

**COUNTRY REPORT: FEDERATED STATES OF MICRONESIA****Nagoya Protocol**

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On 30 January 2013 the Federated States of Micronesia (FSM) became the fifteenth party to the *Convention on Biological Diversity (CBD)*<sup>1</sup> to ratify the *CBD's 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 Nagoya Protocol)*.<sup>2</sup> The Nagoya Protocol, building upon the 2002 Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of Benefits Arising out of their Utilization,<sup>3</sup> aims to implement in a binding agreement the CBD's third objective: the fair and equitable sharing of benefits arising out of the utilization of genetic resources. The text of the *Nagoya Protocol* was adopted by the CBD's tenth Conference of the Parties in October 2010 and will enter into force on the ninetieth day after the date of deposit of the 50th instrument of ratification, acceptance, approval or accession.<sup>4</sup>

This report is divided into three parts. The first summarises core elements of the *Nagoya Protocol*, the second describes steps undertaken and planned by the Government of the Federated States of Micronesia aiming to implement the Protocol, and the final section briefly discusses aspects of the FSM experience indicating legal and cultural issues that other Pacific island countries are likely to encounter when implementing the *Nagoya Protocol*.

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<sup>1</sup> *Convention on Biological Diversity*, signed 5 June 1992, 1760 UNTS 79, entered into force, 29 December 1993.

<sup>2</sup> 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, not in force, text: UNEP/CBD/COP/DEC/X/1 of 29 October 2010.

<sup>3</sup> CBD COP 6 Decision VI/24.

<sup>4</sup> Nagoya Protocol Article 33.

### **Core Elements of the *Nagoya Protocol***

The central purpose of the *Nagoya Protocol* is to regulate the process of ‘access and benefit sharing’ typically referred to by the acronym ABS. ABS indicates the process of accessing genetic resources found in biodiversity and sharing the benefits arising out of the utilization of those resources in a fair and equitable manner. ABS relates to all three of the CBD’s objectives, but is of most relevance to the third objective.

In the context of the *Nagoya Protocol*, ‘genetic resources’ means any genetic material of actual or potential value, and ‘genetic material’ means any material of plant, animal, microbial or other origin containing functional units of heredity.<sup>5</sup> To ‘utilize’ genetic resources in these contexts is to conduct research and development on the genetic or biochemical composition of the resources, including through the application of biotechnology as defined in Article 2 of the Convention.<sup>6</sup>

In essence, the *Nagoya Protocol* seeks to strike a balance between the interests of users of genetic resources (the institutions and individuals who engage in biotechnological research and related activities using genetic material) with the needs and interests of the providers of genetic resources. In simple terms, users are typically interested in having a set of transparent rules and processes to follow when seeking access to genetic resources in a given jurisdiction. Providers, who sometimes include local and indigenous communities, are interested in receiving a fair and equitable share of benefits that might flow from the resource utilization. An important aspect of the *Nagoya Protocol* is that it also encompasses traditional knowledge associated with genetic resources that are accessed and utilized. An example of this traditional knowledge would be that related to plants used in traditional medicinal practices.

In terms of institutional arrangements, Parties to the *Nagoya Protocol* must designate both a National Focal Point (NFP), and one or more Competent National Authorities (CNAs). A single agency may perform the role of both an NFP and a CAN, the roles of which are set out in Article 13. NFPs are responsible for liaison with the CBD Secretariat as well as providing information for applicants seeking access to genetic resources and related traditional knowledge. This may include information on procedures for obtaining prior informed consent and establishing mutually agreed terms, including benefit-sharing. NFPs

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<sup>5</sup> Convention on Biological Diversity Article 2.

<sup>6</sup> Nagoya Protocol Article 2.

also provide information on CNAs as well as relevant indigenous and local communities and other relevant stakeholders.

CNAs are responsible for advising on requirements for obtaining prior informed consent (PIC) and mutually agreed terms (MAT), for granting access or facilitating the granting of access by resource providers, and for issuing written evidence that access requirements have been met.<sup>7</sup> It is not compulsory for Parties to require PIC before granting access, but if they choose to do so it is the CNAs that are responsible for providing information regarding the process by which this must be done.

