

CONSULTATION REPORT

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A. Introduction

The Access Benefit and Sharing Regulations (ABS Regulations) is being developed in accordance with the Nagoya Protocol to the Convention on Biological Diversity. This report details the outcomes of the consultations with the identified stakeholders. Although the ABS Regulations is limited to access to genetic resources in Tuvalu, it is the first to provide a legal basis for the use of traditional knowledge in this context. It has also been found that there are existing requests from overseas researchers to allow their access to genetic resources in Tuvalu. Thus, the effectiveness of the ABS Regulations will require the vital involvement of key stakeholders from its development to implementation.

B. Key Stakeholders

Stakeholders for the Development of the ABS Regulations in Tuvalu. Due to the COVID-19 Outbreak, direct consultations were conducted.

| Key Stakeholder | | Relevancy |
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| Government Agencies | | |
| 1. Department of Education | of | Network of researchers from tertiary education institutions. |
| 2. Department of Agriculture | of | Knowledge and initiatives for development of plants in Tuvalu |
| 3. Department of Culture | of | Main administrator developing policy frameworks for traditional knowledge in Tuvalu. |
| 4. Office of the Attorney General | | One of the OAG divisions is Intellectual Property which relates to the protection of IP rights of the origin owners. Also the OAG will be able to negotiate MAT's terms and conditions when entered into by the Government with user's of genetic resources. |
| 5. Marine Department | | Although a permit requirement is already in place for marine related research, access to genetic resources which may be associated with these minerals are not in place. |
| 6. Lands & Survey Department | | Land tenure issues which may arise and genetic resources taken from the land. |
| 7. Ministry of Local Government & Agriculture | | Government point of contact with all island councils or the Falekaupule through the Local Governments. |
| 8. Business Department | | The Business Department have their own requirements where genetic resources may be accessed for commercial purposes. |
| 9. Department of Environment | of | Key implementing agency in Tuvalu for the Nagoya Protocol. |
| 10. Department of Trade | | Commercializing and past experience in obtaining community consent for use of traditional knowledge. |
| 11. Department of Public Health | | Access to human pathogens for public health preparedness and response purposes, |
| Non-Governmental Organizations | | |
| 12. Tuvalu National Council of Women | | Most of the traditional knowledge associated with genetic resources are reflected through women. Involvement of women is also vital. |

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C. Implementation of the Provisions of the Nagoya Protocol in Tuvalu

| Article | Description | Implementing Section under the Draft ABS Regulation |
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| 1. Objective | The protocol has as its objective the fair and equitable sharing of benefits resulting from the utilization of genetic resources. This objective can only be reached upon access to genetic resources by users. Unlike the CBD itself, this Protocol links benefit-sharing directly and explicitly to conservation of biological diversity. Benefits are supposed to be used for the sake of conservation. | Objective of the Regulations |
| 2. Use of Terms (Definitions) | In this article three very important terms have been defined, i.e. utilization of genetic resources, biotechnology and derivative. Utilization of genetic resources means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the use of biotechnology. Biotechnology means any technological application that uses biological systems, living organisms, or naturally occurring compounds resulting from the expression or metabolism of biological or genetic resources, even in the absence of functional units of heredity (DNA/genes). A derivative has been defined as 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. The definition of utilization of genetic resources is thus wide, but excludes direct use of genetic resources for production purposes. The Nagoya Protocol does not apply to direct use. However, no DNA has to be present in a product for the Nagoya Protocol to apply, as long as such derivative has been obtained by making use of genetic or biological resources. | Interpretation: <i>utilization of genetic resources,</i> <i>biotechnology</i> <i>derivative</i> <i>Codes of Conduct</i> <i>Guidelines</i> <i>Standards</i> <i>Traditional knowledge</i> |
| 3. Scope | The Protocol applies to genetic resources and to traditional knowledge associated with genetic resources. Naturally occurring biochemical compounds accessed independently of genetic resources fall outside the scope if the Protocol. | Scope of Regulation |
| 4. Relationship with other agreements | This article recognizes that relevant ABS provisions also exist in a range of international instruments and processes outside the CBD. It comes from the notion that "one size does not fit all". Countries may negotiate and implement any new international instrument as long as such instrument is supportive of the CBD and this Protocol. The Protocol will not operate in situations where a specialized instrument applies that is consistent with the CBD and this Protocol. | Linkages with developed international instruments |
| 5. Fair and equitable benefit-sharing | Benefit-sharing is a separate set of requirements which may or may not be connected to access procedures. Utilization of genetic resources may take place long after having acquired these genetic resources, and benefit-sharing requirements would still apply. Negotiations towards MAT may take place along the PIC process, or may be negotiated later in time. The separate rights of indigenous and local communities are explicitly recognized. Rights on traditional knowledge rest with the communities holding such knowledge. This article expressly recognizes also that benefits may be monetary and non-monetary. Such options are presented in more detail in | Fair and equitable benefit-sharing |

