



Methodology for Developing Policies and Laws for Access to Genetic Resources and Benefit Sharing

*Robert J. Lewis-Lettington, Manuel Ruiz Muller, Tomme R. Young, Kent
A. Nnadozie, Michael Halewood and Jorge Cabrera Medaglia*



The International Plant Genetic Resources Institute (IPGRI) is an independent international scientific organization that seeks to improve the well-being of present and future generations of people by enhancing conservation and the deployment of agricultural biodiversity on farms and in forests. It is one of 15 centres supported by the Consultative Group on International Agricultural Research (CGIAR), an association of public and private members who support efforts to mobilize cutting-edge science to reduce hunger and poverty, improve human nutrition and health, and protect the environment. IPGRI has its headquarters in Maccaresse, near Rome, Italy, with offices in more than 20 other countries worldwide. The Institute operates through four programmes: Diversity for Livelihoods, Understanding and Managing Biodiversity, Global Partnerships, and Commodities for Livelihoods.

The international status of IPGRI is conferred under an Establishment Agreement which, by January 2006, had been signed by the Governments of Algeria, Australia, Belgium, Benin, Bolivia, Brazil, Burkina Faso, Cameroon, Chile, China, Congo, Costa Rica, Côte d'Ivoire, Cyprus, Czech Republic, Denmark, Ecuador, Egypt, Greece, Guinea, Hungary, India, Indonesia, Iran, Israel, Italy, Jordan, Kenya, Malaysia, Mali, Mauritania, Morocco, Norway, Pakistan, Panama, Peru, Poland, Portugal, Romania, Russia, Senegal, Slovakia, Sudan, Switzerland, Syria, Tunisia, Turkey, Uganda and Ukraine.

Financial support for IPGRI's research is provided by more than 150 donors, including governments, private foundations and international organizations. For details of donors and research activities please see IPGRI's Annual Reports, which are available in printed form on request from ipgri-publications@cgiar.org or from IPGRI's Web site (www.ipgri.cgiar.org).

The geographical designations employed and the presentation of material in this publication do not imply the expression of any opinion whatsoever on the part of IPGRI or the CGIAR concerning the legal status of any country, territory, city or area or its authorities, or concerning the delimitation of its frontiers or boundaries. Similarly, the views expressed are those of the authors and do not necessarily reflect the views of these organizations.

Mention of a proprietary name does not constitute endorsement of the product and is given only for information.

Citation: Lewis-Lettington RJ, Muller MR, Young TR, Nnadozie KA, Halewood M and Medaglia JC. 2006. Methodology for Developing Policies and Laws for Access to Genetic Resources and Benefit Sharing. International Plant Genetic Resources Institute, Rome, Italy.

ISBN 13: 978-92-9043-719-2

ISBN 10: 92-9043-719-7

IPGRI

Via dei Tre Denari, 472/a

00057 Maccaresse

Rome, Italy

© International Plant Genetic Resources Institute, 2006

This document is one of three reports prepared in the context of the IPGRI project *Access and plant genetic resources for food and agriculture: Exploring options to implement the International Treaty on Plant Genetic Resources for Food and Agriculture and Article 15.2 of the Convention on Biological Diversity*.

The other two reports are:

Lewis-Lettington RJ and Dogley D. 2006. Commentary on the Development of the Republic of Seychelles Access to Genetic Resources and Benefit Sharing Bill (2005). International Plant Genetic Resources Institute, Rome, Italy.

Lewis-Lettington RJ and Mwanyiki S. (editors). 2006. Case studies on access and benefit-sharing. International Plant Genetic Resources Institute, Rome, Italy.

Contents

Acknowledgements	iv
Authors' Note	v
Introduction	1
Part I: Policy analysis: defining objectives	3
Part II: Identifying the basic framework	17
Part III: Positioning and drafting	28
Postscript: The methodology in summary form	30
Endnotes	32
Acronyms	35

Acknowledgements

The authors gratefully acknowledge the support and contributions of the participants of the East and West African, Central American, Southern African and Asian Workshops that led to and facilitated the development of this methodology. In addition, the invaluable contributions of Susan Bragdon, Rachel Wynberg and Victor Mosoti at various stages in the process must be recognized. Lani Trenouth, Barbara Ledda and Angelina Mwashumbe provided excellent administrative support during the life of the project. The authors are grateful for the support of the Peruvian Society for Environmental Law (SPDA), the Environmental Law Centre of the International Conservation Union (IUCN-ELC), the Southern Environmental and Agricultural Policy Research Institute of the International Centre of Insect Physiology and Ecology (SEAPRI-ICIPE), and the Food and Agriculture Organization of the United Nations (FAO). Very importantly, the authors acknowledge the initiative and ongoing support of the International Plant Genetic Resources Institute (IPGRI) for coordinating the project, and both IPGRI and the Genetic Resources Policy Initiative (GRPI) for providing intellectual guidance and support as the project progressed.

A series of country case studies were commissioned as inputs into the early stages of the development of this methodology. The commissioned case studies, covering eleven countries (Costa Rica, Guatemala, El Salvador, Mexico, Nicaragua, Panama, Uganda, Ghana, Nigeria, Malawi and South Africa) from three sub-regions (Central America, East Africa, West Africa and Southern Africa), are included in a companion volume 3, entitled *Country Case Studies on Access and Benefit Sharing*. There were

also four regional workshops, held in Ethiopia in December 2003, Costa Rica in January 2004, South Africa in May 2004 and India in Sept 2004, which provided opportunities for participants from thirty six countries to participate in the development of this methodology. Lessons learned from both positive and not-so-positive experiences in national and international ABS policy-making processes and forums that were aired in the case studies and regional meetings were taken into consideration. The final stage in the development of this methodology was a two-week series of meetings with a wide range of stakeholders from the Seychelles, during which the basic steps identified in the methodology were tested and refined. The draft national ABS law developed in the course of those meetings is included in a companion volume 2, entitled *Commentary on the Development of the Republic of Seychelles Access to Genetic Resources and Benefit Sharing Bill (2005)*.

All three volumes were developed within the context of a project executed by the International Plant Genetic Resources Institute (IPGRI) entitled *Access and plant genetic resources for food and agriculture: Exploring options to implement the International Treaty on Plant Genetic Resources for Food and Agriculture and Article 15.2 of the Convention on Biological Diversity*. The project was financially supported by the International Development Research Centre (IDRC), Canada, the German Federal Ministry for Economic Cooperation and Development (BMZ), through the Deutsche Gesellschaft für Technische Zusammenarbeit (GTZ) GmbH, the Swiss Development Corporation (SDC), and the Genetic Resources Policy Initiative (GRPI).

Authors' note

The authors would like to stress that this methodology is not a tool that will provide precise answers from information inputs. It is intended to be a guide to thinking through the process of policy development in the context of access to genetic resources so as to promote the effectiveness of the resulting regimes in the situations in which they are required to function.

The conceptual development of this methodology has been a complex process, both in agreeing on its structure and in conveying sometimes difficult abstract concepts in understandable language. As such, it does not represent the consensus view of all authors on all detailed points, but nevertheless provides a general approach on which all authors were able to agree.



Introduction

Access to genetic resources and sharing the benefits derived from their use—referred to in short-hand as ‘access and benefit sharing’ or ABS—has become the most widely discussed issue emerging from the entry into force of the Convention on Biological Diversity (CBD) in 1993. Subsequently, over the past decade, a large number of related national, regional and international, binding and non-binding, legal instruments and policies have been developed and put into place.

Although a comprehensive assessment of the impacts of existing ABS legislation and policies has not yet been completed, it is safe to say that their impacts have been mixed, at best. They do appear to have increased awareness among a broad range of stakeholders with an interest in genetic resources of the importance of genetic resources in general, including their role in biotechnology development, their relation to traditional indigenous knowledge and intellectual property (IP), their links to the biosafety debate, and the need to establish some kind of benefit-sharing scheme to redistribute benefits associated with their use. That said, some would argue that most ABS laws have also contributed to perpetuating an unfortunately widespread, exaggerated sense of the market value of genetic resources.

Discussions within a number of policy-setting international forums since 1993—e.g. the World Intellectual Property Organization (WIPO); the Council for the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement); the Food and Agriculture Organization of the United Nations (FAO), the Governing Body of the International Treaty on Plant Genetic Resources for Food and Agriculture

(PGRFA) (‘International Treaty’)—have reflected a growing preoccupation with ABS issues.

Currently, some of the best known and most widely referenced ABS-related laws include:

- Executive order no. 247, 18 May 1995 of the Philippines. Prescribing guidelines and establishing a regulatory framework for the prospecting of biological and genetic resources, their by-products and derivatives, for scientific and commercial purposes; and for other purposes.
- Andean Community Decision 391 on a Common Regime on Access to Genetic Resources (1996).
- Law 7788 of Costa Rica. Biodiversity Law (1998).
- Organization of African Unity Model Legislation for the Protection of the Rights of Local Communities, Farmers and Breeders and the Regulation of Access to Biological Resources (1998).
- Provisional Measure 2.126–16 of Brazil on Access to Genetic Resources (2001).

Non-binding ABS (and IP-related) instruments also abound worldwide, including the *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization* (2002) and various international codes of conduct and principles, and institutional policy declarations—all with some bearing on the activities of countries, companies, research institutions, museums, NGOs and indigenous peoples as they relate to access and use of biodiversity and its components, including genetic resources (and related traditional knowledge).

Most national legislation and regulations in force or in the making, as far as the authors are aware, with the exception of those implementing the International Treaty (which has a

very particular approach to regulating ABS), are very similar in form and content.

The three main objectives of the CBD are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the use of genetic resources. Experience to date (even if not fully corroborated by detailed in-depth studies) demonstrates that *something* in the content, structure or development process of these ABS regimes is impeding them from having the intended effect in terms of satisfying the objectives of the CBD in general, and the equitable sharing of benefits in particular.

Notwithstanding the efforts and advances made over the past decade in the policy and legal arena, regions and countries have faced considerable difficulties in the preparation and implementation of these policy and legal instruments. Whether due to need for additional political support at the national level; need for further human and institutional capacity within the countries developing the instrument; excessive expectations by policy-makers and national entities concerning the potential benefits to be derived from the application of ABS regulations; lack of institutional mechanisms to enforce the regime established; or misconceptions about what policy and legislation may be able to achieve in reality, experience since 1993 suggests that many of these policies, laws and regulations have limitations that prevent the expected results and successes.