MATs are legally binding agreements setting out conditions of access and benefit-sharing that are negotiated between users and the providers, and possibly involving other relevant stakeholders. MATs may:

- Identify the agreed applicable law under which the agreement is to be understood and administered;
- Include a dispute settlement clause, including options for alternative dispute resolution;
- Identify the jurisdiction under which the dispute resolution process is to be conducted;
- Include detailed terms on benefit-sharing including intellectual property (IP) rights;
- Ensure Indigenous and local communities' PIC or approval is upon mutually agreed terms
- Include provisions setting out rules or protocols for any subsequent third-party use; and
- Include terms regulating changes in intended use, if applicable.<sup>8</sup>

Importantly in the FSM context, where a Party designates more than one CNA, it must convey to the Secretariat relevant information on the respective responsibilities of its various CNAs. Where applicable, such information must, at a minimum, specify the geographical or sectoral division of responsibilities between the various CNAs so that users are able to understand which CNA will be responsible for the genetic resources sought.<sup>9</sup>

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<sup>7</sup> Nagoya Protocol Article 13.

<sup>8</sup> Nagoya Protocol Article 6.

<sup>9</sup> Nagoya Protocol Article 13.

To summarize the above, Parties to the Protocol must decide whether to require PIC for access and use of their genetic resources and of any associated traditional knowledge. If they do choose to require PIC, Parties must establish clear and fair processes setting out how PIC can be obtained by users, and also how MATs can be reached. These processes are administered by CNAs. The NFP can also assist in advising which CNA a particular user should deal with and on other matters related to a country's ABS systems.

Article 5.1 describes core obligations of the Parties with respect to benefit sharing:

*[B]enefits 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.*

Article 5.2 provides Parties with the capacity to protect the interests of indigenous and local communities, in the following terms:

*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.*

Article 5.5 provides that benefits from the use of traditional knowledge associated with genetic resources subject to MATs are shared with the indigenous and local communities that provided the knowledge:

*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 5.4 makes it clear that benefits may be monetary or non-monetary, and there is an annex to the Protocol providing a non-exhaustive indicative list of possible benefits.

A final core element that Parties are required to address in their administrative or legal systems implementing the *Nagoya Protocol* is that of compliance and monitoring. The Articles most relevant to compliance and monitoring are Articles 15, 16, 17 and 18. In the context of the *Nagoya Protocol* compliance means meeting the requirements and obligations of national (domestic) ABS legislative, administrative, or policy measures on access and benefit-sharing to genetic resources and traditional knowledge associated with genetic resources of both the provider and user countries. In both cases, compliance also requires meeting the requirements and obligations documented in MATs.

Compliance is thus addressed at two levels: compliance with the MATs, and compliance with any applicable national law, policy or administrative measures on ABS. Parties are obliged to take action to support compliance with the ABS requirements of providers of genetic resources, including establishing one or more checkpoints to monitor or enhance transparency in the use of genetic resources. Article 17.1 of the *Nagoya Protocol* specifies obligations of Parties regarding the designation of ‘checkpoints’ to assist in monitoring the utilization of genetic resources. Examples of possible checkpoints include customs authorities, patent offices, market approval offices, research funding agencies, and indigenous and local community representatives. Other aspects of Article 17 relate to the production and issuance of internationally recognized certificates of compliance as mechanisms of monitoring compliance.

### **Implementing the *Nagoya Protocol* in the Federated States of Micronesia**

The nation state of FSM was created in the mid 1980s through the joining of four societies that had, since the conclusion of WWII, been administered by the United States as districts of the former Trust Territory of the Pacific Islands. FSM’s founding fathers consciously and intentionally drafted a National Constitution allocating a high degree of autonomy to the four states: Kosrae, Pohnpei, Chuuk and Yap.<sup>10</sup> The aim of this was to create a country whose national government was sufficiently empowered to represent its citizens in international contexts, while preserving most authority to the states thus allowing them to determine their own policies, laws and programs on most issues.<sup>11</sup> This constitutional history has direct bearing upon how FSM can implement the *Nagoya Protocol* in that the outcome of the constitutional division of authority in FSM is that the state governments are the primary custodians of matters relating to environmental conservation and natural resource

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<sup>10</sup> Glenn Petersen, “The Federated States of Micronesia’s 1990 Constitutional Convention: Calm before the Storm?” (1994) 6 *Contemporary Pacific* 337-69, 340.

