

National Marine Science Plan: Biodiversity Conservation and Ecosystem Health

Marine biotechnology; extracting value from marine biodiversity

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Abstract

The commercial potential of marine biodiversity is changing as technology evolves and we seek new services from our oceans beyond traditional delivery of food and energy supply. New frontiers lie in the areas of functional foods, seafood co-products, pharmaceuticals, agrichemicals, tools for environmental remediation and biofuels. The advancement of marine biotechnology in Australia will deliver health, food, fuel and environmental outcomes through products, sustainable technologies and industries. This paper summarises some of the activities and priorities in Australia, including key issues, challenges and impediments.

Background

The marine environment supports over 95% of the globe's phyla, and marine microbial biodiversity accounts for over 98% of the world's biomass. As a megabiodiverse nation, Australia supports a significant proportion of this global marine biodiversity (eg 30% of the world's sponge fauna) and exceptionally high levels of endemism. An immense range of metabolites with potential biotechnology applications is continually produced by this marine biodiversity, and this is the raw material for Australia's marine biotechnology potential.

Research on natural products in Australian marine organisms has a 50+ year history, with the earliest publications in the 1960s addressing natural products in cyanobacteria (McBarron and May 1966) and useful photosynthetic pigments from marine plants (Jeffrey, 1968). Marine bioscience research has been practiced in established government research agencies, notably CSIRO and the Australian Institute of Marine Science¹ (AIMS), in state agencies, such as Departments of Fisheries, nature conservation, museums and herbaria, and in universities, in all states. Marine biotechnology research has focused on the development of aquaculture for the optimal and sustainable production of food species, and biodiscovery or the identification of attributes in marine biodiversity that can be developed into new commercial products. This paper focuses on marine biodiscovery.

Australia received its first major impetus for pharmaceutically oriented research in 1974 with the establishment of the Roche Institute of Marine Pharmacology in New South Wales, funded by the Swiss pharmaceutical company, Hoffmann-La Roche (Volkman 1999, Rae 2009). Unfortunately, funding for RRIMP was terminated in 1982, but some former RRIMP staff continued marine research in different enterprises at Institutions such as Universities and at AIMS.

Perhaps the longest-running and most successful industry-supported enterprise since RRIMP, is the Eskitis Institute for drug discovery² at Griffith University that hosts Naturebank and established Compounds Australia³ (previously Queensland Compound Library). The Queensland Museum⁴, has been working closely with the Eskitis Institute and its industry partners including the pharmaceutical company AstraZeneca, in drug discovery. Also based in Brisbane are the well-established marine natural products chemistry^{5,6} and molecular⁷ groups at University of Queensland.

AIMS established a thriving biodiscovery pipeline with significant co-investment from the US National Cancer Institute, the Australian pharmaceutical company AMRAD, and the Australian agrichemical company Nufarm. In recent years the AIMS research strategy has refocused away from biodiscovery. However the Bioresources Library of over 30 000 marine invertebrates, plants and microorganisms from over 2000 sites across the length and breadth of Australia's ocean territory, remains as well curated and diverse raw materials for biodiscovery research, and will soon be incorporated with Naturebank at the Eskitis Institute⁸. With this legacy and its heavy investment in resolving access and benefit sharing issues for Australian marine resources, AIMS has helped form the pathway for future biodiscovery research.

The Centre for Marine Bioproducts Development (CMBD)⁹ at Flinders University in South Australia was established as a University-level research centre in 2009 following the identification of industry needs for food, fuel and medicines from marine bioresources. The centre focuses on drug discovery; biofuels; nutraceuticals and agrichemicals. It utilises the marine resources of sponges, macro and micro algae, fish, lobsters and microbes. CMBD has recently started collaborations with the Flinders Centre for Innovation in Cancer¹⁰ (FCIC) The Centre's research in pharmacology ranks at the highest score of 5 on the ERA scale (2012). SARDI Aquatic Sciences, also in Adelaide, has active research in the areas of biofuels (microalgae), aquaculture (macroalgae and fish) and genetics (marine pests). Muradel¹¹ is a South Australian company researching biofuels from microalgae.

The Centre for Marine Bioinnovation¹² at the University of NSW includes research areas of marine chemical ecology and marine microbial ecology. The Shoalhaven Marine and Freshwater Centre¹³ at the University of Wollongong includes conducts research into the use of seaweed in foods, produces a regular publication 'Seaweeds Australia' and recently hosted the 5th Congress of the International Society for Applied Phycology. Venus Shell Systems¹⁴ in Shoalhaven, is a new company using macroalgae for the development of functional foods.

Additional research in Australia includes functional foods from fish oils (CSIRO and Deakin University), and from algae (the company Marinova¹⁵ in Tasmania. At James Cook University, the Centre for Macroalgal Resources and Biotechnology¹⁶ conducts industry-linked research into algal supply of biomass for feedstock, biofuel and other bioproducts, and the Centre for Biodiscovery and Molecular Development of Therapeutics¹⁷ includes marine biodiversity such as box jellyfish as a source for new compounds in their cross-disciplinary program.

There may be other small research groups and businesses in addition to the overview of marine biotechnology research groups and activities provided above. To address the relatively fragmented nature of the marine biotechnology sector and raise its national and international profile, the Australia New Zealand Marine Biotechnology Network¹⁸ was established in 2012 and recently registered as a society hopes to unite the somewhat fragmented groups of marine biotechnologists around Australia (as well as New Zealand). The network lists 163 Australia marine biotechnologists and students on its database. Its aim is to foster collaborations between researchers, technologies, industry and government for both research and industry; it is managed through CMBD at Flinders University. Ausbiotech¹⁹ is an industry body for biotechnology, but has yet to develop a strong marine-based membership. LifeSciences Qld²⁰ is an industry organisation representing stakeholders and has a strong interest in marine biotechnology in Queensland.

Relevance

Biotechnology and the industries it will enable in the future are a key part of Australia's economic prosperity. To varying degrees, agriculture, energy and mining, biomedical, environmental and industrial sectors will all draw on the innovative potential of biotechnology. The benefits of marine biotechnology to the people of Australia can be considered by industry outcomes and products, although, as each process can be considered within 'pipelines' of development, there will be various beneficiaries along the way.

In medicine and health care: the end users include patients, health practitioners, translational medical researchers, and the pharmaceutical industry. The total R&D pipeline from seabed to sick-bed involves many players through the lead discovery and development process followed by clinical evaluation and regulatory approval, and takes decades. Projects currently in the Australian marine pipeline include novel antibiotic compounds produced by sponge-associated bacteria active against antibiotic resistant bacteria; neuroprotective compounds from algae that stimulate brain-derived neurotrophic factor (BDNF) as a possible treatment of neurological diseases such as Alzheimer's and Parkinson's²¹; saponins from sea cucumbers as antiviral compounds²²; mycosporin-like amino acids produced by coral as the basis of a new sunscreen currently in development²³; and chondropsins from Australian sponges as a possible new therapeutic lead for human cancer²⁴.

In functional foods and nutraceuticals: the end users include communities through improving health and lifestyles through marine-sourced functional foods for healthy diets such as Omega oils, functional proteins and carbohydrates for the prevention of lifestyle diseases, such as the reduction in developmental and cardiovascular diseases and diabetes through the reduced uptake of undesirable lipids and sugars from foods, and increased uptake of desirable PUFAs and proteins. There are many

projects currently in progress in Australia, examples include the production of 'ulvan' from seaweed as a promoter of probiotic organisms²⁵; and determination of protein content of fish oil supplements²⁶. In agriculture and agri-chemicals: the end users include farmers benefitting from novel pesticides and herbicides for cropping and orchards, improved plant health and yields through the use of marine-derived beneficial actinobacteria and algae-based fertilisers and improved livestock health and growth through marine-derived nutritional compounds.

In environmental: the community benefits through bioremediation of pollutants and toxins provided by marine microbes; and through the lower environmental impact from the use of novel marine biotechnology agrichemicals. In Australia researchers at RMIT's Applied Science School are looking at microbial remediation of pollution in aquatic (as well as terrestrial) environments²⁷.

In advanced manufacturing: industry through the scale-up manufacture of specialised compounds for various industries through marine bio-production and processing technologies such as cell culture and specialised mariculture.

Research on natural products also enables basic scientific breakthroughs that may not lead directly to a pharmaceutical product, but may nonetheless have profound importance in biomedicine. For example, luciferase enzymes originally isolated from insects and marine organisms are used widely as a tool in biomedical research, drug-screening and hygiene-monitoring. The value of this one class of enzymes is documented to be well over \$100 million per annum (PMSEIC report, 2005).

