABS Regime, it will also be important to consider national/regional measures, both as sources of knowledge concerning the implementation of ABS to date, and as critical elements in the overall future regime, which must, necessarily focus on national implementation..*

Guidance on matters of National Sovereignty – the Bonn Guidelines: The Bonn Guidelines focus on providing assistance to national governments within source countries, with regard to how they utilise and implement ABS concepts at the national and sub-national levels. This means that, at most, they are providing guidance for parties on their internal ABS implementation processes – matters within their national sovereignty, and specifically outside of the scope of the CBD. Thus, although they are a useful input into the ABS process, the role of the Bonn Guidelines should not be overstated. Specifically,

- The Bonn Guidelines provide a basis for sub-national implementation – activities below the level of the CBD obligations, with an overwhelming focus on developing countries. The international understandings needed to make ABS Arrangements fully implementable and enforceable, or to provide any minimum standards for the integration of user and provider countries' legal approaches into an international mechanism for ABS implementation, is a separate issue.

- Within national implementation, the Bonn Guidelines focus on primary matters including –

  - *Basic contract law* (while all countries have contract law, it is useful to ABS officials to have this guidance) Under all contract law, a contract is NOT valid (i) if the parties did not fully understand what they were agreeing to (this is "prior informed consent") and (ii) if the parties did not come to mutual agreement on material terms and conditions (in the CBD this is "mutually agreed terms.)

  - *Public participation* (most countries utilise public participation in many ways, using existing tools and guidance.) In this connection, it should be noted that the CBD's provisions for "prior informed consent" apply to *national governments*. Within each provider country, it is possible (and advisable) to seek informed public involvement in the question of whether the government should consent to a proposed ABS Arrangement, but the nature of this participation is to be decided by country as a matter of national governance. It is not a component of any Party's obligations under the Convention.

  - *Types of "payment":* Annex II to the Bonn Guidelines identify many possible types of activities and inputs that may be identified as "payment" in ABS arrangements (*i.e.,* payments for access, ways of liquidating "benefit-sharing" obligations, etc.) The choice of how payment is made is a matter to be decided in each contract, however, and although an ABS arrangement can include any of payment methods identified in Annex II, it need not. The parties to the contract may select any other form of payment, if they choose. It should also be noted that some forms of payment (such as the sharing of research results, education, training, technology transfer, and others) are separate commitments of the Parties to the Convention, irrespective of ABS responsibilities.

  - *Focal points:* The Guidelines give attention to the issue of creation/designation of an administrative focal point and structure, which has been identified as an important element in decreasing the time and complexity of ABS negotiations. Choices of how to designate focal points, at what level, and what level of authority to give them are, of course, solely matters of national law and not governed by the CBD.

National and Regional measures for ABS Implementation: As noted above, approximately 50 CBD Parties and three regional bodies have adopted (or are in the process of developing and adopting) measures for ABS Implementation. In most of these the legislative approach is closely modelled on one of two or three national legislative provisions.[9] To date, however, national laws have not lived up to their potential and have not resulted in an international regime.

[9] Several documents prepared or co-sponsored by the ABS Project in 2003 have examined these national and regional documents in detail. Available at COP-7 are: J. Cabrera *Analysis of the Implementation of Access And Benefit-sharing Regulations in Selected Countries,* and R. Wynberg, with L. Haidar, W. Nasser, T. Baldursson, L. Ouedraogo, *ABS issues of High-endemism, Low-diversity countries (desert and tundra),* S. Carrizosa, S. Brush, B. Wright, and P. McGuire, eds. Accessing Biodiversity and Sharing the Benefits: Lessons from Implementing the CBD, reflecting the work conducted under a project on ABS legislation in the Pacific Rim countries (publication expected in Summer 2004, by the University of California, in co-operation with IUCN.) The ABS Project is also preparing a database of national ABS legislation and other relevant documents on ABS, that will be available on the internet in the Fall, 2004.