<sup>11</sup> *Ibid*, 342.

management within their jurisdictions.<sup>12</sup> While the FSM Constitution empowers the National Government to ratify treaties, ratifications do not expand or alter national legislative capacities, i.e. ratification of the *Nagoya Protocol* does not empower the National Government to legislate to implement the Protocol's requirements where such authority resides with the states.<sup>13</sup>

A review and consultation process pursuant to implantation of the *Nagoya Protocol* was undertaken from February to May 2013, the outcome of which was a fifty-page report titled 'Gap Analysis on the Implementation of the *Nagoya Protocol* in the Federated States of Micronesia' (Gap Analysis).<sup>14</sup> In preparing the Gap Analysis officers of FSM's Department of Resources and Development and the Office of Environment and Emergency Management visited each state, in the process conducting 46 meetings with more than 150 key stakeholders. The purpose of the consultation process was twofold. Firstly, to share information with key stakeholders about the *Nagoya Protocol* and the implications of FSM putting in place mechanisms to fulfill its obligations under the Protocol. Secondly, to receive comments, advice and feedback from stakeholders on any ABS-related issues of concern to them, as well as guidance regarding how the *Nagoya Protocol* might best be implemented in FSM or in specific FSM states.<sup>15</sup> The remainder of this section summarises key findings of the Gap Analysis.

An initial finding of the Gap Analysis is that there is currently in FSM, with some exceptions of specific agencies of the National and Kosrae State Government, a low level of awareness of ABS issues generally and very low level of awareness of *Nagoya Protocol* specifically.<sup>16</sup> Despite this, many stakeholders in FSM's states indicated high levels of concern regarding the activities of international researchers within FSM.<sup>17</sup> These concerns typically focused on firstly, ensuring that FSM stakeholders are adequately informed about the activities of non-citizen researchers, and secondly that there is some sharing of benefits of the research with FSM and FSM stakeholders (in many cases the core benefit sought by stakeholders was simply copies of the publications or other material stating the outcomes of the research).<sup>18</sup>

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<sup>12</sup> FSM Department of Resources and Development, Gap Analysis on the Implementation of the *Nagoya Protocol* in the Federated States of Micronesia, (Policy Paper, Palikir, 2013), 10.

<sup>13</sup> *Ibid.*

<sup>14</sup> *Ibid.*

<sup>15</sup> *Ibid.*, 11.

<sup>16</sup> *Ibid.*

<sup>17</sup> *Ibid.*, 20. These concerns are substantially broader than *Nagoya Protocol* issues and include all forms of research undertaken by non-citizens in the country.

<sup>18</sup> *Ibid.*

Upon receiving briefings and summaries of the objectives and core elements of the *Nagoya Protocol*, most stakeholders and all key stakeholders expressed high levels of support both for FSM's ratification of the Nagoya Protocol and for the full and expeditious implementation of the Protocol in FSM. Finally, many key stakeholders emphasized strongly that the State Governments should be the primary decision-makers in relation to regulating ABS in FSM, and specifically that each state operate their own CNAs.<sup>19</sup>

The Gap Analysis concluded that there is a substantial gulf between the current situation in FSM and a future situation in which FSM is fully compliant with the *Nagoya Protocol*. The related gaps fall into two broad categories: knowledge and capacity gaps, and institutional gaps.<sup>20</sup> Somewhat obviously, to address knowledge and capacity gaps there will need to be training and capacity building addressing all of the relevant issues associated with implementing an effective national ABS regime. This might include building better local understandings of biotechnological research and its purposes and methods; capacities for negotiating realistically to reach equitable MATs; capacity-building in the fields of ABS policy and law (both international and domestic), as well as ABS-related intellectual property law.<sup>21</sup>

Key institutional gaps are that FSM currently has no National Focal Point for the Nagoya Protocol, no Competent National Authorities, or any ABS checkpoints. Over the coming months and years these institutions will need to be identified and commence implementing the functions required of them by the *Nagoya Protocol*. There is also an absence of policy on ABS, and the development of policy should precede the development of administrative or legal regimes. There is some relevant law and policy in each jurisdiction, but this is limited in scope and is not designed to address ABS obligations. Pohnpei State has the most comprehensive administrative and legal structures relevant to ABS, whereas Chuuk State has the least comprehensive.<sup>22</sup>

Consistent with stakeholder feedback in all five jurisdictions, the Gap Analysis recommended that CNA responsibilities be allocated to the state governments. Not only is this probably the only option conforming to FSM's five Constitutions, it is also consistent with the wishes and expectations of all key stakeholders.<sup>23</sup>

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<sup>19</sup> Ibid, 24.

<sup>20</sup> Ibid.

<sup>21</sup> Ibid.

<sup>22</sup> Ibid.

<sup>23</sup> Ibid.

It was also recommended that FSM stakeholders consider prioritizing and rapidly implementing an *Interim National ABS Policy*. An interim policy would enable substantial (if not fully complete) compliance with FSM's Nagoya Protocol obligations within a comparatively short time period and would provide relevant offices and other stakeholders an opportunity to engage in a 'learning-by-doing' exercise that would inform future development of more permanent policy and law.<sup>24</sup> Fully implementing the *Nagoya Protocol* in FSM will be a complex undertaking and any undue rushing of the process may result in resistance from key stakeholders, or suboptimal institutional design; an interim policy may help in avoiding these negative outcomes.