Science needs

While biodiversity has historically been a fertile source of new products for the pharmaceutical industry, this trend has waned in recent decades (Camp et al 2012, Butler et al 2014). This has been due to a combination of challenges and impediments which have deterred activity in the field, coinciding with the advent of megalibraries of synthetically produced compounds available for high through-put screening programs (Camp et al 2012). This synthetic approach has failed to deliver the expected large number of novel chemical motifs as new chemical entities, and nature remains revered as the best source of molecular diversity for screening programs (Camp et al 2012). There is a growing re-emergence of interest in natural products as a source of molecular diversity for lead development programs.

The key challenges to a flourishing marine biodiversity-based biotechnology sector can be summarised in the following sections, with suggested horizons.

Within 5 years - *Better linkage between marine biodiversity and biotechnology research*

There are many synergies between marine biodiversity and biotechnology research which could be further developed for mutual benefit. Firstly, the marine collection effort currently focused on marine biodiversity research could simply and very cost-efficiently incorporate collection of additional samples for networked bioresources libraries. This will maximise the value return on the collection investment, and support the continued growth of biodiversity represented in the bioresources libraries.

Secondly, data sharing between the biodiversity and biotechnology research sectors should be encouraged and facilitated. For example, a recent data-mining exercise that combined biodiversity and biodiscovery data, demonstrated the suitability of metabolites produced by Australian marine invertebrates in areas of human therapeutic interest, due to shared phylogenetic origins (Evans-Illidge et al 2013). Also, an increased research capacity in the biotechnology applications of Australia's marine biodiversity knowledge would generate novel lines of development. Existing examples include application of knowledge about coral adaptation against the damaging effects of UV exposure leading to a new UV-absorbing sunscreen currently in development (<http://www.csiro.au/Portals/Partner/SME-Engagement/Larissa-Bright.aspx>) and application of knowledge about the ability of some sponges to enzymatically synthesise silica may lead to future production of biosilica for the materials industry (Muller 2014). Many more synergies would emerge if the links between knowledge of marine organisms and biotechnology outcomes were better nurtured in future.

Similarly, the research outputs from biotechnology research are often beneficial to the biodiversity sector. For example, the application of technologies such as gene sequencing and metabolomics will contribute to knowledge of the chemotaxonomy of marine organisms and their functional taxonomy.

The geographical mapping of such taxonomy and the chemo-diversity will support conservation efforts for the future of the resources.

Within 5-10 years – Streamlined access to biodiversity through a Network of National Collections

Access to marine bioresources curated for biodiscovery with legal compliance certainty has traditionally been expensive and fraught with high risk due to uncertainties around marine field operations in a vast ocean territory, biodiverse but poorly described faunas, and the access and benefit sharing regulatory framework. Several national inquiries and international policy forums (eg Voumard 2000, HOR 2001, PMSEIC 2005) have identified these issues as major obstacles to marine based biotechnology research.

The development of marine biodiversity collections suitable for biotechnology programs is a specialist activity requiring expensive marine field work, occupational diving, and marine biological and taxonomic expertise – skill sets that may not overlap with that found within most biotechnology labs and organisations. In addition, the complex legal arrangements for collection permits and benefit sharing agreements often carry a high transaction cost and timeframe due to the lack of clear legislated process in many jurisdictions.

During the past decade, the pharmaceutical industry has seen a massive restructure, and high throughput screening and fragment based discovery has become the primary method for lead identification (Butler 2014, Camp et al 2012). A renaissance of natural products screening will be best served by presenting the industry with samples curated and 'fit for purpose' in a format most amenable to contemporary discovery platforms. Therefore, bioresources repositories are needed with specialist infrastructure and expertise to process the collected marine biomass into formats suited to biotechnology research programs (eg fermentation, extraction, fractionation, chemical fingerprinting), and then despatch them *en masse* to the research sector.

A network of formal collections of bioresources suitable for biotechnology research, which are sourced from expertly collected and identified samples of biodiversity, can demonstrate clear legal certainty and terms for use in research programs, and are appropriately formatted and presented, will deliver an economy of scale to these overheads and promote the use of marine biodiversity as the raw materials for biotechnology programs, by making them more cost-efficient and legally certain to access.

Compounds Australia (formerly the Queensland Compound Library) provides a facility along these lines for members to deposit biodiverse samples and make them available to other members, and as a result has accumulated thousands of marine-sourced compounds from commonwealth and state waters including from Naturebank and, more recently, the AIMS Bioresources Library (GU-AIMS press release 2014). Their facilities and membership program are designed to enable rapid access to enormous numbers of lead-like compounds formatted for high throughput screening, and foster collaborations between organisations that deposit material and others that access them. However this facility is costly to maintain and does not have sustainable financial security. Other collections based at museums and universities could also be further developed, for example the compound collection at Flinders University of hundreds of unique compounds identified from sponge species.

Australia's marine collections are neither coordinated, extensive nor secure due to a lack of policies and resources to support them, and suffer from a lack of understanding of their value to Australia's society and economy.

Within 10-20 years – Scaled production of marine bioproducts

To progress beyond the laboratory or concept stage, new marine biotechnologies need to be made available in quantities sufficient for the various proof-of-concept testing along the R&D pipeline, to demonstrate the manufacture of a compound, test its efficacy in a variety of trials, or enable accurate projection of manufacturing models. For example, the commercial development of promising new and fully synthesised anti-cancer drug Eribulin Mesylate, re-supply of the original natural product Halichondrin B from a marine sponge through both wild harvest and aquaculture production was necessary (Yu et al 2012). While several examples such as this exist, the marine biodiscovery sector suffers from a lack of confidence in the reliability of large-scale supply of natural products to support the development process, even where a purely synthetic alternative production method is the inevitable end goal.

There is a need for supported scale-up supply programs. Biodiscovery has the potential to lead to industries focussed on production of valuable substances or products. Methods of sustainable production include in-sea rearing, cell culture, microbial fermentation and transgenic production of Bioproducts. Australia will need to develop the necessary technologies and skills to support such industries.

Within 10-20 years – *Advanced manufacturing technologies translating scientific discoveries to industry*

Biodiscovery has the potential to lead to industries focussed on production of valuable substances or products. This can involve the production of the raw biological material - 'bioprocessing'. For example, there is increased world-wide scientific interest in the biochemical properties of sedentary marine organisms such as sea sponges and Australia has identified several promising species (e.g. as anti-cancer agents). However the most reliable and effective method for obtaining large quantities of particular species of sponge biomass for drug development and production is sea rearing. This in turn creates demand for skills in aquaculture, and opens the door to the creation of a future bio-manufacturing industry in bio-production and bioprocessing. Additional ways of obtaining increased amounts of material for drug development include cell culture, microbial fermentation and transgenic production of bioproducts. Australia will need to develop the necessary technologies and skills to support such industries.

Perspective

The global market for marine biotechnology products including marine agrichemicals, medicines, biomaterials, biopolymers, lipids, functional foods, aquaculture and other products is estimated at US\$168 billion (pers comm. Pierre Erwes Biomarine), which is 10% of the Australian GDP. However, the Australian share of this market is negligible and has thus far been difficult to quantify. As an example, Australia's largest trade partner, China, has marine biotechnology and seafood industries worth in excess of \$25 billion/yr at more than 15% CAGR since 2000. Australia should position itself to tap into this wealth with this trade partner, but we currently lack both policy and a science and industry platform to do so. This is a serious opportunity cost for Australia, for relations, outcomes and funding that would support scientific endeavours into the future.

Biotechnology and the industries it will enable in the future are a key part of Australia's economic prosperity. To varying degrees, agriculture, energy and mining, biomedical, environmental and industrial sectors will all draw on the innovative potential of biotechnology. Surrounded by one of the world's largest and most diverse ocean territories, the Australian marine biotechnology industry has access to a wealth of untapped biodiversity for the discovery and development of pharmaceutical and other biotechnology products.

The need to address the Science Needs identified for Marine Biotechnology, and build on existing biodiscovery advantages and achievements by developing translational technologies towards products and advanced manufacturing can be illustrated by the following examples of needs with suggested time horizons to meet required needs.

Within 5 years – *Increased focus on Biodiversity knowledge*

The AstraZeneca/Griffith University partnership initiated in 1993 led to the discovery of 37 new plant species and, this and other biodiscovery collections have resulted in knowledge about nearly 1500 new marine organisms. Knowledge of Australia's sponge diversity has increased from around 1,000 species in 1978 to over 5,000 today. This quantum increase in knowledge was primarily due to three major biodiscovery collection efforts, undertaken by Roche Research Institute of Pharmacology (1974-1981), AIMS (1987-present), and the Queensland Museum (1993-present).

