

REGULATION OF ACCESS TO GENETIC RESOURCES AND ASSOCIATED TRADITIONAL KNOWLEDGE: APPROACHES AND CHALLENGES IN THE SOUTH PACIFIC

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Regulatory frameworks regarding access to genetic resources and associated traditional knowledge (TK) with access and fair and equitable benefit sharing (ABS) are of international significance because of their social, economic, and cultural implications for local communities in general and the South Pacific countries in particular. This has led to development of an international regime specifically addressing ABS and to regional and national initiatives in countries including Vanuatu. The main aim of this paper is to examine the current position of regulatory frameworks that address the issue of access to genetic resources and associated TK in Vanuatu. This paper will highlight approaches taken in Vanuatu, examine strengths and weaknesses of the legal and administrative framework, and provide recommendations for the future.

Introduction

THE SOUTH PACIFIC REGION comprises small island countries with indigenous populations. Reliance of South Pacific societies upon biological diversity and its components for economic and sociocultural use is evident. For example, Regenvanu argues that 80 percent of the population in Vanuatu “satisfies most of their food and other requirements from their ancestral land and seas, using traditional methods of agriculture and other forms of resource utilization and conservation.”¹ In addition, one of the most recent surveys of the area, conducted by Bradacs, Heilmann, and

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Weckerle, suggests that there are many different types of medicinal traditional knowledge (TK) used by specialists, including people of high rank in the local social system, and such knowledge is also widely used by villagers throughout Vanuatu.² It is also evident that there is an unbreakable link between genetic resources (GR) and associated TK on the one hand, and local social, economic, and legal systems—such as traditional leadership and customary law and procedure—on the other.³ However, the majority of South Pacific countries are developing countries, and some of them are least developed countries. As Techera has said, these countries encounter a number of challenges such as “pressure from the process of globalization and modernization, as well as population growth, development and environmental development.”⁴ In addressing these challenges, it has been acknowledged that the empowerment of indigenous and local communities is essential for conservation and sustainable use of biological diversity⁵ and also for sustainable development of the South Pacific countries. In particular, a number of studies show that empowerment and involvement of such groups has led to success in the management of natural resources while improving the livelihood of such groups.⁶ It follows, in relation to the control of the exploitation of biological resources, including genetic resources and associated TK, that if indigenous and local communities are involved and benefits are shared in an equitable way, sustainable use of such resources may be achieved.⁷ Therefore, regulation of access to GR and associated TK with access and fair and equitable benefit sharing (ABS) is of international significance, having particular social, economic, and cultural implications for South Pacific countries and their local communities.

The international regime on the sharing of benefits arising from the use of genetic resources and associated TK established by the Convention on Biological Diversity 1992 (CBD)⁸ has entered a new phase, namely, that of domestic implementation, as a result of the recent adoption of 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 2010 (Nagoya Protocol).⁹ Despite this, it remains an elusive task for contracting parties to the convention to identify an effective legal strategy for implementing ABS at the regional and national levels.

The focus of this paper is the regulation of access to genetic resources and associated TK in Vanuatu, and the role that legislation and other regulatory frameworks play in ensuring the empowerment and involvement of the indigenous and local communities concerned. Key regulatory gaps and challenges will be addressed, and recommendations will be made for the future.

Legal, Policy, and Administrative Framework

Vanuatu has ratified the CBD and has signed the Nagoya Protocol. The CBD has three aims: conservation of biodiversity, sustainable use of its components, and fair and equitable sharing of benefits arising from the use of genetic resources.¹⁰ In relation to the third aim, the convention provides a conceptual framework, as well as basic rights and duties for states, for addressing how access to genetic resources and TK is regulated and how benefits resulting from the use of such resources can be shared between the resource providers and resource users. The CBD affirms the sovereign right of a state over its natural resources and specifies the authority of a state to regulate access to genetic resources.¹¹ It addresses the basic obligation of a state in relation to access, which is based upon the intention of linking the ABS system and the first two goals of the convention.¹² It also provides that access to genetic resources is given with the prior informed consent of the party providing the genetic resources,¹³ through its competent national authority(ies), unless otherwise determined by that party.¹⁴ Further, once prior informed consent is granted, the CBD provides that access is upon mutually agreed terms between the party providing genetic resources and the prospective user of the resources.¹⁵ The convention further draws attention to benefit sharing and it states that benefit sharing arising from the use of genetic resources must be upon mutually agreed terms.¹⁶ Ratification of the convention certainly led to development of legislative and policy frameworks in Vanuatu. Vanuatu has a legislative framework that regulates access to genetic resources and associated TK. In addition, regulations related to intellectual property and a new law that addresses TK in particular have been developed, including regulations pertaining to access to TK with equitable benefit sharing.