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| | the Annex to the Protocol. Traditional knowledge does not have to be old to qualify as traditional. The term traditional refers to the context in which the knowledge was generated. | |
| 6. Access to genetic resources | <p>This article stipulates the rights and obligations of providers in regulating access to genetic resources. It reaffirms the sovereign rights of states over their natural resources. In comparison with the CBD, this article is much more concrete as to what providing countries are supposed to undertake in offering access procedures. This includes clarity about the manner, extent and procedure by which PIC should be obtained and how to agree on MAT. A Party should be prepared to provide written evidence of PIC to the user. Parties to the Protocol are not obliged to require PIC. However, users should assume that PIC is required unless expressly stated otherwise. Access to a natural resource for use of a commodity does not come under the Protocol.</p> <p>The provider country is to be either the country of origin or the country that acquired the genetic resources in accordance with the CBD. Where species have become part of new ecosystems and habitats and have developed new distinctive properties, away from their original in situ conditions, the new country would be regarded as the country of origin.</p> | <p>Access for Commercial Purposes</p> <p>Access for Non-commercial Purposes</p> <p>Prior Informed Consent Requirement</p> <p>Mutually Agreed Terms</p> |
| 7. Access to traditional knowledge | <p>This article regulates that Parties ensure that traditional knowledge is accessed with prior informed consent of the indigenous and local communities involved and that mutually agreed terms have been established. Obviously, this Protocol and article only cover traditional knowledge associated with genetic resources and held by indigenous and local communities. The access requirements apply regardless of how long ago the knowledge was generated by such communities, and irrespective how long the knowledge has been publicly available. The issue of rights associated with traditional knowledge is currently the subject of negotiations under the World Intellectual Property Organization, aiming at the effective protection of traditional knowledge.</p> | <p>Traditional Knowledge</p> <p>Role of the Kaupule</p> |
| 8. Special Considerations | <p>This article addresses (1) non-commercial research; (2) emergency cases related to human, animal or plant health; and (3) genetic resources for food and agriculture. These issues should get the particular attention of the Parties to the Nagoya Protocol. (1) A special regime for non-commercial research remains controversial, since non-commercial research may develop into commercial research over time, and the results of the non-commercial research can be used for commercial applications. Any special arrangement allowing non-commercial research under simplified procedures is likely to require renegotiation of PIC and MAT in case of a later commercial intent. (2) Expeditious access and expeditious benefit-sharing can be taken into consideration by countries in case of emergencies, but there is no hard obligation. (3) This article, in combination with Article 4(4) suggests that PGRFA are waived from the provisions of the Nagoya Protocol, as far as they are listed in Annex 1 of the International Treaty and are used for food/feed uses. On-going work under the FAO Commission on GRFA addresses the question if other GRFA would also require specific ABS instruments, which would result in further exemptions from the working of the Protocol.</p> | <p>Special Considerations</p> |
| 9. Contribution | This article provides for measures to be taken by Parties to | Contribution to |