Funding for taxonomy has decreased, and there is an urgent need to support new taxonomists to continue this work, as well as users for the compound libraries which have taken decades to set up (PMSEIC, 2005).

Within 10 years – Establish Marine Biotechnology research policy and infrastructure

Flinders University's Centre for Marine Bioproducts Development (CMBD) recently engaged China's largest privately-owned algae products company the Gather Great Ocean Group through its initial research with a local company AKP Pty Ltd. This resulted in the Chinese company investing into a \$1 million South Australian PRIF Joint Laboratory at Flinders, a multi-million investment into the local company AKP and a \$20 million commitment to advanced manufacturing using the newly developed technologies in regional South Australia. However, in the wider context of Australia, there is no "marine biotechnology" industry or pillar of research policy and infrastructure. This is in stark contrast to major economies such as the EU and China which have marine biotechnology as key policy, with EU's €700b Horizon 2020 innovation program and China's three Blue Economic Zones including Shandong province, South Australia's sister-state, featuring marine biotechnology a key pillar of innovation.

Within 10-20 years – Translate knowledge into products

Product and technology outcomes from CMBD have included: proprietary optimised microalgae strains for high value Omega-3 PUFAs and carotenoids (Lutein); high productivity microalgae photobioreactor inoculants cultivation systems; algal biorefinery being scaled up to pilot scale at an industry site in regional South Australia; algae low-energy processing technology for high value products; functionalised fish protein hydrolysates for healthy seafood; and biodiscovery outputs including anti-cancer compounds for further clinical investigation. This has resulted in industry partnerships through the Australian Seafood CRC with global companies such as Simplot Australia, the award of a Taishan Scholars Program project of the Shandong Provincial Government China for commercialisation of macroalgae processing technologies, with industry partner GGOG; and an international patent on microalgae wet extraction (low-energy clean technology) for algae biorefinery. More such achievements for Australia are possible with the right scientific priorities, policies and infrastructure at the national level.

Within 10-20 years – Build strategy of involvement in international marine biotechnology

Australia must develop a long-term strategy for involvement in international Marine Biotechnology. Australia has a long-standing commitment to the International Convention on the Law of the Sea, and has the world's third largest area of marine exclusive economic zones (the AEEZ). Australia is strongly placed for developments involving the "Pacific-Ocean-rim" countries. Significantly, Australia is also strongly placed for developments in the "Indian-Ocean-rim" countries, and for developments in the Southern Ocean/Antarctic region. Australia will be involved in Marine Biotechnologies in its long-term planning Australia, with more than 80% of its population living within 100km of the Coastline, should have a long-term commitment to wise management of its marine EEZ and its bioresources.

Realisation

While the global marine biodiscovery research effort had identified 18,000 new chemical entities by 2010 (Arrieta et al 2010), with 10,000 of these since 1990 from marine invertebrates alone (Leal et al 2012), contributions from Australian marine biodiversity are conspicuously underrepresented in the literature in a trend that appears to be worsening. During the decade 1980-1990, almost 7% of the over 4000 articles linked through the marine natural products literature database *Marinlit* were based on Australian marine biota, however this figure dropped to 2% of the over 10,000 articles published during the decade to 2010. This trend varies between Australian jurisdictions, but is worst in Western Australia, which contributes over one third of Australia's marine estate, yet only 2% of the Australian marine natural products literature to 2010 related to marine biota from that State (Evans-Illidge et al 2013).

Australia's marine biodiversity and its extraordinary arsenal of metabolic machinery remains a relatively untapped source of raw materials for new innovative products. This is good news in an era of great demand for new products, for example due to increased antibiotic drug resistance and new diseases needing novel therapeutics. However, the field of biodiscovery has struggled with a number of impediments which have hindered the realisation of the opportunity, and which are less about the science and more about the resourcing, policy and legal contexts in which the science must take place. These can be redressed by the actions outlined below.

Ratify the Nagoya Protocol, and give effect to the government's draft model for implementing the Nagoya Protocol in Australia, including accreditation of compliant collections.

One impediment to a flourishing biodiscovery sector has been global uncertainty over legal and jurisdictional issues around access to biota and benefit sharing, ironically spawned by the international treaty, The Convention on Biological Diversity (CBD), which was designed to do the opposite. This dilemma has been a challenge for 20 years, until a major breakthrough occurred in 2010 with consensus and adoption of the **Nagoya Protocol** - a supplementary and legally binding protocol to the Convention on Biological Diversity which has recently come into force. It provides a new framework for transparent, cross-boundary and legally certain access and benefit sharing (See Attachment). Australia has already signed this protocol, but full ratification and domestic implementation is necessary for its benefit to be captured by the Australian biotechnology sector.

The government's draft model for implementing the Nagoya Protocol in Australia proposes that certain collections and institutions, through their collection management and legal compliance procedures, may be accredited as 'trusted institutions' and be given the authority to supply certified bioresources to other parties under the Nagoya Protocol without the need for further government regulation. Such authority bestowed upon Australian collection institutions will empower them to maximise the legal certainty with which they can provide bioresources to the research and development sector. This concept of certifying collections to provide their own Nagoya Protocol compliance certainty, has already been adopted by the new European Union regulations to implement the Nagoya Protocol, and is likely to spawn a new era of interest in sourcing in natural products from such collections (Burton and Evans-Illidge 2013).

Establish Marine Biotechnology as Fields Of Research and Socio-Economic Objective classifications

A fundamental obstacle to research activity in the field of marine biotechnology in Australia is the lack of classification in the Australian and New Zealand Standard Research Classification (ANZSRC) Fields of Research (FOR) and Socio-Economic (SEO) classifications²⁸, and consequently what is surveyed by the Australian Bureau of Statistics (ABS)²⁹ for industry and community impact. This is a major impediment to research activity and funding that starts at the very grassroots of the research community where researchers would be reluctant to identify themselves as marine biotechnologists, or find difficulty in categorising their work; where research organisations are unconvinced of the need to support marine biotechnology due to potential repercussions on Federal Block Funding and state funding, and Excellence in Research Australia (ERA) ranking; and where industry and the communities are unable to see the metrics of the impact or potential of marine biotechnology.

Establish Marine Biotechnology as a Strategic Science Priority of Australia

Leading innovative economies such as Europe, the USA and China have identified marine biotechnology in their Blue Economy Strategies, and have supported it with multi-million dollar programs. Lack of a similar national policy priority in Australia is surprising given Australia's wealth of marine biodiversity and potential, and has resulted in a dearth of government funding and support corresponding to a downturn in research activity, including at publicly funded research agencies such as AIMS. Matching policy and programs that establish marine biotechnology as a national priority is needed for Australia to capture its marine biotechnology potential.

Establish collaborative platforms to enable translation of discoveries to products

A multidisciplinary and multi-institutional approach is needed in today's funding landscape to enable translation of marine biodiscoveries, from functional applications to actual products. This platform for our scientific community remains a gap, apart from non-funded facilitative roles played by the Australia-New Zealand Marine Biotechnology Society, Compounds Australia, and some research groups such as the Flinders Centre for Marine Bioproducts Development. The funding gap, commonly called the 'chasm of death', can be defined as the point at which public funding can no longer support a project (usually soon after lead discovery), and the point at which the lead has been sufficiently developed to attract industry co-investment. Projects within the chasm are characterised as being too commercial for publicly sourced funding, yet too early (not commercial enough) for commercialisation funding or industry investment. Strategies need to be developed to help projects bridge the chasm, by providing both a push from the 'public funding' side with extra support and resources, and a pull from the industry investment side, for example through R&D tax incentives and co-investment programs.

Additional Information

Definition of Biotechnology and comment on the name of the proposed Plan

Marine biotechnology has direct relevance to the challenge of achieving long-term high-level Government, Industry, Investor, and Community support for a practical National Marine Science Plan. In fact, one could recommend strongly that the proposed Plan should be a National Marine Science and Technology Plan, because the successful technologies – derived from scientific discoveries, which may be little understood by non-specialists – will be the publicly obvious outcomes that attract ongoing Government, Industry, Investor and Community support.

The breadth of Biotechnology, and that includes Marine Biotechnology, is well illustrated by the approach taken by the OECD, which recommends a general “single definition”, that covers all modern biotechnology, but which, wherever practicable, be accompanied by a “list-based” definition, which operationalizes the definition for measurement purposes.

