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TOWARDS A CERTIFICATION SYSTEM FOR BIOPROSPECTING ACTIVITIES

STUDY COMMISSIONED BY THE STATE SECRETARIAT FOR ECONOMIC AFFAIRS

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Executive Summary

The Convention on Biological Diversity (CBD) has ushered in a new era. Transactions for genetic resources are to be underpinned by a *quid pro quo*: access to genetic resources in return for a share of the benefits derived from their use. Fifteen States or provinces are regulating access to ensure benefit sharing. At least another thirty-seven are planning to regulate access to ensure benefit sharing.

Developing countries in particular are drafting and enacting legislation. But many laws are ill planned and heavy-handed regulatorily. They reflect defensive reactions to a political, industrial and scientific climate that places the primary burden of ensuring benefits on the providing country. Paradoxically, cumbersome regulatory systems can have the perverse effect of discouraging genetic resource transactions and, consequently, the possibilities for benefit sharing.

A Panel of Experts under the CBD Conference of Parties (CBD COP) has explored the user and provider sides of genetic resource transactions. Among the suggestions in its first report, the Panel noted that the exploration of multilateral mechanisms to support prior informed consent internationally might be necessary. A number of possibilities were listed, among them "certification systems for institutions abiding by rules on access and benefit sharing".

Prior to the Panel's work, the Swiss Government, in May 2000, presented for comment to the Fifth CBD COP meeting, Draft "Guidelines on Access and Benefit Sharing Regarding the Utilisation of Genetic Resources". The Draft Guidelines encourage stakeholders "to create a system of certification (article 14)…which would confirm the abidance to the Guidelines by the stakeholder being certified (Annex D)". The Draft Guidelines would represent the standard against which stakeholders' performance could be judged.

Certification is a market-based concept that verifies an organisation's practices. In its highest form, an independent third party assesses the operations of a private or public organisation against a standard set of criteria. A certificate of conformity is issued as written evidence of verification.

Depending on its architecture, a certification system could apply to the users of genetic resources. It could provide the basis for provider countries to feel more confident about their potential partners. Consequently, access to genetic

resources could be facilitated. Likewise, if the system applied to the legal and institutional systems of provider countries, potential users may have more confidence in their potential partner and step-up their bioprospecting activities. Benefit sharing could be facilitated. A win-win situation could result.

A number of standard setting and certification systems exist today to address various social and environmental concerns. The attributes of these systems can be applied to the development of a bioprospecting certification system.

The feasibility of a bioprospecting certification system refers to the interrelationship of factors that contribute to its design and operation. The major factors that need to be considered include the (1) possible scale and architecture of the system, (2) its costs and the need for supporting funds, (3) the stakeholders that would participate in it and (4) the relationship of the system with other existing certification systems.

Three possible scales for a third party bioprospecting certification system are identifiable: global scale, national scale and small scale. Table 1 summarises possible system attributes. It demonstrates that that all three scales have similar attributes, as well as outstanding issues. The three scales are distinguishable by the extent to which each will harmonise global best practice.

A new or existing, private, independent organisation would develop and operate the system no matter what the system's scale. The formality of governance structures would vary with the system's scale. Regardless of the scale, a set of universally applicable standards would be developed in consultation with an international group of stakeholders. The foundation for the standards would include any guidelines developed by the CBD COP.

Covering operational costs and securing sources of income may be one of the biggest challenges to establishing and operating a bioprospecting certification system. Initial start-up costs could be covered by private or public funds. Sustainably supporting the system financially will be an issue at all system scales.

The major stakeholders that could participate in the system are the private sector, the public sector (e.g., provider countries), intermediaries and indigenous and local communities. The private sector is the most likely stakeholder to participate in the system. However, private sector demand is unclear. Non-profit and commercial intermediaries are the next most likely

participants. The extent of their interest is also unclear. Finally, the extent to which provider countries or indigenous and local communities may wish to participate also needs to be clarified. These last two groups may have the most to gain by participating in a bioprospecting certification system, but they have limited resources to participate. Capacity building measures and low participation costs may encourage participation.

At present, none of the natural resource-based certification systems are addressing bioprospecting activities. Therefore, duplication of effort or conflict between existing systems and a future bioprospecting certification system are not an issue.

Certification is a tool that has already been applied to a wide range of situations. At least in theory, a bioprospecting certification system would be feasible to create. There is nothing to suggest that certification could not be applied to bioprospecting activities.

Notwithstanding this general conclusion, outstanding issues, such as cost and demand, make it difficult to definitively say whether a bioprospecting certification system would be feasible to create and operate in practice. These outstanding issues need to be reviewed more closely in any subsequent exploratory work undertaken in the future.

1. Overview

The Convention on Biological Diversity (CBD) has ushered in a new era whereby transactions for genetic resources are to be underpinned by a *quid pro quo*: access to genetic resources in return for a share of the benefits derived from their use. Seven and a half years into the Convention's implementation 15 States or provinces are regulating access to ensure benefit sharing.[1] At least another 37 are planning to regulate access to ensure benefit sharing.[2]

The emerging legal frameworks to determine access to genetic resources are exciting evidence that the CBD is actually being implemented. Developing countries in particular are rushing to draft and enact legislation. But many laws are ill planned and heavy-handed regulatorily. They reflect defensive reactions to a political, industrial and scientific climate that places the primary burden of ensuring benefits on the providing country (Glowka, 2000).

Providing countries are justifiably suspicious of those seeking access to their genetic resources, especially in light of past experiences they may have had such as unkept promises by researchers to share research papers and research results in other areas of biological research. They are particularly concerned about 'biopiracy'- the removal and subsequent use of genetic resources

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1 The regions, states, or provinces currently regulating access to genetic resources to ensure benefit sharing include: the Andean Pact (Bolivia, Colombia, Ecuador, Peru, Venezuela), Australia (the State of Western Australia and the State of Queensland), Brazil (the States of Acre and Amapa), Cameroon, Costa Rica, the Republic of Korea, Malaysia (the States of Sarawak and Sabah) and the Philippines.

2 Those regions, states, or provinces planning to regulate access to genetic resources to ensure benefit sharing include: ASEAN, Australia (the Commonwealth), Brazil (the State of Sao Paulo), Cote d' Ivoire, Cuba, Ethiopia, Eritrea, Fiji, the Gambia, Guatemala, India, Indonesia, Kenya, Lao PDR, Lesotho, Malawi, Malaysia, Mexico Mozambique, Namibia, Nicaragua, Nigeria, the Organization of African Unity, Pakistan, Papua New Guinea, Samoa, the Seychelles, the Solomon Islands, South Africa, Sri Lanka, Tanzania, Thailand, Uganda, the United States of America (within Yellowstone National Park and other national parks), Vanuatu, Vietnam and Yemen. Belize, China, El Salvador, Ghana, Guyana, Hungary, Iceland, Panama, the Russian Federation and Zimbabwe may also be planning to regulate access to genetic resources.

Adapted from Glowka, 1998.

without prior informed consent (Glowka, 1998). At the same time, they want legitimate transactions to be as fair and equitable as possible, but may not have the capacity to ensure this, determine what deals might be fair and equitable or have a reliable way to determine who might be a good long-term partner.

But cumbersome regulatory systems can have the perverse effect of discouraging genetic resources transactions. For example, the possibility of a protracted regulatory process may result in potential users simply going elsewhere for genetic resources. And, ironically, the laws themselves may not necessarily increase the transaction's legal certainty or certainty over the legal status of the materials transacted. Such an environment of uncertainty creates an additional incentive for genetic resource users to go elsewhere.

It may also cause companies to move research dollars out of genetic resources and into other research approaches (ten Kate, 2001). Either way, important opportunities for benefit sharing may be missed.

The issue is how best to reconcile and balance the desires of providing countries - controlling access to genetic resources with the need to ensure fair and equitable benefit sharing - and the desires of users who need facilitated access and are risk averse to the uncertainties that exist in many countries? Central to resolving this question is establishing a climate of good will between genetic resource providers and users.

The Conference of the Parties (COP) of the CBD is looking more closely at both sides of the genetic resource transaction. At its fourth meeting in Bratislava in 1998, the CBD COP created an Expert Panel on access and benefit sharing. This Panel was charged with developing a common understanding of basic concepts and was directed to explore all options for access and benefit sharing, including guiding principles, guidelines and codes of best practice. For the first time under the CBD, the Panel addressed the user side of the genetic resources transaction.

For example, after its first meeting in October 1999 the Panel concluded that "the degree of legislative simplicity in countries providing genetic resources will increase to the extent that countries and organisations receiving genetic resources take . . . measures to offer security to providers (UNEP, 2000)." It suggested that the CBD COP consider developing international guidelines or

principles for such measures. The Panel also stated, "Guidelines establishing standards for both providers and users of genetic resources . . . and voluntary industry measures and guidelines could also assist Contracting Parties to supplement access legislation and support fair and equitable partnerships."

Finally, the Panel noted that it might be necessary to explore multilateral mechanisms to support prior informed consent internationally. These could be based on regulations or incentives. The Panel listed a number of possibilities, among them "certification systems for institutions abiding by rules on access and benefit sharing" might be considered (UNEP, 2000).

Prior to the Panel's work, a governmental delegation to the CBD COP had suggested the possible usefulness of developing a certification system. In May 2000, the Swiss Government presented for comment to the Fifth Meeting of the Conference of Parties to the Convention on Biological Diversity Draft Guidelines on Access and Benefit Sharing Regarding the Utilisation of Genetic Resources.

Article 14 and Annex D of the Draft Guidelines encourage stakeholders "to create a system of certification (article 14)…which would confirm the abidance to the Guidelines by the stakeholder being certified (Annex D) (**seco**, *et al.*, 2000)." The Guidelines would represent the systems- or process-based standard against which stakeholders' performance could be judged. To date the concept has not been developed.

An independent certification system for bioprospecting activities has yet to be fully considered by commentators in the field. However, certification systems do exist for other natural resources and environmental management systems. These could provide important principles upon which a certification system for bioprospecting activities could be designed.

Depending on its architecture, a certification system could apply to the users of genetic resources and provide the basis for provider countries to feel more confident about their potential partners. Access to genetic resources could be facilitated. Likewise, if the system applied to the legal and institutional systems of providing countries, potential users may have more confidence in their potential partner. Benefit sharing could be facilitated.

With the suspicions of biopiracy and fears of inequity and questions concerning legality of the transaction overcome, a certification system could

instil enough confidence in provider countries to catalyse a second generation of more simplified access legislation in the future. A new found interest in bioprospecting by commercial actors may ensue as well. A win-win situation for providers and users of genetic resources alike could result.

This study was undertaken at the request of the Swiss State Secretariat for Economic Affairs (**seco**). The primary purpose of this study is to explore the possibility of establishing an independent certification system for bioprospecting activities.

The discussion is premised around a generic bioprospecting certification system, but alternatives at the global, national or small scale levels are mentioned. Section 2.0 explores the context for a certification system. Sub-section 2.1 describes certification as a concept. Sub-section 2.2 describes the common attributes of existing standard setting and certification systems and their applicability in a bioprospecting certification system.

Section 3.0 addresses the feasibility of a bioprospecting certification system. Sub-section 3.1 describes the nature of genetic resources transactions. Sub-section 3.2 gauges the possible demand for a system. Sub-section 3.3 summarises the opinions of selected experts. Sub-section 3.4 proposes possible architectural options and draws conclusions on the general feasibility of a bioprospecting certification system.

2. Bioprospecting Activities

2.1 The Certification Concept

Certification is a "market-based system of verification that assesses operations against a standard set of criteria (Falls Brook Centre, ____)." "The assessment criteria often represent widely accepted best practices" in the field that they are applied (Falls Brook Centre, ____) and are potentially most useful when they help organisations meet or exceed requirements specified in national, regional or international laws.

When an organisation verifies that its operation meets or exceeds the standard set of criteria, it may be entitled to publicly make certain claims that, in the absence of verification, it could not credibly, or even legally, make. Where a third party undertakes the assessment process pursuant to a recognised set of standards, a certificate of conformity could be issued as written evidence of the verification.

Depending on the situation, submitting to an assessment and being certified can be a legal requirement, a market requirement or it can be a voluntary undertaking to check internal performance. Governments are increasingly using certification to supplement environmental compliance laws. This exemplifies a general trend away from direct government regulation towards creating more collaborative approaches to environmental compliance (Kanowski, *et al.*, 2000).

A good example is the European Union's Environmental Management and Audit Scheme (EMAS). This voluntary registration scheme attempts to create a competitive advantage for participating organisations in terms of regulatory controls, cost savings and public image (EMAS, ____).

The potential power of policy instruments that attempt to harness consumer choice is increasingly being recognised. Consumer choice can enhance corporate social and environmental performance by creating a market-based incentive for the organisation to meet or exceed the standards applied (Elliott and Donovan, 1996). The growth of independent certification systems also demonstrates a shift in policymaking and implementation from governments

to non-governmental organisations (NGOs) and the private sector (Elliott and Donovan, 1996).

Certification is also being used by private enterprise to provide an objective basis for distinguishing social and environmental performance, products or services and, ultimately, the organisation's reputation in the marketplace.

The assessment process can take three basic forms (Ervin *et. al.*, 1996). First party assessment is an internal assessment of an operation undertaken by the organisation itself. In other words, first party assessment is a form of self-assessment. Standards for assessment could be internally or externally generated.

An example of first party assessment that may be relevant to bioprospecting might be the claims made by an organisation engaged in bioprospecting activities that it complies with the access and benefit sharing obligations of the Convention on Biological Diversity. The claims might be made public in a variety of circumstances, including the organisation's social, environmental or annual reports. Whether accurate or not, and no matter the amount of good will involved, the claims might be criticised for failing to be based on objective standards.

This points to a fundamental problem associated with first party assessment: the inherent possibility for conflicts of interest when an entity assesses itself. The lack of objective standards for making and reporting on the claims can also complicate efforts to make internal comparisons across a multinational company's operations.

A similar problem exists when comparing the performance of two or more organisations. For example, each organisation may have a different interpretation of the CBD's obligations and would more than likely have a different way of measuring and reporting on its performance.

Second party assessment takes a step towards addressing potential inconsistencies and conflicts of interest. In this form of assessment an organisation's customer, or a trade association, assesses the organisation. The standards could be found in the contract between the organisation and its customer or, where a trade association is involved, the standards could have been generated in consultation with stakeholders in the sector with which the trade association is affiliated. These could represent industry best practice.

An example would be where a trade association develops sector-specific standards and a company applies them to itself and also requires its suppliers to apply the standards. The company could be periodically audited for compliance or undertake self-assessment. It could also require its suppliers to be audited to ensure that the standards are being applied. Depending on the circumstances, the company might provide technical or financial support to its suppliers to help them meet the standards.

Potential conflicts could still arise in the bioprospecting area because, for example, the supply contract reflecting the contractor's needs may not reflect adequately the full scope of the CBD's obligations. Or, for example, a trade association's standards may not have been developed in a process involving a broad range of stakeholders. Consequently, the standards may not represent widely recognised principles. Alternatively, they may represent perspectives that conflict with the CBD's obligations or spirit.

Third party assessment has the potential to be farthest removed from inconsistent application of standards and from conflicts of interest. Consequently, it has the greatest potential to be objective and to be recognised as credible. Third party assessment involves an independent organisation assessing another organisation against widely recognised standards and providing written confirmation of conformity.

Third party assessment is premised on the credibility that is inherent in an organisation unrelated to the operation under review assessing the latter for its performance or claims. Credibility is further buttressed where the assessment standards are generated by broad-based stakeholder consensus and where the certification body can be "accredited" by an independent accreditation body to be authorised to conduct assessments. In the social and environmental areas, where certification systems have been established to date, the majority describe themselves as independent third party systems.

While third party assessment provides the possibility for greater credibility, some organisations may not like the idea of opening their bioprospecting-related operations up to third party scrutiny (ten Kate, 2001). In addition, one drawback of third party assessment is the potentially higher costs to set-up and operate the assessment system. Costs to participate in the system may also be problematic for smaller organisations.

2.2 Common Attributes of Existing Standard Setting and Certification Systems and Their Applicability in a Bioprospecting Certification System

The number of standard setting and certification systems that exist today is unknown. It appears that there is an increasing trend to create them, especially in response to social and environmental concerns.

The existing standard setting and certification systems identified and studied for this report address a wide range of social and environmental issues. These include:

?? environmental management and quality management systems (European Eco-management and Audit Scheme (EMAS) and International Organisation for Standardisation (ISO));

?? fairtrade for agricultural commodities (Fairtrade Labelling Organisations International (FLO));

?? marine capture fisheries (Marine Stewardship Council (MSC));

?? forest management (Forest Stewardship Council (FSC));

?? marine ornamentals (Marine Aquarium Council (MAC));

?? organic agriculture (International Federation of Organic Agriculture Movements (IFOAM)); and

?? workplace conditions (Social Accountability International (SAI)).

Details of these systems are provided in Annex I. The attributes common to the existing systems and their applicability in a bioprospecting certification system are described below. Where appropriate, distinctions are made between a generic bioprospecting certification system and systems that could be global, national, as well as systems operated on a smaller scale by a non-profit NGO or commercial enterprise.

2.2.1 Global Nature

With the exception of EMAS, the systems examined are global in nature in two primary aspects.

First, their scope of application is global in nature. The systems are designed to address social or environmental problems in all parts of the world. The systems are intended to be the sole organisation operating in the world on the issue addressed.

Second, in relation to scale, the standard setting processes are global and involve stakeholders from around the world. In addition, they have formal governance structures designed to reflect their stakeholders' views. Where they are membership bodies, membership is open to participants from anywhere in the world.

The global nature of a system lends itself to the broad, universal application of the standards promulgated. It helps to harmonise the application of the system worldwide. Perhaps most importantly, the global nature of a certification system helps to establish its credibility worldwide. This in turn has a direct relationship on the recognition and ultimate success of the certification system.

Bioprospecting is an activity that takes place all around the world. Bioprospecting's global nature suggests that a certification system should have a global nature as well. A global nature will lend itself to broad universal application of the standards promulgated and wide recognition of the system.

A bioprospecting certification system should ideally have a global scope of application. In other words, it should apply to all bioprospecting activities worldwide. This would help to harmonise best practice through out the world.