Vanuatu signed the Nagoya Protocol in November 2011. Going beyond the CBD, the protocol establishes an obligation on the contracting parties to adopt measures to ensure prior informed consent and the involvement of indigenous and local communities in order to grant access to genetic resources with fair and equitable benefit sharing.¹⁷ Although such measures are needed where indigenous and local communities have an “established right” to control access under domestic law, we need to see how each contracting party interprets the provision that deals with collective indigenous rights including rights to self-determination and natural resources.¹⁸ Further, as well as providing a conceptual framework concerning ABS regarding TK¹⁹ associated with genetic resources, the protocol gives details of states’ duties to implement ABS in relation to access to such knowledge. In particular, it obliges states to implement ABS, through national legislation,

policy, and administrative frameworks, in a way that does not conflict with the customary norms and governance system of such groups.²⁰ The ambit of the obligations encompasses also, *inter alia*, duties to establish a mechanism in order to inform prospective users of TK of their obligations,²¹ a community protocol, minimum requirements for mutually agreed terms, and model contractual clauses for fair and equitable benefit sharing in order to assist indigenous and local communities in their participation in the implementation of ABS.²² Another notable feature of the protocol is the specific emphasis upon compliance with the ABS regulations regarding genetic resources and associated TK.²³ Clearly, the absence of a monitoring requirement for compliance with ABS regulations in relation to TK is the one of the most notable limitations in the protocol, one which “might constitute an omission with far-reaching consequences.”²⁴ However, contracting parties need to take “appropriate, effective, and proportionate legislative, administrative or policy measures” to ensure that, if such resources are used within their jurisdiction, they are accessed in accordance with the legislative and regulatory requirements of the party providing such knowledge.²⁵ This obligation clearly rests on the fact that it is the protocol’s aim to “further support the effective implementation” of ABS provisions,²⁶ which reflects the absence of compliance measures in many countries to date.²⁷ Awareness raising and capacity building for local communities are equally essential in ensuring the implementation of ABS regarding TK, and these aspects are also addressed by the protocol.²⁸

At the domestic level in Vanuatu, the National Biodiversity Strategy and Action Plan (NBSAP),²⁹ funded by Global Environmental Facility, was published in 1999 to fulfill the requirement under the CBD. One of the most significant features of the NBSAP is its specific focus on community-centered approaches to the sustainable management of biological diversity, including cooperation with the government and the provinces. The NBSAP was later followed by the NBSAP Add-on Project (NBSAP Phase II).³⁰ NBSAP Phase II identified capacity-building needs within four thematic areas: scientific capacity, functional biodiversity management capacity, indigenous knowledge, and financial and institutional capacity.³¹ Establishment of a National Scientific Research Council, an institutional body to coordinate scientific research involving genetic resources and TK, was also a priority of NBSAP Phase II.

In relation to the Nagoya Protocol requirements, Vanuatu designated the Department of Environmental Protection and Conservation (DEPC), in the Ministry of Lands and Natural Resources, as a national focal point for ABS. This department will report to the Secretariat of the CBD on issues relating to the implementation of ABS. If the protocol enters into

force, this will facilitate communication and information sharing, as well as accumulation of experiences at an international level.

As well as the direct implementation of ABS as examined above, it is evident that Vanuatu has made an effort to provide legislation that covers key issues involving access to genetic resources and associated TK. The Environmental Management and Conservation Act 2002 [Cap 283], establishes a basic framework for ABS regulations in Vanuatu. The act was amended in 2011 and is currently known as the Environmental Protection and Conservation Act 2011 [Cap 283] (EPCA).³² The EPCA establishes a Biodiversity Advisory Committee,³³ which comprises the director of DEPC and an additional five members approved by the minister.³⁴ The mandate of the committee includes any matters that are relevant to the implementation of the CBD, and in particular matters relating to the commercial exploitation of genetic resources and associated TK.³⁵ As well as the establishment of such a body, the act establishes a permit system through which access to TK associated with genetic resources is granted. This system comprises an access application to the director of the DEPC,³⁶ a legally binding and enforceable contract between an access applicant on one hand and landowners or TK owners on the other,³⁷ and access permission from the Biodiversity Advisory Council.³⁸ Additionally, the payment of a bioprospecting information bond is a new requirement under the EPCA in relation to regulation of access to resources. The access applicant needs to pay an application fee of 50,000 Vatu and a bioprospecting information bond of 100,000 Vatu to the DEPC.³⁹ The main purpose of the bioprospecting information bond is to ensure that all information gathered by access to resources and associated TK is provided to the director of the DEPC.⁴⁰ Last and most important, a benefit-sharing agreement with the relevant local communities is a core element of ABS regulation under the act, and no access permit will be granted unless the contract is concluded at the local level.