This is partly due to the fact, as mentioned above, that almost the only countries that have adopted legislation are those that are (or wish to be) providers of genetic resources, so that most of the ABS-related obligations under the Convention have not been addressed in law.

In addition, however, there are other reasons that these legislative provisions have not met expectations. When the system did not work, no analysis of the underlying legal issues and needs of the system was undertaken.

Instead, many countries have accepted the easier explanation – that greater flexibility and shorter processes are necessary in order to entice user entities to enter into ABS Arrangements. This explanation does not actually meet the facts. In many cases, one country may have succeeded in obtaining several ABS Contracts, while another, with virtually identical legislation and institutional arrangements, has none. Countries that have attempted to respond to the stated need for flexibility, have similarly not seen greater success. If there is an easy solution that increases the number of ABS contracts a country can obtain, it is almost certainly not related to the provisions of national ABS legislation.[10]

[10] Although not systematically confirmed yet by the ABS Project's research, in the experience of the author of this summary handbook, commercial entities are most affected by "time" issues – if compliance with a country's ABS system can be completed in a relatively short and predictable amount of time, commercial entities may be willing to absorb additional expenses and requirements.

III. What options and components (approaches, tools and mechanisms) are available for the ABS Regime and how can they be utilised?

The specific tools that will compose the ABS regime must be determined based on the objectives, mandates and analyses described in Parts I and II, above. However, at this point, it will be appropriate to consider how certain intermediate outcomes and primary components will apply within the process.

Given that it will probably not be possible to make final decisions regarding the specific components of the regime at this point, this section will depart from the format used in parts I and II of this handbook. Instead, it will list the types of components and options at each level of action, with specific points on

International Components:

1. Overall policy instruments and national commitments (user and provider)

As noted above, at the level of international policy and formal national commitments there are four basic options:

- ***Existing commitments*** (see table 1 on page 5).

  Focus on the direct obligations of all CBD parties as listed in Table 1.

  Many of these call for *all Parties* to "***take legislative, administrative or policy measures***," or to "***take all practicable measures***" to achieve certain outcomes.

  Fewer than 20% of Contracting Parties have adopted significant legislation on ABS, and nearly all of these are developing countries.[11] Many of the CBD's ABS-related obligations have not been legislated in any country.

  These are binding commitments, which suggests that, before the Parties consider adopting further binding commitments, they should determine what value will be added by such a process, and particularly what additional actions, measures and commitments are desired, and whether a protocol (rather than more easily completed processes, such as an Annex to the Convention, a Guideline, or other mechanism) is needed.

  It may be both quicker and more effective, for the Parties to insist that all parties take the relevant actions and measures to implement their existing commitments.

- ***New instrument:***

  Another option will be the creation of a new instrument. It is impossible to realistically identify the components of such an instrument, given that no parameters of the proponents' expectations have been circulated yet.[12]

  Accordingly, it is not clearly possible to analyse the possible benefits of this approach. However, it will be important to undertake such analysis, as part of the decision to undertake this option

  Concerns about this option include

  - the probably time involved in the process (for a protocol, recent experience suggests that the Parties should anticipate a minimum of 6-12 years), assuming that it ultimately enters into force;
  - the fact that it will not apply to all CBD Parties, unless and until they formally ratify it;
  - the difficulty, financial cost and time commitment of that process;
  - the fact that, through compromise and negotiation, the ultimate result cannot be predicted, and may not ultimately provide the expected benefits;[13]

[11] ABS may be the only area of the convention in which developing countries have dramatically outclassed the developing countries in terms of their compliance with direct obligations of the Convention..

[12] It is currently assumed that the proposals are suggesting a protocol under the CBD rather than a separate free-standing agreement, but this has not been formally confirmed. It is similarly unclear whether other options, including the adoption of an Annex to the Convention under Article 30, have been evaluated.