In terms of scale, there are at least three possibilities for a bioprospecting certification system: (1) a global system; (2) a national system; and (3) a small scale system.

A global scale system would be operated privately by a specially created independent organisation. It would be intended to operate as the sole bioprospecting certification system in the world. Where demand is high, its functions would be limited to standard setting and accreditation. Alternatively, where demand is low it may get involved with actual certification. Its governance structure would be formal and would ensure worldwide multi-stakeholder participation.

A national scale bioprospecting certification system would be operated privately by a specifically created independent organisation. The organisation would certify organisations within the country that it is based, no matter where the organisations operate globally. Its governance structure would be formal and it would ensure multi-stakeholder participation, but on a smaller scale than a global system.

A small scale bioprospecting certification system would be operated privately by an existing non-profit organisation, such as an NGO, or by a commercial enterprise, such as a certification company. It would have the potential to certify organisations globally. It would operate without a formal governance structure, though stakeholders could advise it. The organisation that creates the system would operate and market the system worldwide.

The different scales are further addressed in the context of different system attributes in the text, as well as in Table 1.

2.2.2 Third Party Assessment

All systems examined are third party in nature. The third party nature directly contributes to their credibility. This is because third party systems strive to achieve unbiased judgements of the operations being certified. Unbiased judgements are supported by operational independence demonstrating that the system is not unduly subject to political, social or economic pressures (Ervin, *et al.*, 1996).

The most credible existing certification systems are based on third party assessment. Though more complex, and potentially more expensive to create and implement, a bioprospecting certification system should also be based on third party assessment.

2.2.3 Initiation of the Certification Process

A key characteristic of all of the certification systems reviewed is their voluntary nature. Those seeking certification initiate the process.

For example, forest owners or managers voluntarily submit their forest management practices in a defined forest area to the scrutiny of accredited

third party certification bodies to obtain a Forest Steward Council accredited forest management certificate. The voluntary nature of the international social and environmental certification systems has been cited as the primary reason why they will not be disputed under world trade rules (Ervin, *et al.*, 1996).

A bioprospecting certification system should also be voluntary in nature. This is because it would seem difficult to compel an organisation to obtain certification though, for example, legislation in a provider country could encourage or even require this. The voluntary nature of the system will help to distinguish exemplary organisations that are willing to commit resources to improve their practices in order to obtain a certificate demonstrating conformity with the system.

Trade considerations should not be an issue for a bioprospecting certification system because of the nature of genetic resources and the transactions involving them. Typically both involve discrete amounts of materials. These materials are not commodities typically addressed by the World Trade Organisation.

2.2.4 Basis of Assessment

A set of universally applicable standards is the basis for assessment shared by the majority of the systems examined. Universal applicability means that the standards are generic. They can be used in a wide-range of situations, regardless of the location or the nature of the operation being assessed. The standards reviewed address institutional issues and substantive environmental, social and economic issues.

The number of standards promulgated varies with the system. A general rule is to keep the system simple and avoid generating too many standards. Minimising the requirements prevents the system from becoming unwieldy and impractical to implement (Mallet, 1999). It also helps to keep the system operation costs, and the costs to participate in the system, reasonable.

The standards developed represent best practices. A common attribute is that they are designed to recognise, complement and exceed existing legal requirements (Scott, 2001a). The standards must add value to existing regulations or there will be no benefits to the system's participants.

Consequently, a guiding principle for standards is that they must stretch those seeking certification, while still being achievable.

For example, voluntary standards in the forest management area have been described as aiming to achieve the highest common denominator of forest management practices (Ervin *et. al.*, 1996). They embody best management practices and ideal forest conditions with attainable, but rigorous, goals (Ervin *et. al.*, 1996). In contrast, mandatory forest management standards, applied pursuant to law, have tended to be lowest common denominator approaches characterised by easily obtainable minimum legal requirements for all (Ervin *et. al.*, 1996).

Another guiding principle is transparent application of the standards. Under existing systems, international documents related to the certification are not typically available to the public. However, certification summary reports are made available to the public as a tool for peer review and to ensure transparency. Summary reports are made available on the oversight body's WWW site.

The system's design determines how the standards can be used. Ideally, the standards developed should be applied directly to ensure that certification is delivered consistently around the world (Scott, 2001a). Some of the systems provide the basis upon which individual certification programmes operated by independent certification bodies generate their own certification programmes. Some systems also allow local interpretations of their standards to make them more applicable to local circumstances.

For example, the IFOAM *Basic Standards of Organic Agriculture and Food Processing* promulgated by the International Federation of Organic Agriculture Movements, cannot be used for certification on their own because they are framework standards. In other words, the IFOAM *Basic Standards* are "standards for standards (IFOAM, 2001)." Certification bodies and standardising organisations use them as the basis upon which to develop their own standards that, in turn, take into account local conditions. Locally developed standards must at minimum meet, but can exceed, the IFOAM *Basic Standards.*

According to the Forest Stewardship Council's *Process Guidelines for Developing Regional Standards*, the FSC *Principles and Criteria* were

designed to provide a "consistent framework" to develop locally defined forest management standards (FSC, ___b). The latter would then be applied as a minimum standard by local and international certifiers.

In reality, however, it has been recognised that the FSC *Principles and Criteria* have become the *de facto* standards to measure forest management practices (Rainforest Alliance, 2000; Kanowski, *et al.*, 2000). Complications have also arisen with locally developed standards diverging from the main principles and criteria and not being comparable between regions (Scott, 2001b). This in turn risks changing the threshold at which successful certification is set and can lead to questions on the fairness and equity of the certification system around the world (Scott, 2001a).

Neither the Marine Aquarium Council, nor the Marine Stewardship Council, allows any local variations on its standards (Scott, 2001a). Furthermore, accredited certification bodies are not allowed to produce their own certification scheme (Scott, 2001a). Instead, MAC and MSC standards are designed for direct application to ensure consistent worldwide application. To ensure this, both sets of standards are supported by a certification methodology and guidelines (Scott, 2001a).

For example, the MSC *Principles and Criteria for Sustainable Fishing* are composed of three principles with attendant criteria. They form the basis to independently certify, on a global basis, "well-managed and sustainable marine fisheries". The certifier assesses the fishery (marine fish and invertebrates) against the MSC standards. The certifier must also follow the MSC *Guidelines for Certifiers* and the MSC *Certification Methodology.*

Standards can be systems-based or performance-based. The distinction is not always clear.

Systems-based standards (sometimes called process-based standards) are standards that "provide a systematic approach to developing, implementing, monitoring and reviewing" *what should be done* by an organisation (Kanowski, *et al.*, 2000; Favre, 2001). Systems-based standards concentrate on the processes that contribute to a resulting product or service, but they do not guarantee that the processes will attain a particular level of performance.

While systems-based standards do not contribute directly to performance, performance is influenced by how the processes contributing to a product or

service are managed (ISO, ___d). Some commentators have recognised that performance can be no better than the management systems in place (Viana, *et al.*, 1996). They believe adequate management systems are a precondition to improving performance.

Systems-based standards are exemplified by ISO 9001 (Quality Management System Requirements) and ISO 14001 (Environmental Management System Requirements). ISO 9001 specifies what organisations must do to manage the processes influencing quality. ISO 14001 applies to processes influencing the impact of the organisation's activities on the environment (ISO, ___d).

Both standards require the existence of a particular management system, but they do not specify any particular level of performance (Sugal, 1996). Performance levels are set by the organisation, not by the standard (Ervin *et. al.*, 1996). The organisation that seeks certification is judged by whether it has incorporated management and environmental management objectives and targets into its overall management system, and the extent to which the system is implemented (Ervin *et. al.*, 1996).

Performance-based standards measure *how well* an organisation or its products perform. In general, all of the international social and environmental certification systems that were reviewed, other than that of ISO, use performance-based standards.

For example, the Marine Stewardship Council *Principles and Criteria for Sustainable Fishing* provide indicators against which the state of the fishery can be measured. MSC Principle 1 reads in part "a fishery must be conducted in a manner that does not lead to over fishing or depletion of exploited populations". The "performance measure" of this standard is whether conducting the fishery leads to over fishing or depletion of exploited populations. If so, then the fishery may not be certified. Similarly, if an already certified fishery is becoming over fished it could lose its certification because fishery practices have led to the fishery's degradation. In this way, certification is tied to achieving a certain level of performance.

The MSC system also offers some flexibility in the application of the standards. For example, where a fishery may not meet the full requirements for certification, it can be certified subject to criterion-specific conditions, such as the development and implementation of an action plan.

In reality, most certification systems combine elements of both systems- and performance-based standards though some are more explicitly "hybrid" than others are. For example, Social Accountability 8000 (SA 8000) is a hybrid system that is premised upon international human rights rules. It combines systems- and performance-based standards and applies them to work place practices.

SA 8000 is modelled on the ISO 9000 family of management standards, but it also incorporates specific performance standards set against minimum requirements (SAI, 2000). An example of a systems-based standard is found under section 3.0 (Health and Safety). Criterion 3.4 requires that a company "establish systems to detect, avoid or respond to potential threats to the health and safety of all personal." In contrast, criterion 3.5, a performance-based standard, requires a company to provide clean bathrooms and access to potable water.

EMAS also appears to be a hybrid system. As one condition of registration, it requires organisations to develop and implement an environmental management system. It goes beyond ISO 14001 by requiring the organisation to have its publicly available environmental statements and reports verified by an accredited "verifier". There is a general requirement for the registered organisation to continuously improve its environmental performance.

Any bioprospecting certification system should be based on a set of system- and performance-based standards. These should be universally applicable to one or more of the major stakeholder groups involved in genetic resources transactions: private sector, public sector, intermediaries or indigenous and local communities (see Section 3.2).

Standards could be derived from the future guidelines to be developed under the CBD. Existing codes of conduct could also be used as sources for standards. Details for applying the standards should be supplied in supplemental guidance documents. Guidance could be tailored to specific stakeholder groups.

Depending on the scale of the system, the standards could be applied directly by a single certification body, or they could be used as the basis upon which individual certification bodies generate their own evaluation criteria.

However, judging from the MAC and MSC experience, it may be advisable to generate a single set of universally applicable standards. Consequently, local variations would not be allowed to ensure the consistency of the system and the standards where they are applied.

Finally, a bioprospecting certification system should be simple to operate. Ensuring this relates in part to minimising the number of standards promulgated.

2.2.5 Standards Development Process

A multi-stakeholder standards development process is common to all of the systems examined.

Standards alone cannot provide the basis for a credible certification programme (Ervin *et. al.*, 1996). This recognises the more general principle that the process to develop standards is just as important as the standards themselves.

The standards development process should be consultative in nature and characterised by stakeholder involvement. The goal is to bring in "as many diverse groups as possible within realistic financial and time constraints" (FSC, ___b). The standards of the majority of international social and environmental certification systems were developed in conjunction with multi-stakeholder international advisory bodies composed of representatives from NGOs, the private sector and, in some cases, government.

One group of important stakeholders is the non-governmental community. NGOs have been at the forefront of raising public awareness on social and environmental issues. More mainstream NGOs, especially in western countries, are developing closer relationships with industry to establish dialogue with it on social and environmental compliance issues. One of the outcomes of this are NGO affiliated certification systems. Certification systems have been developed as part of a suite of tools by NGOs to use market-based incentives to meet and exceed the requirements of existing laws.

NGOs have a relatively high level of credibility with the public. Their expertise in a particular subject area that may be amenable to certification

may be invaluable to the standards development process (Scott, 2001b). Therefore, NGO involvement can be an indicator of the potential for success in a standards development process and when the system is operated (Donovan, 1996).

Certification bodies are another important stakeholder group that should be involved early on in the standards development process. Perhaps the foremost contribution certification bodies can make is their knowledge of certification systems. While there may be an ethical issue with having certifiers directly involved with developing the standards that they may ultimately apply, realistic standards cannot be developed without the certifiers' involvement (Favre, 2001). Most importantly, they can help to ensure that the standards are workable. This can ultimately help to ensure the system's proper operation.

The standards are developed by consensus. They are typically recognised as a compromise between the stakeholders involved. For example, the consultative processes to develop the FSC standards are guided by the principle that standards should be developed "which are acceptable to the broadest range of stakeholders without endangering the high level of integrity needed for certification to work as a credible mechanism (FSC, ___b)."

The standards development process in some of the systems reviewed is characterised by a bottom-up or grass roots approach. This, then, can influence the acceptability of the standards being produced.

For example, the horizontal, grass-roots approach of the Marine Aquarium Council has resulted in a high level of "buy-in" from stakeholders (Holthus, 2001b). The process has been characterised by discussion groups, feasibility studies and other fact-finding and opinion-finding tools. The secretariat has undertaken a great deal of consensus building and awareness raising as well.

Social Accountability International developed the SA8000 system in conjunction with an international advisory board whose members included experts from trade unions, business and NGOs (Zaid, 2001). The participants represented a wide range of expertise including human rights, child labour, labour rights, socially responsible investment, auditing and supply chain management. The SA8000 standard reflects this group's consensus.

Industry sectors working through a national member of ISO initiate the development of ISO standards. The ISO national member then brings the

proposal forward for the consideration of the ISO membership. If the proposal is accepted, a technical committee is formed and negotiations begin to develop the standard.

ISO national members are required to bring a single national position to the negotiations. This requires a stakeholder consultation process within the particular country. The transparency of the consultation and the level of participation, especially by NGOs, vary with the country.

The MSC *Principles and Criteria for Sustainable Fishing* were developed through an 18 month international consultation process involving over 300 fisheries experts (MSC, ____a). The consultation was designed to ensure that the standard was internationally relevant and applicable.

An experts workshop in September 1996 developed a draft set of principles and criteria whose conceptual underpinnings included international soft and hard law instruments on fisheries. To ensure global representativeness and make improvements, the principles and criteria were discussed at eight regional consultative workshops with fisheries stakeholders held in America, Europe, Australasia and Africa.

Informal discussions were also held. A final experts workshop, held in December 1997, agreed and presented to the MSC Board a first draft of the principles and criteria. Notwithstanding this process, the foreword to the MSC *Principles and Criteria* notes "A standard is always a compromise and although this document may have been produced through an almost unprecedented international consultation process it will never satisfy the full spectrum of stakeholder clients (MSC, 1998)."

Transparency and broad-based participation should help the standard gain wide recognition upon adoption and implementation. Internet supported standards development processes may make it easier to now supplement the internal process to develop a standard with a public review component. For example, MAC has posted its draft core standards on its WWW site for public review and comment.

The length of the standards development process can vary with the scope and complexity of the standards developed. The level of controversy associated with the subject area being addressed can also influence this.

For the independent systems examined the average length of time appears to be between 18 months to 2 years. In contrast, ISO standards development processes can take years. For example, it took 10 years to develop ISO 9000.

The relationship of the proposed system with pre-existing certification programmes already run by other organisations is another factor influencing the length and complexity of the standards development process. In the areas of forest management or fairtrade, individual certification programmes run by NGOs or commercial entities pre-dated the international system under which they are presently accredited. In other cases, such as marine ornamentals and work place conditions, the international systems were designed from the ground up without the complication of pre-existing systems.

The length and complexity of the standards development process may determine the ability of stakeholders to remain meaningfully involved throughout the process. For example, because of the length and complexity of the ISO standards development process, NGOs may find themselves unable to participate fully in the process at the national level (Favre, 2001).

A pilot phase is another important component of the standards development process. The pilot phase of a certification system tests the application of the standards in real world situations.

A pilot phase requires partners willing to test the system and provide feed back on its operation. Feed back helps to fine tune the system prior to its formal operational debut.

A pilot phase can also be used to develop and operate a small scale test system and standards with a limited number of participants. This would help to avoid large up-front resource commitments on a full-blown standards development process. The pilot system's workability can be tested. Practical lessons learned from this experience can be translated into a scaled-up more widely applicable version of the system and its standards (Jeker, 2001).

In mid-2001, the Marine Aquarium Council will initiate its system's pilot phase (Holthus, 2001b). The MAC *Core Standards and Best Practices* are interim documents and will be first applied in a series of test certifications. The experience gained from the test certifications will be fed into the second phase of the standards development process. The output will be the MAC *Full Standards and Best Practices* (MAC, 2001a).

In all cases examined, the systems and their integral standards are kept under periodic review. This helps to ensure that the systems represent the "state of the practice" and that the standards represent the "state of the art."

Review or monitoring and evaluation processes look at the substance of the standards, their practical implementation and the overall impact of the systems designed to support their application. In this way, the system and the standards "evolve or live".

For example, the IFOAM *Basic Standards of Organic Agriculture and Food Processing* reflect "the current state of organic production and processing methods", but they are not considered to be "final statements." Instead they are viewed as "works in progress" and are kept under review (IFOAM, 2001).

Given the complexity and political sensitivity of the access and benefit sharing issue, bioprospecting certification standards for a global or national system will need to be developed in a multi-stakeholder process. A smaller scale non-profit or commercial system would also need to be developed with relevant stakeholders, but perhaps in a way proportional to the reach and representativeness of the system.

In all cases, stakeholders may need to be supported in the process to facilitate their development. The extent to which this may be feasible may vary with the scale of the system proposed and availability of funds.

A core standards working group could develop the basic standards and any supporting documentation, such as guidelines. These then could be issued for public comment.

Public comments could be solicited via the Internet and in a series of regional stakeholder workshops. Regional workshops should have a dual role of awareness raising and information gathering.

The private sector, intermediaries and local and indigenous organisations should be involved in the process. NGOs should be involved early on as well. Certification bodies should also be involved early on, especially to ensure the workability of the system and to help them gain understanding of the bioprospecting area.

2.2.6 Accreditation

With the exception of Fairtrade Labelling Organisations International, the organisations that generate the global standards upon which a certification system is based are not involved in the actual process of certification or conformity assessment. Independent certification bodies, whether commercial or non-profit, do the actual certifying.

With the exception of ISO and FLO, all of the systems examined accredit third party certification bodies to participate in and apply the standards of the system. Accreditation is simply the process of certifying the certifier (Ervin, *et al.*, 1996).