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| <p>to conservation and use</p> | <p>ensure that benefits deriving from utilization flow to efforts linked to the conservation and use of biodiversity. This may seem obvious, but it is not. The CBD itself has no similar provision, and the flow of benefits to those responsible for conservation has so far only be assumed.</p> | <p>conservation and use</p> |
| <p>10. Global Multilateral Benefit-Sharing mechanism</p> | <p>A multilateral solution is suggested for situations in which compliance with ABS requirements is too complex from a political or practical point of view. Such situations include transboundary situations where a specific genetic resource occurs in several countries, in cases in which it is not possible to trace the country of origin of ex situ held materials, and in any other situations where no legal benefit-sharing obligations with a providing party exist but users nevertheless wish to share benefits. The article calls for a discussion between Parties about the desirability and feasibility of such multilateral mechanism. It is expected that the development and implementation of such mechanism will take several years.</p> | <p>NIL</p> |
| <p>11. Transboundary cooperation</p> | <p>Biodiversity follows natural boundaries and not political borders. Genetic resources may have several countries of origin, and the same traditional knowledge associated with genetic resources may be held by different indigenous and local communities. Acknowledging this fact, through this article cooperation among countries of origin (being Parties) is promoted in implementing the objective of this Protocol.</p> | <p>Transboundary cooperation</p> |
| <p>12. Traditional knowledge associated with genetic resources</p> | <p>This article contains some issues dealing with traditional knowledge not included in articles 5 (benefit-sharing), 7 (access) and 16 (compliance). It regulates that Parties shall take into consideration customary law and community protocols, and that Parties shall inform potential users of traditional knowledge about their obligations. It also requires Parties to help communities in developing minimum requirements for Mutually Agreed Terms and model contractual clauses. Finally, the article holds the obligation for Parties to not restrict the use and exchange of genetic resources and the associated traditional knowledge between indigenous and local communities themselves.</p> | <p>Community Access Community Awareness and Consultations Government Assistance in developing Mutually Agreed Terms</p> |
| <p>13. National Focal Points and Competent National Authorities</p> | <p>Each Party is obliged to nominate a national focal point (NFP) on ABS. It is up to the Party to decide which institution will fulfil that role. The NFP is responsible to make information on ABS in the country available. It informs potential users about the applying ABS procedures. Each Party is also obliged to designate at least one competent national authority (CNA) on ABS. These functions may be combined. The NFP is to serve as a helpdesk or information hub in relation to applicants seeking access to genetic resources or to traditional knowledge, and to provide information on the CNA(s) and relevant indigenous and local communities. The NFP liaises with the CBD/Nagoya Protocol secretariat. The CNA is responsible for granting access and issuing written evidence thereof, and for advising applicants on how to fulfil PIC and MAT requirements. Contact details of NFPs and CNAs should be communicated with the CBD secretariat</p> | <p>Appointment of National focal point and the Competent National Authority</p> |
| <p>14. The ABS Clearing House</p> | <p>The Access and Benefit-Sharing Clearing House is established as part of the CBD Clearing House Mechanism. It will involve a database on ABS information communicated by Parties to the CBD Secretariat. In particular, access information should allow</p> | <p>Communications of information to the Access and Benefit-Sharing</p> |

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| | providers and users to ascertain their rights and obligations before entering into any agreement or other relationship regarding the use of genetic resources and/or traditional knowledge associated to these. Information classified as confidential will not be communicated to the Clearing House. | Clearing House |
| 15 and 16. Compliance with domestic regulations or regulatory requirements | These innovative articles (15 on genetic resources and 16 on associated traditional knowledge) require that Parties take measures to provide that genetic resources utilized within their jurisdiction have been accessed in accordance with PIC and MAT requirements of the providing country, and if applicable the indigenous and local communities involved. Only cases of utilization within the jurisdiction of the Party are covered by this Article. When a user does not observe such providing country obligation, the Party where utilization takes place should take “appropriate, effective and proportionate” measures. In cases of alleged violation, Parties are supposed to co-operate. | Dispute Resolution |
| 17. Monitoring utilization | Like 15 and 16, this article requires another active role of countries where genetic resources are used. It introduces two new elements, i.e. checkpoints and certificates of compliance. A Party must nominate at least one entity that is responsible for monitoring the (importation) and utilization of genetic resources. Such checkpoints would collect or receive relevant information regarding PIC, the source of a genetic resource, the establishment of MAT and the utilization of a specific genetic resource. Users would be obliged to provide such information, including the permit showing PIC from the providing country. Appropriate entities in the providing country would be informed. A permit in accordance with Article 6 (Access) and communicated to the Clearing House (Article 14) constitutes an internationally recognized certificate of compliance. A common format does not exist but may be developed in the future. International exchange of genetic resources listed in Annex 1 of the Treaty takes place under the Standard Material Transfer Agreement that in such cases is equivalent with a certificate of compliance. This article also states that the certificate of compliance should at least contain the following information: issuing authority, date of issuance, provider, unique certificate identifier, user to whom PIC was granted, subject matter, proof of MAT and PIC obtained and intended commercial and/or non-commercial use. | Checkpoints Certificate of Compliance |
| 18. Compliance with MAT | This article completes the set of provisions covering “user country measures”. Mutually Agreed Terms normally take the form of a civil law contract. These are usually not dealt with through a public international law instrument such as the Nagoya Protocol. This article therefore encourages the contract parties agreeing on MAT to include provisions in MAT for dispute resolution, e.g. on applicable jurisdiction, applicable law, and alternative dispute resolution options. | Development of Mutually Agreed Terms |
| 19 and 20 Model contractual clauses. Codes of conduct, guidelines and best practices and/or | Through promoting the use of model clauses, Article 19 aims to bring consistency in the way that access and use of genetic resources is being negotiated. Such consistency would help to bring more legal certainty to providers and users alike and would reduce transaction costs. Model clauses are supposed to be optional. The text of article 20 mirrors article 19, but adds the option that the Conference of the Parties may consider adoption of specific codes of conduct, guidelines and best practices and/or standards. Codes of conduct set out the | Schedule: Model Contractual Clauses Power of the Minister to adopt specific codes of conduct, guidelines and best practices |