[13] In this connection, it is worth comparing the final text of the Cartagena protocol (which focuses only on international transfer of GMOs) with Article 19.3 of the Convention, which anticipates that the Biosafety Protocol would deal with "safe transfer, handling and use" of GMOs

– such a document will be fixed and inflexible (it could only be changed by an amendment – which will again require a multi-year process.) Few ABS systems are working well, and that those systems' experience has not been easy for other programmes to emulate. If the Protocol were to mandate specific processes and institutions, those processes would be virtually unchangeable, even if better solutions later become evident (on the basis of practical experience after the international system becomes functional);

- ***Separate Agreement of Selected Parties:***

  Another possibility is for countries that share the same interests and concerns, or that are regionally aligned, to develop a separate agreement or collaborative document or institution. Such an approach has been suggested as a means for creating a single set of standards to be used by all countries within the group, and agreements for mutual co-operation in asserting and protecting source countries' rights (a sort of mutual aid arrangement). The legal implications of such an instrument would need to be carefully considered, particularly if it proposed to limit ABS arrangements to users governed by countries that were parties to this separate agreement.

- ***Combined approach:***

  It may be possible to combine these choices. For example to exhort parties to comply with their existing commitments, and to develop one or more limited policy-level commitments or binding instruments, focused solely on issues that are not already resolved. This process should be limited to "policy level" needs, given the factors described under the previous bullet.

2. <u>More detailed "regulatory" components of the regime</u>).

As noted above (pages 6-9) and in COP Resolution VI/23, the concepts created under the ABS objective and the ABS obligations are very new. There are no systems in national and international law that are applicable or provide models for dealing with matters such as the creation of legal rights in "genetic resources." As a consequence of this, ABS lacks the basic legal underpinnings that would enable it to operate in a more streamlined, flexible manner while still adequately protecting the parties to ABS arrangements.

In addition to the primary legal issues ("genetic resources" and "ownership" issues), a number of other needs should be addressed somehow within the international regime:

- <u>*Co-operation and "Economies of scale" – ombudsman, enforcement, oversight, monitoring, tools and other matters*</u>*:* A number of problems relating to the effective implementation of ABS have been discerned, where the problem is not the need for additional agreement on commitments or terms, but rather the need for collaborative action.

  In some cases (particularly enforcement), the primary concern is co-operation – the need for countries to enable mutual action to enforce ABS arrangements involving private entities, academic institutions, etc.

  In other situations, it is clear that there is a general need shared by many or all parties (such as the need for ombudsman services, oversight of the users and uses of genetic resources, interchange of patenting and other relevant information, monitoring of post-removal compliance with ABS arrangements, and the adoption of key tools for the process.) It would be financially very costly, and in some cases, practically much less effective, to address these needs at the national level, when a single international solution would be both cheaper and more effective.

- <u>*Market oversight -- market information, registration, market "fairness*</u>"

  There is one factor that is clearly the most relevant in limiting ABS Implementation, and contributing to the concerns of provider countries, which causes them to increase the level of internal procedures and ratification processes, as a means of protecting national interests and the interests of persons and entities under their jurisdiction. That factor is the lack of market information, and the connected need for some protections of the participants in ABS Arrangements.

  In situations involving a market in "intangible" goods (stocks, intellectual property, "futures,") as well as situations in which the market is controlled or limited by one side of the transaction (trade in gold and certain other limited commodities whose value is controlled by a relatively small number of buyers or sellers), principles of "good governance" require that the market is controlled at

the national or international level, to protect parties against abuse.[14]

As it has been envisioned by current practices, the entire realm of "access and benefit-sharing" is basically a market in an intangible commodity – genetic resources (see discussion on page 7 headed "Genetic Resources.") The parties are, moreover, fully aware that the value given and conditions imposed in ABS transactions are not generally known, and are typically made "confidential" according to the terms of the ABS arrangements.[15] Yet the Parties are also aware that information regarding these matters is essential to the parties' (especially the provider countries') ability to confidently enter into these arrangements. This lack of knowledge creates a fear of entering into a "bad deal" and thereby failing in their obligation to protect national interests, and the public. This fear, in turn leads to more detailed legislation, more internal ratification and verification processes, etc., which lead commercial entities to complain that they will not participate in ABS arrangements, because until the process can be "streamlined."