In the medium to long term all five jurisdictions will need to develop and adopt Nagoya-consistent policy and administrative systems, and they will also consider developing legislation specifically addressing ABS issues. Whether this means amendments to existing researcher permitting provisions or new ABS-specific laws is an issue that stakeholders in each jurisdiction will consider more fully during coming months. It is likely that compliance, enforcement and monitoring in particular will be more fully effective if supported by ABS-specific provisions.

It would be possible, but not necessary, for each of the four states to adopt the same or very similar ABS policies, administrative systems and laws. Consistent policy and law across all FSM's states would assist the interests of users, and the idea of having the same or very similar laws in each jurisdiction is likely to be advocated or preferred by external experts and donors. Nevertheless, observers fully familiar with FSM's cultural, political and legal context are aware that the disadvantages of attempting to achieve nationwide consensus may outweigh the real or perceived benefits of doing so. This is particularly the case given there are obligations contained in the *Nagoya Protocol* relating to indigenous and local communities. That is, each state has its own protocols and approaches to liaising with local communities and traditional leaders in decision-making processes.<sup>25</sup>

Finally, the Gap Analysis recommended that all FSM's future ABS policies and administrative procedures ensure that negotiation of MATs is a not only a whole-of-government activity, but one also involving non-governmental organizations (NGOs). An advantage of involving multiple government agencies in this stage of the ABS process, as well as NGOs, is that the full spectrum of potential needs and opportunities be properly

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<sup>24</sup> Ibid, 24-25.

<sup>25</sup> Ibid, 25.



identified. Also, NGOs in FSM and throughout the Pacific are often crucial in playing the role of institutions that can mediate between the spheres of government and science, and the interests and perspectives of traditional and local communities.<sup>26</sup>

### **Pacific-Wide Issues for Nagoya Protocol Compliance**

The federal structure of government in FSM provides additional legal and institutional complexities to many governance challenges, including that of implementing the *Nagoya Protocol*. While other Pacific island countries do not have to deal with the issues of national – state jurisdictional divisions, the FSM experience in commencing implementation of the Nagoya Protocol does indicate a number of challenges that will be experienced by most of its regional neighbors as they ratify and address the task of implementing this treaty.

The first issue in this context is that low levels of technical and administrative capacity are common to most governments and public agencies throughout the region. Accordingly, capacity-building in the sphere of ABS and *Nagoya Protocol* procedures and requirements will be much needed in coming years. The Secretariat of the Pacific Regional Environment Program and the Secretariat of the CBD are among the organisations and donors to have commenced addressing this need.<sup>27</sup>

Another, perhaps less obvious, factor that will complicate *Nagoya Protocol* implementation in Pacific island countries is the plural nature of the Pacific's legal landscapes. While a full discussion of legal pluralism in the Pacific region is beyond the scope of this report, it is simply noted that the systems of law upon which Pacific island governments are founded continue to co-exist with ancient systems of customary law that are deeply embedded in Pacific societies.<sup>28</sup> Often, the everyday lives of Pacific islanders, particularly in rural areas, are more responsive and more directly determined by customary than government norms, rules and procedures. This is particularly evident in relation to matters of natural resource ownership and use, as well as the control and distribution of traditional knowledge linked to

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<sup>26</sup> Justin Rose 'Le défi de déterminer un "espace légal" pour la gouvernance localisée de la biodiversité dans la région des îles du Pacifique'. In: Carine David and Nadege Meyer *L'intégration De La Coutume Dans L'élaboration De La Norme. Environnementale: Eléments d'ici et d'ailleurs* (Bruylant, 2012).

<sup>27</sup> For example, SPREP and the CBD Secretariat co-hosted the *Pacific Sub-Regional Workshop on Access and Benefit Sharing* in Suva, Fiji, 25-29 November 2013.

<sup>28</sup> Justin Rose "Community-Based Biodiversity Conservation in the Pacific: Cautionary lessons in regionalising environmental governance" in Jeffery M, Firestone J and Bubna-Litic K (eds.) *Biodiversity Conservation, Law and Livelihoods: Bridging the North-South Divide* (Cambridge University Press, 2008), 204.

natural resources.<sup>29</sup> These matters of course are at the centre of *Nagoya Protocol* implementation.

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<sup>29</sup> Ibid.