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| standards | rules for the members of an organization, such as the International Plant Exchange Network IPEN in which botanical gardens have been organized. Guidelines generally aim to promote particular approaches. Standards set out rules, guidelines or characteristics for products or related processes. For example, the Ethical BioTrade standard includes ABS requirements for companies working with natural ingredients. | and/or practices |
| 21 and 22 Awareness raising. Capacity building | Article 21 provides for a range of outreach measures to promote awareness of the core objectives of the Protocol. Such measures may involve promotion of the Protocol, capacity building of providers, including indigenous and local communities, and users, promotion of experiences and promotion of tools as mentioned in articles 19 and 20. Article 22 addresses capacity building in developing country Parties. Lack of capacity on the ABS issue has been a continuous concern for Parties and many stakeholders. Capacity building may concern a large number of aspects, including legal and institutional development, training to negotiate mutually agreed terms, development and use of valuation methods, bioprospecting studies. | Outreach measures Capacity building |
| 23. Technology Transfer, collaboration and cooperation | This article requires Parties to the Protocol to cooperate in technical and scientific research and development, including through technology transfer. It stresses implicitly the importance and value of non-monetary forms of benefit-sharing that may also be part of MAT between two private parties. | Technology Transfer, collaboration and cooperation |
| 24 to 36 Articles overseeing the functioning of the Protocol | This set of articles regulates how the Protocol will be operationalized. The articles deal with non-parties, finance, decision-making, subsidiary bodies, secretariat, monitoring, compliance to the Protocol, review, signature, entry into force, reservations, withdrawal and authentic texts (read languages) of the Protocol. The Protocol will enter into force after the fortieth ratification | NIL |
| Annex | The Protocol contains an annex with non-exhaustive examples of monetary and non-monetary benefits | Schedule: Monetary and non- monetary benefits |

E. Stakeholder Views

1. Department of Culture – *Ms. Taulosa Karl, Acting Director*

The view presented by Ms. Karl on behalf of the Department was in support of the ABS Regulations. Although there were previous efforts to document traditional knowledge associated with herbal medicines, the Department faced challenges in receiving the consent from the individuals or communities who have knowledge and skills in the use of plants for healing purposes. The Department's database has yet to be actioned. On a positive note, the Department is trying to revive the Cultural Council established under the Tuvalu Cultural Council Act, 1991 which is currently inactive. Institutional reform and presence of a legal framework for culture is restraining these developments.

2. Department of Agriculture – *Mr. Matio Lonolona, Director*

The Department supported the development of the ABS Regulations as there is no existing framework in the country to administer this type of activity. Another important reason is the Government's ascension to the FAO International Treaty on Plant Genetic Resources for Food

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and Agriculture, adopted by the Thirty-First Session of the Conference of the Food and Agriculture Organization of the United Nations on 3 November 2001 which facilitates access to the genetic materials of the 64 crops in the Multilateral System for research, breeding and training for food and agriculture.

3. Ministry of Public Works Labour Meteorology Environment and Disaster – *Mr. Sumio Silu, Acting Secretary*

The Acting Secretary to the Ministry responsible for Environment provided support for the development of the ABS Regulation but recommended that the Ministry is made the National Competent Authority under the Nagoya Protocol. This position is to be confirmed.

4. Office of the Attorney General – *Ms. Losa Teo, Crown Counsel*

The Office of the Attorney General presented imperative views due to the current reform they are handling with the laws on Intellectual Property. As part of the review, traditional knowledge is seen as part of Patent and thus consultations with communities were conducted. The main issue discovered was how legal owners of traditional knowledge were to be ascertained in situations of community and individual/family conflicted over the subject. The target of the review is to complete by next year after a Legal Drafter will be hired.

5. Department of Environment – *Ms. Tilia Tima, Biodiversity Officer & Acting Director*

The Acting Director was firm on the need to develop the ABS Regulations due to pending requests from researchers to access genetic resources in Tuvalu. In the absence of a Government policy, the Department is keen to have the ABS Regulations in place but also noted challenges for traditional knowledge associated with genetic resources. Past effort was undertaken to document traditional knowledge associated with genetic resources in Funafuti but were unsuccessful as the community refused for secrecy requirements of such traditional knowledge.