The single definition of Biotechnology is: The application of science and technology to living organisms, as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services.

The following table gives an indicative list of biotechnology techniques functions as an interpretative guideline to the single definition. The list is indicative rather than exhaustive and is expected to change over time as data collection and biotechnology activities evolve. All topics in the “List” are relevant to marine biotechnology.

<i>DNA/RNA</i>	Genomics, pharmacogenomics, gene probes, genetic engineering, DNA/RNA sequencing/synthesis/amplification, gene expression profiling, and use of antisense technology.
<i>Proteins and other molecules</i>	Sequencing/synthesis/engineering of proteins and peptides (including large molecule hormones); improved delivery methods for large molecule drugs; proteomics, protein isolation and purification, signaling, identification of cell receptors
<i>Cell and tissue culture and engineering</i>	Cell/tissue culture, tissue engineering (including tissue scaffolds and biomedical engineering), cellular fusion, vaccine/immune stimulants, embryo manipulation.
<i>Process biotechnology techniques</i>	Fermentation using bioreactors, bioprocessing, bioleaching, biopulping, biobleaching, biodesulphurisation, bioremediation, biofiltration and phytoremediation
<i>Gene and RNA vectors</i>	Gene therapy, viral vectors
<i>Bioinformatics</i>	Construction of databases on genomes, protein sequences; modelling complex biological processes, including systems biology
<i>Nanobiotechnology</i>	Applies the tools and processes of nano/microfabrication to build devices for studying biosystems and applications in drug delivery, diagnostics etc.

Biotechnology cross overs with other submissions

This submission does not consider marine aquaculture *per se*, or biofuels as we presume these will be included under the submissions ‘Food security’ and ‘Energy security’ respectively. However, value adding to seafood products and functional foods are briefly addressed in this submission.

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In addition text has been used from the following:

Evans-Illidge (2013) Sea of miracles: industrial uses for ocean biodiversity. The Conversation. Available at <http://theconversation.com/sea-of-miracles-industrial-uses-for-ocean-biodiversity-13172>

Nagoya protocol

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (the Protocol) is a global agreement that implements the access and benefit-sharing obligations of the Convention on Biological Diversity (CBD). It was adopted in Nagoya, Japan in October 2010, after six years of negotiations. Australia signed the Protocol in January 2012, and is now developing its approach to implementation and ratification.

“The objective of this Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components”.

The Commonwealth Government Department of the Environment is the key agency in Australia Nagoya Protocol fact sheet - <http://www.environment.gov.au/system/files/pages/9fc06ac0-f5af-4b47-a80f-d9378088d743/files/nagoya-factsheet.pdf>

Endnotes (websites)

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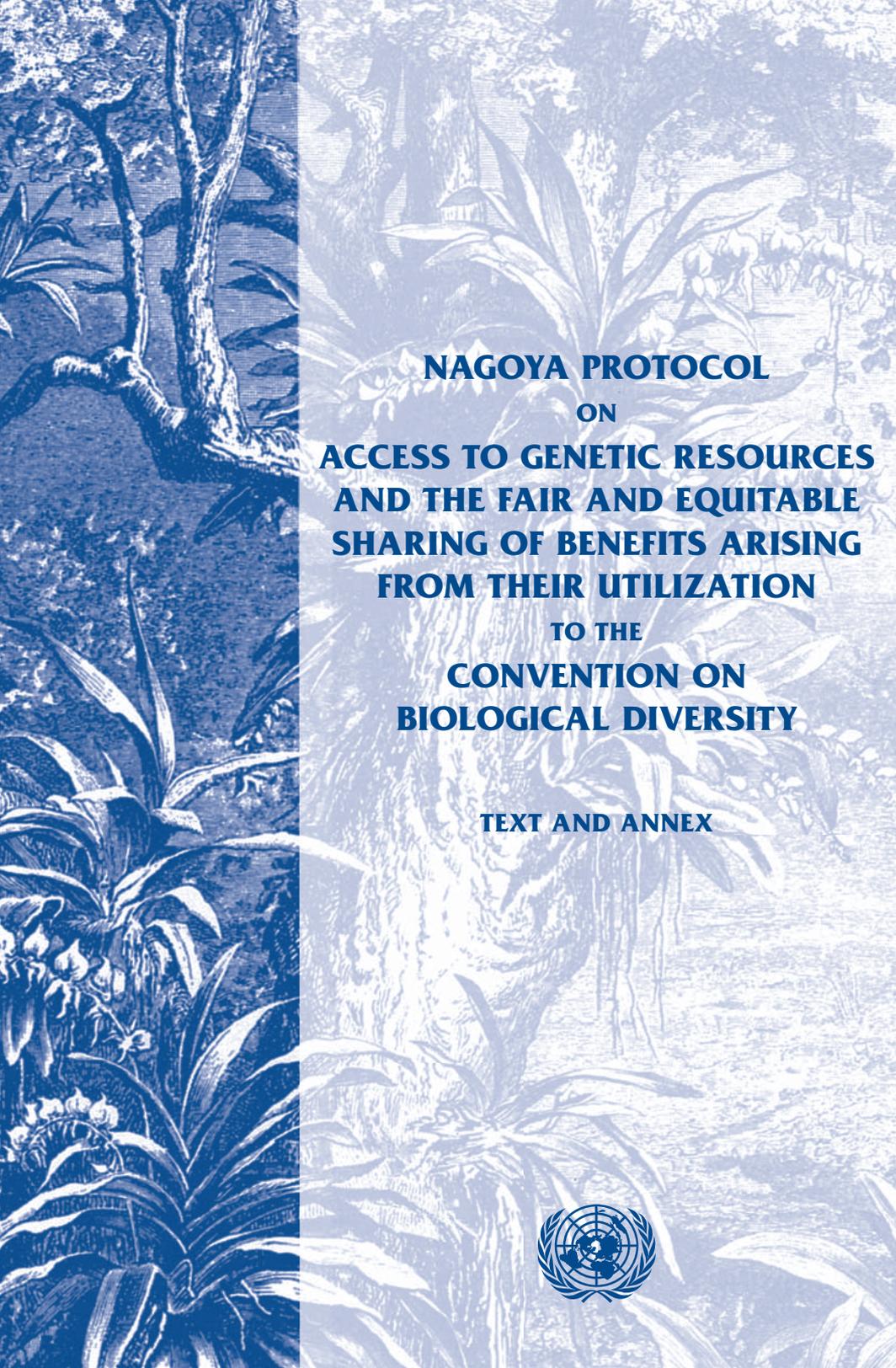
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**NAGOYA PROTOCOL
ON
ACCESS TO GENETIC RESOURCES
AND THE FAIR AND EQUITABLE
SHARING OF BENEFITS ARISING
FROM THEIR UTILIZATION
TO THE
CONVENTION ON
BIOLOGICAL DIVERSITY**

TEXT AND ANNEX



NAGOYA PROTOCOL
ON
ACCESS TO GENETIC RESOURCES
AND THE FAIR AND EQUITABLE
SHARING OF BENEFITS ARISING
FROM THEIR UTILIZATION
TO THE
CONVENTION ON
BIOLOGICAL DIVERSITY

TEXT AND ANNEX

SECRETARIAT OF THE CONVENTION
ON BIOLOGICAL DIVERSITY
MONTREAL

Convention on Biological Diversity
United Nations



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For further information please contact the Secretariat of the Convention on Biological Diversity

Introduction

The Convention on Biological Diversity was opened for signature on 5 June 1992 at the United Nations Conference on Environment and Development (the Rio “Earth Summit”) and entered into force on 29 December 1993. The Convention is the only international instrument comprehensively addressing biological diversity. The Convention’s three objectives are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of benefits arising from the utilisation of genetic resources.

To further advance the implementation of the third objective, the World Summit on Sustainable Development (Johannesburg, September 2002) called for the negotiation of an international regime, within the framework of the Convention, to promote and safeguard the fair and equitable sharing of benefits arising from the utilisation of genetic resources. The Convention’s Conference of the Parties responded at its seventh meeting, in 2004, by mandating its Ad Hoc Open-ended Working Group on Access and Benefit-sharing to elaborate and negotiate an international regime on access to genetic resources and benefit-sharing in order to effectively implement Articles 15 (Access to Genetic Resources) and 8(j) (Traditional Knowledge) of the Convention and its three objectives.

After six years of negotiation, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity was adopted at the tenth meeting of the Conference of the Parties on 29 October 2010, in Nagoya, Japan.