In effect, the oversight organisation certifies that the certifier meets specified criteria and that, in its judgement, the certifier has the capacity and experience to undertake third party assessments. The certification programme is evaluated on the extent to which it incorporates and has the capacity to apply the system's standards.

Accreditation has three primary goals (Ervin, *et al.*, 1996). The first goal seeks to ensure that the certification standards are consistently applied across different certification bodies and their respective certification programmes. Consistent application of the system standards worldwide creates confidence that certification determinations will be comparable across organisations.

The second goal seeks to ensure that the certification programmes used by different certification bodies are credible in the public's eye. In areas such as forest or fisheries management, where products are purchased by the consuming public, consumers ultimately determine the credibility of an accreditation system because they determine how well the system represents their particular values (Ervin, *et al.*, 1996).

The global system's reliability and integrity depend on the reliability and integrity of the individual certification body participating in the system. Therefore, the third goal of accreditation seeks to ensure and verify the integrity of the conformity assessment process and claims made by the certification body. An accreditor is ultimately responsible for ensuring the implementation of the overall system. Therefore it must ensure that

participating certification bodies maintain a specified level of performance. To ensure this, periodic auditing of the accredited organisation supports accreditation.

ISO is not directly involved with accreditation activities. For example, certification bodies that certify organisations to ISO standards are not accredited by ISO. However, certification bodies may be accredited under national conformity assessment schemes pursuant to national legislation. While ISO does not accredit certification bodies, most new ISO standards are produced to enable them to be used to accredit conformity assessment schemes (Scott, 2001a). Furthermore, the ISO Guide 60 Series describes how certification and accreditation activities should be undertaken (Scott, 2001a).

Oversight organisations have been created to support and monitor accreditation bodies. For example, the International Social and Environmental Accreditation and Labelling (ISEAL) Alliance was formed by a group of international social and environmental accreditation organisations[3] to monitor their accreditation programmes.

ISEAL will help to maintain quality control and may one day promulgate standards against which its members' programmes may be judged. This in turn will ensure that the systems stay focussed and will contribute to maintaining the programmes' credibility in the public's eyes (ISEAL, ___a). ISEAL will also support, monitor and help to ensure that its members' standards are in line with the requirements of the Code of Good Practice for the Preparation, Adoption and Application of Standards under the World Trade Organisation Agreement on Technical Barriers to Trade (Scott, 2001a).

Another example is the International Accreditation Forum (IAF), a worldwide association of national accreditation and certification bodies. IAF works to establish the equivalency of accreditation programmes operated by its members through its Multilateral Mutual Recognition Agreement.

IAF's goal is to establish a system to assist an organisation with an accredited conformity assessment certificate, granted in one part of the world, to attain the certificate's recognition in other parts of the world (IAF, 2000). This

[3] Forest Stewardship Council, the International Federation of Organic Agriculture Movements, the Marine Stewardship Council and the Fairtrade Labelling Organisations International.

would be possible because the accreditation programme that accredited the certification body, which issued the original certificate, would be recognised as equivalent to a similar accreditation programme in another part of the world. This would obviate the need for the certified organisation to be certified again by another accredited certification body in the new region.

The need for accreditation is an important outstanding issue for a bioprospecting certification system. The issue needs to be explored particularly in the context of the scale and the demand for certification. These variables may, in turn, influence how many certification bodies may want to get involved and lead to a decision on the need for accreditation.

If the system is global, and demand for certification is high, then the system almost certainly will have to be designed around accreditation to ensure consistent application by multiple certification bodies. At the other extreme, if demand is limited and there are no certification bodies interested in applying the system developed, the oversight body could engage in the certification process itself, negating the need for accreditation altogether. Something similar would be applicable to a national or smaller scale system.

2.2.7 Unit of Certification

There are two primary units of certification that are addressed under the international social and environmental systems reviewed. The first addresses production practices in definable areas such as forests, fisheries or factories. The second addresses chain of custody. Some certification systems apply to both.

Where production practices in a defined area are being certified, certification allows the producer to distinguish itself from others producing similar products, but using different production methods. Certification systems that evaluate production practices are designed to objectively distinguish between producers.

If a government initiated such programmes, and the products were in international trade, the systems might come under the scrutiny of the World Trade Organisation, if there were suspicions of discriminatory application. In contrast, the existing international social and environmental certification

systems are private, non-governmental undertakings. Their voluntary nature, consensus-based standards and non-discriminatory policies keep them from running afoul of world trade rules such as the WTO's Agreement on Technical Barriers to Trade and its Code of Good Practice for the Preparation, Adoption and Application of Standards.

Interestingly, environmental certification systems generally recognise that their standards cannot be a direct measure of sustainability when the use of natural resources is at issue. In the forest area, for example, directly measuring sustainable forest management is complicated by multiple definitions in terms of environmental quality, economics and social factors (Heaton and Donovan, 1996).

What certification can do is to distinguish between the key elements of what contributes to good and poor forest management as a means to clarify the path to sustainability (Heaton and Donovan, 1996). When viewed as a process requiring continual performance improvement, certification can move producers towards the ideal of sustainability (Heaton and Donovan, 1996).

A supply chain for a product very often involves different companies that transport and process the product on its way to being offered for sale to consumers. Chain of custody refers to "how an organisation keeps track of a product's inventory and handling up to the point of the product's sale or transport to other parties" along the supply chain (Rainforest Alliance, 2000). In other words, chain of custody is "an unbroken trail of accountability that ensures the physical security of samples, data and records (Groves, *et al.*, 1996)."

For certification, the integrity of a chain of custody is measured against specifically developed standards. Certification of production practices is typically a prerequisite to chain of custody certification for sustainably sourced natural resource-based products.

In the systems examined, chain of custody certification is typically associated with a product logo or label. The logo or label indicates the social or environmental friendliness of the product being offered for sale. Chain of custody certification assures a consumer that the products offered for sale and associated with a particular logo or label have been produced in accordance with the claims associated with the certification system. Certifying the chain

of custody from the production site to the retailer allows the retailer to display the product in conjunction with the logo. In theory, this offers the retailer a competitive advantage when consumers recognise the logo and choose the product over another.

In chain of custody certification what actually gets audited is the physical evidence of a product's life history from raw material to finished end product (Groves, *et al.*, 1996). Physical evidence includes documents, tags and labels that accompany the materials through the production process. Certificates of origin are particularly useful.

Chain of custody certification also audits the management systems that are put in place, for example, to ensure that the certified materials are not co-mingled with non-certified materials. For wood products, "chain of custody refers to the complete process by which wood is transformed from a tree in a forest to a final end product provided to a consumer in a wholesale or retail market (Rainforest Alliance, 1998)."

For marine ornamentals, chain of custody "means the sequence of commercial operations or people responsible for the collection and trade in marine aquarium organisms" beginning with the collector, extending to the retailer and ultimately to the end buyer (MAC, 2001a). "For a retailer to be able to offer certified marine organisms, all components of the chain of custody handling the organisms must be certified (MAC, 2001a)."

For edible fish products, the MSC *Chain of Custody Certification Standard* is "designed to provide a high level of confidence that the products carrying the MSC logo originate from an MSC-certified fishery while not imposing unreasonable compliance costs on the industry (MSC, 2000)." Anyone wishing to apply a Marine Stewardship Council logo to fish products must first obtain a chain of custody certificate.

The development process for a bioprospecting certification system needs to address the unit of certification. Bioprospecting practices, such as securing prior informed consent and negotiating mutually agreed terms, would likely be addressed. Benefit sharing or other issues would also be addressed.

It is unclear, however, whether the system should include chain of custody certification. For example, in a bioprospecting system, the "consumer" will be the genetic resources end-user. In contrast to other established certification

systems, the end-user is not the consumer on the street. More typically, the end-user will be a company or a research institute.

Without prejudging the possibilities, it would not seem that there is a need to certify chain of custody, unless a claim would be made in relation to a consumer product. However, from a systems point of view, creating and implementing chain of custody systems will ensure that genetic resources are tracked. These could be a requirement of certification.

Another important issue is the extent to which individual genetic resource transactions can or should be certified as "fair and equitable" up-front. Ten Kate and Laird (1999) have suggested indicators for fair and equitable bioprospecting agreements. However, it may be very difficult to certify transactions *per se* because of the individuality and confidentiality of each deal. Where there is adequate information to all negotiating parties, what is "fair and equitable" is up to the parties to decide. Furthermore, transaction costs may be high.

In the end, it may not be necessary to declare every transaction fair and equitable because a certified user will have had to demonstrate its commitment to fairness and equity both in corporate policy and in practice. By generating indicators it may be easier to judge a user's past performance by evaluating the extent to which the indicators were taken into consideration in previous deals.

There could also be an aspect of certification where the individuals or institutions within the provider country are interviewed by the certifier to ascertain performance relative to a certain transaction or agreement. This could be accomplished as a condition of certification or during auditing after certification is obtained.

2.2.8 Proof of Certification

The independent social and environmental certification systems were created to provide a market-based tool to differentiate and choose between products produced with socially and/or environmentally friendly processes.

One of the primary advantages that accrues to an organisation that obtains third party certification is the public recognition that its products or services

conform to social and environmental standards. The improved public image associated with certification could be translated into a competitive advantage when products or services can be associated with a form of proof that can be used in public. Consequently, the incentive to voluntarily participate in the system is embodied in the competitive advantage that certification is supposed to create.

In its most basic form, proof of certification is simply written evidence that an organisation complies with the standards against which it was assessed. The image that comes to mind is a diploma-like certificate of compliance that can be displayed in the chief executive's office or in the foyer of the organisation's corporate headquarters.

Obtaining the certificate becomes a marketing tool when it can be associated with a recognisable and trusted label or logo that can be displayed in the marketplace. A logo can be displayed on products sold in shops, or it can be used on company letterhead or in a company report.

A logo may be the only connection the consumer has with the certification system. As with any other brand, maintaining the credibility of the logo in the consumer's eye is a primary goal of the organisation overseeing the certification system. With the exception of ISO, all of the systems reviewed have an associated logo or label.

A self-evident rule associated with the use of the logo is the basic requirement that an organisation must be certified in order to use the logo. Other rules may also apply.

For example, a registered organisation may only use the EMAS logo on (1) validated information, (2) validated environmental statements, (3) organisational letterhead, (4) information advertising participation in the EMAS programme and (5) advertisements for products, activities and services. Because the EMAS logo is not an indication of the environmental friendliness of products or services themselves, it cannot be used on products or packaging, or in conjunction with comparative claims concerning other products or services.

Programmes accredited by IFOAM are licensed to enable them to display the IFOAM logo along side their own logo. They can also sub-license the IFOAM logo to the producers that they certify, in conjunction with their own

programme's logo. A multilateral agreement provides signatory certifiers with reciprocal recognition of their labels.

Under the Marine Stewardship Council system, the certified fishery can display the issued certificate as part of marketing materials. Depending on the situation, the MSC logo can be placed on fish containers after entering into a license agreement and pursuant to MSC *Rules and Regulations.* A certified fishery can "claim that the fish it sells on to retailers processors and consumers…emanates from a sustainable and well-managed fishery (MSC, 1998)." The claim demonstrates that fishery's commitment to sustainable fishing and allows the fishery to benefit in the marketplace. The certifier and/or the MSC must review all publicly made claims for accuracy prior to their release.

Under the SAI system, certification gives the organisation the ability to display the SA8000 certification mark in a certified factory. The certification mark can be used as a marketing and public relations tool with customers and shareholders.

Certification systems have proliferated in recent years and so have their logos and labels. Like competing claims, competing logos can cause confusion in the marketplace.

Some organisations have realised that logo proliferation is potentially problematic. For example, ISEAL is exploring the possibility for a joint certification assessment between its members in those areas where the programmes overlap. Joint certification could lead to the issuance of a "super seal" designed to help reduce logo proliferation.

The need for and application of a logo or label in a bioprospecting certification system may depend on the scope of the system, in particular, the certification unit. In general, however, an associated logo or label would appear to be an important marketing tool for the system, even if there will not be a tangible product on which to display it. In other words, without a product, a logo or label can still be associated with the system itself.

A logo or label's real value may be defined by those certified under the system. In this case, the logo or label can be used as a marketing tool. When

used by bioprospectors the mark may offer a competitive advantage such as facilitated access. The logo might be used in conjunction with public relations, marketing and reporting materials.

When used by provider countries in a system in which they are certified, a logo or label may result in a greater likelihood of attracting more bioprospecting and with it an increased possibly for benefit sharing.

Drawing on the FSC and MSC "check-mark" logo, a double helix check mark might be developed for a bioprospecting certification system. Rules would be needed for the logo or label's use.

2.2.9 Operational Funding and Costs to Participate in the System

The international social and environmental systems reviewed are not self-supporting. The primary funding sources are private foundations and government aid money.

Some systems, especially those dealing with chain of custody, hope to become self-supporting one day by passing a premium on to the consumer. Other systems recognise that donor support will always be needed. The representatives of some systems believe that donor money helps to maintain credibility and avoid conflicts of interest.

FLO claims to be the only certification system in the world where producers do not pay to be certified (FLO, ____). Through pass-ons, the consumer ultimately pays a "fairtrade price" incorporating a "fairtrade premium" that producers take. In addition, national fairtrade initiatives charge the licensee a fee for using the Fairtrade label. The licensing fee pays for FLO's certification and monitoring costs and for the marketing/awareness raising expenses of the national initiatives.

SAI is primarily funded from donor money. Membership dues do not and will not cover operating costs. It is envisioned that donor support will always be needed (Zaid, 2001).

SAI collects a percentage from certification fees charged by accredited certification bodies. Fees are generated from training courses that are available to auditors and the general public. Increasingly companies are paying for their supplier's factories to improve and be certified and there is a

“supply chain peer pressure” for these factories and their customers to become certified (Zaid, 2001).

The Forest Stewardship Council has five sources of income: (1) evaluation fees paid by certification bodies to cover the cost of accreditation; (2) licensing fees charged to accredited certification bodies for use of the FSC logo; (3) grants and donations that are unconditional; (4) membership dues (based on a sliding scale and designed to be non-discriminatory against southern members); and (5) returns from investments and services (FSC, 1999a).

The Marine Stewardship Council does not charge certification bodies for accreditation, other than a nominal application fee (Scott, 2001a). The rationale behind this is to ensure that the MSC can make its decisions on issuing and withdrawing accreditation independent of the need for income resulting from that accreditation activity (Scott, 2001a).

The Marine Aquarium Council is funded presently with foundation and bilateral development aid grants and some industry contributions. The ultimate goal is for MAC, and the system, to be self-supporting, perhaps through a price premium on marine ornamentals, dues/fees from certified companies and use of the quality control and inventory tracking system that the certification system requires and that will be developed by MAC (Holthus, 2001a).

Funding the bioprospecting certification system and the costs to participate in the system are major considerations that need to be addressed in developing the system. They directly or indirectly will affect the operational feasibility of the system.

At least initially, the funds to design and operate a global bioprospecting system would probably come from foundations, bilateral development aid and other sources of government funding. It is important to keep in mind however that a global system may never be fully self-supporting because of the inability to cover its operating costs directly from operating the system.

National or smaller scale systems may also benefit initially from private and public funds. Because of their scale, there may be a greater likelihood that costs can be covered through alternative means once the system is operational.

The ability to recoup costs and make a reasonable profit may directly influence the extent to which a private enterprise may wish to be involved with any aspect of a certification system. . This may especially be the case in the design and operation of its own system.

The costs of a certification system go beyond simply funding the basic programme. A key design consideration for the system is to keep costs to participate in the system low enough to prevent cost from becoming an entry barrier for potential participants. Where this threshold may be for bioprospecting certification is a key design and marketing question, especially if the system intends to be self-supporting.

Keeping participation costs down will ultimately contribute to maintaining equal access to all organisations that seek certification. It will also minimise claims of discrimination. This will contribute to the system's universal application.

The costs to the organisation seeking certification include (1) the cost of an initial assessment, (2) the costs to improve its practices so that they reach a level acceptable for certification, (3) the annual costs to participate in the system, (4) annual or bi-annual surveillance auditing costs, (5) logo licensing fees and (6) membership fees, where applicable. Similar costs can also accrue to the certification body designing and implementing a certification programme based on recognised standards and seeking accreditation.

Costs have been considered by developing countries in other existing certification systems as a burden due in large part to the lack of nationally based certification bodies. In many cases, for example, certifying products or systems in developing countries involves paying an accredited, but foreign, certification body. The costs directly or indirectly associated with this can quickly become onerous. Therefore, if a certification system for provider countries is to be developed, its design should consider the need to train local certifiers and to establish accredited local certification bodies to minimise costs (Normand, 2001).

2.2.10 Governance

Governance structures of the international social and environmental certification systems reviewed are premised on the same basic components. Variations depend on whether the oversight organisation is membership or non-membership-based.

The basic components common to the international systems include a board of directors, an advisory board, a secretariat, a standards committee, an accreditation committee and a dispute settlement or appeals process. Technical working groups may be created as the need arises.

A membership-based system will likely have a body in which members can participate in the broad decision-making affecting the overall system such as standards development and accreditation.

The Forest Stewardship Council may be one of the most complex examples of a membership based certification system. Its governance structure strives to be highly participatory while balancing the power of three primary stakeholder constituencies.

FSC's governance structure has been criticised as cumbersome. Notwithstanding this its individual elements are illustrative.

FSC members can be individuals or organisations. In their membership application, prospective members must provide written evidence that they support FSC as an organisation, its aims and activities and the FSC *Principles and Criteria* (FSC, 1999a).

The FSC members act collectively in the General Assembly, FSC's supreme authority and the highest organ of the association (FSC, 1999b). The General Assembly meets once every three years. It normally restricts its decisions to revising the FSC *Statutes*, *By-laws* and *Principles and Criteria*, admitting and expelling members, electing the Board and acting as the final authority in dispute resolution (FSC, 1999a). The General Assembly has delegated operational activities and most decision making to the Board.

The General Assembly is composed of three chambers "to maintain the balance of voting power between different interests without having to limit the number of members (FSC, 1999a)." The chambers are further sub-divided according to voting power to achieve a balance between Northern and Southern perspectives. These organisations have 50 percent of the voting power, respectively.