The Fisheries Act 2005 [Cap 315] provides a framework through which access to marine species is regulated. This includes, *inter alia*, regulations of scientific research conducted in marine areas within the jurisdiction of Vanuatu,⁴¹ access to resources within marine reserves⁴² and protection of marine mammals.⁴³ However, steps to obtain permission at a domestic level are too general and are less precise than those in the EPCA considered above. As observed above, regulations under the EPCA make it clear that those who wish to access genetic resources and TK must proceed by obtaining a permit and following the regulations that set out the process by which a permit is granted. What is notable about the regulatory framework under the Fisheries Act is that conditions for access to marine species are largely

at the discretion of the director of the Department of Fisheries. Clearly, these regulations are not consistent with the requirements of the Nagoya Protocol. The protocol requires that ABS regulation must provide for “legal certainty, clarity, and transparency,” “information on how to apply for prior informed consent,” and “clear rules and procedures upon which mutually agreed terms are required and established.” While it remains to be seen how the criteria in the protocol can be objectively assessed, it is evident that the regulations under the Fisheries Act are less precise and that the criteria for obtaining authorization for access to marine species remain elusive when compared with those of the EPCA. Provisions in the Fisheries Act may add to the conservation and sustainable management of marine species, but, as discussed below, the division of rules between two pieces of legislation has contributed to regulatory inconsistency in how ABS is addressed.

The Patents Act 2003 addresses, among other things, a key issue of ABS, namely, compliance of regulations for access to TK associated with genetic resources. The statute follows a western intellectual property law model.⁴⁴ Yet it provides that a patent that is “based on, arose out of, or incorporates elements of”⁴⁵ TK will only be granted if there is compliance with ABS, and that, in particular, there is prior informed consent and a benefit-sharing agreement with the custom owner(s) of such knowledge. Further, the act provides that where the custom owner cannot be identified, or ownership is in dispute, the National Council of Chiefs must enter into a benefit-sharing agreement with the patent applicant.⁴⁶ Apart from the Patents Act, there is to be a separate piece of legislation solely concerned with the protection of TK. The Draft TK Bill will, for example, include a register of TK, and anyone wishing to use this knowledge will need to pay compensation to the owner of the knowledge.⁴⁷ It is also hoped that the Draft TK Bill will complement the intellectual property legislation referred to above.⁴⁸ Notwithstanding, the legislation, if enacted, may present further difficult challenges, namely, the identification of the legitimate owners of genetic resources and associated TK who are to retain control over access to such resources and to receive benefits from their use. The legislation considered above is tacit on how to identify the owner of a particular piece of TK. Concerns will arise where TK is transmitted over generations among communities, or where the same knowledge is held by more than one community. This concern has been addressed by Forsyth, and it is likely to remain a complex issue.⁴⁹

The Vanuatu Cultural Research Policy (VCRP) provides a permit system through which access to TK is regulated and through which benefits from the use of such knowledge is shared with the local communities concerned. The Vanuatu National Cultural Council (VNCC) is responsible for the

research permit system. The members of the council include the director of Vanuatu Cultural Centre (VCC), president of the National Council of Chief (*Malvatumauri*), a member of the Public Service Commission, a representative from the National Council of Women, as well as a senior employee from VCC. The VCRP applies to cultural research involving *kastom*, which is “indigenous knowledge and practice and the ways it is expressed and manifested.”⁵⁰ The focus of the VCRP is not research activities involving genetic resources and associated TK, which is where the issue of ABS under the CBD and the Nagoya Protocol arises. However, it is a responsibility of the VNCC to assist in regulating access to genetic resources and associated TK, where there is a risk of these being exploited in a way that violates the rights of local communities, inter alia, the right to be involved in the obtaining of prior informed consent and benefit sharing. In relation to this responsibility, a concern arises to ensure the adequate monitoring of activities of approved researchers. Approved researchers may collect samples of genetic resources and associated TK without the VNCC’s knowledge or permission in remote islands in Vanuatu. In addition, Vanuatu has a limited provision for the infrastructure that is essential for the biochemical screening of collected materials. Consequently, research activities involving genetic resources and associated TK often can be undertaken outside of Vanuatu. Therefore, the prominent challenge for the VCRP is the incapacity of the VNCC and the VCC based in the capital (Port Vila) to monitor the activities of approved researchers undertaking research once this is carried out in the remote islands and when overseas.⁵¹ Yet one of the most notable features of the VCRP is its collaborative and cooperative approach, which involves relevant communities, volunteer field workers, researchers, and the VCC in research activities involving TK. Arguably, experience and networks gained through the VCRP could provide valuable lessons for the regulation of access to genetic resources and associated TK within the context of the CBD and the Nagoya Protocol.