The Protocol significantly advances the Convention’s third objective by providing a strong basis for greater legal certainty and transparency for both providers and users of genetic resources. Specific obligations to support compliance with domestic legislation or regulatory requirements of the Party providing genetic resources and contractual obligations reflected in mutually agreed terms are a significant innovation of the Protocol. These compliance provisions as well as provisions establishing more predictable conditions for access to genetic resources will contribute to ensuring the sharing of benefits when genetic resources leave a Party providing genetic resources. In addition, the Protocol’s provisions on access to traditional knowledge held by indigenous and local communities when it is associated with genetic resources will strengthen the ability of these communities to benefit from the use of their knowledge, innovations and practices.

By promoting the use of genetic resources and associated traditional knowledge, and by strengthening the opportunities for fair and equitable sharing of benefits from their use, the Protocol will create incentives to conserve biological diversity, sustainably use its components, and further enhance the contribution of biological diversity to sustainable development and human well-being.

**NAGOYA PROTOCOL ON ACCESS TO GENETIC
RESOURCES AND THE FAIR AND EQUITABLE SHARING OF
BENEFITS ARISING FROM THEIR UTILIZATION TO THE
CONVENTION ON BIOLOGICAL DIVERSITY**

The Parties to this Protocol,

Being Parties to the Convention on Biological Diversity, hereinafter referred to as “the Convention”,

Recalling that the fair and equitable sharing of benefits arising from the utilization of genetic resources is one of three core objectives of the Convention, and recognizing that this Protocol pursues the implementation of this objective within the Convention,

Reaffirming the sovereign rights of States over their natural resources and according to the provisions of the Convention,

Recalling further Article 15 of the Convention,

Recognizing the important contribution to sustainable development made by technology transfer and cooperation to build research and innovation capacities for adding value to genetic resources in developing countries, in accordance with Articles 16 and 19 of the Convention,

Recognizing that public awareness of the economic value of ecosystems and biodiversity and the fair and equitable sharing of this economic value with the custodians of biodiversity are key incentives for the conservation of biological diversity and the sustainable use of its components,

Acknowledging the potential role of access and benefit-sharing to contribute to the conservation and sustainable use of biological diversity, poverty eradication and environmental sustainability and thereby contributing to achieving the Millennium Development Goals,

Acknowledging the linkage between access to genetic resources and the fair and equitable sharing of benefits arising from the utilization of such resources,

Recognizing the importance of providing legal certainty with respect to access to genetic resources and the fair and equitable sharing of benefits arising from their utilization,

Further recognizing the importance of promoting equity and fairness in negotiation of mutually agreed terms between providers and users of genetic resources,

Recognizing also the vital role that women play in access and benefit-sharing and affirming the need for the full participation of women at all levels of policy-making and implementation for biodiversity conservation,

Determined to further support the effective implementation of the access and benefit-sharing provisions of the Convention,

Recognizing that an innovative solution is required to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent,

Recognizing the importance of genetic resources to food security, public health, biodiversity conservation, and the mitigation of and adaptation to climate change,

Recognizing the special nature of agricultural biodiversity, its distinctive features and problems needing distinctive solutions,

Recognizing the interdependence of all countries with regard to genetic resources for food and agriculture as well as their special nature and importance for achieving food security worldwide and for sustainable development of agriculture in the context of poverty alleviation and climate change and acknowledging the fundamental role of the International Treaty on Plant Genetic Resources for Food and Agriculture and the FAO Commission on Genetic Resources for Food and Agriculture in this regard,

Mindful of the International Health Regulations (2005) of the World Health Organization and the importance of ensuring access to human pathogens for public health preparedness and response purposes,

Acknowledging ongoing work in other international forums relating to access and benefit-sharing,

Recalling the Multilateral System of Access and Benefit-sharing established under the International Treaty on Plant Genetic Resources for Food and Agriculture developed in harmony with the Convention,

Recognizing that international instruments related to access and benefit-sharing should be mutually supportive with a view to achieving the objectives of the Convention,

Recalling the relevance of Article 8(j) of the Convention as it relates to traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising from the utilization of such knowledge,

Noting the interrelationship between genetic resources and traditional knowledge, their inseparable nature for indigenous and local communities, the importance of the traditional knowledge for the conservation of biological diversity and the sustainable use of its components, and for the sustainable livelihoods of these communities,

Recognizing the diversity of circumstances in which traditional knowledge associated with genetic resources is held or owned by indigenous and local communities,

Mindful that it is the right of indigenous and local communities to identify the rightful holders of their traditional knowledge associated with genetic resources, within their communities,

Further recognizing the unique circumstances where traditional knowledge associated with genetic resources is held in countries, which may be oral, documented or in other forms, reflecting a rich cultural heritage relevant for conservation and sustainable use of biological diversity,

Noting the United Nations Declaration on the Rights of Indigenous Peoples, and

Affirming that nothing in this Protocol shall be construed as diminishing or extinguishing the existing rights of indigenous and local communities,

Have agreed as follows:

Article **1** **OBJECTIVE**

The objective of this Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components.

Article **2** **USE OF TERMS**

The terms defined in Article 2 of the Convention shall apply to this Protocol. In addition, for the purposes of this Protocol:

- (a) “Conference of the Parties” means the Conference of the Parties to the Convention;
- (b) “Convention” means the Convention on Biological Diversity;
- (c) “Utilization of genetic resources” means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention;
- (d) “Biotechnology” as defined in Article 2 of the Convention means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use;

- (e) “Derivative” means a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.

Article **3** **SCOPE**

This Protocol shall apply to genetic resources within the scope of Article 15 of the Convention and to the benefits arising from the utilization of such resources. This Protocol shall also apply to traditional knowledge associated with genetic resources within the scope of the Convention and to the benefits arising from the utilization of such knowledge.

Article **4** **RELATIONSHIP WITH INTERNATIONAL AGREEMENTS AND INSTRUMENTS**

1. The provisions of this Protocol shall not affect the rights and obligations of any Party deriving from any existing international agreement, except where the exercise of those rights and obligations would cause a serious damage or threat to biological diversity. This paragraph is not intended to create a hierarchy between this Protocol and other international instruments.
2. Nothing in this Protocol shall prevent the Parties from developing and implementing other relevant international agreements, including other specialized access and benefit-sharing agreements, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.
3. This Protocol shall be implemented in a mutually supportive manner with other international instruments relevant to this Protocol. Due regard should be paid to useful and relevant ongoing work or practices under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.
4. This Protocol is the instrument for the implementation of the access and benefit-sharing provisions of the Convention. Where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and this Protocol, this Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument.

Article

5**FAIR AND EQUITABLE BENEFIT-SHARING**

1. In accordance with Article 15, paragraphs 3 and 7 of the Convention, benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention. Such sharing shall be upon mutually agreed terms.
2. Each Party shall take legislative, administrative or policy measures, as appropriate, with the aim of ensuring that benefits arising from the utilization of genetic resources that are held by indigenous and local communities, in accordance with domestic legislation regarding the established rights of these indigenous and local communities over these genetic resources, are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms.
3. To implement paragraph 1 above, each Party shall take legislative, administrative or policy measures, as appropriate.
4. Benefits may include monetary and non-monetary benefits, including but not limited to those listed in the Annex.
5. Each Party shall take legislative, administrative or policy measures, as appropriate, in order that the benefits arising from the utilization of traditional knowledge associated with genetic resources are shared in a fair and equitable way with indigenous and local communities holding such knowledge. Such sharing shall be upon mutually agreed terms.

Article

6**ACCESS TO GENETIC RESOURCES**

1. In the exercise of sovereign rights over natural resources, and subject to domestic access and benefit-sharing legislation or regulatory requirements, access to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that Party.
2. In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that the prior informed consent or approval and involvement of indigenous and local communities is obtained for access to

genetic resources where they have the established right to grant access to such resources.

3. Pursuant to paragraph 1 above, each Party requiring prior informed consent shall take the necessary legislative, administrative or policy measures, as appropriate, to:
 - (a) Provide for legal certainty, clarity and transparency of their domestic access and benefit-sharing legislation or regulatory requirements;
 - (b) Provide for fair and non-arbitrary rules and procedures on accessing genetic resources;
 - (c) Provide information on how to apply for prior informed consent;
 - (d) Provide for a clear and transparent written decision by a competent national authority, in a cost-effective manner and within a reasonable period of time;
 - (e) Provide for the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms, and notify the Access and Benefit-sharing Clearing-House accordingly;
 - (f) Where applicable, and subject to domestic legislation, set out criteria and/or processes for obtaining prior informed consent or approval and involvement of indigenous and local communities for access to genetic resources; and
 - (g) Establish clear rules and procedures for requiring and establishing mutually agreed terms. Such terms shall be set out in writing and may include, *inter alia*:
 - (i) A dispute settlement clause;
 - (ii) Terms on benefit-sharing, including in relation to intellectual property rights;
 - (iii) Terms on subsequent third-party use, if any; and
 - (iv) Terms on changes of intent, where applicable.