The Social Chamber is comprised of social and indigenous organisations and assigned individuals. The Environmental Chamber is comprised of environmental organisations and assigned individuals. The Economic Interest Chamber is comprised of organisations and individuals with an economic interest in the forest production trade.

The Board of Directors is elected by a free vote of all FSC members (FSC, 1999a). Its responsibilities include the formulation of high-level policies, strategies and plans and agreeing FSC strategic direction and priorities.

The Secretariat is headed by an Executive Director who is responsible to the Board for, among other things, effective implementation of FSC policies and programmes (FSC, 1999a). The Secretariat elaborates on the responsibilities of the Executive Director including international marketing, promotion and fund-raising, co-ordination across the FSC network and operational and administrative decision making.

Social Accountability International is a membership organisation (Zaid, 2001). Members pay dues. Members are provided conditional membership and must meet eligibility criteria such as presenting a plan for continuously increasing the percentage of certified supplier factories that they work with within three years of becoming a member (Zaid, 2001). They must also be open to internal and external audits. A benefit of membership is that a member can publicly state that they are an SAI member and that they are improving their performance.

The Marine Stewardship Council is not a membership based organisation and this was initially criticised for being undemocratic. A governance structure was developed to ensure MSC accountability, but it has proven to be "(1) cumbersome; (2) expensive to operate; and (3) leaves the MSC open to potential capture by particular interest groups or sectors (MSC, ___c)."

The MSC governance structure is under review. The initial conclusions from a public survey have indicated four primary characteristics are needed: "(1) 'form should follow function'; (2) MSC's governance should be flexible; (3) MSC needs a strong main board, an expert technical capability, an efficient corporate capability and a better defined role and purpose for its stakeholders; and (4) a closer link between the main board and the stakeholder groups (MSC, ___c)".

Governance structures for a global or national bioprospecting certification system will depend upon the resolution of two issues. First, whether a new independent oversight body will be set-up. If so, the basic components of a formal governance structure should include a board of directors, an advisory board, a secretariat, a standards committee, an accreditation committee (if accreditation is deemed necessary) and a dispute settlement or appeals process.

A small scale bioprospecting certification system may not need such a formal governance structure. Instead, it may operate with a secretariat and an advisory board.

The second issue is whether the oversight body will be membership based. If membership based, an additional governance component may be necessary. This would provide a mechanism through which the members may participate in the organisation. In keeping with the ISO 60 Series, it appears that there is a trend away from membership organisations to avoid conflicts of interest.

A simple alternative might follow the lead of the Marine Aquarium Council. MAC is not a "membership" organisation *per se*. Instead, it is a "network" of concerned parties and stakeholders working together (Holthus, 2001a).

2.2.11 Legal Status and Affiliation

The legal status and affiliation of the certification system are related to governance.

In most cases reviewed, the certification system is overseen by a private organisation. A private body should probably oversee the bioprospecting system's development and implementation as well.

The scale of the system, and potential demand envisioned, may determine the type of private body that should oversee the system's development and implementation. For example, a global or national system may require the creation of a completely new body.

However, an alternative to creating a new body, at least initially, would be to base the system out of an existing private organisation. This organisation could be a non-profit, such as an environmental NGO that operates certification programmes in other areas. It also could be a commercial enterprise, such as a company that already operates as a certifier. In either case, it would be advantageous to work with an organisation that may already oversee existing certification schemes because the organisation would be expected to have already gained significant experience that could be applicable to the bioprospecting area.

To ensure the credibility of the system, commentators and documentation on existing international environmental and social certification systems continually emphasise the importance of independence from political, economic and other influences.

A first issue related to affiliation and independence is who initiates the process to develop the bioprospecting certification system? The international social and environmental systems were initiated by groups of stakeholders led by a "lead" private organisation or a group of organisations such as NGOs. In the case of MSC, an international NGO worked with a large multi-national corporation.

A single organisation or a group of organisations would be expected to take the lead for a global or national bioprospecting certification system. As an alternative to this, a non-profit NGO or commercial enterprise could be envisioned to take the lead and develop its own small scale system that it alone would operate and market.

Another issue relates to the relationship between the ISO and a global bioprospecting certification system. One of the reasons that the existing international social and environmental certification systems were built outside of the ISO process was to ensure their independence from governmental influence. ISO national members typically are governmental organisations

and governments may be involved in decisions at odds with the systems' objectives (Scott, 2001b).

Other reasons for not working through the ISO process included the management system orientation of the ISO 9001 and 14001 standards. This was deemed incompatible with a performance-based approach. Another reason was the national member initiated process to make proposals for new ISO standards. The limited transparency of the standards development process and its long length of time were also problematic. One final reason why ISO was likely by-passed is the advantage that a private, independent organisation has in overseeing a voluntary system of standards. Trade-related problems with the WTO can be avoided.

For these reasons, as well as the political sensitivity of the issue, it would appear that a global or national bioprospecting certification system should be developed independent from the ISO.

The need for political independence also suggests that any process to develop and operate a global certification system will need to actively engage, but remain independent from, the CBD. The extent to which CBD engagement would be necessary for a national system or a smaller scale system would be less than for that for a global system. However, it would still be necessary for these systems to engage the CBD to, for example, track developments, obtain feedback and maintain transparency to ensure the legitimacy of the system.

Links should be built with the CBD (1) to ensure that the policies of the Conference of Parties are reflected in the standards development process and (2) to share information.

The access and benefit sharing guidelines that will be developed under the CBD will be the most direct link to the bioprospecting certification system. These will likely be technical guidelines that are politically accepted by the CBD Contracting Parties.

The guidelines can provide the foundation upon which the more detailed standards of the certification system are based. Basing the standards upon the guidelines would provide political and international legal legitimacy to the standards and the system. A useful bridge to the CBD and its processes could be established.

Other links to the CBD COP will also need to be built where the system would be global and involve an independent oversight body. The CBD should be represented in the governance structure. To establish direct liaison, CBD representatives, such as the chairman of the Subsidiary Body on Scientific Technical and Technological Advice (SBSTTA) or the CBD Secretariat, could be invited to sit as observers on the oversight body's board or on any advisory board that is created. CBD representatives might also observe any multi-stakeholder process to develop standards.

In addition, it will be important to brief the CBD COP on a periodic basis either directly through information documents, or indirectly through side events at CBD meetings. This should be initiated early on as a system is developed.

Links could also be built from the CBD Clearinghouse Mechanism (CHM) to the system's WWW site. The CBD CHM could be used as a tool to disseminate information and to increase the system's transparency. For example, public summary reports on certifications could be available through the CBD CHM.

Most ideally, it could be very useful for a future CBD COP decision to refer positively to the bioprospecting certification system. Seeking a reference could be premised on the argument that the certification system will support the implementation of the CBD Guidelines.

2.2.12 Dispute Settlement

An innovative characteristic found in some of the systems examined is a dispute settlement mechanism. For example, SAI has a decentralised complaints and appeals process. The SAI Board oversees it.

Accredited bodies and SAI "shall have in place a procedure to review appeals and complaints and to initiate another audit - at the company's or certification body's expense if required (SAI, ___c)." The process created must include a provision "for the individual or organisation that filed the complaint or appeal to receive a report of the corrective action taken."

Special SAI guideline (no. 304) suggests against whom complaints can be made, the actions justifiable for appeals and who could make a complaint or

an appeal. For example, complaints can be lodged by certified companies against SAI accredited certification bodies. SAI personnel can lodge complaints about the management system or SAI's service. Third, parties can lodge complaints or make appeals about the appropriateness of a certification or an accreditation.

Complaints can be raised either with the certification body or with SAI directly. Procedures and information requirements for making a complaint or appeal are described in the guidelines.

The extent to which a bioprospecting certification system needs to include a dispute settlement mechanism would seem to depend primarily on the scale of the system. A global system or a national system would probably operate more smoothly with a dispute settlement mechanism. Either system might also be viewed as more transparent, and possibly more legitimate, with a dispute settlement process.

On the other hand, a smaller scale system, operated exclusively by a non-profit NGO or commercial enterprise, could provide for dispute settlement contractually. A formal dispute settlement process would probably not be needed. Instead, the contract to provide certification services would simply define the means of dispute settlement. This could be through the court system or through alternative means such as mediation or arbitration. It might also include a choice of law provision that would be helpful in clarifying which law to apply in contractual disputes.

2.2.13 Public Awareness and Capacity Building

Certification is a very specialised tool that may initially be useful only to a limited number of organisations. Public awareness and capacity building are two key objectives in a number of the international systems reviewed.

Public awareness campaigns can help create demand for the system, help increase the system's recognition and could be a pre-requisite for initial acceptance by both potential participating organisations and the general public. Public awareness raising is typically undertaken by the secretariat of the certification system's oversight body.

For example, FSC conducts educational activities. These focus on the importance of improved forest management and how forest certification could help to achieve this. FSC also provides policymakers, forest managers and legislators with guidance and assistance on forest management issues.

Awareness raising may need to be supplemented with capacity building efforts for the primary stakeholders participating in the system. Capacity building may be important when organisations have limited means to participate in the system. But where the oversight body is involved with both certification and capacity building, real or perceived conflicts of interest may emerge. These could potentially tarnish the credibility of the system.

For example, disadvantaged agricultural producers are certified by FLO who not only monitors them, but also provides them with marketing and other support if needed. FLO is restructuring in part because it perceives that its present roles as both a certification body and a provider of support to disadvantaged producers could affect its credibility in the marketplace. In a move to bolster its credibility, FLO is considering separating the certification body from its support activities.

Training is a key component of the MAC *Core Standards and Best Practices*. MAC will work to develop MAC approved training courses that will be available to the certification client.

SAI plans to use international consultative workshops to raise awareness about SA8000 and how to improve workplace conditions. The workshops will take place in five sub-regions throughout the world. The sub-regions have been identified for their emphasis on or growth in export manufacturing.

The workshops will be used as a means to build the capacity of key stakeholders. This should ensure that they could get effectively involved in the auditing process. Technical training will be provided through workshops aimed to facilitate better working relationships between management, NGOs and trade unions in producer countries.

ISO has a programme to assist developing countries. It consists of training seminars, sponsorships/fellowships and publications.

Any bioprospecting certification system will need to undertake awareness raising exercises (i.e., marketing) to inform the public about the system, how the system operates and the system's advantages. Target audiences would

include potential clients and those that will ultimately judge the client or accept the certification.

Depending on the scope of the system, in particular whether it will apply to provider countries or indigenous and local communities, capacity building will likely be needed to enable these stakeholders to participate in the system.

3. The Feasibility of a System to Certify Bioprospecting Activities

3.1 The Nature of Genetic Resources Transactions

The negotiations of the CBD's access and benefit sharing provisions were premised on the ideal genetic resources transaction: a simple one-off transaction between a provider and a user. However, the negotiations and the resulting Convention text overlooked the depth of the complexity.

The complexity of the situation quite simply stems from the fact that genetic resources are widely available; are easily replicable even in minute quantities; and are used in a myriad of ways by a wide range of users. In contrast to the idea of a simple bilateral exchange, the number of actors potentially involved is quite great, while the different routes and transactions that lead to an end use can be quite varied.

An added complexity is the ambiguous legal status of genetic resources in many countries. This makes it difficult to know who owns the materials and who has the right to share in the benefits generated from their use.

Consequently, for these reasons, it is not possible to describe the nature of a typical transaction.

However, the inability to describe a generic genetic resource transaction may not be problematic for a bioprospecting certification scheme. In setting up a basic certification system it may be more important to simply identify stakeholders that provide and use genetic resources.

3.2 Gauging the Possible Demand for and Incentives from a Bioprospecting Certification System

The research for this study cursorily sampled the opinions of experts on the possible demand for a bioprospecting certification system. These were gathered on an *ad hoc* basis and cannot be substituted for a more definitive study on demand perhaps in the form of a market survey. In lieu of a definitive survey, an estimate of the incentives for primary actors to participate in a certification system could be used as a surrogate to gauge possible demand.

The primary actors involved in genetic resources transactions are: (1) the private sector; (2) the public sector; (3) public and private intermediaries; and (4) indigenous and local communities (ten Kate and Laird, 1999). All of these actors may be interested in participating in a bioprospecting certification system.

3.2.1 Private Sector

The private sector focuses on the commercial use of genetic resources. It discovers, develops and markets products based on genetic resources.

There are seven primary industry sectors that use genetic resources: (1) pharmaceuticals, (2) botanical medicines, (3) major agricultural crops, (4) horticulture, (5) crop protection, (6) biotechnology (outside of health care and agriculture), as well as (7) cosmetics and personal care products (ten Kate and Laird, 1999). Of these, the pharmaceutical, crop protection and biotechnology sectors may be most suited to initially participate in a bioprospecting certification system.

Companies within these sectors are actively searching for and using genetic resources from plant, animal and microbial sources. They also use combinatorial technologies to generate additional diverse materials for screening. Commentators have concluded that within these sectors the demand for genetic resources is likely to grow in the future (ten Kate and Laird, 1999).

But the same commentators are quick to point out that this likelihood is qualified against three conflicting scenarios (ten Kate, 2001). The tension between these makes it very difficult to predict how private sector demand will affect bioprospecting, the consequent demand for access to genetic resources and, ultimately, the demand for a bioprospecting certification system.

Kerry ten Kate (2001) has pointed out that in the first scenario one could argue that the development of new technologies would aid the discovery of new genes, new biochemicals and their innovative use. This in turn could lead to increased demand for biological materials from *in situ* sources and a new impetus for bioprospecting. One could foresee another scenario where the

same new technologies catalyse a retreat from *in situ* sources in favour of exploring existing collections. In the final scenario, the uncertainty, transaction costs and bureaucracy attributed to the CBD will drive demand down. Some combination of all three scenarios could result.

The uncertain demand for genetic resources is a sobering reality check on the feasibility of developing a bioprospecting certification scheme.

In general, the materials and practices used by the pharmaceutical, crop protection and biotechnology sectors more closely fit the intent of the *CBD's* access provisions which envision bilateral exchange of genetic resources. The supply chains and pedigrees of products may be amenable to chain of custody procedures because discreet amounts of materials are typically used. In fact, because of the multiple relationships companies have with other companies to share materials through cross-licensing, they need to install management systems to keep track of this movement, especially for purposes of intellectual property rights (Rosenthal, 2001).

These sectors also rely less on bulk commodities of plant and other biological materials than, for example, the botanical medicines, cosmetics and personal care products sectors. Therefore lines of sourcing are potentially clearer because the quantities of materials involved are more discrete.

The majority of germplasm used in the major agricultural crops sector comes from *ex situ* sources, particularly in-house collections. Consequently, one would not expect a great demand for new undescribed germplasm from *in situ* sources presently (ten Kate and Laird, 1999). This defining characteristic could influence the sector's need and desire to participate in a bioprospecting certification system.

Another factor complicating the sector's potential participation is the re-negotiation of the FAO International Undertaking on Plant Genetic Resources for Food and Agriculture. The extent of interest to participate in a certification system will be clearer when the negotiations are completed.

The horticulture sector also relies on *ex situ* sources such as in-house collections (ten Kate and Laird, 1999). Therefore it also may not be attractive for this sector to become involved in a bioprospecting certification system early on.

Since the *CBD* has entered into force commentators have noted that companies are scaling back on direct field collecting (ten Kate and Laird, 1999). There are two primary reasons for this.

First, many companies have been scared off by bad experiences in those countries in which they have tried to gain access (Christoffersen, 2001). High perceived or real transaction costs are associated with obtaining prior informed consent and negotiating mutually agreed terms. In some cases where deals have been finalised the legality of the transaction has been subsequently questioned creating uncertainty over the legal status of the materials collected. In short, risk aversion keeps companies at home.

Second, the scale back has coincided with technological advances such as combinatorial technologies. These have shifted emphasis away from screening biodiversity to the screening of synthetically produced diversity.

One result of both of these developments is that companies still involved with natural products development out-source collecting and rely more heavily on genetic resources obtained from public and private intermediaries. Greater emphasis is also being placed on obtaining and screening value-added samples (Eldridge, 2001). In addition, end users are increasingly requiring suppliers to guarantee that materials supplied are legally obtained.

Even with the pull back from field collecting, and the waxing and waning of natural products development, a bioprospecting certification system may offer the private sector four primary advantages. For example, suspicions in a provider country are always a problem - whether before or after a deal has been finalised. Depending on the legal system in a provider country, certification could promote facilitated access because a credible third party certificate could demonstrate a level of corporate practice that engenders trust and confidence that a company will do what it promises.

Certification might be especially useful in situations where the providing country does not have access and benefit sharing legislation in place. It might also provide an advantage to certified companies located in States that are not yet a CBD Contracting Party.

In short, facilitated access could concomitantly translate into a competitive advantage to the certificate holder. Therefore, the first advantage of certification is the possibility for facilitated direct access to genetic resources and lower transaction costs.

Certification's second advantage may be the ability of a company to make verifiable public claims about its access and benefit sharing activities. Relatedly, certification may also provide a tool that a company can use to defend itself against both honest misperceptions and malicious misinformation campaigns.

Third, despite the initial investment, certification may lead to cost savings within a company as it examines its management systems in order to comply. The cost savings may be most relevant to small companies; especially where they have not yet been exposed to the advantages of implementing ISO 9000 management system standards. The bioprospecting certification programme could act as a catalyst to implement the broader ISO management standards in other operational areas.

Larger companies are likely to be most familiar with ISO 9000, especially with principle 8: "An organisation and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value (ISO, ____a)." Their familiarity with ISO 9000 may make them more receptive to a bioprospecting certification scheme because participating in it would be a further refinement of the management systems already in place to implement principle 8.

Fourth and finally, certification may also attract direct investment in the company from the growing field of socially and environmentally responsible investors. Certification standards can provide investors with criteria against which they can judge the claims made by companies and the evidence that a company lives up to those claims.

3.2.2 Public Sector

The public sector has multiple roles in genetic resources transactions (ten Kate and Laird, 1999).

On the provider side of the transaction, governments fund and maintain large genetic resources collections that can act as intermediaries (see Section 3.2.3).

Governments of provider countries also develop policies, laws and institutions on access and benefit sharing. The results of this work and its implementation greatly influence the attractiveness of the country to bioprospectors.