Policy and legal measures seek to change and alter reality, but, at the same time, need to be informed and influenced by it in order to be effective. Implementation difficulties usually arise because either:

1. laws are totally disconnected from the reality they seek to influence (i.e. they often unintentionally do not take into account social, economic, cultural, political, scientific or institutional realities at a given time);
2. they are technically flawed in their content or impose burdens that significantly elevate transaction costs; or
3. their process of development has not integrated and adequately internalized the interests and needs of key actors towards whom these laws are directed (the main beneficiaries).

It is in this context that the project *Exploring Options to Implement the International Treaty on Plant Genetic Resources for Food and Agriculture and Article 15.2 of the Convention on Biological Diversity* proposed a conceptual and practical exercise to assist countries in developing their ABS policies and in a manner such that they can be more effective once implemented, and simultaneously also to aid in reviewing existing ABS policies and laws.

Far from being a menu of options from which a solution may be identified and 'picked' or a set of alternatives or models to be chosen among, this methodology stresses the *process* and *reasoning* behind the options and alternatives identified, and aims to establish a methodology by which these options may be tested (conceptually and in practice) against social, economic, institutional, policy, scientific and legal considerations, according to each country's specific needs and interests.

The methodology has three phases, consisting of ten steps in total, which do not necessarily have to flow sequentially. It can be used in the generation of new policies or laws; alternatively, it could also be applied in the context

of evaluating existing policies and legislation to identify where gaps, administrative burdens and transaction costs in general may be negatively affecting implementation.

Part I: Policy analysis: defining objectives

The starting point for the development of any policy or regulatory framework is to have a clear idea of what it is supposed to achieve. A law or policy that is developed with undue haste, without careful and deliberate consideration of what it should and can reasonably achieve, in many instances is likely to prove redundant or, at worst, destructive. Experience demonstrates that many national access laws are often developed in haste in response to a particular political, widely publicized, event. Determining the purpose of the ABS regime one seeks to develop is analogous to laying the foundations of a house: the foundations determine not only the nature and character of a house, but also its quality in terms of durability and adaptability. To stretch the analogy a little further: any additional time and effort devoted to the laying of foundations is, almost invariably, directly rewarded in terms of the quality of the final structure.

These first two steps of the methodology focus on the process of determining, first, the primary purpose, and, second, the component objectives of any potential ABS law. These two steps are complemented by the exercise of identifying, gathering and synthesizing relevant baseline information—information that informs what the objectives of the law should be, and can be used to check whether the objectives identified potentially respond to the on-the-ground realities of the community, country or region concerned. In an ideal world, all relevant background data would already be fully appreciated by a wide range of stakeholders before any decisions about the objective (or any other elements) of an ABS regime are decided upon.

However, as we discuss below, decisions to put ABS laws in place are often made at high levels of government without much—or indeed any—guidance about the actual structure or content of the regime to be developed, leaving lower-level functionaries and legal experts to work out the details. As a result, too often those with responsibility for actually drafting legislative or regulatory instruments will not have all the information they need to make fully informed decisions. The second-best situation is therefore that drafters should have the ability to circle back from time to time, collecting situation-specific data to inform the tailoring of the various elements into a balanced and comprehensive law or regulation. The authors of this document are aware, however, that most legal drafters in most countries do not have the financial or human resources to gather and fully consider the implications of data in this way. As a result, drafters often find themselves in the unenviable position of having to make assumptions in the absence of sufficient and reliable data. The theme of collecting baseline data to inform decision-making will reappear in Parts II and III, below.

Step 1. Determining the purpose or high-level objectives

It is important to note that there are three basic sources for impetus to develop an ABS law or policy, and that the content of the objective(s) is likely to be influenced by whichever of those sources predominates.

Sources of impetus

The three main sources of the impetus to develop an ABS policy or law are:

National government, through:

- National Biodiversity Strategies and Action Plans (NBSAPs);
- framework statutory provisions;
- executive decisions; and
- national undertakings to which the country has adhered.

Technical agencies, and motives include:

- need to regulate research;
- need to control existing activities that depend upon access to genetic resources; and
- interest in potential income-generating activities.

Special-interest groups addressing:

- protection of heritage or patrimony;
- equity through benefit sharing;
- income diversification; and
- predictability in the regulatory framework.

Typical cross-cutting conceptual elements to be considered when defining the purpose of the legislation include:

- promoting the conservation and sustainable use of biodiversity;
- reacting to concerns over biopiracy;
- promoting food security and agricultural research;
- facilitating community development; and
- promoting equity in natural resources exploitation.

Government-derived aims

National governments' decisions to develop a national ABS framework often take the form of elements of NBSAPs, but may also come from framework environmental laws or executive instructions. In these instances, the

relevant documents or decisions become the basis for the policy development process. However, statutory mandates or executive decisions often lack specificity, and therefore supplementary research to clarify the reasoning and motivations underlying the initial governmental stimulus may be necessary. In such cases, it is necessary to consider other sources of the impetus to create an ABS law, namely technical agencies and special-interest groups.

Technical agencies

Commonly, it is an environment authority that is the technical agency with the most obvious interest in the regulation of ABS, deriving from its usual role as the lead national implementing agency for the CBD. However, protected-areas authorities, agricultural regulatory authorities, public research institutions, universities and other organizations will frequently have strong interests in the content of ABS law. Bad experiences with, or a desire to promote, bioprospection are frequently a motivation for the involvement of such organizations. Such motivation is obviously legitimate, but note that, if their motives have not been critically and fully analyzed, they can be sources of short-termist approaches that may prove prejudicial in the medium to longer term, or may even be counterproductive.

For example, experiences concerning activities that are perceived as abusive often lead to restrictive or burdensome regulatory regimes as a means of stemming the particular activity. However, such an approach can have inadvertent side effects. One such side effect is that the flow of resources is significantly curtailed or stopped completely, along with the research that is dependent on it, and consequently, related local or global benefits.¹ This

effect has been experienced in many fields of technology where excess government regulation has influenced or distorted research paths and agendas.² The second effect is that those seeking access are actually encouraged to avoid or evade the system, as the benefits are outweighed by the burden of compliance. This latter effect is possible in situations where monitoring and enforcement capacities are limited, and can be exacerbated if many actors are not somehow encouraged to perceive avoidance or evasion as 'wrong' because they are accustomed to relatively open access to the genetic resources in question, or because they are not actually breaking one country's law by seeking the resource in another.

Agricultural research authorities are, increasingly, initiators in the development of ABS regimes. The reason for this is that, despite the occasional prominent headlines featuring other sectors, the agricultural sector has what is arguably the longest history of systematically moving genetic resources within and across national borders. This history continues today, with the International Agricultural Research Centres (IARCs) of the Consultative Group on International Agricultural Research (CGIAR) annually providing approximately 80 000 samples—from a total 'in-trust' collection of over 600 000 accessions—from their collections each year. Other collections are also active. During the 1990s, approximately 16 300 samples of ten different crops were distributed internationally each year from collections in the USA. During the same period, the Netherlands distributed approximately 2200 samples per year; the Nordic Gene Bank distributed 1550 samples per year; Brazil distributed 2200 samples per year; and Canada 1500 samples per year,

all internationally (i.e., outside their own borders).³ There is also evidence that, in a number of countries, there are high levels of distributions from *ex situ* collections to researchers, breeders and conservationists.⁴ Crop improvement and regional genetic resources networks also play an important role in facilitating the movement of significant amounts of material. The preservation and promotion of this pattern of exchange was the primary motivation for the development of the International Treaty, which, at the time of writing, had just passed the landmark of its 104th ratification. The entry into force in 2004 of this international framework for ABS relating to plant genetic resources for food and agriculture, expressly designed to be in harmony with and mutually reinforce the CBD, has provided an added stimulus for the development of corresponding national and regional regimes.

Due to differences in the volumes of activity and, very often, levels of capital and profit margins, between the ABS interests of the agricultural and the environmental sectors, these interests are often perceived to be at odds. The agricultural sector tends to prefer a relatively open system with minimal transaction costs, as illustrated by the International Treaty, while the environmental sector tends to prefer an approach based on case-by-case negotiations as a means of maximizing opportunities to capture benefits, as illustrated by the bilaterally-oriented regimes developed by most countries and regions to date. However, this potential conflict only exists if one takes a monolithic view of access to genetic resources. It is quite possible to develop access regimes that accommodate both restrictive and more open approaches according to particular needs. Indeed,

any country that implements the International Treaty while maintaining a bilateral regime for resources other than plant genetic resources for food and agriculture would be doing exactly this. Even prior to the adoption of the International Treaty text in 2001, the majority of countries that had developed ABS regimes had begun to experiment with graduated regimes, most commonly by making distinctions between academic and non-academic applicants. To date, at least three bases for distinctions have been used in different national and international regimes:

- the nature of the applicant, e.g. academic versus non-academic;
- the intended use of the genetic resource, e.g. research, training, or breeding for food and agriculture; and
- the physical nature or category of the resource, e.g. marine versus terrestrial origin, or higher plants versus microorganisms.

Interestingly, despite a trend in legislative drafting to focus on the physical nature of genetic resources in the context of definitions, distinctions based on physical nature and the definitions developed from it were, prior to the distinctive treatment of PGRFA under the International Treaty, the rarest of three options presented here.⁵ These distinctions are not mutually exclusive; for example, the International Treaty refers to PGRFA that are used for the purposes of research, conservation and training. Nonetheless, when blending them in a regulatory regime, one needs to pay particular attention to avoiding either overlaps or gaps that might undermine effectiveness.

Special-interest groups

A wide range of special-interest groups may have objectives relating to the

development of ABS policies and regulatory frameworks. The broad range of public and private sector interests—from plant breeding, to developing pharmacological agents, to pollution control—mean that it is impossible to provide an exhaustive list of the interests and interest groups that may coalesce around ABS regulatory issues in a community, country or region. However, in an attempt to highlight some concerns, three subcategories of special-interest groups are considered here: non-governmental organizations (NGOs), rural communities, and the private sector.

NGO⁶ objectives may have reactive or proactive objectives. Reactive objectives may include seeking to limit perceived irregular access to genetic resources or inequitable benefit sharing, while proactive objectives usually revolve around the enhancement of rural livelihoods through income diversification. It is important to keep in mind that NGOs are not, at least theoretically, special-interest groups per se, but rather they are organizations that are established to represent, directly or indirectly, special-interest groups. Therefore, to adequately understand, or gain a better perspective of, NGO objectives, some understanding of their intended constituency is also often necessary. Even where NGO objectives may not have directly contributed to the decision to develop an ABS framework, it can be rewarding to actively seek their input as early as the point of identification of the objectives of the intended legislation. Depending upon the context and the particular NGO, they can provide information ranging from technical or commercial data to insights on community perspectives and the potential viability of particular mechanisms.