Article

7**ACCESS TO TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES**

In accordance with domestic law, each Party shall take measures, as appropriate, with the aim of ensuring that traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with the prior and informed consent or approval and involvement of these indigenous and local communities, and that mutually agreed terms have been established.

Article
8**SPECIAL CONSIDERATIONS**

In the development and implementation of its access and benefit-sharing legislation or regulatory requirements, each Party shall:

- (a) Create conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including through simplified measures on access for non-commercial research purposes, taking into account the need to address a change of intent for such research;
- (b) Pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally. Parties may take into consideration the need for expeditious access to genetic resources and expeditious fair and equitable sharing of benefits arising out of the use of such genetic resources, including access to affordable treatments by those in need, especially in developing countries;
- (c) Consider the importance of genetic resources for food and agriculture and their special role for food security.

Article
9**CONTRIBUTION TO CONSERVATION AND SUSTAINABLE USE**

The Parties shall encourage users and providers to direct benefits arising from the utilization of genetic resources towards the conservation of biological diversity and the sustainable use of its components.

Article
10**GLOBAL MULTILATERAL BENEFIT-SHARING MECHANISM**

Parties shall consider the need for and modalities of a global multilateral benefit-sharing mechanism to address the fair and equitable sharing of benefits derived from the utilization of genetic resources and traditional knowledge associated with genetic resources that occur in transboundary situations or for which it is not possible to grant or obtain prior informed consent. The benefits shared by users of genetic resources and traditional knowledge associated with genetic resources through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally.

Article
11**TRANSBOUNDARY COOPERATION**

1. In instances where the same genetic resources are found *in situ* within the territory of more than one Party, those Parties shall endeavour to cooperate, as appropriate, with the involvement of indigenous and local communities concerned, where applicable, with a view to implementing this Protocol.
2. Where the same traditional knowledge associated with genetic resources is shared by one or more indigenous and local communities in several Parties, those Parties shall endeavour to cooperate, as appropriate, with the involvement of the indigenous and local communities concerned, with a view to implementing the objective of this Protocol.

Article
12**TRADITIONAL KNOWLEDGE ASSOCIATED WITH GENETIC RESOURCES**

1. In implementing their obligations under this Protocol, Parties shall in accordance with domestic law take into consideration indigenous and local communities' customary laws, community protocols and procedures, as applicable, with respect to traditional knowledge associated with genetic resources.
2. Parties, with the effective participation of the indigenous and local communities concerned, shall establish mechanisms to inform potential users of traditional knowledge associated with genetic resources about their obligations, including measures as made available through the Access and Benefit-sharing Clearing-House for access to and fair and equitable sharing of benefits arising from the utilization of such knowledge.
3. Parties shall endeavour to support, as appropriate, the development by indigenous and local communities, including women within these communities, of:
 - (a) Community protocols in relation to access to traditional knowledge associated with genetic resources and the fair and equitable sharing of benefits arising out of the utilization of such knowledge;
 - (b) Minimum requirements for mutually agreed terms to secure the fair and equitable sharing of benefits arising from the utilization of traditional knowledge associated with genetic resources; and
 - (c) Model contractual clauses for benefit-sharing arising from the utilization of traditional knowledge associated with genetic resources.

4. Parties, in their implementation of this Protocol, shall, as far as possible, not restrict the customary use and exchange of genetic resources and associated traditional knowledge within and amongst indigenous and local communities in accordance with the objectives of the Convention.

Article
13

NATIONAL FOCAL POINTS AND COMPETENT NATIONAL AUTHORITIES

1. Each Party shall designate a national focal point on access and benefit-sharing. The national focal point shall make information available as follows:
 - (a) For applicants seeking access to genetic resources, information on procedures for obtaining prior informed consent and establishing mutually agreed terms, including benefit-sharing;
 - (b) For applicants seeking access to traditional knowledge associated with genetic resources, where possible, information on procedures for obtaining prior informed consent or approval and involvement, as appropriate, of indigenous and local communities and establishing mutually agreed terms including benefit-sharing; and
 - (c) Information on competent national authorities, relevant indigenous and local communities and relevant stakeholders.

The national focal point shall be responsible for liaison with the Secretariat.

2. Each Party shall designate one or more competent national authorities on access and benefit-sharing. Competent national authorities shall, in accordance with applicable national legislative, administrative or policy measures, be responsible for granting access or, as applicable, issuing written evidence that access requirements have been met and be responsible for advising on applicable procedures and requirements for obtaining prior informed consent and entering into mutually agreed terms.
3. A Party may designate a single entity to fulfil the functions of both focal point and competent national authority.
4. Each Party shall, no later than the date of entry into force of this Protocol for it, notify the Secretariat of the contact information of its national focal point and its competent national authority or authorities. Where a Party designates more than one competent national authority, it shall convey to the Secretariat, with its notification thereof, relevant information on the respective responsibilities of those authorities. Where applicable, such information shall, at a minimum, specify which competent authority is responsible for the genetic resources sought. Each Party shall

forthwith notify the Secretariat of any changes in the designation of its national focal point or in the contact information or responsibilities of its competent national authority or authorities.

5. The Secretariat shall make information received pursuant to paragraph 4 above available through the Access and Benefit-sharing Clearing-House.

Article
14

THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE AND INFORMATION-SHARING

1. An Access and Benefit-sharing Clearing-House is hereby established as part of the clearing-house mechanism under Article 18, paragraph 3, of the Convention. It shall serve as a means for sharing of information related to access and benefit-sharing. In particular, it shall provide access to information made available by each Party relevant to the implementation of this Protocol.
2. Without prejudice to the protection of confidential information, each Party shall make available to the Access and Benefit-sharing Clearing-House any information required by this Protocol, as well as information required pursuant to the decisions taken by the Conference of the Parties serving as the meeting of the Parties to this Protocol. The information shall include:
 - (a) Legislative, administrative and policy measures on access and benefit-sharing;
 - (b) Information on the national focal point and competent national authority or authorities; and
 - (c) Permits or their equivalent issued at the time of access as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms.
3. Additional information, if available and as appropriate, may include:
 - (a) Relevant competent authorities of indigenous and local communities, and information as so decided;
 - (b) Model contractual clauses;
 - (c) Methods and tools developed to monitor genetic resources; and
 - (d) Codes of conduct and best practices.
4. The modalities of the operation of the Access and Benefit-sharing Clearing-House, including reports on its activities, shall be considered and decided upon by the Conference of the Parties serving as the meeting of the Parties to this Protocol at its first meeting, and kept under review thereafter.

Article
15**COMPLIANCE WITH DOMESTIC LEGISLATION
OR REGULATORY REQUIREMENTS ON ACCESS
AND BENEFIT-SHARING**

1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures to provide that genetic resources utilized within its jurisdiction have been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the other Party.
2. Parties shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.
3. Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.

Article
16**COMPLIANCE WITH DOMESTIC LEGISLATION OR
REGULATORY REQUIREMENTS ON ACCESS AND BENEFIT-
SHARING FOR TRADITIONAL KNOWLEDGE
ASSOCIATED WITH GENETIC RESOURCES**

1. Each Party shall take appropriate, effective and proportionate legislative, administrative or policy measures, as appropriate, to provide that traditional knowledge associated with genetic resources utilized within their jurisdiction has been accessed in accordance with prior informed consent or approval and involvement of indigenous and local communities and that mutually agreed terms have been established, as required by domestic access and benefit-sharing legislation or regulatory requirements of the other Party where such indigenous and local communities are located.
2. Each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance with measures adopted in accordance with paragraph 1 above.
3. Parties shall, as far as possible and as appropriate, cooperate in cases of alleged violation of domestic access and benefit-sharing legislation or regulatory requirements referred to in paragraph 1 above.