The CBD Parties have clearly recognised this need, asking, for example in COP 6 for

> "information regarding:
>
> (a) User institutions;
>
> (b) The market for genetic resources;
>
> (c) Non-monetary benefits;
>
> (d) New and emerging mechanisms for benefit-sharing;
>
> (e) Incentive measures;
>
> (f) Clarification of definitions;
>
> (g) Sui generis systems; and
>
> h) 'intermediaries.'"[16]

The conference of Parties has repeatedly noted that such information is "a critical aspect of providing the necessary parity of bargaining power … in access and benefit-sharing arrangements."

Tools for achieving this objective, include a variety of tools that have been used for many years in other contexts and could be adapted to the ABS context, as part of the development of an international regime, including –

- **Market tools** –
  - registration of transactions, (whether including or excluding pricing information or the manner of calculating benefit-shares)
  - certification (including certificates of origin or legal provenance) of genetic resources, as a prerequisite of use or further transfer.
  - key mechanisms and terms, enabling oversight of implementation of ABS arrangements, especially after removal from the source or country of origin.
  - Oversight bodies, institutions or frameworks
- **Protective measures** (provisions protecting less sophisticated parties, the environment and "third parties" (people and entities that are not included in the Agreement, but may be injured by it) against possible system-based abuses)
- **Commercial and legal support mechanisms:** It may be possible and necessary to agree on specific approaches and procedures, including the issues of genetic tracking (certificates of origin or legal provenance, disclosure of origin and source in patent applications, etc.) If such measures are used, it will be necessary to firmly integrate them into legally mandated processes relating to international transport of genetic material, IPRs and controls on marketing and commercialisation, so that the user parties to ABS Arrangements have a strong incentive to comply with these mechanisms.

[14] In this connection, it should be noted that such "abuse" is not the fault of the commercial or industrial entities. Rather, it is an outgrowth of the basic nature of such entities. They are created to engage in commerce, and to earn profits. They are not created for charitable purposes or the conservation of the environment. In many countries, they are specifically required to demonstrate that they put their shareholders' interests first – that is, that they do not allow other non-primary objectives to interfere with their primary responsibility to make money for their shareholders. As a result, it is not reasonable or possible to simply expect corporate, commercial or industrial entities to voluntarily take actions that would empower the parties they are negotiating with or otherwise diminish the entity's profits from a particular transaction. This is the basic justification for official governance

[15] In many commercial situations, it is common to keep the contents (or at least key financial matters) of particular contracts confidential. These confidentiality clauses often state that the contract will cease, if the confidentiality requirement is breached.

[16] CBD COP Resolution V/26.

– **Integration with Institutions and Materials not Covered in the Convention:** In this connection, it is also appropriate to mention the need to co-ordinate and develop understanding with key sectors and institutions that are not covered by the Convention – in particular, the special provisions in the Convention excepting pre-Convention specimens from coverage of the ABS requirements suggest a need to develop special relationships regarding *ex-situ* collections of biological specimens, and ensuring that they do not become the primary "loophole" used to evade ABS obligations at the level of individual ABS arrangements.

- *Types of tools and instruments for making "regulatory" choices at the international level:*

  It is not essential that all of the matters discussed in this handbook (or in the COP negotiations) must appear in a single instrument. The regulatory issues mentioned above may be a part of a policy instrument, but may also be effectively dealt with in one or more separate documents.

  A multiple-document approach may be valuable, particularly where there are many ideas and proposals that have not been legally tested, where there are many expectations that have not been met, or where it is not clear that particular experiences of one country will be replicable in other countries. All of these factors is true with regard to ABS.