For example, in its second report, the CBD Expert Panel on Access and Benefit Sharing emphasised that "legal, administrative or policy measures need to be clear, simple, flexible and enforceable" (UNEP, 2001). Almost eight years into the CBD's implementation this marketing lesson is just reaching provider countries.

Governments in provider countries may be interested to participate in a certification system for four primary reasons. First, as CBD Contracting Parties, they have the legal obligation to facilitate other Contracting Parties' access to their genetic resources under CBD article 15(2). Certification of a country's access and benefit sharing system could lead to the facilitation of access and a greater likelihood that benefit sharing could result.

Second, certification could help market a country to bioprospectors. The country could gain a competitive advantage from having its access and benefit sharing system certified as meeting or exceeding agreed standards. Because at least 50 countries have created or are planning to create access and benefit sharing measures, certification could be useful tool to distinguish a country from the crowd and to help it to market itself and its biodiversity. Risk averse bioprospectors may be attracted to the country, resulting in more possibilities for benefit sharing.

Third, a certification system might be able to help providers police the implementation of agreements. The regular auditing of certified users by the certification body would provide the basis for this to happen because the threat of losing certified status, and perhaps having this publicly announced, would be an incentive for organisations to comply. This may be especially

attractive to countries that do not have access legislation in place. Relatedly, certification might also provide the basis for a risk averse provider country to avoid or deflect criticism of bioprospecting deals that it has entered by demonstrating the deal's compliance with international best practice (ten Kate, 2001).

Fourth, participation in the certification system could lead to improved management systems and increased efficiency. This could lead to a better use of an institution's human and financial resources. The experience and lessons learned from streamlining management systems related to access and benefit sharing could be spun off and applied in other public management areas as well.

A certification system, applied to governmental institutions to improve public management systems, already exists as an example. PM 9000, developed by the certification company SGS, is adapted from ISO 9000. It has been applied for three years in order to help public institutions integrate their management systems. SGS is currently bringing it up to ISO 9000 (2000) specifications.

PM 9000 is systems-based. However, the stipulation for continuous improvement requires the institution to put in place processes and procedures to drive the necessary improvements. This makes the standard similar to a performance-based standard (Bieler, 2001).

In a context where a number of developing countries already have difficulties to implement appropriate access and benefit sharing systems due, in part, to inadequate financial resources and capacity, establishing a certification system for provider countries could be interpreted as an additional burden (Normand, 2001). Funding will likely be the primary limitation for the provider countries to participate in a system. Innovative funding mechanisms, combined with legal and institutional (e.g., management systems) capacity building to bring a country up to a standard will need to be encouraged.

On the user side of the transaction, governments fund and undertake research and development involving genetic resources (ten Kate and Laird, 1999).

Additionally, in those countries where the majority of genetic resource based industries are located, governments have hesitated to take legal measures to ensure genetic resources are obtained pursuant to prior informed consent and mutually agreed terms. This is despite their obligations under CBD article

15(7) to take legal, administrative or policy measures to support fair and equitable benefit sharing. At the same time, user countries party to the CBD have an interest in minimising the high transaction costs presently associated with access.

The governments of those countries with industries that depend on genetic resources should be interested in a certification system because of its potential to harness market forces to ensure compliance in lieu of regulatory measures. Consequently, governments of countries with major users of genetic resources may be willing to support certification systems, especially by funding provider country participation.

3.2.3 Intermediaries

Intermediaries both acquire and provide genetic resources. In many cases, intermediaries act as a link between the ultimate provider and the ultimate end user of genetic resources. Intermediaries include both non-profit and commercial public and private botanic gardens, universities, research institutes, culture collections, gene banks and brokers (ten Kate and Laird, 1999).

Intermediaries can be involved in exclusively non-commercial research involving biological resources and genetic resources. As such, they act as an end-user of genetic resources. Intermediaries may also undertake exclusively commercial activities with the genetic resources that they obtain. Finally, intermediaries may be involved with both non-commercial research and commercial activities.

Several intermediaries may be involved between the collector and a sample's ultimate end use. Direct transactions can be monitored and enforced relatively easily.

However, when more than one intermediary is involved, the chain of custody back to a source country or community can be severed and with it opportunities for benefit sharing may be lost. Greater awareness, shorter and less complicated supply chains, appropriate management and tracking systems, including a paper trail such as contracts or material transfer

agreements, could all help to overcome this. These are systems-based requirements that could be ensured by a certification system.

As a nexus for many genetic resources transactions, intermediaries could have the greatest interest in a bioprospecting certification system. For example, since the CBD's entry into force, institutions involved with non-commercial biological research are increasingly having difficulty gaining access to biological resources because of cumbersome access procedures[4]. Therefore, research institutions may be amenable to certification if it can help them gain access.

A certification system's development could be facilitated where a sector has already created a code of conduct. More broadly speaking, a certification system could bring coherence to the proliferation of codes of conduct that address intermediary activities. Some existing codes, such as the Botanic Garden Common Policy Guidelines and Micro-organisms Sustainable Use and Access Regulation International Code of Conduct (MOSAICC), could be used as the basis to develop sector specific guidance applied in conjunction with the system's standards.

End-users increasingly require suppliers to provide guarantees that genetic resources are legally obtained. Dealing with certified provider countries could help intermediaries secure this guarantee. Therefore, intermediaries might encourage countries to certify their legal and institutional systems.

3.2.4 Indigenous and Local Communities

Indigenous and local communities are potential sources of genetic resources and associated knowledge. In many cases they are the ultimate providers of genetic resources and associated knowledge. Access and benefit sharing laws increasingly recognise their right to provide prior informed consent and enter into benefit sharing arrangements.

A certified user of genetic resources may be in a position to gain facilitated access to genetic resources and associated knowledge. Indigenous and local

[4] Because of complaints from its research community, the Phillippines now facilitates access to its universities where they have in place a code of conduct covering the activities of its researchers.

communities may also be interested in the third party policing function that a certification system could build in. In order to attract bioprospecting, communities may be interested in participating in a certification system that demonstrates that they are potentially good partners with whom to enter into access and benefit sharing arrangements.

Community access protocols are already defining the conditions under which some indigenous and local communities are willing to work with outsiders engaged in research and/or bioprospecting (Crucible II Group, 2001). They could be an important source of guidance that supplements standards developed under the system. In addition, community access protocols could be used as the basis to certify communities, especially where they help to clarify access procedures.

3.3 General Opinions of Selected Experts

Twenty-two people were contacted on an *ad hoc* basis for this study. Their expertise ranged from bioprospecting to certification.

The objective was to seek their opinions on (1) the general concept of bioprospecting certification and (2) the possible demand for a bioprospecting certification system. The experts also provided general advice and lessons learned that may be useful in developing a bioprospecting certification system.

Representatives of large companies, with various stakes in natural products development, tended to be most sceptical of the certification concept. People from companies with small stakes questioned whether certification could provide them with enough incentive to justify their participation. These people tended also to believe that the problem was not with the private sector but with provider countries.

On this last point, one representative commented that certifying provider countries was interesting but, as pointed out a number of times by other people, the bioprospecting world is quite small. Word gets around as to which countries and companies to deal with. He noted that, in the end, somebody is needed in the provider government to take responsibility and “sign-off” that a user has fulfilled all regulatory requirements.

Industry people also tended to point out that many companies already have access and benefit sharing policies in place. But when asked, one representative commented that there are no criteria against which to judge those policies, or to measure the claims made by various companies even though auditors regularly examine the general environmental and social claims many companies make in their reports. In addition, another company representative said that there was little peer pressure within industry to live up to the policies in place.

A representative from a non-profit organisation actively involved with bioprospecting noted that the incentives for his organisation to get involved would be low because it is already doing work to a high standard. He questioned the overall private sector demand for a system.

He foresaw a number of problems that would need to be overcome if a certification system would be developed. He noted that it may be difficult to determine standards and emphasised the need for a transparent standards development process. Furthermore, he noted that the diversity of stakeholders in bioprospecting is quite large and sectors with existing certification schemes tended to be more homogenous. Another problem would be to overcome entry barriers such as the additional cost to enter and participate in the system.

According to the representative of an indigenous peoples' network, entry barriers for indigenous and local communities would also be an issue. To help to overcome entry and participation barriers, a key component of a future system would need to be support to communities, provided both financially and in-kind (e.g., training). This would facilitate their entry and participation. In general, however he found the idea to be interesting.

One representative from a research institute noted that, while the idea was interesting, the time might not be ripe to create a certification system. Research organisations such as botanical gardens would not buy into the system unless it really could significantly improve their abilities to undertake research. Another person representing a national association of botanical gardens noted that a certification system would be of interest, but that it is too early to consider. Its members are still working on the practical implications of implementing the Botanic Garden Common Policy Guidelines.

At the same time, most industry people acknowledged that research institutes and others in academia have been the major stakeholder not at the table in the CBD's access and benefit sharing discussions. As an intermediary this sector is quite "leaky" and needs to be brought up to speed on the CBD and its provisions. One person noted that "academia needs to be made aware that it is a user of genetic resources".

More enthusiastic comments from industry tended to come from representatives whose companies are already leaders in the field. One person commented that:

"I'm sure that all companies that have established CBD-compliant agreements to cover their bioprospecting activities would be very pleased to have some formal certification provided this could be obtained without entering into some hugely bureaucratic process."

She continued saying that:

"Most companies value good public relations and a certification system would help this...The biotech and pharmaceutical companies would probably welcome this kind of initiative the most... Anything that helps industry ethics would be welcomed."

Finally she noted that "starting small, perhaps by developing criteria for policy development and reporting, might be a good start ... it might be most useful to discuss the general concepts with industry trade associations". Her company would welcome the opportunity to participate in a teleconference call to scope some of the ideas out with others.

Another representative of a leading company said that his organisation was actively looking for a way to objectively demonstrate that it was doing the right thing and making legal ABS agreements. For example, they had been looking at awards from industry organisations in order to distinguish the company. His company had been the subject of good faith misperceptions and suspicions in provider countries even after deals were finalised. His organisation spends a lot time working with their partners in provider countries providing them with information to overcome these problems.

He noted that there are NGOs working actively to undermine legitimate bioprospectors doing the right thing. This ultimately undermines the CBD's objectives.

This representative believed that:

"Some credible mechanism would help companies demonstrate that they meet a certain standard and could overcome misinformation campaigns ... it would definitely facilitate access to genetic resources by helping to eliminate suspicions ... it might also encourage companies to re-engage in the ABS issue, especially since they could better defend themselves against malicious or unfactual claims."

He pointed out, however, that he did know how much demand existed for a certification system because, unlike his company, comparatively few companies are directly involved with bioprospecting in other countries. Many companies are staying home or getting genetic resources from the leakage connected to academia. Because of its interest, his company would be willing to pay to participate in a certification system.

Those most enthusiastic about the possibilities for a bioprospecting certification system were two people actively involved in developing certification systems in the environmental and social area.

The most telling comment about the feasibility of such a system was that "certification can done in any field" and that a number of scenarios could be envisioned for bioprospecting, both on the provider and user sides of the transaction. For example, provider countries could be certified against systems-based standards. Users could be "pre-qualified" for facilitated access.

In addition, it was mentioned that it is very important to incept any standard setting and accreditation bodies according to the ISO Guide 60 Series (Administration of Standard Setting and Accreditation Bodies). This would help to minimise conflicts of interest early on and ensure proper management systems are put in place.

Both persons were quick to point out that a major selling point of a certification system, especially to provider countries and communities, would be that oversight of a deal could be "out-sourced" to a third party: the certification body that certifies the bioprospector and conducts regular audits.

Both also agreed it might be most useful to develop a pilot project to scope the feasibility of a larger global system. Finally, it was suggested that it would be straightforward to secure foundation or aid money to further explore, and then set up, a certification system. They also mentioned that costs to participate in the system could be kept low.

3.4 Possible Architectural Options and the General Feasibility of a Bioprospecting Certification System

3.4.1 Possible Architectural Options

Three possible scales for a bioprospecting certification system have been alluded to throughout this report: global scale, national scale and small scale.

For example, it was suggested that a global scale certification system could operate privately through a specially created independent organisation that would develop standards and either accredit other certifiers or, where demand was low, certify directly. It could certify genetic resource users and providers.

The global system would operate as the sole bioprospecting certification system in the world. Its governance structure would be formal and would ensure worldwide multi-stakeholder participation.

A global system's primary advantage would be its potential to harmonise bioprospecting best practice worldwide through voluntary standards. But actually creating a global system may be difficult because of cost, the complexity of governance and other infrastructure, the need to ensure transparency through stakeholder participation or simple lack of demand.

It was also suggested that a national scale bioprospecting certification system could be created. Like the global system, this would be operated privately by a specially created, independent organisation.

Though it would not have global application, the organisation would certify organisations within the country that it is based, no matter where the organisations operate globally. By definition, it would not apply to genetic resources providers.

Its governance structure would be formal and it would ensure multi-stakeholder participation, but on a smaller scale than a global system.

One drawback of a national scale system would be that it would not harmonise global practice because its participants would be limited to those within a country. Furthermore, if other national systems are developed, a proliferation of standards may cause competition and confusion.

While ensuring a particular national standard of bioprospecting best practice, a national certification system would have the advantage of helping to distinguish organisations within the country, thereby potentially providing them with a competitive advantage *vis à vis* other countries' organisations. The system could also be used as test bed for a larger global system.

The costs to develop a national system might be similar to those for a global system. However, operational costs might be lower due to a smaller governance structure and stakeholder process.

A small scale bioprospecting certification system could be operated privately by an existing non-profit organisation, such as an NGO, or by a commercial enterprise, such as a certification company. It would have the potential to certify organisations globally.

In contrast to the global and national systems, it could operate without a formal governance structure, perhaps with only a secretariat and an advisory board. This may make a small scale system more flexible to manage.

Like a global system, a small scale system could have global applicability. However, it could avoid problems related to cost and infrastructure associated with a truly global system. Such a system could also be used as a test bed for a larger scale version. An important issue would be finding an existing organisation that would be willing to host and start-up the system.

Each of the three system scales could provide the foundation upon which a bioprospecting certification system could be designed and operated.

An international group of stakeholders would be common to all system scales. Table 1 implies that the size of the group and its representativeness would vary with the scale of the system.

The representatives of the group might also vary with the system's focus. For example, if the system would focus on the user side of the genetic resources transaction, then representation from the private sector and intermediaries might be emphasised. It should also be kept in mind that those who would

ultimately accept the certification, such as genetic resource providers, would also need to be included to ensure that the certification system meets their needs. In other words, the system should not be developed in a vacuum.

The group would be tasked with developing a set of universally applicable standards. The standards could be derived from international legal principles, international guidelines, such as those being developed under the CBD and, perhaps, existing codes of conduct as well as other sources of best practice. Ideally, a combination of systems- and performance-based standards would be created.

Depending on the system scale, a certification system would require either a new private, independent organisation to be created, or it would rely on existing private organisations, such as non-profit NGOs or a commercial enterprise.

At global or national scales, a new organisation would likely be desirable to maximise independence, credibility and legitimacy. A formal governance structure should be created to support these aims. The components of the governance structure should include a board of directors, an advisory board, a secretariat, a standards committee and a dispute settlement mechanism.

Where accreditation is deemed necessary, the governance structure would also include an accreditation committee. It appears advisable to forego a membership orientation in order to minimise conflicts of interest.

A small scale system would rely on an existing organisation that may have an interest in creating, operating and marketing a bioprospecting certification system on its own. A small scale system would operate without a formal governance structure though, as it develops standards, it should be advised by stakeholders to ensure credibility and legitimacy.

Whatever its structure, the organisation created or chosen would develop and keep the system and its standards under review.

In all system scales, the organisation could act as a certification body to undertake conformity assessment. In a global or national system, this might be necessary where there is insufficient demand to participate in the system, or where there is insufficient demand by other organisations to participate in the system as certification bodies.

Alternatively, where demand in a global or national system is high, and where there are a number of certification bodies willing to be involved, the organisation could refrain from conformity assessment. Instead, it could act solely to further develop the standards, accredit certification bodies and keep the system under review. Accredited certification bodies would do the actual on-the-ground certifying.

The stakeholders targeted by a bioprospecting certification system could include the private sector, the public sector (i.e., provider countries), intermediaries and indigenous and local communities.

Because interest in certification is likely to be highest in the private sector, initially it may be desirable to focus standards development on the user side of the genetic resources transaction. Ideally, however, the focus of the system should broaden to include the provider side of the genetic resources transaction.

Therefore, a step-by-step process that gradually broadens the certification system to apply to provider countries and indigenous and local communities could be envisioned. This could coincide with awareness raising targeted to provider countries and communities that would explain how the system could apply, how they could participate in the system and the advantages of participation.

Alternatively, it may be simpler and more efficient to design the system up-front with both genetic resource users and providers in mind. Stepwise implementation could occur as awareness of and demand for the system grows.

Importantly, a system at any scale would need to have an awareness and capacity building function. The objective would be to help stakeholders to learn more about, and enable them to participate in, the system. This service would need to be designed to minimise any appearance of a conflict of interest with the system's governance structures.

3.4.2 Conclusion: General Feasibility of a Bioprospecting Certification System

The feasibility of a bioprospecting certification system refers to the interrelationship of factors that contribute to its design and operation. The major factors that need to be considered include the (1) possible scale of the system, (2) its costs and supporting funds, (3) the stakeholders that would participate in it and (4) the relationship of the system with other existing certification systems.

The first three factors have been alluded to in earlier sections of this study and are addressed further below. The last factor is addressed below for the first time in the study.

Table 1 compares possible system attributes that could be applied to the three different system scales. The system attributes are drawn from existing certification systems described in earlier sections of the study.

A major conclusion that can be drawn from Table 1 is that the three system scales share the majority of possible system attributes listed. For example, major attributes shared include the desirability of a third party assessment, the basis for assessment and legal status and affiliation.

The table also demonstrates all three system scales share almost the same outstanding issues. For example, it is unclear whether a bioprospecting certification system should address the fairness and equity of a genetic resource transaction or whether chain of custody should be addressed.

Table 1 also indicates that the primary difference between the system scales is the extent to which some of the attributes need to be applied.