Article
17**MONITORING THE UTILIZATION OF GENETIC RESOURCES**

1. To support compliance, each Party shall take measures, as appropriate, to monitor and to enhance transparency about the utilization of genetic resources. Such measures shall include:
 - (a) The designation of one or more checkpoints, as follows:
 - (i) Designated checkpoints would collect or receive, as appropriate, relevant information related to prior informed consent, to the source of the genetic resource, to the establishment of mutually agreed terms, and/or to the utilization of genetic resources, as appropriate;
 - (ii) Each Party shall, as appropriate and depending on the particular characteristics of a designated checkpoint, require users of genetic resources to provide the information specified in the above paragraph at a designated checkpoint. Each Party shall take appropriate, effective and proportionate measures to address situations of non-compliance;
 - (iii) Such information, including from internationally recognized certificates of compliance where they are available, will, without prejudice to the protection of confidential information, be provided to relevant national authorities, to the Party providing prior informed consent and to the Access and Benefit-sharing Clearing-House, as appropriate;
 - (iv) Checkpoints must be effective and should have functions relevant to implementation of this subparagraph (a). They should be relevant to the utilization of genetic resources, or to the collection of relevant information at, *inter alia*, any stage of research, development, innovation, pre-commercialization or commercialization.
 - (b) Encouraging users and providers of genetic resources to include provisions in mutually agreed terms to share information on the implementation of such terms, including through reporting requirements; and
 - (c) Encouraging the use of cost-effective communication tools and systems.
2. A permit or its equivalent issued in accordance with Article 6, paragraph 3 (e) and made available to the Access and Benefit-sharing Clearing-House, shall constitute an internationally recognized certificate of compliance.
3. An internationally recognized certificate of compliance shall serve as evidence that the genetic resource which it covers has been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required

by the domestic access and benefit-sharing legislation or regulatory requirements of the Party providing prior informed consent.

4. The internationally recognized certificate of compliance shall contain the following minimum information when it is not confidential:

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

Article 18

COMPLIANCE WITH MUTUALLY AGREED TERMS

1. In the implementation of Article 6, paragraph 3 (g) (i) and Article 7, each Party shall encourage providers and users of genetic resources and/or traditional knowledge associated with genetic resources to include provisions in mutually agreed terms to cover, where appropriate, dispute resolution including:
 - (a) The jurisdiction to which they will subject any dispute resolution processes;
 - (b) The applicable law; and/or
 - (c) Options for alternative dispute resolution, such as mediation or arbitration.
2. Each Party shall ensure that an opportunity to seek recourse is available under their legal systems, consistent with applicable jurisdictional requirements, in cases of disputes arising from mutually agreed terms.
3. Each Party shall take effective measures, as appropriate, regarding:
 - (a) Access to justice; and
 - (b) The utilization of mechanisms regarding mutual recognition and enforcement of foreign judgments and arbitral awards.
4. The effectiveness of this article shall be reviewed by the Conference of the Parties serving as the meeting of the Parties to this Protocol in accordance with Article 31 of this Protocol.

Article 19

MODEL CONTRACTUAL CLAUSES

1. Each Party shall encourage, as appropriate, the development, update and use of sectoral and cross-sectoral model contractual clauses for mutually agreed terms.
2. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall periodically take stock of the use of sectoral and cross-sectoral model contractual clauses.

Article 20

CODES OF CONDUCT, GUIDELINES AND BEST PRACTICES AND/OR STANDARDS

1. Each Party shall encourage, as appropriate, the development, update and use of voluntary codes of conduct, guidelines and best practices and/or standards in relation to access and benefit-sharing.
2. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall periodically take stock of the use of voluntary codes of conduct, guidelines and best practices and/or standards and consider the adoption of specific codes of conduct, guidelines and best practices and/or standards.

Article 21

AWARENESS-RAISING

Each Party shall take measures to raise awareness of the importance of genetic resources and traditional knowledge associated with genetic resources, and related access and benefit-sharing issues. Such measures may include, *inter alia*:

- (a) Promotion of this Protocol, including its objective;
- (b) Organization of meetings of indigenous and local communities and relevant stakeholders;
- (c) Establishment and maintenance of a help desk for indigenous and local communities and relevant stakeholders;
- (d) Information dissemination through a national clearing-house;

- (e) Promotion of voluntary codes of conduct, guidelines and best practices and/or standards in consultation with indigenous and local communities and relevant stakeholders;
- (f) Promotion of, as appropriate, domestic, regional and international exchanges of experience;
- (g) Education and training of users and providers of genetic resources and traditional knowledge associated with genetic resources about their access and benefit-sharing obligations;
- (h) Involvement of indigenous and local communities and relevant stakeholders in the implementation of this Protocol; and
- (i) Awareness-raising of community protocols and procedures of indigenous and local communities.

Article
22
CAPACITY

1. The Parties shall cooperate in the capacity-building, capacity development and strengthening of human resources and institutional capacities to effectively implement this Protocol in developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, including through existing global, regional, subregional and national institutions and organizations. In this context, Parties should facilitate the involvement of indigenous and local communities and relevant stakeholders, including non-governmental organizations and the private sector.
2. The need of developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition for financial resources in accordance with the relevant provisions of the Convention shall be taken fully into account for capacity-building and development to implement this Protocol.
3. As a basis for appropriate measures in relation to the implementation of this Protocol, developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition should identify their national capacity needs and priorities through national capacity self-assessments. In doing so, such Parties should support the capacity needs and priorities of indigenous and local communities and relevant stakeholders, as identified by them, emphasizing the capacity needs and priorities of women.

4. In support of the implementation of this Protocol, capacity-building and development may address, *inter alia*, the following key areas:
 - (a) Capacity to implement, and to comply with the obligations of, this Protocol;
 - (b) Capacity to negotiate mutually agreed terms;
 - (c) Capacity to develop, implement and enforce domestic legislative, administrative or policy measures on access and benefit-sharing; and
 - (d) Capacity of countries to develop their endogenous research capabilities to add value to their own genetic resources.
5. Measures in accordance with paragraphs 1 to 4 above may include, *inter alia*:
 - (a) Legal and institutional development;
 - (b) Promotion of equity and fairness in negotiations, such as training to negotiate mutually agreed terms;
 - (c) The monitoring and enforcement of compliance;
 - (d) Employment of best available communication tools and Internet-based systems for access and benefit-sharing activities;
 - (e) Development and use of valuation methods;
 - (f) Bioprospecting, associated research and taxonomic studies;
 - (g) Technology transfer, and infrastructure and technical capacity to make such technology transfer sustainable;
 - (h) Enhancement of the contribution of access and benefit-sharing activities to the conservation of biological diversity and the sustainable use of its components;
 - (i) Special measures to increase the capacity of relevant stakeholders in relation to access and benefit-sharing; and
 - (j) Special measures to increase the capacity of indigenous and local communities with emphasis on enhancing the capacity of women within those communities in relation to access to genetic resources and/or traditional knowledge associated with genetic resources.
6. Information on capacity-building and development initiatives at national, regional and international levels, undertaken in accordance with paragraphs 1 to 5 above, should be provided to the Access and Benefit-sharing Clearing-House with a view to promoting synergy and coordination on capacity-building and development for access and benefit-sharing.

Article
23**TECHNOLOGY TRANSFER, COLLABORATION
AND COOPERATION**

In accordance with Articles 15, 16, 18 and 19 of the Convention, the Parties shall collaborate and cooperate in technical and scientific research and development programmes, including biotechnological research activities, as a means to achieve the objective of this Protocol. The Parties undertake to promote and encourage access to technology by, and transfer of technology to, developing country Parties, in particular the least developed countries and small island developing States among them, and Parties with economies in transition, in order to enable the development and strengthening of a sound and viable technological and scientific base for the attainment of the objectives of the Convention and this Protocol. Where possible and appropriate such collaborative activities shall take place in and with a Party or the Parties providing genetic resources that is the country or are the countries of origin of such resources or a Party or Parties that have acquired the genetic resources in accordance with the Convention.

Article
24**NON-PARTIES**

The Parties shall encourage non-Parties to adhere to this Protocol and to contribute appropriate information to the Access and Benefit-sharing Clearing-House.

Article
25**FINANCIAL MECHANISM AND RESOURCES**

1. In considering financial resources for the implementation of this Protocol, the Parties shall take into account the provisions of Article 20 of the Convention.
2. The financial mechanism of the Convention shall be the financial mechanism for this Protocol.
3. Regarding the capacity-building and development referred to in Article 22 of this Protocol, the Conference of the Parties serving as the meeting of the Parties to this Protocol, in providing guidance with respect to the financial mechanism referred to in paragraph 2 above, for consideration by the Conference of the Parties, shall take into account the need of developing country Parties, in particular the least developed countries and small island developing States among them, and of Parties

with economies in transition, for financial resources, as well as the capacity needs and priorities of indigenous and local communities, including women within these communities.