  There are several possible ways to address these concerns, which may be used in combination, if necessary. Some of these include –

  - ***COP Decisions and Guidelines:*** Given that these documents are primarily intended to create "understandings" that will facilitate better implementation, the COP process may provide a relatively rapid and flexible method of developing such documents, and giving them a basis based on the presumption of broad acceptance.
  - ***Annex to the Convention:*** Frequently overlooked, the mechanism of a CBD Annex offers many potential advantages, being a stronger and less equivocal indication of the commitment and consensus of the Parties, but being adopted by process that is easier to complete, and thus potentially shorter than the development of a protocol.
  - ***Regulatory-level Protocol:*** It is possible that a Protocol could utilise a more detailed, "regulatory" level of detail, making the necessary understandings (and even specific processes and institutions) mandatory. However, it will be important to consider the issues described under the heading "new instrument" on the previous page, before deciding to take this option.
  - ***Separate Bi-lateral, Regional or Like-Minded Group Level:*** It is also possible for these understandings, and commitments to be the subject of a separate agreement or collaborative document or institution, as described above under the heading "Separate Agreement of Selected Parties," but subject to the same concerns about legal effectiveness.

  In deciding which tools are most appropriate for each issue or mechanism, the most important questions will be

  (1) How urgently is the provision or mechanism needed?

  (2) Is there a likelihood that amendment or flexible interpretation will be needed in bringing the mechanism or provision into full force or in the first years of operation?

  These answers will help to choose between the tools that take the most time (protocols and other international agreements) and are therefore relatively difficult to amend, and those that are easier to adopt and thus easier to adjust (such as COP decisions and (possibly) annexes.)

National components:

The national elements of the ABS Regime will include both the compliance with the national commitments specifically included within the Convention, and legislative measures and other implementation activities at the national and subnational levels. These are basically matters within national sovereignty, unreviewable by the international communityso long as they constitute, at a minimum, measures that enable the Party to meet its international commitments. (It should be noted that there are many other commitments and objectives of the CBD that are relevant to the Parties' decisions regarding implementation of the ABS Regime. Many of these are included in the tables in Appendix A to this Summary Handbook.)

Addressing International Commitments: At a minimum, each Party's implementation of the international regime on ABS *must* include the following:

- **Create –**
  - conditions to facilitate access to genetic resources for environmentally sound uses.
- **legislative, administrative or policy measures for –**
  - fair and equitable sharing of benefits arising from the utilization of genetic resources. (Art. 15.7.)
  - fair and equitable sharing of the results of research and development arising from the utilization of genetic resources. (Art. 15.7.)
  - providing access to and transfer of technology which makes use of genetic resources. (Art. 16.3.)
  - effective participation in biotechnological research activities by countries, which provide genetic resources "where feasible in such Contracting Parties." (Art. 19.1.)
- **all practicable measures for –**
  - priority access to the results and benefits arising from biotechnologies based upon genetic resources. (Art. 19.2.)
- **fairly and equitably**
  - share the results of research arising from the utilization of genetic resources. (Art. 15.7.)
- **provide and avail themselves of,**
  - financial support for national activities to achieve CBD objectives (Art. 20.1.)
  - incentives for national activities to achieve the CBD objectives. (Art. 20.1.)
  - financial resources for CBD implementation. (Art. 20.3.)
- **consider**
  - strengthening existing financial institutions for the conservation and sustainable use of biological diversity. (Art. 21.4.)
- **develop and carry out**
  - scientific research, with the full participation of, and where possible in, such Contracting Parties. (Art. 15.6.)

All of the above requirements relate to the direct action by national governments of countries that are parties to the CBD. While these measures will often focus on the activities of individual, as well as private and governmentally owned entities, institutions, it is the governments that have the responsibility to enact and implement these measures, and to revise them if their initial efforts are unsuccessful in achieving the required outcomes.