For example, the global and small scale systems should be applicable globally, in other words, to all parts of the world. However, while a small scale system may have a global scope of application, its size and governance structure would contribute to minimising its operational complexity in comparison to a global system.

Similarly, the standards development process for all systems should involve stakeholders and facilitate their participation. But the table indicates that the extent to which the standards development process takes into consideration stakeholder views will vary with the scale of the system.

A global system would be expected to have the broadest stakeholder involvement in the design and implementation of the system because of its unique position as the sole certification system globally. This may also make a global system the most legitimate of the three system scales. In contrast, a small-scale system would be expected to have multi-stakeholder consultations, but on a more limited basis.

An important point to take away is that there may not be great substantive differences among the three system scales. The primary difference will be the extent to which a particular system scale harmonises global best practice. This will likely have an impact on the cost to design and operate the system. In other words, system costs will vary with system scale.

Section 2.2.9 among other things addressed operational funding.

Table 1 indicates that, at least initially, all system scales will likely require outside funding from public or private sources such as governments or foundations.

Small scale systems operated by a private commercial enterprise, such as an existing certification company, may be less dependent on external funding sources because they would tend to be self-financed. However, to a commercial enterprise, the attractiveness of self-financing, or even developing or participating in a system, will be related to demand and, consequently, the ability to recover costs, while making a reasonable profit as a reward for risks assumed.

Even where the profit motive is removed, as in the case of NGOs, the costs to explore, design and operate the system will still need to be covered.

At least initially, financial resources may not be problematic. Based on the comments of experts, it appears that foundation or government money is available to support a scoping exercise, a standards development process and the system's initial operation. Therefore, it seems likely that a bioprospecting system could be further explored and even initiated.

Table 1 indicates, however, that an outstanding issue at all system scales is the extent to which the system can be self-supporting. This issue is important because the sustainability of donor interests and funding is always unknown.

Judging the ability of any system to be self-supporting relates to costs and the future demand to participate. It also depends on the ability of the system to capture rents necessary to support itself. This is may be especially problematic for a bioprospecting certification system.

Unlike the natural resources addressed by other certification systems, genetic resources do not circulate in the consumer economy. Where they do, it is not necessarily in a way where consumers could easily distinguish whether the products embodying them are coming from a certified source without a label or logo. Furthermore, even with a label or logo, there may be no viable mechanism to pass-on and capture costs as with, for example, marine ornamentals or fairly traded agricultural commodities.

Furthermore, extending the system to provider countries, or indigenous and local communities, brings into the system constituencies that have very limited financial resources and other capacities to participate. Assistance would likely need to be provided to facilitate participation. This has important cost implications for the system.

For all these reasons, covering operational costs and securing sources of income may be one of the biggest hurdles to overcome in establishing a bioprospecting certification system and making its operation feasible. How to do this will need to be examined more closely in a system's exploratory phase.

The major stakeholders that could participate in the system have been described in Section 3.2 and alluded to throughout this study. They are the private sector, the public sector, intermediaries and indigenous and local communities.

Notwithstanding the qualifications expressed by private sector representatives in Section 3.2.1, the private sector is the most likely stakeholder to participate in the system. This is because companies are constantly looking for ways to improve their competitive advantage, provided it is cost effective and adds value to their bottom line.

The next most likely participants are non-profit and commercial intermediaries, with the qualification that research institutions, such as botanical gardens, may wish to participate although perhaps not initially. A system's scale may have something to do with this group's desire or ability to participate in the system. This group may wish to participate in a national system, especially where it is supported by government and incentives are provided to participate.

An outstanding question for all system scales is the extent to which provider countries or indigenous and local communities may wish to participate in the system. Provider countries and indigenous and local communities have limited resources to participate. But these groups may have the most to gain by participating in the system. If their participation can be combined with capacity building measures, and if it leads to more opportunities to attract bioprospecting activities, then participation could be attractive.

One problem with ascertaining their demand is that neither group is easily definable or identifiable. The exploratory phase of any system will need to better identify these groups and ascertain their needs.

Finally, on the provider side of the transaction, the relationship of the certification system with other policy measures may also need to be considered.

For example, a bioprospecting certification system will not eliminate the need for access legislation in provider countries, or legislation that protects indigenous and local communities. Before considering joining a certification system, a higher priority for a country may be to first adopt legislation.

If legislation is already in place and works effectively, then there may be little demand for these stakeholders to participate in the system. Notwithstanding this, in countries where the legal and institutional situation is problematic, certification under the system could be made conditional on putting in place efficient legal or other institutional measures that facilitate access while they ensure benefit sharing. To help meet this condition, capacity building could be provided as an incentive and a means to bring the country or community up to the certified standard.

The relationship of a bioprospecting certification system with other existing certification systems has not been addressed in the study thus far. The

possibility of other certification systems operating on bioprospecting does have a bearing on the feasibility of the system.

To prevent duplication of effort, as well as competition and confusion, it would be important for developers of a global scale bioprospecting certification system to ascertain the extent of overlap between the proposed system and existing systems. Where there is overlap, it may be advantageous for a global scale bioprospecting system to collaborate with the other system as a partner. At the risk of inconsistent application, one possibility might be for the "competing" system to operate this aspect of its programme as an accredited extension of the bioprospecting certification system.

To date, however, none of the natural resource-based certification systems reviewed are presently addressing bioprospecting activities, though the issue has come up in the Forest Stewardship Council and the Marine Aquarium Council.

The Forest Stewardship Council comes closest to addressing bioprospecting in its work on non-timber forest products (NTFP). Within the FSC NTFP Working Group, the role of bioprospecting in certification criteria has been discussed, although not to any explicit level (Mallet, 2001). One of the roles of the Working Group has been to develop guidance to certifiers in the objective evaluation of NTFPs.

In the Working Group's recommendations under Principle 3, referring to indigenous groups, a subjective statement is made to the effect that indigenous groups must be adequately consulted (Mallet, 2001). Another section states that indigenous and local communities are to be remunerated for any use of their knowledge (Mallet, 2001). Further information from FSC would be necessary to ascertain its interest in bioprospecting issues.

Bioprospecting has also been flagged as an issue in the development of standards under the Marine Aquarium Council (Davenport, 2001). Presently it is not being addressed and probably will not be addressed for the foreseeable future (Davenport, 2001).

From the preceding treatment in this other and sections of the study, at least in theory, a bioprospecting certification system would be feasible to create. This conclusion relies on the realisation that certification is a tool that has already been applied to a wide range of situations. There is nothing to suggest that certification could not be applied to bioprospecting activities.

Notwithstanding this general conclusion, outstanding issues, such as cost and demand, make it difficult to definitively say whether a bioprospecting certification system would be feasible to create and operate in practice. These outstanding issues need to be reviewed more closely in any subsequent exploratory work undertaken in the future.

Table 1: Possible System Attributes Applicable to Three Different Scales of a Bioprospecting Certification System				
Possible System Attributes[5]	**System Scale**			**Comments**
	Global[6]	**National**[7]	**Small**[8]	
1.0 Global Nature (Sec. 2.2.1)				
1.1Global scope of application?	+++	n/a[9]	+++	Global and small scale systems should be applicable globally (e.g., to all parts of the world). The national scale would be focused on organisations operating in all parts of the world, but which are located in one country.

5 Derived from existing international social and environmental certification systems.

6 A global scale certification system would be operated privately by a specially created independent organisation. It would be intended to operate as the sole bioprospecting certification system in the world. Where demand is high its functions would be limited to standard setting and accreditation. Alternatively, where demand is low it may get involved with actual certification. Its governance structure would be formal and would ensure world-wide multi-stakeholder participation.

7 A national scale bioprospecting certification system would be operated privately by a specially created independent organisation. The organisation would certify organisations within the country that it is based no matter where the organisations operate globally. Its governance structure would be formal and it would ensure multi-stakeholder participation, but on a smaller scale than a global system.

8 A small scale certification system would be operated privately by an existing non-profit organisation, such as an NGO, or by a commercial enterprise such as a certification company. It would have the potential to certify organisations globally. It would operate without a formal governance structure, though it could be advised by stakeholders. The organisation that designs it would operate and market the system itself world-wide.

9 n/a: not applicable.

Table 1: Possible System Attributes Applicable to Three Different Scales of a Bioprospecting Certification System				
Possible System Attributes[5]	**System Scale**			**Comments**
	Global[6]	**National[7]**	**Small[8]**	
1.2 Scale (e.g., global (g), national (n) or small(s))?	g	n	s	
2.0 Third Party Assessment (Sec. 2.2.2)				
2.1 Third party?	+++	+++	+++	All systems scales should be based on third party assessment to ensure the certification decision is objective.
3.0 Initiation of the Certification Process				
3.1 Voluntary initiation?	+++	+++	+++	All system scales should be based on voluntary initiation of the certification process.
4.0 Assessment Basis (Sec. 2.2.4)				
4.1 Universally applicable standards?	+++	+++	+++	All system scales should develop standards that are generic (i.e., applicable in all situations) without the need for local adaptations.
4.2 Complement existing laws?	+++	+++	+++	All system scales should design standards to complement existing laws.
4.3 Transparent application?	+++	+++	+++	All system scales should transparently apply their standards.
4.4 Direct application?	+++	+++	+++	All system scales should design standards for direct application.

Table 1: Possible System Attributes Applicable to Three Different Scales of a Bioprospecting Certification System				
Possible System Attributes[5]	**System Scale**			**Comments**
	Global[6]	**National[7]**	**Small[8]**	
5.0 Standards Development Process (Sec. 2.2.5)				
5.1 Multi-stakeholder consultation?	+++	++	+	The extent to which the standards development process takes into consideration stakeholder views will vary with the scale of the system. A global system would be expected to have the broadest stakeholder involvement because of its unique position as the sole operational certification system worldwide. A small-scale system would be expected to have multi-stakeholder consultations but on a more limited basis.
5.2 Facilitated stakeholder participation?	+++	++	+	As in sec. 5.1 above, the global system would be expected to facilitate the participation of stakeholders who may not have the capacity to participate otherwise.
5.3 Consensus development?	+++	+++	+++	All system scales would be expected to generate consensus on the standards to the extent practicable.
5.4 Pilot phase?	+++	+++	+++	All system scales would likely benefit from a pilot operational phase.
5.5 Periodic review?	+++	+++	+++	All system scales would likely benefit from periodic review (e.g., monitoring and evaluation) to draw lessons learned and adapt the system accordingly.

Table 1: Possible System Attributes Applicable to Three Different Scales of a Bioprospecting Certification System				
Possible System Attributes[5]	**System Scale**			**Comments**
	Global[6]	**National[7]**	**Small[8]**	
6.0 Accreditation (Sec. 2.2.6)				
6.1 Accreditation component?	?	?	n/a	An outstanding issue for the global and national system scales is the need for an accreditation component. The need for accreditation will generally be related to the demand for the certification system and the likelihood that multiple certification bodies will be involved. Where multiple certification bodies will be involved, accreditation is a key tool to ensure consistent application.
7.0 Certification Unit (Sec. 2.2.7)				
7.1 Bioprospecting-related activities?	+++	+++	+++	All system scales should use as their certification unit bioprospecting-related activities of the major stakeholders involved in genetic resources transactions.
7.1.1 Fair and equitable transactions?	?	?	?	An outstanding issue for all system scales is the extent to which a certification system should address the fair and equitable nature of a genetic resources transaction because this is difficult to objectively determine.
7.2 Chain of custody?	?	?	?	An outstanding issue for all system scales is whether chain of custody should be certified or whether a systems-based standard to create chain of custody systems is enough.

Table 1: Possible System Attributes Applicable to Three Different Scales of a Bioprospecting Certification System				
Possible System Attributes[5]	**System Scale**			**Comments**
	Global[6]	**National**[7]	**Small**[8]	
8.0 Proof of Certification (Sec. 2.28)				
8.1 Logo or label?	+++	+++	+++	All system scales should be associated with a logo or label to market the system and to visibly provide a certified organisation with proof of certification and a marketing tool.
8.2 Rules for use?	+++	+++	+++	All system scales should develop rules for the logo or label's use.
9.0 Funding and Costs (Sec. 2.2.9)				
9.1 Outside funding?	+++	+++	++	All system scales will likely need outside funding to initially design and implement a certification system. The exception may be in a smaller scale system that is developed by a commercial enterprise that could self-fund.
9.2 Self-supporting?	?	?	?	An outstanding issue for all system scales is the ability of the system to be self-supporting financially. This will be related in part to demand for the system's services. Commercial enterprises may not participate if their costs cannot be recovered and where a reasonable profit cannot be made.
9.3 Cost as an entry barrier?	+++	+++	+++	All system scales will need to be mindful of the potential for the cost to participate in the system to be an entry barrier and to keep participation costs under control.

Table 1: Possible System Attributes Applicable to Three Different Scales of a Bioprospecting Certification System				
Possible System Attributes[5]	**System Scale**			**Comments**
	Global[6]	**National**[7]	**Small**[8]	
10.0 Governance (Sec. 2.2.10)				
10.1 Formal structure?	+++	++	+	The formality of the governance structure will vary with the system scale. A global scale system operating as the sole certification system in the world will require a more formal system than that at the national or small scale levels.
10.2 Membership organisation?	?	?	n/a	An outstanding issue primarily for a global system, is whether the oversight body should be membership-based. This would be less of an issue for a national scale system because its nature is characteristically less representative.
11.0 Legal Status and Affiliation (Sec. 2.2.11)				
11.1 Private?	+++	+++	+++	All system scales should have a private legal status.
11.2 Independent?	+++	+++	+++	All system scales should be based around private, independent organisations.
11.2.1 Links to CBD?	+++	++	+	All system scales should maintain links to the Convention on Biological Diversity (CBD) but the extent of the links would vary with the system. A global system should include CBD representation on its board, whereas a national or small scale system might simply periodically report to the CBD on its operations. Linkages to the CBD Clearinghouse Mechanism should be encouraged.

Table 1: Possible System Attributes Applicable to Three Different Scales of a Bioprospecting Certification System				
Possible System Attributes[5]	**System Scale**			**Comments**
	Global[6]	**National**[7]	**Small**[8]	
12.0 Dispute Settlement (Sec. 2.2.12)				
12.1 Formal mechanism?	+++	++	?	All system scales should address dispute settlement, but the nature of the mechanism is likely to vary. A global system, and perhaps a national system, would need a formal dispute settlement process to ensure transparency and create legitimacy. A smaller scale system may suffice with measures provided for in a contract.
13.0 Public Awareness and Capacity Building (Sec. 2.2.13)				
13.1 Public awareness?	+++	+++	+++	All system scales should address public awareness to develop recognition and acceptance for the system.
13.2 Capacity building?	?	?	?	An outstanding issue for all system scales is the need for capacity building. This is linked to which stakeholders will participate in the system. Where provider countries or indigenous and local communities seek certification then, depending on the circumstances, it would be appropriate to assist to enhance their abilities to participate in the system. Furthermore, in a global system, it may be advantageous to train local certification bodies, especially to keep certification costs low in developing countries.

Annex I: Summary Chart of Organisations, Standard-setting or Certification Systems Reviewed					
Organisations or Certification Schemes	**Subject Matter**	**Develops Standards?**	**Accredits?**	**Conformity Assessment?**	**General Overview**
European Eco-management and Audit Scheme (EMAS)[10]	EMS[11] and performance	yes	yes	no	EMAS was introduced in 1993 as Regulation (EEC) No. 1836/93. It has since been revised as Regulation (EC) No. ___/2000 of the European Parliament and of the Council of Allowing Voluntary Participation by Organisations in a Community Eco-management and Audit Scheme (EMAS) which was approved on 20 December 2000. The objective of EMAS is promoting continuous improvements in the environmental performance of organisations by (1) establishing and implementing environmental management systems; (2) evaluating performance systematically, objectively and periodically; (3) providing environmental information to the public; and (4) actively involving and training employees. It is a voluntary system applicable to organisations within the European Union. EMAS is a registration system composed of system- and performance-based standards. It is overseen and implemented at the EU Member level. It

10 Compiled from Regulation (EC) No. ___/2000 of the European Parliament and of the Council of Allowing Voluntary Participation by Organisations in a Community Eco-management and Audit Scheme (EMAS) and various documents obtained from the EMAS Helpdesk WWW site (accessed February 2001): *Answers to Some of the Helpdesk's Most Frequently Asked Questions* (date unknown)(____).

11 Environmental management systems.

Annex I: Summary Chart of Organisations, Standard-setting or Certification Systems Reviewed					
Organisations or Certification Schemes	**Subject Matter**	**Develops Standards?**	**Accredits?**	**Conformity Assessment?**	**General Overview**
					supplements existing regulatory laws and is seen as potentially adding value to organisations in terms of regulatory control, cost savings and public image. Any organisation can participate in EMAS. To be registered in the scheme an organisation generally must: (1) conduct an *environmental review* of its activities; (2) implement an *environmental management system* addressing areas specified in an annex to the regulation in light of the results of the environmental review; (3) undertake an *environmental audit* of the organisation's environmental performance according to requirements expressed in an annex to the regulation; (4) prepare an *environmental statement* addressing requirements listed in an annex including results achieved against environmental objectives and targets and the requirement of continuous environmental performance improvement; (5) verify by an accredited *third party environmental verifier* the environmental review and, if appropriate, the environmental management system, environmental audit procedure and environmental statement and validate by the environmental verifier the environmental statement; and (6) forward the validated environmental statement to the competent authority of the Member State in which the organisation seeking the registration is located, and after registration, making publicly available the environmental statement. If an

Annex I: Summary Chart of Organisations, Standard-setting or Certification Systems Reviewed					
Organisations or Certification Schemes	**Subject Matter**	**Develops Standards?**	**Accredits?**	**Conformity Assessment?**	**General Overview**
					organisation comprises one or more sites each of the sites to which EMAS applies must comply with all of the EMAS requirements, including continual improvement. To maintain EMAS registration the organisation must have the environmental management system and audit programme verified on a periodic basis. In addition, the organisation must annually forward validated updates of the environmental statement to the competent authority and make them publicly available. Registration can be suspended or deleted depending on the extent to which the organisation fails to submit its yearly validated reports, pay its registration fees or for other administrative reasons. A registered organisation may use the EMAS logo on (1) validated information; (2) validated environmental statements; (3) organisational letterhead; (4) information advertising participation on the EMAS programme; and (5) advertisements for products, activities and services. Because the EMAS logo is not an indication of the environmental friendliness of products or services themselves it cannot be used on products or packaging or in conjunction with comparative claims concerning other products or services.