Although NGOs may provide insights on community perspectives, it is also helpful to seek more direct inputs from the communities themselves and, ideally, in all but the smallest countries, this may require some form of local-level consultation. This can be challenging, but direct rural community input into the process of identifying and developing locally sensible objectives of an ABS regime can have the dual benefits of enhancing the perceived legitimacy of the regime put in place and, in the longer run, its enforceability.

Of all types of special-interest group, the private sector is probably the most underestimated in terms of its complexity. Depending upon one's perspective, it is also often the most underrated in terms of its importance for ABS. With the exception of a handful of large-scale, public-sector projects⁷, the private sector is the primary means of generating benefits, in particular financial benefits, from genetic resources. Part of the complexity of private-sector interests derives from the varied applications for which genetic resources may be used. Different applications may require varying levels of capital and technological input, and generate similarly varying profits. In addition, private-sector companies with established interests in genetic resources vary enormously in scale, from relatively small start-ups and natural-product enterprises, to giant pharmaceutical and agrochemical corporations. There can be fundamentally different views between those companies that operate primarily at national or regional level and those that are genuinely global in operation. The private sector is often the most difficult special-interest group to actively engage in ABS policy processes. Private-sector interest in the development of policies or regulatory frameworks usually

focuses on the issue of predictability and efficiency. The clearer and simpler a process for access to genetic resources, and the more certain and defined the rights and benefit-sharing commitments that result from it, the more attractive the situation is likely to be for private-sector investment.

In general terms, the main challenge in engaging special-interest groups lies in the fact that, unlike policy-makers, only occasionally are they concerned with achieving compromise solutions, and tend to view policy development as a zero-sum game between themselves and governmental authorities, who they perceive as either being unduly influenced by other interest groups, or acting as a final arbiter among competing and strongly stated opinions. Of course, not all special interest groups pursue their own objectives with identical strategies, and forms of competition between ideas and interests, leading to a compromise solution, is the philosophical basis of much of democratic policy-making.

Identifying the conceptual scope

Broad-level aims or objectives are usually relatively simple to identify and, perhaps because of this, are often taken for granted. Where there is no more than a simple instruction from a high-level government body to develop an ABS framework, a process such as a SWOT (strengths, weaknesses, opportunities and threats) analysis focusing on ABS regulation in the particular context of the community, country or region concerned may prove a useful starting point. However, whether there is only a simple instruction or more detailed terms of reference to work with, some form of consultation and research process should also be coordinated by the authority developing the law to gather

baseline data of the nature discussed earlier, without which it is difficult (or impossible) to identify relevant and practical objectives. Workshop conclusions or research reports can be useful sources of information, but interviews or small meetings are usually the most appropriate means for identifying actual aims or intended outcomes. Interviews and meetings allow full discussion of appropriateness of the tentatively identified objectives in the circumstances of the community, country or region concerned. It should be noted that several of the most commonly stated broad-level aims in national ABS policies and laws derive directly from international agreements, sometimes verbatim. The most commonly cited international agreements in this regard are the CBD and the subsequent Bonn Guidelines, and, more recently, the International Treaty. In this context, it is important to note that it is not sufficient to simply state that the objective of any national ABS law is to implement international obligations pursuant to the CBD or International Treaty. To do so would be to short circuit the thought process that is required to develop an appropriately tailored regime. Of course, countries have obligations to implement international agreements that they have ratified; at the same time, however, it is clear that the means by which those obligations can be most efficiently and effectively implemented can only be understood by going through a process of examination of the underlying objectives of those international agreements. Therefore, where a handed-down government directive is to 'implement international obligations', it may be necessary to examine the texts or rationales underlying these obligations to accurately identify objectives at the national and community levels.

Example: Seychelles.

Purpose

Promote the conservation and sustainable use of genetic resources.

Provide facilitated access to and utilization of genetic resources.

Limit or prevent access to and utilization of genetic resources other than in accordance with the regulatory regime.

Ensure fair and equitable sharing of the benefits resulting from facilitated access to and utilization of genetic resources.

Component objectives

Identify and know available resources; ensure use is within yield potentials; promote foreign access; promote domestic use and development; restrict irregular or unmonitored access within cost and capacity limitations; enhance domestic capacity for use; ensure domestic access to agricultural resources; maximize overall potential of benefit-sharing options; promote inter-state collaboration; develop, enrich and promote implementation of CBD and the International Treaty.

Information check

To what degree do components of the identified purpose reflect actual national and institutional experiences and aims, as opposed to assumed 'generic' aims adopted from international discourse?

If they are internationally derived aims, how are they reflected at national level?

Step 2. Component objectives within the identified purpose

The second step of the methodology focuses on identifying component or subobjectives of the overall purpose or objective identified in the first step. Where the identification of the overall purpose can be compared with the preparation of the foundations for a house, then the identification of the component objectives may be compared with the plan of that house, or the basic structure of walls and windows: they provide the map and frame the detailed elements of any resulting law or policy, and hence the clearer they are, the more efficient the structure. In addition, the component objectives provide a more detailed view of what the various aspects of any resulting law or policy are intended to achieve.

Component objectives are shaped by national experiences and situations in a

way that the overall purpose often is not. They describe the rationale underlying the larger proposed purpose in more detailed terms and provide the basic 'instructions' for what a policy or regulatory regime should achieve. Component objectives are situation-specific because they focus on significance in a national context and what might be required to satisfy the proposed overall purpose. This is in essence the translation of somewhat abstract political concepts into practical potential actions. Note that some of the most immediately obvious component objectives may require further division into sub-components to provide a reasonably coherent final set of component objectives to be included in the law (and that can be acted upon in the later steps of the development methodology).

For example, for any country adopting 'conservation of genetic resources' as an initial overall purpose or objective, identifying the resources present and information regarding their conservation status is likely to be a

 Example:

Possible purpose	Possible component objectives
Promote the conservation and sustainable use of biodiversity	<ul style="list-style-type: none"> • Prevent depletion of diversity of genetic resources. • Facilitate income-generating projects based on genetic resources. • Inventory genetic resources.
Promote food security and agricultural research	<ul style="list-style-type: none"> • Prevent erosion of the diversity of farmers' varieties of key crops. • Facilitate access to broad diversity of genetic resources for key crops. • Promote access to technology and training.

primary objective. However, at the level of component objectives, the country-specific question of the scope and quality of existing taxonomic and status data becomes relevant to deciding whether the component objective becomes to further develop data collection, to improve the coordination and analysis of existing data, or simply to ensure that the implementation of ABS policy is tightly linked with authorities generating and monitoring data that are already adequate.

Similarly, any country that identifies 'agricultural research' in the form of traditional plant breeding as an initial overall purpose might have maximizing access to a diversity of germplasm as a primary objective. At the level of component objectives, this might translate into a need to ensure accessibility to information regarding germplasm available in the country, to further the development of existing collections and breeding programmes, or to facilitate access to exotic germplasm.

The component objectives in these examples are not mutually exclusive. Some countries might wish to include all the component objectives (and possibly others) included in the examples above.

The principle idea behind step 2 is that of moving from the general language of an intention or instruction,

or its primary objectives, to a more specific definition of what an ABS regime is intended to do. As with step 1, some component objectives may be readily available from existing policies or decisions, such as NBSAPs or policies for the implementation of the Global Plan of Action for the Conservation and Sustainable Utilization of Plant Genetic Resources for Food and Agriculture (GPA). However, even where this is the case, some form of analysis is recommended to ensure that component objectives fully reflect nationally-determined priorities—priorities that may go beyond the scope of NBSAPs or the GPA.

It should be recognized that, as noted in step 1, the process of identifying component objectives can be variably complex, depending upon the level of detail provided by the terms of reference for the framework-development exercise. In countries where the initial terms of reference are relatively specific, the concepts of primary and component objectives as discussed here could be almost synonymous, but where the starting point is more of a generalized statement or non-specific directive, detailed analysis and consultation becomes desirable, if not obligatory.

There are two fundamental questions when identifying component objectives.

The first question is whether the needs of different sectors or types of genetic resource lead to different component objectives. The clearest example of this situation can be found in the 1997 Nairobi Declaration's recognition that the provisions of the CBD did not adequately address some aspects of the needs of the agricultural sector, leading to the subsequent negotiation and adoption of the International Treaty. Mirroring this development at the international level, a number of countries, such as Uganda, have or are engaged in closely related, but nevertheless distinct, processes of developing policies for PGRFA and for genetic resources more generally. Since both the CBD and the International Treaty are going to be almost universal in acceptance, it will be necessary for all countries to consider this issue. Most ABS regimes developed to date have recognized a division between the academic and commercial sectors as users of genetic resources. The Seychelles government is currently considering a national ABS law that has four different categories of genetic resource identified—all of which require individual component objectives.

The second question that should be considered in the development of component objectives involves 'double checking' tentatively identified component objectives against the overall purpose. This involves analyzing

whether all of the elements of the overall purpose have in fact been reflected in greater detail in the component objectives. If not, perhaps they have simply been overlooked, and should be further developed. Alternatively, this is possibly a sign that at least some elements of the overall purpose are not practical enough to be reflected in more specific language; in short, these are rogue elements of the overall purpose that have been included more because of their rhetorical or political appeal than their potential guidance for what the instrument is meant to do. If such is the case, despite the rhetorical appeal of those elements, they should be dropped from the overall purpose. They will only add confusion—and possibly build unrealistic expectations—in the longer term.

Having undertaken this analysis, one should then reverse the process and review the identified component objectives in terms of the overall purpose. The basic things to ask here are whether there are identified component objectives that do not fit comfortably with at least one element of the purpose, or whether there are additional component objectives that you would like to introduce but that do not appear readily to fit into the proposed purpose. If the answer to either of these is 'yes', then a return to step 1 and a further review of the overall purpose is warranted.

Information check:

Do your component objectives match the full scope of your purpose? If not, are there additional component objectives that might be considered?

Have you developed component objectives that are beyond the original scope? If so, should the original purpose be revisited?

Have you considered the interests of the various sectors and stakeholder groups that may have an interest in, or be affected by, ABS systems, including environment, agriculture, fisheries, forestry, health, science and technology, private sector (e.g. pharmaceuticals, pesticides, agrobiotech, industrial chemicals), and indigenous and local communities?