Tools and mechanisms for this processes can be described as follows

- policy instruments, strategies, national institutions, programmatic planning, and specific legislation and procedures regarding access and internal procedures for negotiating, adopting and ratification of ABS Arrangements, including the creation of specific rules and procedures, contractual systems, licenses, permits, codes of practice and conditions.
- Legislative authority and guidance relating to ensuring, supporting, and fostering benefit-sharing. Areas of concern include the various issues of tracking the genetic materials and institutions involved, the adoption and integration of certificates of origin and legal provenance, disclosure of origin and source, as well as other disclosures and certificates, access the legal and enforcement systems of the user country.
- National systems for transfer of technology, supporting scientific research and other measures, to the extent that these objectives cannot be met through direct legislative obligations imposed on the user individuals, entities and institutions.

Matters within National Sovereignty: Sub-national Implementation

Below the level of national commitments, the activities of the national parties are within national sovereignty. In many cases, the tools for implementation already exist. As to these matters, existing national legal, institutional and practical matters will be adapted to ABS, as appropriate. The Bonn Guidelines provide significant suggestions regarding these matters, relevant to these matters, for Parties that have not undertaken such processes, or that wish to amend their systems. Among the matters that can be adapted to ABS are the following

- Designation and authorisation of national officials and agencies ("ABS focal points", etc.)
- Contract Law (PIC & MAT)
- Participation and community involvement
- Receipt of (or distribution of governmentally received) benefits

Beyond these, the parties will probably need to take measures to ensure that responsibilities for actions implementing ABS commitments, and powers to enforce them distributed to sub-national government levels, and included in legislative provisions of other sectors and of sub-national units of government and resource management.

Appendix A:

CBD Objectives that Can Be Furthered by a Well Constructed ABS Regime

Other Primary Principles of the CBD that Can Guide the Development of the ABS Regime
Power of each Sovereign Party
Sovereign rights over their own biological resources (preamble 4th Para)
Sovereign right "to exploit their own resources pursuant to their own environmental policies" (Article 3)
Sovereign rights over natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation. (Art. 15.1.)
Jurisdictional Scope of the convention:
The Convention applies to the 'components of biological diversity', when 'in areas within the limits of its national jurisdiction;" (Art. 4(a))
The Convention applies to "processes and activities, regardless of where their effects occur,"when they are "carried out under a Parties' jurisdiction or control, within the area of its national jurisdiction or beyond the limits of national jurisdiction."
Each Contracting Party shall, as far as possible and as appropriate, cooperate with other Contracting Parties, directly or, where appropriate, through competent international organizations, in respect of areas beyond national jurisdiction and on other matters of mutual interest, for the conservation and sustainable use of biological diversity. (Art. 5.))
Jurisdictional Mandate of the Convention:
The CBD is an agreement among sovereign nations, not binding on entities or individuals, and does not give them rights or obligations.

The convention also suggests other provisions that could be furthered, by the ABS mechanism.

The ABS Regime could be a Tool toward Attaining Other Obligations, including the Parties' duty to
… provide the conditions for compatibility between present uses and the conservation of biological diversity and the sustainable use;"(Art. 8(i).)
… adopt economically and socially sound measures as incentives for the conservation and sustainable use . (Art. 11.)
… establish and maintain programmes for scientific and technical education and training in measures for the identification, conservation and sustainable use … and provide support for such education and training for the specific needs of developing countries; (Art. 12(a))
… promote and encourage research which contributes to the conservation and sustainable use, particularly in developing countries (Art. 12(b).)
… promote and cooperate in scientific advances in … research in developing methods for conservation and sustainable use. (Art. 12(c).)
… promote technical and scientific cooperation with other Contracting Parties, in particular developing countries, in implementing this Convention, … through the development and implementation of national policies … [giving] special attention to the [building] national capabilities. (Art. 18.2.)