Regulatory Gaps and Challenges

Drawing upon this analysis, it is evident that Vanuatu has made significant advances in developing a comprehensive regulatory framework. However, some concerns remain in order to effectively regulate access to these resources and to prevent misappropriation of genetic resources and associated TK. The major challenges in Vanuatu can be described in the following three ways: overcoming some inconsistencies between regulatory frameworks; ensuring improved coordination among the relevant government departments and institutions; and encouraging the participation of stakeholders, particularly at the local level.

It is clear that the current legislative framework regulating access to genetic resources and associated TK in Vanuatu operates on a sectorial basis. For example, the Fishery Department regulates access to marine genetic resources under the Fisheries Act, whereas access to TK is regulated by the VNCC under the VCRP. Access regulation under different regulatory standards can lead to different outcomes in various sectors. Furthermore, the ABS regime in place in Vanuatu is drafted in broad terms and backed by different policy goals. In some cases, regulation of access to genetic resources and TK has been undertaken outside the EPCA regulations. Therefore, this could lead to divergent interpretations of internationally described terms in ABS, and inconsistency in the regulation and mandate of competent authorities unless the law and/or the policies are harmonized through a common understanding among different government agencies.

Apart from legislation, the important lesson to be learned from the implementation of the VCRP is that a regulatory framework for access to genetic resources and TK will not be effective without an institutional body to implement it. In Vanuatu, there are a number of government departments that are currently regulating access to genetic resources and associated TK. As discussed, the DEPC is regarded as the principal government agency for implementing the domestic ABS regime in light of the requirements of the CBD, with the Department of Trade primarily concerned with compliance of prior informed consent and benefit sharing, the Fisheries Department having a basic legislative framework, and other departments—such as the Forestry Department or Quarantine Services—having no clear regulatory standard or institutional arrangements for regulating access to genetic resources and associated TK. This leads to different views on the transactions concerning such resources and knowledge that are subject to ABS.

Law and policy makers in Vanuatu have recognized the needs for the coordination at the administrative level. In 2001, the Council of Ministers endorsed the establishment of a National Scientific Research Council, and the establishment of such a body clearly draws on the experience of research coordination under the VCRP.⁵² However, resourcing is a critical challenge to functional operations of such a body. Mainly because of a lack of funding and institutional incapacity, the National Scientific Research Council has not been operationalized yet. For the same reason, the Biodiversity Advisory Committee under the EPCA has not been established. Related concern includes a lack of common understanding of the issues both at the national and the local level, which certainly undermines the effort toward coordination and collaboration among government bodies.⁵³ Different levels of

awareness across Vanuatu certainly undermine the efforts toward coordination and collaboration between the relevant government departments and institutions: for example, some are mindful about unilateral exploitation of genetic resources and associated TK that undermines communities' control, whereas others are more conscious of the promotion of research activities involving such resources.

Establishment of comprehensive ABS regulations and a system for ABS administration is not an easy task and may not be a feasible goal within a short period of time. Of course, as a common understanding grows among different government agencies and there is more international support, improved cooperation might be expected with a better exchange of information and better regulation of access to genetic resources and TK associated with genetic resources. Yet, until that time, it is necessary for Vanuatu to identify the roles and responsibilities of relevant government departments and institutions, in order to examine how coordination and collaboration on regulation of access can be carried out in the future. The establishment of the Biodiversity Advisory Council and National Scientific Research Council should remain a priority to assist in promoting and harmonizing coordination among relevant government departments.

Despite the significant efforts being made, in light of requirements of the CBD and the Nagoya Protocol, Vanuatu needs to identify the most effective regulatory options for achieving the conservation and sustainable use of genetic resources and associated TK with equitable benefit sharing. Regulatory frameworks involving the regulation of access to genetic resources and associated TK have led to many difficulties for law and policy makers because of the multifaceted nature of the issue: the environment, intellectual property, and collective rights of traditional communities are all involved. At the international level, a major effort to address legal strategy in relation to access to genetic resources and associated TK has been undertaken at the CBD, World Intellectual Property Organization (WIPO), and United Nations (UN) Food and Agriculture Organization. At the regional level, the Secretariat of the Pacific Regional Environmental Programme (SPREP) and Melanesian Spearhead Group (MSG) have developed regional regulatory instruments in this area. The Pacific Islands Forum Secretariat, in cooperation with the Secretariat of the Pacific Community, SPREP, and WIPO, developed and led the implementation of the Traditional Knowledge Action Plan in 2009. The main aim of this Action Plan is to provide technical assistance in the development of national systems for the protection of TK that, among other things, address key issues such as the regulation of access to TK associated with genetic resources. Importantly, Vanuatu is one of six beneficiary countries in a pilot program under the Action Plan.