Example: Seychelles

Primary objectives:

Identify and assess knowledge of available resources; ensure use is within yield potentials; promote foreign access; promote domestic use and development; restrict irregular or unmonitored access within cost and capacity limitations; enhance domestic capacity for use; ensure domestic access to agricultural resources; maximize overall potential of benefit-sharing options; promote inter-state collaboration; develop, enrich and promote implementation of CBD and the International Treaty.

Component objectives:

Marine—Increase knowledge; regulate and monitor; guarantee minimum rights; promote and monitor access; identify (taxonomy and passport data); ensure financial benefit sharing only in the event of commercialization.

Agricultural—Facilitate access to exotic germplasm; develop local collections; promote access to foreign resources by Seychelles (user measures?); promote development and use of local collections.

Endemic terrestrial—Strictly regulate access and use; generate revenue; maximize protection; control access; maximize benefit sharing; promote academic and commercial research.

Non-endemic terrestrial—Promote use to generate benefits through volume; promote research and access, and in general maximize benefit sharing on a volume basis.

Step 3. Baseline information

Baseline information refers quite simply to the on-the-ground social, cultural, economic, scientific, political and legal data and information that provide a basis for informed decision-making in a particular community, country or region. It is the qualitative and quantitative information that, in the ideal scenario, should form the basis for a government's decision to venture into the process of developing an ABS regime in the first place. As a fall-back position, information gathering and analysis is an integral component of refining the overall purpose and its component objectives (and subsequent steps in the development of ABS legislation) once a team has received its marching orders from higher political levels to develop a law. Baseline information should allow decision-makers to consider and define the overall goal or general purpose and the related component objectives of a policy or legislation in terms of specific mechanisms or actions that reflect the reality of the needs and interests country or region.

In many situations, because either data and information are not available in a processed form, or because they have never been collected, systematized and analyzed, the decision-making relies more on abstract political or ideological objectives than on scientific data. This has a direct bearing on the probable eventual effectiveness of policies and legislation, because purposes and objectives not founded on a situational analysis of the country or region, or where they exist in an abstract context, are likely to be, or to rapidly become, redundant. Analyzing existing information, and acquiring new baseline information where gaps exist, is probably the issue that most clearly reflects the point made in the introduction that the steps presented in this document are not necessarily sequential. Almost all of the steps require some form of information gathering to be fully effective. In addition, although the process and methodology of identifying the purpose and setting component objectives may vary among communities, countries and regions (i.e.

some may decide to set a policy goal and objectives *a priori*, and then assess the available baseline information; others may decide to undertake a baseline information analysis prior to defining a policy goal and objective), the process of gathering and considering baseline information remains critical.

Part of the information gathering process may be served by established methods of analysis, such as PEST (political, economic, social, technological)⁸. However, PEST analysis, focusing on the general nature of environments in which one intends to operate, is usually accompanied by two further steps. One is an analysis of relevant environments and, in the current context, this means the collection of information directly relating to the elaboration and assessment of component objectives. The second step is an internal analysis of the levels of political will, institutional capacity, and possible budgetary support. Furthermore, understanding the past, present and likely future patterns of the local supply of genetic resources to domestic and foreign users, and conversely the domestic consumption of foreign genetic resources is critical. Experience suggests that these patterns of the exchange of genetic resources vary significantly between sectors and, often, between actors within a given sector. If one seeks to create a supportive environment for continued and higher levels of exchanges, it is probable that the objective and constituent elements of the legislation will differ from those aimed at prohibiting existing patterns of access or supply. In terms of internal analysis, it is useful to have a reasonable idea of the capacity of the country to make use of the technologies associated with access, and potential products. For example, the technologies associated with some aspects of industrial enzyme

development probably will not be of more than marginal benefit to many developing countries, and the products are unlikely to have any fundamental economic or social significance. In contrast, many of the products of agricultural research, particularly where this research targets a developing country context, can be immensely beneficial. As clear as these examples might seem, one should exercise caution in making any generalizations. Cutting-edge biotechnology approaches in pharmaceutical development could lead to solutions for severe threats, such as HIV/AIDS or malaria, and developments with enzymes have significant potential for environmental protection, while many innovations in agricultural research may only be relevant to large-scale, high-input farming and therefore not a high priority for smallholder-dominated agricultural economies.

As stated earlier, the purpose and objectives of the legislation will turn on existing information about ongoing patterns of supply and uses of genetic resources, and the probability that a policy intervention in the form of a tailored ABS law will produce the desired readjustment of behaviour. At the same time, the kind of information that might be required, or that might be useful, may also depend upon the component objectives that have been identified. For example, issues relating to the nature and volume of activity can be perceived quite differently depending upon whether one is asking in the context of seeking to limit or control irregular access, or as a means of targeting scientific fields for domestic development. To determine what information should be sought, one can begin by considering each component objective in the light of questions such as:

- What sorts of activities are likely to be associated with the component objective? In this context, it is important

to consider the country's situation both as a provider and as a user of genetic resources.

- What types of genetic resources do the activities relating to the component objective affect or involve?
- To what degree are likely activities, by their nature, directly or indirectly beneficial or prejudicial at local, national, regional or international levels?
- What sorts of actors have, or may in the future have, an interest in likely activities?
- What sorts of technologies are associated with likely activities and to what degree do these exist or constitute a national priority in the country?
- What is the relative level of endemism of the genetic resources involved, and are there other potential sources for the same or similar material?
- Where are the types of genetic resource likely to be of interest most commonly found in geographical and legal terms, e.g. protected areas, public land, private land?

Ultimately, it is not really possible to predict all the specific questions one might need to ask as their nature and relative significance will vary on a case-by-case basis. However, one should be sure to think in terms of what information might be needed to make a reasonably informed decision as to how to proceed with a given component objective.

Information gathering can be as simple or as complex a task as the available resources and time allow. As much as the absence of an information gathering process may prejudice future outcomes, it must also be recognized that there is probably a point at which further information gathering would produce proportionately fewer returns in substantive inputs, a fact that needs to be respected given that most policy-makers

do not have the time or financial resources to dedicate to digging up exhaustive data sets. A more thorough information gathering process usually pays dividends, but where this is not possible, a shorter, more ad hoc, approach could provide a minimum that might be acceptable. Even such a minimalist approach should, however, include contacts with relevant national and international agencies, as well as with NGOs and, where possible, private-sector actors representing different genetic resources interests. These contacts do not necessarily have to be in the form of workshops but could be based on smaller meetings or interviews. Where this is not possible, the views of different organizations can sometimes be discerned from their Web sites. This direct contact should be supplemented with some form of literature review that includes consideration of the content of debate in forums such as the WIPO Inter-Governmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC)⁹, the CBD Ad Hoc Open-ended Working Group on Access and Benefit Sharing¹⁰ and the FAO Commission on Genetic Resources for Food and Agriculture.¹¹ In addition to simple information about their activities, the Web pages of these forums also generally provide quite extensive background information in the form of technical papers and reports.

Wherever possible, it is recommended to have a range of professional disciplines involved in the collection and review of information. The broader perspectives can be valuable, as can the fact that a multi-disciplinary team will be probably have a wider range of contacts and be aware of a wider range of activities and information sources.

There are two final points regarding information gathering.

First, one should be aware of the possible time frames associated with policy-making processes. Awareness of the time frames associated with the different options influences how much information gathering is possible. The following estimates are not written in stone, but they approximate to those commonly used as rules of thumb in legal drafting.

- In the case of a simple policy statement, one should be aiming at a period of relevance of at least five years, given that such an instrument is a statement of intention more than a binding commitment and can be relatively easily amended or superseded should the need arise. This means that a policy statement can be largely based upon an understanding of current and historical dynamics in the field, with only limited concern for future developments, which can be reacted to as and when they arise.
- Where a more formally adopted policy statement or subsidiary regulations are under consideration, the relevant time frame for relevance should be extended to at least 10 or 15 years. This type of instrument is, depending upon the prevailing political circumstances, somewhat more difficult to amend than a simple policy statement and is more binding upon those it regulates, with consequently greater impacts.
- If the outcome of the policy process is primary legislation, then a time frame of at least 25 years is most appropriate. Legislative instruments are, almost universally, complex things to amend or repeal and have the most definitive impacts of all the possible options. ABS, because of the rapidly evolving technologies of the life sciences associated with it, is dynamic and therefore any legislative instrument should be based on a sufficiently sound understanding of current trends and

patterns to allow for their reasonable extrapolation into future expectations.

Another point is that information-gathering activities should not only inform the policy-making process but also provide a framework for some of the outcomes of that process, particularly where one is considering legislation or subsidiary regulations. Some means of monitoring and analyzing the nature and volumes of activity, patterns of applications and values, and similar evolving activities will probably be a fundamental element in any long-term framework, as a basis for its being able to adapt to changing circumstances. Such monitoring and analysis requires a mechanism that can link different agencies and interested parties, and will not be effective unless it is supported by sufficient human resources to allow proper interpretation and application.

By this point, at the end of step 3, the overall purpose and component objectives of the ABS legislation should be clearly stated and their underlying rationale well understood. These are probably the most critical elements of this methodology, and the more time devoted to them, the better. If things are not completely clear, or members of the working group involved are not comfortable with the conclusions reached¹², then it is wiser to go back and review the issues in question, rather than proceed.

It is useful to note that the thought processes underlying, and decisions made in, step 2 can provide the bulk of information required for a basic policy statement on access to genetic resources, whether this is intended as a stand-alone document or as a supporting explanation of what is intended in the implementation of another instrument.