Annex I: Summary Chart of Organisations, Standard-setting or Certification Systems Reviewed					
Organisations or Certification Schemes	**Subject Matter**	**Develops Standards?**	**Accredits?**	**Conformity Assessment?**	**General Overview**
					Member States have the responsibility of establishing an accreditation system for the independent environmental verifiers (certification bodies) and the supervision of their activities. Member States are permitted to use existing accreditation institutions, the designated competent authority or designate or set up another body as the national accreditation body. Accreditation is pursuant to the requirements found in an annex to the regulation. Accredited verifiers can operate throughout the EU. A forum of the accreditation bodies is to be established to develop guidance on accreditation and supervision issues. The forum will also develop a system of peer review to ensure that the individual accreditation systems of each Member State fulfil the requirements of the regulation EMAS and ISO14001 are viewed as complementary. EMAS incorporates the requirements of ISO14001 for environmental management systems and in so doing has eliminated the perception of competition between the two systems. However, EMAS is still more rigorous than ISO14001. For example, the EMAS Helpdesk notes that ISO 14001 does not require (1) an initial review; (2) a register of environmental effects; (3) public availability of details of the company's programme and EMAS and site performance in addition to its environmental policy; (4) does not specify the frequency of audits; (5) detailed

Annex I: Summary Chart of Organisations, Standard-setting or Certification Systems Reviewed					
Organisations or Certification Schemes	**Subject Matter**	**Develops Standards?**	**Accredits?**	**Conformity Assessment?**	**General Overview**
					levels of control of suppliers and contractors; and (5) the extent to which performance must be improved. The EMAS system of registration and accreditation is to be supported by a system of fees determined and administered by Member States.
Fairtrade Labelling Organisations International (FLO)[12]	Agriculture commodities and chain of custody	yes	no	yes	FLO is a non-profit, membership-based umbrella organisation founded in 1997 by a group of 17 European national Fairtrade initiatives. National initiatives are all non-profit organisation that own or partly own a label. Among other things, the national initiatives lobby governments, negotiate with traders, advertise Fairtrade and undertake education campaigns. FLO sets Fairtrade standards, certifies and monitors Fairtrade producers and traders, controls the Fairtrade system and guarantees to consumers that the Fairtrade label reflects that Fairtrade criteria have been met for a product all along the supply chain. Fairtrade labelling aims to create market access and benefits for disadvantaged producers of agricultural commodities by assigning a consumer recognisable mark to products produced and marketed according to

12 Compiled from *How Does FLO Work?* (date unknown)(____) obtained from the FLO WWW site (accessed February 2001).

Annex I: Summary Chart of Organisations, Standard-setting or Certification Systems Reviewed					
Organisations or Certification Schemes	**Subject Matter**	**Develops Standards?**	**Accredits?**	**Conformity Assessment?**	**General Overview**
					Fairtrade criteria. The Fairtrade label guarantees to producers and consumers (1) fair trading relations and (2) fair production conditions. FLO has developed Fairtrade criteria for coffee, tea, cocoa, honey, sugar, orange juice and bananas. These are developed taking into consideration the particular situation of producers for a particular commodity. The FLO Fairtrade system involves different actors in the production and marketing process: producers, traders, licensees and consumers. Producers are certified by FLO who monitors them and also provides them with marketing and other support if needed. The producers sell raw product to FLO certified traders authorised to participate in the scheme. Traders can be alternative trading organisations or commercial traders. FLO also monitors the traders. Traders in turn sell products to other traders licensed by FLO and authorised to use the Fairtrade label in their sales to consumers. Licensees must buy the product from FLO-authorised traders. Licensees can also be certified traders. FLO controls the system by ensuring the quantity of Fairtrade goods sold by producers under Fairtrade conditions matches the total amount sold to consumers with the Fairtrade label FLO claims to be the only certification system in the world where producers do not pay to be certified. The consumer ultimately pays the Fairtrade price and

Annex I: Summary Chart of Organisations, Standard-setting or Certification Systems Reviewed					
Organisations or Certification Schemes	**Subject Matter**	**Develops Standards?**	**Accredits?**	**Conformity Assessment?**	**General Overview**
					Fairtrade Premium that producers take. In addition, the national initiatives charge the licensee a fee for using the Fairtrade label. The licensing fee pays for FLO's certification and monitoring costs and for the marketing/awareness raising expenses of the national initiatives. FLO is restructuring in part because it perceives that its present roles as both a certification body and a provider of support to disadvantaged producers could affect its credibility in the marketplace. In a move to increase its credibility it is considering separating the certification body from its support activities. The restructuring process will take into consideration the needs and comments of producers.

Annex I: Summary Chart of Organisations, Standard-setting or Certification Systems Reviewed					
Organisations or Certification Schemes	**Subject Matter**	**Develops Standards?**	**Accredits?**	**Conformity Assessment?**	**General Overview**
Forest Stewardship Council (FSC)[13]	Forests and chain of custody for forest products	yes	y	no	The FSC is an independent, non-profit, international institution that promotes "environmentally appropriate, socially beneficial, and economically viable management of the world's forests." It is membership-based. FSC operates in over 40 countries. The FSC uses its Principles and Criteria for Forest Stewardship as the primary basis for a voluntary accreditation programme for certification of forest management in tropical, temperate and boreal forests. The application of the FSC Principles and Criteria is supplemented by additional guidance such as the FSC Guidelines for Certification Bodies. The FSC also conducts educational activities. These focus on the importance of improved forest management and how forest certification could help to achieve this. Finally, FSC provides policymakers, forest managers and legislators with guidance and assistance on forest management issues.

[13] Compiled from various documents obtained from the FSC WWW site (visited February 2001): *FSC Principles and Criteria* (revised February 2000); *FSC A.C. By-laws* (revised February 1999) (1999a); *Roles and Responsibilities of FSC Players* (31 May 1999) (1999b); *FSC Statutes* (date unknown)(____a); *FSC Protocol for Endorsing National Initiatives* (February 1998); and *FSC Process Guidelines for Developing Regional Certification Standards* (date unknown)(____b).

Annex I: Summary Chart of Organisations, Standard-setting or Certification Systems Reviewed					
Organisations or Certification Schemes	**Subject Matter**	**Develops Standards?**	**Accredits?**	**Conformity Assessment?**	**General Overview**
					While the FSC's primary function is accrediting certification bodies, perhaps its ultimate goal is to help clear up public confusion over conflicting environmental claims related to wood and wood products through its recognisable and respected worldwide standard and label. FSC accredited certification bodies applying uniform standards certify that a forest is "being managed according to agreed social, economic and environmental standards." The accredited certification body issues FSC-endorsed certificates when forest management meets or exceeds the FSC standard. Furthermore, forest products originating from certified forests can carry the FSC logo where chain of custody from forest to retailer has been evaluated and certified. The accreditation process evaluates the ability of independent certification bodies to provide an independent and competent forest evaluation service. The FSC Principles and Criteria are not designed to be applied directly in the field. Rather they are to be incorporated into the evaluation systems and standards of accredited certification bodies. Accredited certification bodies include for profit and not profit organisations such as the Rainforest Alliance Smartwood Programme and SGS and Scientific Certification Systems two for-profit certifiers. Accredited certifiers can operate internationally and evaluate any forest type. The development of national and local standards (see below)

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Organisations or Certification Schemes	**Subject Matter**	**Develops Standards?**	**Accredits?**	**Conformity Assessment?**	**General Overview**
					should support local certification bodies to be accredited. FSC monitors the performance of the accredited certification bodies. In order to better implement the FSC standards at the local level, regional and national initiatives are developing interpretations of the FSC Principles and Criteria specifically tailored to national and local conditions. A primary goal for these initiatives is to decentralise the FSC's work and to encourage local participation. Initiatives can be either established by FSC or can be established independently though the latter must be ultimately endorsed by FSC pursuant to the FSC Protocol for Endorsing National Initiatives. The processes to develop these standards are led by working groups. Stakeholders from the region or a country are consulted to develop consensus on the standards. The working groups are guided by FSC Guidelines for Developing Regional Certification Standards. Relatedly, in order to decrease entry barriers for small landholdings, FSC has developed Guidelines for Group Certification. Principle 3 addresses indigenous peoples' rights. Criterion 3.4 specifies that "indigenous peoples shall be compensated for the application of their traditional knowledge regarding the use of forest species or management systems. This compensation shall be formally agreed upon with their free and

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					informed consent before operations commence. In addition, the FSC Principles and Criteria note that they are also relevant "to varying degrees" to forests managed for non-timber products and other services. "Non-timber products" are defined as "all forest products except timber, including other materials obtained from trees such as resins and leaves, as well as any other plant and animal products. An FSC Working Group has been established to review the feasibility of developing a standard for non-timber forest products. The FSC has a Dispute Resolution Committee though the dispute settlement procedures do not seem to be available on the FSC WWW site. FSC is a membership organisation. FSC members can be individuals or organisations. In their membership application, prospective members must provide written evidence that they support FSC as an organisation, it aims and activities and the FSC Principles and Criteria. The FSC members act collectively in the General Assembly, FSC's supreme authority and the highest organ of the association. It meets once every three years. It normally restricts its decisions to revising the FSC Statutes, By-laws and Principles and Criteria, admitting and destituting members, electing the Board and acting as the final authority in dispute resolution. It delegates

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					operational activities and most decision making to the Board. The General Assembly is composed of three chambers "to maintain the balance of voting power between different interests without having to limit the number of members." The chambers are further sub-divided according to voting power to achieve a balance between Northern and Southern perspectives. These organisations have respectively 50 percent of the voting power. The Social Chamber is comprised of social and indigenous organisations and assigned individuals. The Environmental Chamber is comprised of environmental organisations and assigned individuals. The Economic Interest Chamber is comprised of organisations and individuals with an economic interest in the forest production trade. The Board of Directors is elected by a free vote of all FSC members. Its responsibilities include the formulation of high-level policies, strategies and plans and agreeing FSC strategic direction and priorities. The Secretariat is headed by an Executive Director who is responsible to the Board for among other things effective implementation of FSC policies and programmes. The Secretariat elaborates on the responsibilities of the

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					Executive Director including international marketing, promotion and fund-raising, co-ordination across the FSC network and operational and administrative decision making. FSC has five sources of income: (1) evaluation fees paid by certification bodies to cover the cost of accreditation; (2) licensing fees charged to accredited certification bodies for use of the FSC logo; (3) grants and donations that are unconditional; (4) membership dues (based on a sliding scale and designed to be non-discriminatory against southern members); and (5) returns from investments and services.
International Accreditation Forum (IAF)[14]	Worldwide equivalent recognition of conformity assessment	no	no	no	IAF is a worldwide association of accreditation bodies, industry representatives and accredited certification bodies. IAF seeks to develop "a worldwide programme of conformity assessment which will promote the elimination of non-tariff barriers to trade." IAF works to promote worldwide acceptance of certificates of conformity issued by certification bodies accredited by an accreditation body that is a

[14] Compiled from *What is the International Accreditation Forum, Inc.?* (2000) obtained from the IAF WWW site (accessed February 2001).

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					member of IAF through tools such as peer review and the Multilateral Mutual Recognition Agreement. The Agreement seeks to establish equivalence of accreditation programmes operated by its members who are national accreditation bodies. The ultimate goal of such a system is to assist an organisation with an accredited conformity assessment certificate granted in one part of the world in getting the certificate recognised in the rest of the world. This would be possible because the accreditation programme that accredited the certification body which issued the original certificate would be recognised as equivalent to a similar programme in another part of the world obviating the need for the certified company to be certified again by another accredited certification body in the new part of the world. IAF has traditionally been open only to national accreditation bodies but in November 2000 it agreed to permit membership of international accreditation bodies (with conditions).

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International Federation of Organic Agriculture Movements (IFOAM)[15]	Organic agriculture	Yes	Yes	no	IFOAM is a membership-based, democratic federation that represents the worldwide movement of organic agriculture and provides a global platform for its members to exchange information amongst themselves and others. Its World Board, committees, working groups and task forces carry out IFOAM activities. IFOAM sets and regularly revises the international IFOAM Basic Standards of Organic Agriculture and Food Processing. These reflect "the current state of organic production and processing methods." The Basic Standards are not considered to be "final statements" but are viewed as "works in progress" and kept under review. The Basic Standards cannot be used for certification on their own. They are a framework. In other words, they are the basis for certification bodies and standardising organisations to use them as the basis upon which to develop their own standards, taking into account local conditions. In short, the Basic Standards are "standards for standards."

15 Compiled from various documents obtained from the IFOAM WWW site (accessed February 2001): *Information About IFOAM* (date unknown) (____); *IFOAM Basic Standards for Organic Production and Processing* (September 2000)(2000a); *IFOAM Accreditation Criteria* (Public Draft 1 - 25 July 2000)(2000b); and IFOAM ACCREDITATION PROGRAMME NEWSLETTER #0101 (February 2001).

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					Locally developed standards must meet but can exceed the IFOAM Basic Standards. Producers and processors that market products with an organic label must work within and be certified against standards that meet or exceed the IFOAM Basic Standards. The IFOAM Basic Standards note that organic agriculture can be implemented differently in different areas and this affects how certification can be undertaken. The goal is to find a balance between regional or local variation and the need for international harmonisation that in turn forms the basis for trade, fair competition and consumer trust. IFOAM acknowledges that a proliferation of standards is potentially problematic but also recognises that the proliferation is emblematic of the organic movement's growth. Its policy on variation in standards states that there will only be one IFOAM standard. In general, IFOAM states that variations are acceptable provided they are consistent with the general aims of the Basic Standards and the Accreditation Criteria. It will formulate criteria for variations and create an approval procedure.

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					In 1992, IFOAM established the IFOAM Accreditation Programme (IAP). IAP establishes international equivalency of organic quality claims by evaluating whether organic certification programmes meet the IFOAM Criteria for Certification Programmes and the IFOAM Basic Standards. The International Organic Accreditation Service (IOAS) under license from IFOAM manages IAP. The IOAS Board of Directors is appointed by IFOAM, but the programme operates independently from other IFOAM activities. The Accreditation Criteria are presented in the format of principles supplemented by more specific criteria. The Criteria are under review and, among other things, are being restructured according to ISO Guide 65. Any certification programme can apply for accreditation with the payment of a fee. It does not have to be an IFOAM member (IFOAM membership does not necessarily mean that the member is IFOAM accredited). The following certification categories can be accredited: crop production, processing, livestock, wild products, input manufacturing, retailing and certificate transference. IOAS evaluates a certification programme seeking IFOAM accreditation against two primary criteria. First, IOAS evaluates the performance of the certification programme against the IFOAM Accreditation Criteria. Second, it

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					evaluates the certification programme's standards against the IFOAM Basic Standards. Accredited programmes are audited regularly. They are entitled to display the IFOAM logo along side their own programme's logo via a license. They can also sub-license the logo to their certified producers, in conjunction with their programme's own logo. A Multilateral Agreement provides signatory certifiers with reciprocal recognition of their labels.
International Organisation for Standardisation (ISO)[16]	Management systems	yes	no	no	ISO is a worldwide federation of national standards bodies from 130 countries (one from each country). ISO is a membership-based, non-governmental organisation whose central secretariat is located in Geneva. Established in 1947, ISO promotes "the development of standardisation and related activities in the world with a view to facilitating the international exchange of goods and services and to developing co-operation in the spheres of intellectual, scientific, technological and economic activity." ISO's work results in

[16] Compiled from a telephone conversation with Christian Favre of ISO on 11 April 2001 and various documents obtained from the ISO WWW site (accessed February 2001): *ISO 14000 – Meet the Whole Family* (1998); *ISO Quality Management Principles* (date unknown)(____a); *ISO Frequently Asked Questions* (date unknown)(____b); and *An Introduction to ISO* (date unknown)(____c).

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					international agreements that are published as International Standards. ISO's scope covers all technical fields except electrical and electronic engineering. The vast majority of the ISO standards apply to the product performance specifications in a wide variety of industrial and other sectors. These generally represent harmonised technical specifications that when applied by industry in an industry-wide fashion help to rationalise international trade and lower technical barriers to trade because they provide a "reference framework and common technological language". A newer group of management system standards applies to quality management and quality assurance systems (ISO 9000: 2000 family) and environment management systems (ISO 14000 family). ISO membership is open only to those national standards institutes or similar organisations most broadly representative of standardisation in their countries. Some of the national members are wholly private organisations. Other organisations may be private sector but operate in ISO with a special mandate from their home government. Organisations may also be governmental. ISO standards are developed according to four principles: (1) they are based on consensus; (2) they are to be applied industry-wide; (3) they are voluntary

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					in nature; and (4) are for international use. ISO standards represent consensus agreements between the national delegations of members that in turn represent all concerned economic stakeholders in the country including suppliers, users and governmental agencies. ISO standards are voluntary, but some standards have been adopted into law by some countries or are referred to by legislation. ISO standards can become market requirements. Industry sectors usually express the need for a standard to a national ISO member body. The member then proposes the new work to ISO as a whole. If accepted, the technical scope of the future standard is defined by working groups of technical experts working in technical committees from countries interested in the subject matter. The national delegations of the countries, which are appointed by their countries' national standards institute, then negotiate the standard's detailed specifications and try to develop consensus. ISO rules require the national standards institutes to take account of the views of a range of parties interested in the standard and to present "a consolidated, national consensus position to the technical committee's work." When approved by ISO after circulation to the membership an International Standard is published. ISO standards are kept under review at intervals not to exceed five years.

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					In addition to its technical product related standards, ISO has developed two families of generic standards, guidelines and supporting terminology that apply to management systems: ISO 9000:2000 and ISO 14000. Management systems refer to “what the organisation does to manage its processes or activities.” Both families are systems based and do not apply to products per se though it is recognised that management systems do affect product quality and environmental impact. The standards are generic i.e., applicable to management systems of any organisation. The ISO 9000:2000 family is the updated and consolidated version of the ISO 9000:1994 family applicable to quality management or “what the organisation does to ensure that its products conform to the customer’s requirements.” The twenty standards embodied in ISO 9001:2000 are premised on eight quality management principles that provide a framework for organisations to improve their performance and are derived from technical consultations by experts in ISO Technical Committee 176. Principle 8 is potentially relevant to bioprospecting. It recognises that “an organisation and its suppliers are interdependent and a mutually beneficial relationship enhances the ability of both to create value.”