It is evident that legal instruments developed by SPREP and MSG provide a useful framework for the development of a national regulatory framework and reflect the region's specific concerns. Notwithstanding, the implementation of any legislative or other type of framework that regulates access to genetic resources and associated TK must ensure that all stakeholders, particularly at the local level, are involved. As discussed, the Environmental Conservation and Protection Act has clearly provide a framework supporting the involvement of local communities in regulating access to resources. As seen, for example, in the requirement of prior informed consent at the local level, which has been suggested as a part of customary international law,⁵⁴ and is a core element of both international and national ABS regime. However, some issues needs to be addressed in this area, such as the establishment of PIC procedures as well as using different types of regulatory options, including, *inter alia*, customary law, community protocols, and traditional governance systems.⁵⁵ Customary law plays a central role, in particular, for access to TK,⁵⁶ and the Nagoya Protocol establishes clear obligations to take it into account in implementing ABS. Prior informed consent procedures and the use of customary law and community procedures certainly enhance the participation to access, control, and benefit sharing of communities. Clearly, it remains to be seen how and to what extent customary law can be used in relation to access to genetic resources and TK in Vanuatu. Vanuatu could learn, in this regard, from the experience of other countries and regions. For example, the Secretariat of the CBD has developed a database of ABS measures showing the legal, policy, and administrative approaches taken in different countries and regions.⁵⁷ Further, the UN Environment Programme (UNEP) has developed a database of community protocols, and this experience from other countries could contain valuable implications for the regulatory approaches taken by Vanuatu.⁵⁸

Apart from legal, policy, and administrative frameworks, it is necessary for Vanuatu to identify a policy strategy and approaches that integrate the issue of access to genetic resources and associated TK with the broad goals of the CBD and the Nagoya Protocol, namely, the conservation of biological diversity with sustainable use of its components. The interface of ABS and conservation has been clearly recognized by the Vanuatu government. It is noted by the DEPC that they will be considering ABS-related issues in the review of the NBSAP early in 2013, as well as their National Environment Policy that will be drafted in 2013.⁵⁹ It is also hoped that such a strategy is aligned with Vanuatu's national strategy for sustainable development, which covers environmental, economic, and social development. Clearly, it is important that the sharing of benefits resulting from genetic

resources and associated TK promotes the economic and social development of local communities and of the country as a whole, while also ensuring environmental sustainability. The need to integrate ABS into sustainable development is also relevant to a fundamental duty under the Vanuatu's Constitution.⁶⁰ Section 7(d) of the Constitution establishes a duty of every one to "safeguard the national wealth, resources and environment in the interests of the present generation and of future generations."

Conclusion

The focus of this research has been to identify the strengths and some weaknesses of law and other regulatory frameworks in Vanuatu for ABS. The current position of ABS regulation in Vanuatu is a pioneering attempt in the South Pacific region to achieve the international goal of fair and equitable benefit sharing in the use of genetic resources and associated TK. The legislation considered above addresses all key issues relating to access to genetic resources and TK, both benefit sharing and compliance. In legislation, particularly the EPCA, Vanuatu has opted for cooperative approaches, which, *inter alia*, address the involvement and participation of relevant local communities in regulating access to genetic resources and associated TK.

Although this paper identified some challenges, these are also recognized by officers in the Vanuatu government. Therefore, Vanuatu's approach to ABS should be warmly welcomed. Furthermore, experiences from Vanuatu contain valuable lessons for other South Pacific countries, as well as elsewhere in the world, in establishing a national strategy on ABS. Based upon the analysis above, set out below is a recommendation for Vanuatu to strengthen its legal regime for dealing with the complex challenges associated with ABS. Most importantly, it is preferable for the responsibility to implement ABS to fall under one office of government, in order to summarize key issues and concerns that need to be addressed to regulate access to genetic resources and associated TK. In this regard, the establishment and operation of the Biodiversity Advisory Committee and National Scientific Research Council should remain a priority to assist in promoting and harmonizing coordination among all relevant government departments. Only then will the future of Vanuatu's genetic diversity and associated TK be assured.

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NOTES

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