Possible objectives†	Type of baseline information required
Prevent depletion and erosion of genetic diversity	<p>Where is genetic diversity geographically most concentrated in the country or region, and what are the main activities (who are the key actors?) affecting or influencing these areas?</p> <p>How valuable are genetic resources in these areas?</p> <p>What are the underlying factors for undertaking activities affecting genetic resources (economic reasons, social pressure, perverse incentives (what type?), limited awareness of value of genetic diversity and biodiversity in general, tradition)?</p>
Facilitate income-generating projects based on genetic resources	<p>How will regulating access to, and benefit sharing concerning, the target resources affect their depletion?</p> <p>What types of genetic resources are found in the country (and within the region) and what are they used for?</p> <p>Who (institutions, scientists, entrepreneurs) are engaged in projects making direct and indirect use of genetic resources in the country?</p> <p>What is the commercial demand for genetic resources from the country or region?</p> <p>What are the predicted financial benefits to be gained through the operation of the ABS legislation?</p>
Prevent genetic erosion in local and native varieties	<p>What genetic resources are reflected in local and national consumption patterns?</p> <p>What are the main causes for genetic erosion of local and native varieties?</p> <p>What type of incentives (fiscal, administrative, economic?) do small-scale farmers (especially those who conserve diversity) have to conserve and market local and native varieties?</p> <p>What is the level of awareness among the public, decision-makers, etc., about the social, cultural and economic importance of local and native farmer varieties?</p> <p>What are the most threatened varieties and where are these threats most acute?</p> <p>What are the threats?</p> <p>How will regulating access to and benefit sharing concerning the target resources affect their depletion?</p>
Ensure access to a broad diversity of genetic resources for breeding crops of national importance for food security	<p>What type of R&D is being undertaken in the country (region) with regard to genetic resources? How dependent is that research on genetic resources located within the country concerned? In other countries?</p> <p>What are the main legal and administrative burdens that might affect possible access to genetic resources of importance for food and agriculture or other uses?</p>

NOTES: † Either complete in themselves, or objective components as elements in the more general purpose, goals or objectives.

Part II: Identifying the basic framework

This Part focuses on identifying the changes that any ABS law needs to be able to effect in order to achieve its purpose and component objectives. This exercise is divided into three steps, being steps 4, 5 and 6 of the overall process. Step 4 consists of identifying the prerequisite institutional capacities and behaviours of people at community, national or regional levels that are necessary for the purpose and component objectives to be realized. These capacities and behaviours are referred to as 'prerequisite conditions,' or 'preconditions' throughout this section of the text. Step 5 consists of identifying existing gaps between the preconditions (or ideal state of affairs) identified in step 4 and the actual situation on-the-ground in the community, country or region concerned. Step 6 involves analysis of:

- the elements of policy or legal interventions that would be necessary to close the gaps identified (to create or promote the prerequisite conditions);
- whether those interventions can be reasonably included within ABS laws; and
- whether there is a reasonable chance, given the resources available within the community, country or region, for those interventions to succeed.

Step 4. Institutional capacities and human behaviours that are prerequisite conditions for achieving component objectives

Once a set of component objectives has been established one should look to identify the preconditions that need to

be in place to achieve those component objectives. The following two examples illustrate, in a simplified manner, the link between purpose, component objectives and necessary preconditions.

Example 1. Preventing erosion of diversity in forest genetic resources

The component objective of preventing the depletion of the diversity of genetic resources is one possible element of the overall purpose to conserve and sustainably use biodiversity. Assume that, in a given country, an assessment of baseline information reveals that the major threats to the national diversity of genetic resources are the loss of forests due to land conversion, and unsustainable extraction of medicinal plants for local use. However, also assume that forest genetic resources provide options for income diversification among forest-adjacent communities and that medicinal plants are a major source of primary healthcare for the rural poor.

One way to prevent the loss of forests would be to limit land conversion. Another (potentially complementary) way would be to create incentives to conserve the forest by allowing local peoples to gain benefits (e.g. money, technology transfer, inclusion in research projects, training) in return for supplying genetic resources gathered from the forest. Income diversification options that forest genetic resources offer can be both a threat, through stimulating unsustainable extraction, and an opportunity, in terms of demonstrating the value of forest conservation to the neighbouring communities that may constitute the most likely source of both threat—through their overuse of the resource and conversion of the land to other purposes—and opportunity—through gaining benefits from the supply of resources and sharing their associated specialized knowledge

about those resources. This would suggest that some form of managed access to forests, or to forest genetic resources, and possibly the traditional knowledge of local peoples concerning those resources, might be a pragmatic alternative to simply banning land conversion through legislation.

Just as strictly banning conversion of forest land is probably the most direct means of preserving forests, so the most obvious means of stemming a decline in medicinal plant populations is to simply limit access to those populations and absolutely prohibit their collection and use. As a sole approach however, this may not be terribly effective, as preventing access to a resource that is considered a necessity is likely to be met by efforts to circumvent or ignore the prohibition and could require policing resources that are not available. A less restrictive limitation that facilitates a minimum level of access has a far higher chance of success, combined with efforts to boost awareness of conservation imperatives and to boost supply through socially acceptable alternatives, such as inventorying to define the resource size and biologically sustainable exploitation level, and the establishment of nurseries to provide alternative supplies. Thus one precondition for the success of the objective of preventing depletion of the genetic diversity of the population would be that systems are in place to control access for limited harvesting of the resources, in particular areas, for particular uses and by particular users. These limitations could be adjusted in response to changes in the level of threat of genetic erosion of the resource in question. Another precondition would be that local peoples are able to gain benefits—monetary or otherwise—through sustainable harvest and supply of genetic resources.

Example 2. Gaining access to plant genetic resources for food and agriculture

The component objective of accessing a broad diversity of genetic resources for key crops is a possible element in the overall purposes of promoting food security and agricultural research. The assumed baseline parameter is that the breeding programme of the country in question makes significant use of crop germplasm from international collections and other countries. The country also has minimal locally available diversity to support its research priorities. One fairly clear precondition for the realization of the component objective would be facilitated access to exotic germplasm.

Preconditions should be identified from consideration of component objectives, in the context of relevant baseline information. This helps identify those precondition of direct relevance.

When conducting this exercise in practise, the range of possible preconditions will be far greater than those presented here, reflecting the diversity inherent in the real-world situation and the range of different purposes and objectives of ABS law. Going through this step, it is likely that some preconditions will be identified that relate to more than one component objective. This outcome is fine; in fact, it indicates that those objectives in particular are 'in synch' with one another and that they can probably both be advanced simultaneously through the same form of policy intervention (a subject discussed in subsequent steps). Going through this step, it is important to maintain a direct line of causal connection between the requisite preconditions, the overall purpose and the component objectives. Approaching the identification of preconditions as an abstract exercise, or in relationship to the totality of the component objectives,

Examples

Possible component objective	Baseline Information	Possible preconditions
Prevent depletion of diversity of genetic resources.	Level of threat to forest diversity as a result of land conversion	Limited land conversion
	Forest genetic resources present an option for income diversification	Managed access to forests or to forest genetic resources
	Medicinal plant populations declining due to unsustainable local use	Limited access to, use of, medicinal plants
Facilitate access to a broad diversity of genetic resources for key crops	Rural communities are significantly dependant on medicinal plants for primary healthcare	Inventories and conservation programmes for medicinal plants
	Extent and significance of inflows and outflows of germplasm of different varieties and species in support of breeding programmes	Facilitated access to foreign germplasm
	Extent of local collection and conservation	
	Key crops listed in Annex I, FAO Treaty	Being a member country of the International Treaty, able to take advantage of the Multilateral System of Access and Benefit-sharing it creates

is likely to undermine the logic that the methodology is intended to promote, and thereby undermine its ultimate effectiveness.

Step 5. Gap analysis: which preconditions are unmet?

Step 5 consists of assessing the current true status of the institutional capacities and human behaviours that have already been identified as preconditions for the realization of the overall purpose and objectives. The output from this step should be a list of currently unrealized or unmet preconditions, or put another way, the gaps between the ideal state of affairs wherein the objectives of the law could be realized and the reality of the

situation on the ground in the countries concerned.

Step 5 is a natural extension of step 3, in that it consists of information gathering. However, here the need is to assess the current status of an identified precondition. Unlike the somewhat broad scope of investigation that is required in step 3, the need here is for research that specifically focuses on the institutional capacities and human behaviours that have already been identified as preconditions.

Qualitative information can be as important as quantitative in this instance. This means that while clear pieces of information that can be objectively assessed, such as the existence or otherwise of relevant legislation, should be used as a starting point, more qualitative information, such

as the levels of their implementation or effectiveness should be actively sought. Qualitative data of this nature is particularly critical, as it assists analysts to distinguish between theory and practice; it is however, data most overlooked in the field. This is partly because it is usually more difficult to collect than quantitative data, influenced as it may be by the beliefs and opinions of the individuals providing and analyzing it.

Step 6. Policy interventions to achieve change

Elements of potential policy or legal interventions

Having determined what gaps exist and need to be filled in Step 5, attention in Step 6 turns to an analysis of policy and legal interventions available for filling them. The identification of options for achieving change should be firmly rooted in reality. The ongoing gathering and synthesis of community-, country- or region-specific information clearly plays an important role in this step.

Where a particular means of achieving a change seems immediately apparent, an effort should be made to identify alternatives, as, even where these are ultimately rejected, they can prove useful for comparing and contrasting, and their consideration will generally inform decision-making. In common with most, if not all, policy and regulatory frameworks, one should consider both 'carrot' and 'stick' options. Just as, at its strongest, the law establishes offences and penalties as a means of discouraging activities, it also creates incentives where appropriate for what is understood as 'correct behaviour'. ABS laws should

combine both approaches. Preventing irregular access is an objective of many ABS laws; at the same time, ABS laws may also try to preserve or promote access. Concern about enforcing benefit sharing should not obscure the underlying fact that, access is required for benefits to be generated. Therefore, the aim is to encourage those who might engage in irregular access to move to an accepted, regularized process that incorporates benefit-sharing measures. This will require penalties to raise the risks associated with irregular activity, at the same time as the creation of a system for regular access that is sufficiently easy to render unattractive the taking of the risk associated with non-compliance.¹³

Again, it is impossible here to consider all of the elements that could be included in an ABS law to create or promote the prerequisite conditions for the realization of the objectives and purposes identified in the previous steps. However, a few such elements are discussed in the examples below.

Can the interventions identified reasonably be included within ABS policies or legislation?

Once a range of options for achieving change has been laid out, two further issues must be considered. The first issue, addressed in this subsection, is whether the changes that need to be made can be reasonably addressed within the context of an ABS policy or law.