6. Department of Business – *Ms Petesa Finikaso, Director*

The Department of Business remarked on this development for raising issues of access to genetic resources by overseas business which was very new to them. The view provided was that if the research or the access required was for commercial purposes, then a registration under Tuvalu's relevant business laws will need to apply. In other words, a local business license is proposed to be listed as a requirement for grant of access. This will also enable the Government to run background checks before grant of business license.

7. Department of Education – *Mr Neaki Letia, Director*

Mr. Letia relayed that the Department has not received any requests for research regarding access to genetic resources. The only incident was in relation to a Tuvaluan student who did his PhD Thesis in the area of agriculture. Otherwise, there are also no protocols in place by the Department if any requests are received.

8. Ministry of Local Government and Agriculture – *Ms Lototasi Morikao, Acting Secretary*

The Ministry is currently facing issues of access to two of the outer-islands. This was an example put forth by the Acting Secretary that any visits or trips to the outer-islands must be endorsed by the Island Council (Falekaupule) through the island's Local Government and the Ministry. Thus it was suggested that all applications for access to genetic resources would need

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addressing by the Government Advisory Committee to inform all concerned ministries. The role of the Ministry in communicating and coordinating approvals by the Falekaupule was stressed as a vital part to be considered in the development of the Regulation.

9. Marine Department – *Mr Taasi Potoi, Director*

It was relayed that the Marine Department has its own permit process for mining. However if this regulation comes into effect then requirements of the two frameworks must be complied with for any mining activities to take place. The Director was in support of the regulation development especially its purpose.

10. Lands & Survey Department – *Mr Faatasi Malologa, Director*

For the Department, they have not come through any requests for research. However recently in Nui Island, there were Japanese who dug up the bones from their graveyards and retrieved their bones. Likewise there were archaeologists who were looking for evidence of Lapita potteries from Vaitupu Island. However it is unknown as whether there was any process followed.

11. Department of Trade – *Mr. Daryl Ishkbal, EIF Project Manager*

The Department of Trade shared their unique experience with one of the coconut oils made from the *ponuponu* in Nanumea Island. The report is annexed herein for information but makes the following highlight: Sufficient time must be spent with the communities to ensure they have the amicable opportunity to raise their concerns or questions regarding the access that is sought.

12. Department of Public Health – *Mr. Vine Sosene, Chief Public Health Officer*

The Department have no procedures in place for the access or use of genetic resources. Thus, it supports this development.

F. Legislative Gap Analysis

In consideration of the related legislation in place, there is no identified conflict for this development.

G. Key Results

The following key results are noted from the consultations:

- Protection of beneficiaries with traditional knowledge associated with genetic resources must be ensured pending the completion on the review of the laws under the area of Intellectual Property which are the UK legislation applied: *Copyright Act, Patent Act and Trademark Act*;
- Access to the communities must be requested through the Ministry of Local Government & Agriculture. In this sense, the local governments will inform the Falekaupule (island council) in advance of the researcher's trip to their respective islands;
- Instead of forming a Committee, it is best to require the focal point upon receipt of application for access to genetic resources, to consult listed Government agencies (key stakeholders) directly;
- Communities must have sufficient knowledge of the purpose of proposed research and the benefit that may be shared;

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- Office of the Attorney General to be part of the negotiations for the Mutually Agreed Terms;
- A team of key stakeholders must conduct awareness to all the communities of Tuvalu of this ABS Regulation;
- Communities or families to be directly consulted by interested researchers. The researchers are to bear their own costs;
- Researchers from foreign companies are required to have the appropriate local business license before any activity can take place;
- Access to genetic resources for education purposes must be exempted;
- Third parties who are interested to use ideas derived from the genetic resources must inform the Government and beneficiaries;
- Offences and penalties to match those under the Environment Protection (Impact Assessment) Regulations.

H. Conclusion

In conclusion, the ABS Regulation needs to be adapted to the local arrangements in place especially from the institutional to community levels. The islands of Tuvalu have a total of eight island councils overseeing the affairs of their communities. The access thus requires consent from the Government and concerned communities provided that this is a new framework. Finally, the development of the ABS Regulations is well supported by the stakeholders.

I. Recommended Skeleton Regulation

In light of the above views from the stakeholders and the implementing provisions of the Nagoya Protocol, the recommended general outline of the Draft ABS Regulations to assist in the drafting process.

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