The Convention also includes provisions that give guidance regarding elements and outcomes of the ABS Regime:
Noting further that the fundamental requirement for the conservation of biological diversity is the in-situ conservation of ecosystems and natural habitats and the maintenance and recovery of viable populations of species in their natural surroundings (Preamble 10th para)
Aware that conservation and sustainable use of biological diversity is of critical importance for meeting the food, health and other needs of the growing world population, for which purpose access to and sharing of both genetic resources and technologies are essential, (preamble para 19)
Stressing the importance of, and the need to promote, international, regional and global cooperation among States and intergovernmental organizations and the non-governmental sector for the conservation of biological diversity and sustainable use , (Preamble Para 14)
Benefit sharing shall be "in accordance with Art.16&19 and, where necessary, through the financial mechanism established by Art. 20&21"
Transfer of technology, etc may be supported through the financial mechanisms described in Art. 20&21 (Arts. 16, 18, and 7, 11, 12, 13, 17)
Transfer of technology based on genetic resources provided by a Party, shall be "on mutually agreed terms" (Article 16.3, etc.)
Art. 18.2. Access to biotechnology and sharing of the benefits from biotechnology, arising from use of GR shall be on mutually agreed terms.
Art 9(a) Adopt measures for the ex-situ conservation of components of biological diversity, preferably in the country of origin of such components;
Art 9(b) Establish and maintain facilities for ex-situ conservation of and research on plants, animals and micro-organisms.. in the country of origin;
Art 9(c) Adopt measures for the recovery and rehabilitation or reintroduction of threatened species … under appropriate conditions;
Art 9(e) Cooperate in providing financial and other support for ex-situ conservation and ex- situ conservation facilities in developing countries.
Art. 13(a) Promote and encourage understanding of the importance of, and the measures required for, conservation,
Art. 13(b) Cooperate with other States and international organizations in developing educational and public awareness programmes.
Art. 10(b) Adopt measures relating to the use of biological resources to avoid or minimize adverse impacts on biological diversity;

Art. 10(d) Support local populations to develop and implement remedial action in degraded areas where biological diversity has been reduced.
Art. 10(e) Encourage cooperation between its governmental authorities and its private sector in developing methods for sustainable use.
Art. 16.1. Each Contracting Party, ..., undertakes ... to provide and/or facilitate access for and transfer … technologies that are relevant to the conservation and sustainable use or make use of genetic resources and do not cause significant damage to the environment.
Art. 16.2. Access to and transfer of technology ... to developing countries shall be provided and/or facilitated under fair and most favourable terms, including on concessional and preferential terms where mutually agreed, and, where necessary....
Art. 16.4. Each Contracting Party shall take legislative, administrative or policy measures..., with the aim that the private sector facilitates access to, joint development and transfer of technology... for the benefit of both governmental institutions and the private sector of developing countries.
Art. 16.2.In the case of technology subject to patents and other intellectual property rights, ... access [to] and transfer [of such technology] shall be provided on terms which recognize and are consistent with the adequate and effective protection of intellectual property rights.
Art. 16.5. The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.
Art. 17.1. The Contracting Parties shall facilitate the exchange of information, from all publicly available sources, relevant to the conservation and sustainable use of biological diversity, taking into account the special needs of developing countries.
Art. 17.2. Such exchange of information shall include exchange of results of technical, scientific and socio-economic research, as well as information on training and surveying programmes, specialized knowledge, indigenous and traditional knowledge as such and in combination with the technologies referred to in Article 16, paragraph 1. It shall also, where feasible, include repatriation of information.
Art. 18.1. The Contracting Parties shall promote international technical and scientific cooperation in the field of conservation and sustainable use of biological diversity, where necessary, through the appropriate international and national institutions.
Art. 18.4. The Contracting Parties shall, in accordance with national legislation and policies, encourage and develop methods of cooperation for the development and use of technologies, including indigenous and traditional technologies, in pursuance of the objectives of this Convention. For this purpose, the Contracting Parties shall also promote cooperation in the training of personnel and exchange of experts.
Art. 18.5. The Contracting Parties shall, subject to mutual agreement, promote the establishment of joint research programmes and joint ventures for the development of technologies relevant to the objectives of this Convention.