The second issue, considered below, follows from the first: if indeed the change is one that can be reasonably included in an ABS law, are there resources available within the country concerned to actually implement the law or policy. A common problem that has undermined a number of ABS regimes is that efforts have been

 Examples of elements of potential policy or legal interventions

Possible preconditions	Gap analysis	Elements of potential interventions
Limited land conversion	No clear demarcation of land use status No effective limitation on excision of forests land Existing rules frequently ignored	Scheduling or zoning of land uses Enhanced protection of forest land Enhanced enforcement and penalties for irregular conversion
Managed access to forests or to forest genetic resources	Access to forests either unrestricted or prohibited	Introduction of permitting system allowing limited access for individuals or groups for stated purposes
Limited access to or use of medicinal plants	No system of enhancing availability of popular plants to relieve stress on wild populations	Amend mandates of relevant lead agencies to include propagation of medicinal plants
Inventories and conservation programmes for medicinal plants	Currently absent or fragmented among diverse agencies	Amend mandates of relevant agencies to promote activity or to establish coordination of efforts
Facilitated access to foreign germplasm	Absence of agreements to support regional or international exchange of germplasm other than case by case	Create structure for establishment or membership of crop networks Promote regional cooperation in germplasm conservation and research Ratify and implement International Treaty on Plant Genetic Resources for Food and Agriculture to guarantee access at international level

made to 'bend' such regimes to address issues that do not fall within its natural scope, such as problems associated with enforcement of protected areas regulation or natural resources extraction. Ineffective enforcement of protected areas should be addressed directly, rather than by using ABS as a proxy. Similarly, an inability to capture what are perceived as equitable, or indeed any, benefits from natural resource extraction often leads to efforts to restore balance through ABS mechanisms.¹⁴

In discussion of step 4 above, there was discussion that the best means of preventing erosion of forest genetic resources would be to prevent the

conversion of forest lands to alternative uses. This kind of legal intervention, for example, would be outside the scope of an ABS law.

Resources/capacity for implementation

If, in fact, the intervention considered could be included in any access legislation, it is equally important to assess whether there is any chance of actually achieving the change desired, given the resources available, history of cooperation between the constituent groups affected by the legislation, the enforcement agencies, and so forth.

 Examples of relevance of elements to ABS

Elements of potential interventions	Relevance to ABS
Scheduling or zoning of land uses	No relevance—land or planning law
Enhanced protection of forest land	No relevance—forest law
Enhanced enforcement and penalties for irregular conversion	No relevance—land, planning or forest law, or, perhaps, general penal code
Introduction of permitting system allowing limited access for individuals or groups for stated purposes	Potential element of an ABS regime—an ABS policy might either allow for or limit such a system or could even be used to establish it.
Amend mandates of relevant lead agencies to include propagation of medicinal plants	No relevance—addressed in parent legislation of agencies, although aspects of benefit-sharing policy in an ABS policy could be directed to support this role
Amend mandates of relevant agencies to promote activity or to establish coordination of efforts	No relevance—addressed in parent legislation of agencies, although aspects of benefit-sharing policy in an ABS policy could be directed to support this role
Create structure for establishment or membership of crop networks	Possible element of ABS regime—should, at least, be allowed for by ABS regime
Promote regional cooperation in germplasm conservation and research	Possible element of ABS regime—could be promoted by ABS regime by providing for recognition
Ratify and implement International Treaty on Plant Genetic Resources for Food and Agriculture to guarantee access at international level	Possible element of ABS regime—implementing measures for ITPGRFA could be incorporated with broader ABS measures

This process of assessment can be complex, particularly as some of the criteria against which a potential intervention needs to be assessed would be community, country or region specific. Other criteria may be relatively common across a range of countries, although their relative significance may vary according to circumstances. For example, different countries are likely to have different levels available of technical skills, financial resources, scientific infrastructure or enforcement capacity, even though these factors are likely to be relevant in all cases. In identifying criteria against which the potential success of an element might be assessed, one should try to consider all of the local factors that might determine whether that option will succeed or fail in the particular context. One should, of course, try to think of the

advantages that options may present, but particular effort should be made to identify disadvantages. There is a natural tendency to favour particular options, for reasons that are as varied as the options themselves, and the easiest way to neutralize this tendency is to adopt a consciously critical approach to all options.

As much as the process of assessment may be complex and the criteria of assessment often case specific, some criteria are fundamental and will exist to varying degrees in all situations. Such basic criteria likely to be relevant to the assessment of options include:

- What is the cost of implementing each particular element of the regime, and of the regime as a whole? What human resources would be required to implement (and enforce) the regime? How much of a challenge is it

to monitor people potentially leaving the country with genetic resources that they do not have the right to access? Are there resources to support the necessary presence of border enforcement to ensure acceptable levels of overall compliance?

- Will local people cooperate constructively with government on implementing the policy or law?
- Is the approach of the law or policy consistent with the prevailing customs and beliefs of the people most affected by it, and of those expected to participate in its implementation?
- Is there a commercial market (locally, nationally or globally) for the genetic resources within the community, country or region to which the legislation restricts or prohibits access? Could the funds raised underwrite the costs of effectively implementing the law?
- Are the genetic resources most threatened by erosion useful in any way to local people?
- Do the benefits to be obtained through the operation of the legislation outweigh the costs of its implementation?
- What are the likely impacts on and interests of different stakeholders and sectors? This relates closely to and will probably significantly overlap with questions of risks and benefits.
- Does the legislation create any inadvertent, so-called perverse, incentives for people to engage in behaviours with a negative impact?
- What form of intervention would be required? Some options may only require a policy statement or the publication of guidelines, whereas others, particularly where the establishment of penalties is involved, will require more robust legal force. As a general principle, the lowest level of legal force necessary for the purpose

should be adopted. (The issue of what form of policy instrument is considered again in Part III below.)

The ultimate aim of the critical assessment is to divide the options for achieving change into the rough categories of yes, no or possibly. Those that are clearly viable, and those that might be, can be carried forward, while those that are clearly unacceptable can be rejected after review.

Where it appears that options are unacceptable, it is advisable to revisit the component objective and consider whether it can still be considered either valid or achievable. If it can, one should repeat steps 4, 5 and 6 to determine if an alternative, more acceptable, set of options for change can be developed. If it appears that no acceptable alternative options are available, and the component objective in question is fundamental to the fulfilment of the overall purpose, it may be necessary to go all the way back to step 1 and reconsider the overall purpose itself. While this may involve costs in terms of time and resources, the effort should not be considered wasted, as the development and analysis of different options, even if subsequently rejected, usually increases understanding of the dynamics impinging on options that may ultimately be adopted.

Step 7. Reconciliation and prioritization of options for change

At the end of step 6, one should be left with a series of sets of options for potential policy and or legal interventions that have been determined as being both practical and politically feasible. However, at this point, these options are isolated and parallel, rather than coordinated into the larger overall strategy required for

an effective law or policy. Step 7 seeks to address this situation by focusing on the relationships among options for change, both individually and collectively.

The first element in this step is to re-group the options remaining at the end of step 6 according to their role or function, (as opposed to the earlier groupings based on component objectives). The basic types of role or function are relatively common to policies or law in any sector, e.g. to create rights or obligations with the intention of restricting or promoting particular behaviours, and to provide processes for the administration and regulation of those rights, responsibilities and behaviours. The most fundamental functional groupings are considered below.

Restrictive measures

In the case of access to genetic resources, restrictions usually exist in the form of requirements that specified activities be licensed or permitted according to some combination of fixed and variable terms and conditions. The most restrictive regimes tend to emphasize variable conditions that are the subject of negotiations between applicants for access and multiple actors with defined roles as providers. Such regimes tend to be the most restrictive for two reasons. First, the transaction costs involved with such complex negotiations are generally high, particularly because of the often varying situations of the different actors, which requires significant effort to accommodate. Second, the involvement of these different actors is usually motivated by the potential to capture benefits, thereby multiplying the cost of terms and conditions.

The fact that high transaction and agreement costs increase the incentives

for avoidance or evasion of the system often leads to more restrictive approaches to the eligibility of applicants, the application process, terms and conditions and the monitoring and enforcement of those terms and conditions. This scenario is frequently exacerbated by the fact that access to genetic resources often involves transboundary transactions and asymmetrical relationships in terms of information and economic influence.

Less restrictive regimes generally follow one of two basic patterns.

One is to leave the entire process in private hands, usually allowing access negotiations to regard those holding tenure of land as the providers of the resources found on that land and subjecting the relationship to the standard provisions of contract law. Such an approach is likely to favour the interests of those seeking access, due to the fact that the bargaining power of individual holders of tenure is limited. As such, it is most commonly adopted, usually as some form of policy statement, in relatively developed countries, where the value of research and commercialization is placed above that of the value of the raw materials that support that research and commercialization. Another feature of this approach is that what transaction costs there are largely accrue directly to the parties, with the remainder being borne by the judicial system in the event of a dispute.

The second common pattern among less restrictive regimes is the use of largely standard terms and conditions and focal points for the granting of access. Such an approach depends upon a collective approach to negotiations, usually through a government-established administrative mechanism. It has the advantage of mitigating asymmetries in relationships and, potentially, of maximizing the value of

genetic resources, whether by enhancing bargaining power or, more often, by limiting transaction costs and the range of actors involved in benefit sharing.

Promotional measures

The promotion of activities in the context of ABS generally mirrors the restrictive aspects of regimes, in that the provision of a simple and predictable framework, that allows for reasonable calculations of risk, is the most common and effective incentive. Other efforts at promotion usually revolve around questions of capacity and infrastructure, with the case of InBio in Costa Rica being perhaps the best known example. InBio has used ABS as an opportunity to develop its scientific capacity and this capacity has, in turn, probably acted as an attractant for further access requests due to the quality of local partnership and assistance.

Terms and conditions

The above discussion of restrictive and promotional elements touches on a number of the other themes or functions that should be considered. The methodology should produce at least some specific terms and conditions to be attached to the grant of access. These terms and conditions may be a 'pre-packaged group', such as those developed under the International Treaty, or may be more varied, having been developed for the specific case in question in other sectors. The two main areas that should be considered in the context of terms and conditions are those that relate to the monitoring and enforcement of terms and conditions, and those that relate to benefit sharing. The former tend to be relatively precise while, in the most effective regimes, the latter tend to

be more flexible, highlighting principles and desired strategies rather than fixed requirements, although combinations of basic administrative fees with other more flexible options are common.

Administrative measures

Options for change that relate to administrative processes and structures can play a critical role in the relative efficiency of a framework and should be carefully considered. Clarity and transparency are the main considerations, but concentrating capacity and decision-making can also be advantageous. At a more practical level, budgetary issues can be a determining factor. Complex systems requiring detailed negotiation and subsequent monitoring and enforcement will need skilled human resources and significant funding for implementation. This highlights the fact that, in identifying administrative options, one should consider both process- and capacity-related issues.