4. In the context of paragraph 1 above, the Parties shall also take into account the needs of the developing country Parties, in particular the least developed countries and small island developing States among them, and of the Parties with economies in transition, in their efforts to identify and implement their capacity-building and development requirements for the purposes of the implementation of this Protocol.
5. The guidance to the financial mechanism of the Convention in relevant decisions of the Conference of the Parties, including those agreed before the adoption of this Protocol, shall apply, *mutatis mutandis*, to the provisions of this Article.
6. The developed country Parties may also provide, and the developing country Parties and the Parties with economies in transition avail themselves of, financial and other resources for the implementation of the provisions of this Protocol through bilateral, regional and multilateral channels.

Article
26**CONFERENCE OF THE PARTIES SERVING AS THE
MEETING OF THE PARTIES TO THIS PROTOCOL**

1. The Conference of the Parties shall serve as the meeting of the Parties to this Protocol.
2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, decisions under this Protocol shall be taken only by those that are Parties to it.
3. When the Conference of the Parties serves as the meeting of the Parties to this Protocol, any member of the Bureau of the Conference of the Parties representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.
4. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall keep under regular review the implementation of this Protocol and shall make, within its mandate, the decisions necessary to promote its effective implementation. It shall perform the functions assigned to it by this Protocol and shall:

- (a) Make recommendations on any matters necessary for the implementation of this Protocol;
 - (b) Establish such subsidiary bodies as are deemed necessary for the implementation of this Protocol;
 - (c) Seek and utilize, where appropriate, the services and cooperation of, and information provided by, competent international organizations and intergovernmental and non-governmental bodies;
 - (d) Establish the form and the intervals for transmitting the information to be submitted in accordance with Article 29 of this Protocol and consider such information as well as reports submitted by any subsidiary body;
 - (e) Consider and adopt, as required, amendments to this Protocol and its Annex, as well as any additional annexes to this Protocol, that are deemed necessary for the implementation of this Protocol; and
 - (f) Exercise such other functions as may be required for the implementation of this Protocol.
5. The rules of procedure of the Conference of the Parties and financial rules of the Convention shall be applied, *mutatis mutandis*, under this Protocol, except as may be otherwise decided by consensus by the Conference of the Parties serving as the meeting of the Parties to this Protocol.
6. The first meeting of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be convened by the Secretariat and held concurrently with the first meeting of the Conference of the Parties that is scheduled after the date of the entry into force of this Protocol. Subsequent ordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held concurrently with ordinary meetings of the Conference of the Parties, unless otherwise decided by the Conference of the Parties serving as the meeting of the Parties to this Protocol.
7. Extraordinary meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol shall be held at such other times as may be deemed necessary by the Conference of the Parties serving as the meeting of the Parties to this Protocol, or at the written request of any Party, provided that, within six months of the request being communicated to the Parties by the Secretariat, it is supported by at least one third of the Parties.
8. The United Nations, its specialized agencies and the International Atomic Energy Agency, as well as any State member thereof or observers thereto not party to the Convention, may be represented as observers at meetings of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any body or agency, whether national or international, governmental or non-governmental, that is qualified in matters covered by this Protocol and that has informed the Secretariat

of its wish to be represented at a meeting of the Conference of the Parties serving as a meeting of the Parties to this Protocol as an observer, may be so admitted, unless at least one third of the Parties present object. Except as otherwise provided in this Article, the admission and participation of observers shall be subject to the rules of procedure, as referred to in paragraph 5 above.

Article
27
SUBSIDIARY BODIES

1. Any subsidiary body established by or under the Convention may serve this Protocol, including upon a decision of the Conference of the Parties serving as the meeting of the Parties to this Protocol. Any such decision shall specify the tasks to be undertaken.
2. Parties to the Convention that are not Parties to this Protocol may participate as observers in the proceedings of any meeting of any such subsidiary bodies. When a subsidiary body of the Convention serves as a subsidiary body to this Protocol, decisions under this Protocol shall be taken only by Parties to this Protocol.
3. When a subsidiary body of the Convention exercises its functions with regard to matters concerning this Protocol, any member of the bureau of that subsidiary body representing a Party to the Convention but, at that time, not a Party to this Protocol, shall be substituted by a member to be elected by and from among the Parties to this Protocol.

Article
28
SECRETARIAT

1. The Secretariat established by Article 24 of the Convention shall serve as the secretariat to this Protocol.
2. Article 24, paragraph 1, of the Convention on the functions of the Secretariat shall apply, *mutatis mutandis*, to this Protocol.
3. To the extent that they are distinct, the costs of the secretariat services for this Protocol shall be met by the Parties hereto. The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, decide on the necessary budgetary arrangements to this end.

Article
29**MONITORING AND REPORTING**

Each Party shall monitor the implementation of its obligations under this Protocol, and shall, at intervals and in the format to be determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, report to the Conference of the Parties serving as the meeting of the Parties to this Protocol on measures that it has taken to implement this Protocol.

Article
30**PROCEDURES AND MECHANISMS TO PROMOTE COMPLIANCE WITH THIS PROTOCOL**

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, consider and approve cooperative procedures and institutional mechanisms to promote compliance with the provisions of this Protocol and to address cases of non-compliance. These procedures and mechanisms shall include provisions to offer advice or assistance, where appropriate. They shall be separate from, and without prejudice to, the dispute settlement procedures and mechanisms under Article 27 of the Convention.

Article
31**ASSESSMENT AND REVIEW**

The Conference of the Parties serving as the meeting of the Parties to this Protocol shall undertake, four years after the entry into force of this Protocol and thereafter at intervals determined by the Conference of the Parties serving as the meeting of the Parties to this Protocol, an evaluation of the effectiveness of this Protocol.

Article
32
SIGNATURE

This Protocol shall be open for signature by Parties to the Convention at the United Nations Headquarters in New York, from 2 February 2011 to 1 February 2012.

Article
33**ENTRY INTO FORCE**

1. This Protocol shall enter into force on the ninetieth day after the date of deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organizations that are Parties to the Convention.
2. This Protocol shall enter into force for a State or regional economic integration organization that ratifies, accepts or approves this Protocol or accedes thereto after the deposit of the fiftieth instrument as referred to in paragraph 1 above, on the ninetieth day after the date on which that State or regional economic integration organization deposits its instrument of ratification, acceptance, approval or accession, or on the date on which the Convention enters into force for that State or regional economic integration organization, whichever shall be the later.
3. For the purposes of paragraphs 1 and 2 above, any instrument deposited by a regional economic integration organization shall not be counted as additional to those deposited by member States of such organization.

Article
34**RESERVATIONS**

No reservations may be made to this Protocol.

Article
35
WITHDRAWAL

1. At any time after two years from the date on which this Protocol has entered into force for a Party, that Party may withdraw from this Protocol by giving written notification to the Depositary.
2. Any such withdrawal shall take place upon expiry of one year after the date of its receipt by the Depositary, or on such later date as may be specified in the notification of the withdrawal.

Article
36**AUTHENTIC TEXTS**

The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

IN WITNESS WHEREOF the undersigned, being duly authorized to that effect, have signed this Protocol on the dates indicated.

DONE at Nagoya on this twenty-ninth day of October, two thousand and ten.

Annex

MONETARY AND NON-MONETARY BENEFITS

1. Monetary benefits may include, but not be limited to:
 - (a) Access fees/fee per sample collected or otherwise acquired;
 - (b) Up-front payments;
 - (c) Milestone payments;
 - (d) Payment of royalties;
 - (e) Licence fees in case of commercialization;
 - (f) Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
 - (g) Salaries and preferential terms where mutually agreed;
 - (h) Research funding;
 - (i) Joint ventures;
 - (j) Joint ownership of relevant intellectual property rights.
2. Non-monetary benefits may include, but not be limited to:
 - (a) Sharing of research and development results;
 - (b) Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources;

- (c) Participation in product development;
- (d) Collaboration, cooperation and contribution in education and training;
- (e) Admittance to *ex situ* facilities of genetic resources and to databases;
- (f) Transfer to the provider of the genetic resources of knowledge and technology under fair and most favourable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity;
- (g) Strengthening capacities for technology transfer;
- (h) Institutional capacity-building;
- (i) Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;
- (j) Training related to genetic resources with the full participation of countries providing genetic resources, and where possible, in such countries;
- (k) Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;
- (l) Contributions to the local economy;
- (m) Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in the Party providing genetic resources;
- (n) Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;
- (o) Food and livelihood security benefits;
- (p) Social recognition;
- (q) Joint ownership of relevant intellectual property rights.