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					The ISO Technical Committee 207 developed the ISO 14000 family as a collection of environmental management system standards and tools. The central premise of this family is that an environmental management system is a fundamental determinant of the organisation's environmental policy, objectives and targets. These standards can expand the management systems put in place pursuant to ISO 9000:2000 and are intended to help to managers move beyond mere compliance with existing environmental legislation. The family includes standards general principles and guidelines on environmental management systems (ISO 14001 (specification with guidance for use) – the only certifiable standard; ISO 14004 –general guidelines on principles, system and supporting techniques), on environmental auditing(ISO 14011 to ISO 14012) , a series on environmental labels and declarations - ecolabelling (ISO 14020 (general principles) and ISO 14021 (self-declared environmental claims) and ISO 14024 (principles and procedures)) , a series on environmental performance evaluation (ISO/DIS 14031 and ISO 14032 (guidelines and examples) and a series on life-cycles assessment ISO 14040 to ISO 14049. ISO/TR 14061 provides information to assist forestry organisations in the use of environmental management system ISO 14001 standards and 14004 guidelines. Finally, Technical Committee 207 has

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					developed a draft guide on general requirements for bodies undertaking assessment and certification/registration of environmental management systems (ISO/IEC draft Guide 66). ISO does not undertake conformity assessment and does not operate systems to assess conformity of management systems with ISO 9001: 2000, or ISO 14001. In other words, it does not actually certify that products, processes, services or systems meet these ISO standards. There is no such thing as “ISO certification”. Conformity assessment, and therefore the issuance of certificates, is left up to the private sector and government (where required by law). Independent third party testing laboratories and certification bodies offer conformity assessment services involving ISO standards. To help make conformity assessment more harmonised worldwide, ISO has developed guides and standards, representing best practice, which can be used by organisations carrying out conformity assessment. ISO does not accredit certification bodies. Accreditation is undertaken by national accreditation bodies that generally oversee activities related to ISO 9001 and 14001, including certification, within the particulate country. Certification bodies can be accredited to certify conformance against the ISO 9001 standards and/or ISO 14001. Accreditation and certification bodies are

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					following ISO/IEC Guides 61 and 62 prepared by the ISO Committee on Conformity Assessment to conduct their tasks. Auditors are typically also certified or registered as having the needed skills and knowledge to undertake certification. Certificates will specify the standard against which the particular management system has been evaluated. Certification may be needed to fulfil "contractual requirements, for market reasons or customer preference, regulatory requirement, risk management or to set a clear goal for internal quality development." ISO has a programme to assist developing countries. It consists of training seminars, sponsorships/fellowships and publications. ISO national members pay subscriptions that contribute to the operational cost of the ISO Central Secretariat. Dues paid are proportional to a country's GNP and trade figures. Standards and other publications are sold and this covers another 30 percent of the budget. The budget for the Central Secretariat represents 20 percent of the cost to operate the ISO system. The balance of the costs are borne by the organisations that manage ISO's projects and loan technical experts.

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International Social and Environmental Accreditation and Labelling Alliance (ISEAL)[17]	Accreditation of int'l accreditors	no	no	no	The ISEAL Alliance was formed to establish a dialogue and the basis for further collaboration between international accreditation organisations involved with environmental and social issues. The Alliance has four objectives (1) gaining recognition for the international accreditation organisations complying with ISO 6O series guidance; (2) improving the quality of the systems of the participating organisations; (3) defending the interests of international accreditation organisations; and (4) exchanging information. The accreditation organisations initially participating include the Forest Stewardship Council, the International Federation of Organic Agriculture Movements, the Marine Stewardship Council and the Fairtrade Labelling Organisations International. Prior to setting up ISEAL, the international accreditation organisations reviewed existing organisations set-up to represent accreditation organisations but concluded that "none project an international view on conformity assessment certifier accreditation (and)…do not demonstrate the openness and transparency of operations ISEAL

[17] Compiled from various documents obtained from the ISEAL WWW site (accessed February 2001): *About ISEAL Alliance* (date unknown)(____a) and *Agreement in Principle* (date unknown)(_____b).

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					members believe is fundamental to their integrity." In effect ISEAL is being designed as an oversight body for the international accreditation agencies. It will help to maintain quality control and may one day promulgate standards that its membership will be judged against. It is seen as something that will keep the international systems focused and will contribute to maintaining the credibility of their programmes. Considerable overlap exists between the various programmes overseen by the international accreditation organisations and the potential exists for collaboration. Recognising this the participating organisations will jointly study such areas as: (1) accreditation procedures and the development of common protocols; (2) open and transparent peer review processes for accreditation; (3) overlap between system standards and a framework to increase compatibility; (4) joint training programmes; and (5) trademark use and logo proliferation.

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Marine Aquarium Council (MAC)[18]	Marine ornamentals and chain of custody	yes	yes	no	MAC is an independent, not-for-profit, non-governmental international organisation "working to conserve marine ecosystems and achieve sustainable, responsible, environmentally appropriate, socially beneficial and economically viable marine aquarium fisheries that maintain the biological diversity, productivity and ecological processes of the marine environment." It is a non-membership organisation. MAC is developing an independent third party certification performance system to ensure quality and sustainability in the collection, culture and commerce of marine ornamentals that will play a

[18] Compiled from a telephone conversation with Paul Holthus of the Marine Aquarium Council on 29 March 2001 and various documents obtained from the MAC WWW site (accessed February and March 2001): *Core Ecosystem Management Practices International Performance Standard for the Marine Aquarium Trade* (26 February 2001 Draft)(2001a); *Best Practice Guidance for the Core Ecosystem Management Practices International Performance Standard for the Marine Aquarium Trade* (8 March 2001 Draft)(2001b); *Core Collection and Fishing Practices International Performance Standard for the Marine Aquarium Trade* (26 February 2001 Draft)(2001c); *Core Best Practice Guidance for the Core Collection and Fishing Practices International Performance Standard for the Marine Aquarium Trade* (8 March 2001 Draft)(2001d); *Core Handling and Transport Practices International Performance Standard for the Marine Aquarium Trade* (26 February 2001 Draft)(2001e); *Best Practice Guidance for the Core Handling and Transport Practices International Performance Standard for the Marine Aquarium Trade* (8 March 2001 Draft)(2001f); and untitled background information.

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					role in conserving and restoring coral reef ecosystems, facilitate coral reef conservation and ensure that the global market in coral reef organisms does not degrade or deplete coral reef ecosystems or organisms. The system will: (1) establish standards for quality products and practices; (2) provide a mechanism to certify compliance with standards; (3) label the certification results to assure quality; and (4) create consumer demand. MAC has split its standards development process into two phases to meet the immediate need for certification. In the *first phase*, "core standards" and "best practices" are being developed at present by the MAC Standards Committee in consultation with stakeholders inside and outside the sector some of whom are represented in the MAC Standards Advisory Group. These will address three areas: (1) ecosystem management and practices; (2) collecting and fishing practices; and (3) handling and transport practices. The *MAC Core Standards* and *Best Practices* are designed to be globally applicable. The *MAC Best Practices* will serve as interpretative guidance for stakeholders seeking to be certified in compliance with the *MAC Core Standards* by providing clarification, background information and examples of compliance. They describe the type of performance evidence that

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					auditors/certifiers will be looking for when certifying an operation against the *MAC Core Standards*. They also are designed to help auditors/certifiers develop their auditing techniques against the *MAC Core Standards*. The *MAC Core Standards and Best Practice* are interim documents and will be used until June 2003 until the *second phase* of the standards development process is complete and results in adoption of the *MAC Full Standards and Best Practices*. The *MAC Core Standards* and *Best Practices* have been distributed to the public for comment and then will be used in a series of test certifications to begin in 2001. The experience gained in the test certifications will be fed into the second phase of the standards development process to develop the *MAC Full Standards* and *Best Practices*. The *MAC Full Standards* will address the three areas described earlier plus a fourth area on Mariculture and Aquaculture Practices. MAC will work with the entire industry chain of custody from collectors to exporters to importer/wholesalers to retailers and the consumer. The MAC logo can be displayed by retailers where the chain of custody of the marine ornamentals for sale has been certified. Training is a key component of the *MAC Core Standards and Best Practices*.

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					MAC will work to develop MAC approved training courses that will be available to the certification client though not a condition of certification. MAC is funded presently with foundation money. The ultimate goal is for MAC and the system to be self-supporting perhaps through a price premium on marine ornamentals.
Marine Stewardship Council (MSC)[19]	Fisheries and chain of custody for fish and fish products	yes	yes	no	MSC is an independent, charitable, not-for-profit non-governmental international organisation. Established in 1997, by WWF and Unilever, it aims to achieve a balance between social, ecological and economic interests in fisheries by (1) evaluating and accrediting certifiers, (2) encouraging the development of national standards for fisheries and (3) promoting training and education. MSC has overseen the development and keeps under review two global

[19] Compiled from various documents obtained from the MSC WWW site (accessed February 2001): *MSC Principles and Criteria for Sustainable Fishing* (Airlie House Draft) (1 October 1998)(1998); and *History of the Marine Stewardship Council's Principles and Criteria* (date unknown)(____a); MSC *Governance Review Commission Terms of Reference* (date unknown)(____b); and *Memo from Joint Chairmen of the MSC Governance Review Commission* (date unknown)(____c).

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					standards that form the basis of a voluntary, third-party performance-based certification system. The MSC Principles and Criteria for Sustainable Fishing, composed of three principles and attendant criteria, form the basis to independently certify on a global basis “well-managed and sustainable marine fisheries”. The MSC Chain of Custody Certification Standard addresses chain of custody verification for fish and fish products originating from fisheries certified to the MSC standard. MSC standards are seen as “living documents” and are kept under review by MSC. Stakeholders in a fishery such as a fisher’s organisation, a governmental body management authority or a processor decide to seek certification for the fishery and secure an MSC-accredited certifier. Equal access to certification is promoted regardless of the size of the fishing operation. The certifier assesses the fishery (marine fish and invertebrates) against its own standards and criteria, which are in turn in conformity with the MSC Principles and Criteria (the MSC Standard) and follows the MSC Guidelines for Certifiers. A peer reviewed certification report is made. If all conditions are met according to generic scoring guidelines the fishery is eligible for a five-year Fisheries Management Certificate that is issued by the certifier but only after a publicly

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					available certification report, communicating findings to the public, is transmitted to the MSC for publication on its WWW site. Certification is subject to annual monitoring by the certifier. Certification can be made subject to criterion-specific conditions such as the development and implementation of an action plan. The certified fishery can display the issued certificate as part of marketing materials. Depending on the situation the MSC logo can be placed on fish containers after entering into a license agreement and pursuant to MSC Rules and Regulations. A certified fishery can "claim that the fish it sells on to retailers processors and consumers…emanates from a sustainable and well-managed fishery." The claim demonstrates that fishery's commitment to sustainable fishing and allows the fishery to benefit in the marketplace. The certifier and/or the MSC must review all publicly made claims for accuracy prior to release. Chain of custody certification applies to fish that is subsequently manufactured from the certified fishery and is a pre-requisite to the fish products being able to carry the MSC logo. The MSC Chain of Custody Certification Standard provides the basis for an independent certification "system that ensures the MSC logo on fish and fish products is a credible assurance that the fish is

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					derived from a well-managed and sustainable fishery." Chain of custody procedures are applied at key transfer points where the fish can be controlled to avoid confusion with fish from fisheries that are not certified. A certification report is issued. The MSC Fisheries Standard was developed through an 18 month international consultation process involving over 300 fisheries experts. The consultation was designed to ensure that the standard was internationally relevant and applicable. An experts workshop in September 1996 developed a draft set of principles and criteria whose conceptual underpinnings included international soft and hard law instruments on fisheries. To ensure global representativeness and make improvements, the principles and criteria were discussed at 8 regional consultative workshops with fisheries stakeholders held in America, Europe, Australasia and Africa. Informal discussions were also held. A final experts workshop, held in December 1997, agreed and presented to the MSC Board a first draft of the principles and criteria. MSC is not a membership based organisation and this was initially criticised for being undemocratic. A governance structure was developed to ensure MSC accountability but it has proven to be "(1) cumbersome; (2) expensive to operate; and (3) leaves the MSC open to potential capture by particular

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					interest groups or sectors. The governance structure is under review. Initial conclusions from a public survey have indicated four primary characteristics: "(1) "form should follow function"; (2) MSC's governance should be flexible; (3) MSC needs a strong main board, an expert technical capability, an efficient corporate capability and a better defined role and purpose for its stakeholders; and (4) a closer link between the main board and the stakeholder group".
Social Accountability International (SAI)[20]	Workplace conditions	yes	yes	no	SAI (formerly Council on Economic Priorities Accreditation Agency) was established in 1997 to develop and verify the implementation of voluntary corporate social responsibility standards known as Social Accountability 8000 (SA8000). As part of SAI's broader mission it convenes key stakeholders to develop consensus-based voluntary standards; (2) accredits organisations to verify compliance; and (3) promotes understanding and encourages implementation of the standards worldwide.

[20] Compiled from a telephone communication with Rochelle Zaird of SAI on 9 March 2001 and various documents obtained from the SAI WWW site (accessed February 2001): *A General Introduction* (date unknown)(____a); *Criteria for Accreditation of Social Accountability System Certification Bodies* (2000); *Social Accountability 8000 (SA8000) Standards Document* (date unknown)(____b); and *SAI Guideline 304: Making a Complaint or Appeal* (date unknown)(____c).

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					SA 8000 and its verification system were developed by SAI partially in response to the results of research conducted by the Council on Economic Priorities on workplace codes of conduct applied by North American and Western European companies to their factories and those of their suppliers. It was shown that a proliferation of codes was confusing to consumers and made it difficult for companies to comply. The codes tended to be highly inconsistent. They were also found to be expensive and inefficient to monitor because they used unclear definitions and there was a lack of trained auditors. The codes and their monitoring systems also tended to be insensitive to local laws and customs. SAI developed the SA8000 system in conjunction with an international advisory board whose members included experts from trade unions, business and NGOs. The experts represented a wide range of expertise including human rights, child labour, labour rights, socially responsible investment, auditing and supply chain management. The SA8000 standard reflects this group's consensus. The SA8000 system is modelled on the ISO 9000 standards for quality management systems. Additionally, the SA8000 system (1) incorporates specific performance standards set against minimum requirements; (2)

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Organisations or Certification Schemes	**Subject Matter**	**Develops Standards?**	**Accredits?**	**Conformity Assessment?**	**General Overview**
					requires auditors to consult with and learn from interested parties at the local level prior to the factory audit (as a kind of due diligence); and (3) creates a complaints and appeals mechanism for individuals and organisations to raise issues of non-compliance with the standard at certified facilities (supported by SAI *Guidelines for Making a Complaint or Appeal*). A section on management systems requires policies, procedures and documentation systems to demonstrate on-going compliance with the standard. In conjunction with its international advisory body and other stakeholders, SAI keeps the system under review as part of its commitment to continuous improvements, as well as its sensitivity to regional and cultural differences. The SA8000 standard is universally applicable to geographic location, industry sector and company size. It is divided into nine core areas each with a set of detailed process and performance-based criteria. Importantly, the SA8000 standard is founded upon international human rights principles reflected in a number of international legal instruments notably International Labour Organisation Conventions, the United Nations Convention on the Rights of the Child and the Universal Declaration on Human Rights. Accreditation is viewed as the key to the strength and efficacy of the SA8000

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					system. SAI accredits certification auditors (certification bodies) to perform SA8000 audits. SAI reviews the organisation's ability to audit a workplace pursuant to SA8000 using a set of *Criteria for Accreditation*. The organisation's policies, procedures and documentation are reviewed. In addition, "witness audits" are undertaken along with periodic re-evaluations or surveillance audits. Certification auditors can be either corporate entities or NGOs. SAI runs auditor training workshops and has produced an *Auditor Guidance Document*. Facilities are certified to be in compliance with SA8000. This in effect means that the facility has been examined according to SAI auditing procedures and has been found to be in conformance with the SA8000 standard. Each certified facility is subjected to semi-annual surveillance audits. Certification brings with it the ability to display the SA8000 certification mark in a certified factory. The certification mark can be used as a marketing and public relations tool with customers and shareholders. SAI plans to use international consultative workshops to raise awareness about SA8000 and how to improve workplace conditions in 5 sub-regions in the world identified for their emphasis or growth in export manufacturing. The workshops will be used as a means to build capacity of key stakeholders,

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					which in turn should ensure that they can get effectively involved in the auditing process. Technical training will be provided through the workshops aimed to facilitate better working relationships between management, NGOs and trade unions in producer countries. SAI is a membership organisation. Members pay dues. Members are provided conditional membership and must meet eligibility criteria such as presenting a plan for continuously increasing the percentage of certified supplier factories within three years. They must also be open to internal and external audits. Members can publicly state that they are an SAI member and that they are improving their performance. SAI is primarily funded from donor money. Membership dues do not and will not cover operating costs and it is envisioned that donor support will always be sought. SAI collects a percentage from certification fees charged by accredited certification auditors. Fees are generated from training courses that are available to auditors and the general public. Increasingly companies are paying for their supplier's factories to improve and be certified and there is a "supply chain peer pressure" for these factories and their customers to become certified.

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List of Acronyms

CBD	Convention on Biological Diversity
COP	Conference of Parties
EMAS	European Eco-management and Audit Scheme
FLO	Fairtrade Labelling Organisation International
FSC	Forest Stewardship Council
IAF	International Accreditation Forum
IFOAM	International Federation of Organic Agriculture Movements
ISO	International Organisation for Standardisation
ISEAL	International Social and Environmental Accreditation and Labelling Alliance
MAC	Marine Aquarium Council
MSC	Marine Stewardship Council
SAI	Social Accountability International
SBSTTA	Subsidiary Body on Scientific, Technical and Technological Advice