Monitoring and enforcement

Questions of enforcement are fundamental to most legislative regimes and are also a consideration in other policy frameworks. Enforcement is commonly understood as relating to offences and penalties, but, in practice, can be significantly broader, with offences and penalties only representing the strongest possible measures in the spectrum. In identifying options for change, other means of enforcement, in addition to the general pattern of incentives and risks discussed above, should have been identified. These will probably relate to monitoring, but could also relate to other areas, such as benefit sharing, where the establishment of a framework that encourages cooperation can be as,

or even more, effective in enforcement than nominally stronger measures. Somewhere in between these very hard and soft options lies the consideration of alternative dispute resolution, whether consisting of some form of mediation or arbitration, or both. The introduction of such mechanisms can be particularly useful because of the international character of many access to genetic resources relationships, where recourse to judicial systems can be expensive or impractical, and may also help in the maintenance of relationships.

Information

The issue of information is a less obvious category than the others mentioned here, but is probably one of the most important, and certainly constantly relevant. Even in a regime that is based on private transactions, the availability of information is a critical factor. As noted earlier, the step of gathering baseline information is not only an ongoing process throughout this methodology but also something that may need to be built into the operational structure of any regime.

Prioritization

The categories considered may well interconnect on various levels. However, having precisely defined, mutually exclusive categories is not necessary, provided that there is sufficient coherence for the purposes of analysis. The basis of this analysis is to consider the relationships both within and between groups, including both their positive and negative aspects.

The purpose is to identify opportunities to rationalize the number of options remaining by merging them wherever possible. One should

therefore be looking for options that are of a complementary or otherwise compatible nature or that may involve similar powers. Consolidating them to the degree possible will still serve the purpose of streamlining the pattern of options.

The basis for dealing with any contradictions or other incompatibilities should be the prioritization of options for change and the exploration of possible compromise solutions.

Prioritization facilitates the adoption or rejection of options, but also provides a focus for considering how to link the different options and where to concentrate efforts that involve significant resource demands. The prioritization exercise will again involve referring back to the component objectives and overall purpose that underlie the possible legal and policy interventions. It may be necessary to consider rejecting some options where these clearly conflict with others of a higher priority, but this should be considered as an extreme option. In the majority of cases it is more likely that some form of a compromise solution can be developed.

The most obvious of such compromise techniques in regimes developed to date is that of 'segmenting' the system in some manner. This is usually in terms of either using different approaches with different actors, such as academic versus commercial, or for different uses of resources, such as agricultural versus pharmaceutical or chemical. Distinctions can also be made on the basis of geography, such as resources found in marine versus terrestrial environments. The advantage of segmentation is that it allows for more- or less-restrictive or open approaches according to circumstances. One risk is that having entered into this segmentation approach, some areas will get left out inadvertently

as a result of not adequately defining the demarcations between different segments, thereby creating loopholes or ambiguous ('grey') areas. It is acceptable to decide not to include a category of resources in the scope of the law, on the basis that existing systems for addressing ABS with respect to those resources is adequate. However, that decision must be informed and deliberate, not the result of inadvertent oversight. One also needs to be certain that the basis for distinctions is well founded. For example, one of the factors that has undermined confidence in some systems using academic versus commercial distinctions is that this is based on the assumption that academic research produces public goods, whereas, increasingly, academic work may be undertaken in partnership with, or as a precursor to work by, commercial actors, and so does not become freely available in the public domain. Therefore, it is clear that a proper basis for an academic versus commercial distinction must look beyond the nominal identity of actors to consider also the nature of their proposed activities and ultimate end-use of their research results.

The development and proliferation of national-level ABS law has been slow in the 13 years since the CBD came into force. At least part of the reason is that, from the outset, people have been overly optimistic about creating one-size-fits-all national ABS law through which requests for access to all of the different types of a country's genetic resources for all kinds of uses could be filtered. The relatively recent coming into force of the International Treaty, which creates a Multilateral System of Access and Benefit-sharing for listed PGRFA for the purposes of research, training and conservation, underlines this point. For a portion—PGRFA—of the overall range of genetic resources in the world,

it was possible to develop a specifically tailored ABS agreement that provided support for desirable, time tested patterns of exchange and use of those genetic resources. The even more recent adoption by the Governing Body of the Treaty of the Standard Material Transfer Agreement to be used for all transfers of materials within the Treaty's Multilateral System of Access and Benefit-sharing further illustrates the advantage of the world community considering the *sui generis* nature of different categories of genetic resources and their uses when considering appropriate terms and conditions for their regulation.

Once the process of internally reconciling options for change has been completed, the basic picture of the regime to be put in place will be sketched out. The objectives, mechanisms and general incentive patterns should be clear in terms of their detail, feasibility and justifications. There should also be coherence, both within the different objectives that the framework may embody and between the approaches adopted to achieve these objectives.

Part III: Positioning and drafting

Having formulated the policy framework, one's focus should now turn to its realization. While Parts I and II above involved considerable participation and consultation of a broad range of technical experts and stakeholders, these final steps depend more exclusively on legal experts.

Step 8. External reconciliation of options for change

This step involves contextualizing the proposed framework in the existing legal and policy environment. This is something of a bridging step between the processes of policy formulation and that of its translation into a formal instrument in that it serves the dual purposes of deciding the final shape of the framework and of laying the foundations for its implementation. This is a direct continuation from step 7 in that, where step 7 focused on the internal reconciliation of the proposed framework, this step focuses on its external reconciliation. The groups of options developed under step 7 should be examined for compatibility with other existing national laws and policies, and international obligations that the country may have under international agreements such as the CBD and the International Treaty that have not yet been implemented.

There should also be clear delimitation of the application of the framework, to distinguish it from other frameworks where alternative categories of nominally genetic resources are involved, such as for microorganisms, aquatic living organisms, species vital to

national security, species listed in CITES annexes, and deriving from other international agreements of relevance. In parallel, the ABS framework must be compatible with any relevant legislation or similar on biotechnology-related activities, such as attitudes to genetically modified organisms, and biosafety. Care must be taken to reconcile differences and harmonize similar elements so that the national codex of legislation has a consistent approach to similar elements appearing in different contexts.

One is primarily looking for conflicts and synergies. The options for addressing conflicts are limited as it will be beyond the ability of the drafters of the ABS law to alter other existing laws. Therefore, this should only be proposed where it appears that the possibility of achieving a component objective is threatened and where that objective clearly appears to be a higher priority than that advanced by the conflicting law or policy. In such a case, one would be working towards an omnibus bill that would simultaneously pass the ABS draft into law and amend conflicting laws. Considering a compromise within the text of the ABS draft is a pragmatic alternative approach, in which case creating exceptions in the ABS framework can be considered.

Synergies between the ABS draft and existing laws are easier to address. Efficiencies can be gained through reliance on existing personnel working within existing regulatory frameworks, particularly with respect to procedures for the granting of access, monitoring and enforcement. For example, environmental authorities may have much of the capacity required to assess access applications, and quarantine authorities may be in a position and have a mandate to take a key role in local enforcement. In the agricultural sector, a country's gene bank or breeding

programmes may already possess many of the necessary institutional capacities that need to be included in the daily operation of an ABS regime that includes PGRFA within its scope.

At the end of this step, one should have a refined framework that links directly with existing frameworks, taking advantage of structures and capacities where possible and providing for exceptions in the event of unavoidable incompatibilities.

Step 9. Identification of most appropriate policy or legal instrument

This step addresses the question: what type of instrument is most appropriate to implement the framework developed so far? If in fact the type of instrument was already prescribed in the terms of reference handed down from higher political offices, it may not be open for consideration. Otherwise, it is useful to delay such a decision until this stage in the process, as the decision taken should reflect work that has been completed in the earlier steps. Different types of instrument suit different circumstances, but as a general principle, the lowest level of legal force necessary for the purpose should be adopted. Where the proposed framework requires changes in the policies and practices of national institutions and a signalling of objectives and intentions to foreign actors, a policy statement may be sufficient. This should not be seen as a 'weak' option. Policy statements, particularly where formally adopted, can have significant effects on the spending and staffing practices of institutions and on the way they interpret their mandates. Through this approach, it may be possible to achieve impacts similar to those attainable

through legislative measures. This approach is probably best suited to a situation where decentralized regulation is desired and a regime will therefore be independently implemented by a range of lead agencies (with, perhaps, a minimal level of coordination). At the opposite end of the spectrum, a legislative instrument may be required where it has been determined that new offences and corresponding penalties should be established, or where institutional modification is needed, such as where changes to the powers of enforcement officers are needed, or where significant new funding and staffing resources have been agreed upon.

In cases where these are not necessary, a legislative instrument may still be considered for at least one of two reasons. First, it may be needed to ensure a more significant level of coordination or harmonization in existing institutional and legal frameworks. Second, it may be deemed necessary to indicate the level of political priority that is attached to ABS, a sensitive subject in many countries.

Between these two ends of the spectrum—policy statements and legislation—are a range of options, such as subsidiary regulations, executive orders and similar instruments, which may vary considerably according to the traditions of individual jurisdictions. Such instruments are more flexible than legislative options, as they can be updated and otherwise amended without reference to legislatures, but they also are either dependent on parent legislation for, or completely lack, the budgetary and enforcement power of those legislative options.

Step 10. Drafting

The final step is to actually draft the instrument selected. Drafting of this

nature is a specialized field of endeavour and we do not purport to address processes involved other than to raise the two following issues.

First, the refined framework of options for change should be translated as clearly and precisely as possible, as ambiguities can have a negative impact on the way stakeholders react to a framework, as well as undermining its enforceability.

Second, it is important to ensure that the content and text of the instrument is consistent with the legal traditions of the country in which it is to be implemented. Legislative drafting is a complex skill and, where it has been determined that a legislative instrument is necessary, lawyers with experience in this area, from the country concerned, should lead the process. Most attorney generals' chambers or ministries of justice will probably have drafting departments and many law schools may also have lecturers with the relevant experience. Experts from a variety of different kinds of organizations—CSOs, indigenous peoples organizations, international research organizations, private industry—can be introduced into the process to provide technical back-up. FAO and UNEP have standing budgets and in-house expertise to provide such assistance upon request from member states. The preparation of subsidiary regulations, executive orders and other similar instruments, if they are necessary, will also require drafting skills. The preparation of policy statements may be the exception to this pattern, depending upon the level of detail such a statement is intended to convey and the changes it is projected to effect.

Postscript: The methodology in summary form

Part I: Policy analysis

Step 1: Overall purpose

What is the overall purpose of the law?

Is the law to be developed in response to a generic higher level directive from within government that specifies the purpose? If so, what purpose is provided?

Is the exercise of investigating the law in response to pressure from non-governmental groups? If so, what would the purpose of legislation be that would meet, at least partially, their demands?

Step 2: Component objectives

What lesser and included specific objectives are included within the overall purpose?

Are they different for different sectors or kinds of genetic resources?

Do they actually represent more detailed breakdown of the components of the overall purpose, or do they represent some qualitatively different priority?

Step 3: Baseline information

What information might you require to make an informed decision about the component objectives you have identified?

If you can not get all the information you initially identify, what minimum subsets of that information is sufficient?

How can the necessary information be collected and synthesized? By whom, and through what processes?

Part II: Policy formulation

Step 4: Prerequisite conditions for success

What institutional capacities and human behaviours (preconditions) are necessary for the component objectives to be realized?

Step 5: Evaluation of preconditions

What gaps exist between the requisite preconditions and the situation on the ground in the country concerned?

What information do you need to critically assess those gaps?

Step 6: Validation of component objectives

What options are there for legal and policy interventions to close those gaps?

Can those interventions be packaged within an ABS law?

What are the relative chances of success or failure for each option?

In the light of the viable options for change, are the identified component objectives likely to be effective? Do they represent approaches that are acceptable in the light of the standards, beliefs and precedents applicable in the country, i.e. is it politically feasible?

Step 7: Reconciliation and prioritization of options for change

Can the elements of legal or policy interventions be grouped according to their role or function.

Are any of the options repetitive? Are any irreconcilable? If so, is it possible that the component objectives need reconceptualization? Do some options need to be rejected?

Part III: Policy iteration and legal drafting

Step 8: External reconciliation of options for change

How do the grouped options 'sit' with existing laws and policies in the country concerned?

Step 9: Identification of basic legal approach and mechanism

What form of legal or policy instrument is most appropriate?

Step 10: Drafting

Who will take the next step, translating the framework developed in the previous steps into a formal legal instrument?

Endnotes

- 1 "Outcomes and Recommendations of the Meeting of 'Biodiversity—the Megascience in Focus'", UNEP/CBD/COP/8/INF/46. This is a report of a meeting hosted by the Brazilian government, 15-19 March 2006, immediately prior to the Eighth Conference of the Parties to the Convention on Biological Diversity (COP 8), which involved participation of approximately 200 scientists from across Latin America. The report includes the statements that "[b]asic biological research is seriously hampered by many of the current national ABS regimes", and "[d]istrust, rather than trust, is presently dominating the situation in many countries, hampering biological research. This holds for national as well as international research." The participants included a recommendation that "[a]ll countries are encouraged to review their processes for permits on research, collection, import, and export of specimens to rationalize and streamline the ABS process. In addition, rules and regulations need to be practicable." See also C. Correa, "Do national access regimes promote use of genetic resources and benefit sharing?", *Int. J. Environment and Sustainable Development*, Vol. 4, No. 4, 2005; M. Halewood & R. Sood, "Genebanks and public goods: political and legal challenges to building collections for the international community," prepared for the 20th session of the Genetic Resources Policy Committee (GRPC) of the Consultative Group on International Agricultural Research (CGIAR), August, 2006 [unpublished]
- 2 The concept of perverse outcomes, basically counter-productive or otherwise unforeseen negative outcomes of policy intervention, is almost universally highlighted as a fundamental risk in all legislative and policy formulation activities in the literature. For example, see G.C. Thornton *Legislative Drafting* (LexisNexis UK, 1996), Bennion, F. A. R., *Understanding Common Law Legislation: Drafting and Interpretation* (OUP, 2001) and Seidman, R. B., Abeyesekere, N., *Legislative Drafting for Democratic Social Change: A Manual for Drafters* (Kluwer Law International, 2000). For a number of historical examples of the impact of government policies on research and development paths see Diamond, Jared, *Guns, Germs and Steel: The Fates of Human Societies* (New York, 1997). For the specific issue of perverse outcomes in access and benefit sharing policy see, for example, Correa, C., *Do national access regimes promote the use of genetic resources and benefit sharing?* (*Int. J. Environment and Sustainable Development*, Vol. 4, No. 4, 2005).
- 3 Fowler, C. and Hodgkin, T. 2004. Plant Genetic Resources for Food and Agriculture: Assessing global availability. *Annual Review of Environmental Resources* 29: 10.1–10.37 at pp 10.14-10.17
- 4 *Ibid.*
- 5 However, of the pre-CBD legal regimes for access to genetic or biological resources, such as for laurel tree in Syria or the coco de mer nut in Seychelles, almost all were based on the physical nature of the material to which access was sought. This approach had the advantage of being extremely clear as to which activities did or did not fall within the scope of regulation, but the disadvantage remained of the rigidity of a 'one size fits all' approach to users and uses.
- 6 For the sake of brevity, the term NGO is here used to describe organizations that describe themselves as NGOs, together with civil society organizations (CSOs), or simply as 'civil society'.
- 7 The Shoals of Capricorn, Seeds for Life, the Eden Project and the International Cooperative Biodiversity Groups are probably the best known, primarily public supported, projects that have at least touched on ABS issues and have, to varying degrees, specifically incorporated benefit-sharing measures in their proposals. The collections maintained by the CGIAR and other regional or international centres of a similar nature also constitute what is, in essence, an ongoing ABS project. Probably, the highest volume of activity in

- access to genetic resources tends to occur among public-sector institutions, such as research institutes and universities, within particular national or sub-regional borders, but rarely involves much in the way of direct benefit-sharing provisions. This is generally because, where the issue has been considered, the activities of national institutions tend to be accepted as a benefit in the sense that they are undertaken on behalf of the public of the particular country.
- 8 PEST, sometimes known as STEP, analysis is one element of a tool for assessing business and market environments in the context of business management.
 - 9 See www.wipo.int
 - 10 See www.biodiv.org
 - 11 See www.fao.org/ag/cgrfa
 - 12 Of course, in all but the rarest instances, it will not be possible to reach complete consensus on all aspects of policy development. However, to optimize the chances of successful implementation, one should aim for at least a compromise that all those involved can accept.
 - 13 This dynamic is very closely related to the reason that access issues were introduced into the CBD in the first place, namely the perception that recognizing and formalizing the potential value of biodiversity, in particular of the relatively low impact and potentially profitable activities associated with genetic resources, would allow for the capture of at least some of that value to support conservation efforts. It was felt that this approach would also promote the cause of conservation by highlighting biodiversity's potential direct applied value, as well as its more traditionally accepted, but more remote, existence value. Another activity that countries are almost always seeking to preserve and promote is that of the exchange of genetic resources to support agricultural research and production. The exchange of a range of genetic resources, plant, animal and microbial, is so well established that it is often taken for granted. However, it is, in most cases, still an example of access to genetic resources and this must be borne in mind when developing an ABS framework.
 - 14 Confusion about the application of ABS law to resolve orthodox natural resources exploitation issues is further clouded by a lack of clarity—distinguishing between something being accessed as a biological resource or as a genetic resource. The division between these two terms is not neat, inasmuch as the definition of genetic resource turns in part upon the use of the material in question. In the case of natural resources extraction, one is dealing with a traditional commodity question of price relative to quantity, i.e. the value of a tangible good with uses that do not involve the reproduction of the biological material involved. In the case of genetic resources, one is focusing more on the intangible quality of the material accessed, i.e. the genetic information encoded in a biological resource, and the intention on the part of the recipient to reproduce the material received or its genetic parts or components. Inevitably, it appears, the definition become functional in nature, turning on the intended use of the biological material. As a result, confusion still persists in some circles about the potential applicability of blanket access law for all biological materials. One optional approach—which is appealing in its conceptual simplicity—would be to say that all biological resources will be considered as genetic resources. However, this has a fundamental drawback: the effective regulation of the exchange of biological resources, as commodity transactions, is fairly straightforward, and consequently cheap, whereas the effective regulation of the exchange of genetic resources tends to be more complex, and expensive. As a result, making all biological resources subject to genetic resources regulation would submit a huge number of relatively routine transactions to a heavy burden of transaction costs, ranging from negotiations and monitoring to accounting for the costs and benefits of benefit-sharing mechanisms. At a minimum,

some form of exception will be necessary to allow for conventional activities that are almost universally accepted as beyond the scope of access to resources in genetic terms, such as trade in timber or foodstuffs. A useful starting point is to demarcate between the point where the use of a resource involves its direct consumption, and those using it must therefore seek a further supply to continue their activities, and between activities that involve cultivation or reproduction by some means and where the user does not need to secure an ongoing supply. Scenarios involving different resources and activities can then be tested against this demarcation to see which side of it they would fall, and hence some form of definition of access to genetic resources that suits national interests and objectives can be arrived at.

Another substantive decision that should be taken concerns the determination of how to define the actual material and activities that will be subject to the framework. Neither the CBD nor the International Treaty are particularly precise in this regard, although the latter does provide somewhat more detail than the former. The definitions of genetic resources and the provisions on scope in these two international agreements leave the main decisions to national implementation, and a failure to address the issue, usually through the simple adoption of the international definitions, can create a dangerous ambiguity in what is, and what is not, subject to regulation at national level. The refined framework that has been developed under this methodology should provide a clear indication as to how scope and definition should be constructed, and the main point here is that this is an issue that must be specifically considered and addressed.

Acronyms

ABS	Access and Benefit Sharing	NGO	non-governmental organization
Bonn Guidelines	Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization	PEST	political, economic, social, technological [analysis]
CBD	Convention on Biological Diversity	PGRFA	Plant Genetic Resources for Food and Agriculture research and development
CGIAR	Consultative Group on International Agricultural Research	R&D	research and development
CGRFA	[FAO] Commission on Genetic Resources for Food and Agriculture	SWOT	strengths, weaknesses, opportunities and threats [analysis]
FAO	Food and Agriculture Organization of the United Nations	TRIPS	Trade Related Aspects of Intellectual Property Rights
GPA	Global Plan of Action for the Conservation and Sustainable Utilization of Plant Genetic Resources for Food and Agriculture	WIPO	World Intellectual Property Organization
IARC	International Agricultural Research Centre		
IGC	Inter-Governmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore [of WIPO]		
IP	intellectual property		
IPR	intellectual property right		
IPGRI	International Plant Genetic Resources Institute		
International Treaty	International Treaty on Plant Genetic Resources for Food and Agriculture		
NBSAP	National Biodiversity Strategy and Action Plan		