



Brazil • Bulgaria • Croatia
Ethiopia • India • Kenya
Norway • South Africa
Uganda • Vietnam

Review of Selected National Legislations Relating to Access and Benefit-sharing



Centre for Biodiversity Policy and Law
National Biodiversity Authority

2019

Review of Selected National Legislations Relating to Access and Benefit-Sharing

Liv-Stephanie Bantle

Norwegian Environment Agency

and

Anjali Sugadev

Centre for Biodiversity Policy and Law,
National Biodiversity Authority, India



Centre for Biodiversity Policy and Law
National Biodiversity Authority

2019

Citation

Liv-Stephanie Bantle and Anjali Sugadev, Review of Selected National Legislations Relating to Access and Benefit-sharing, Centre for Biodiversity Policy and Law, National Biodiversity Authority of India and Norwegian Environment Agency.

Corresponding Authors

Liv-Stephanie Bantle <liv-stephanie.bantle@miljodir.no>

Anjali Sugadev <anjusuhadev@gmail.com>

Copyright © National Biodiversity Authority 2018

ISBN : 978-81-932753-8-2

Published by

Centre for Biodiversity Policy and Law (CEBPOL)

National Biodiversity Authority

5th Floor, TICEL Biopark, CSIR Road, Taramani

Chennai – 600 113, Tamil Nadu, India

Website: <http://nbaindia.org/cebpol/>

Layout and Design:

N. Singaram

IT Executive, CEBPOL

Disclaimer: This publications is prepared as an initiative under CEBPOL programme. All the views expressed in this publication are based on established legal principles. Any error or lapse is purely unintended and inconsequential and shall not make either the NBA or the CEBPOL liable for the same.

Some pictures and images included in this publication are sourced from public domain. This publications is purely for non-commercial purposes including awareness creation and capacity building.



FOREWORD

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 provides an international legal framework for implementing one of the three objectives of the Convention on Biological Diversity, the fair and equitable sharing of the benefits arising out of the utilization of genetic resources. This objective, in turn contributes to the conservation and sustainable use of biodiversity. The Protocol aims to create greater legal certainty for both providers and users of genetic resources by establishing more predictable conditions for access to genetic resources.

It has been four years since the Protocol entered into force on 12 October 2014. Now, more than 100 countries have ratified the Protocol and many of them have national laws in place on access and benefit-sharing. At this juncture, it is highly pertinent to study these regulations and assess the status of implementation of the Nagoya Protocol at the domestic levels.

The CEBPOL study reviewing national legislations is an attempt to compare the laws relating to access and benefit-sharing enacted by Parties and non-Parties to the Nagoya Protocol. The findings of the study identify aspects of the Protocol that have been successfully implemented, while also exposing those others that are still lagging, therefore demanding attention. The outcome of such assessment reveals how the international treaty has been adopted by nations, thereby producing interesting inferences when such laws are appraised

against the ecological, economic and cultural backgrounds unique to each country. The study report is expected to be a useful tool for national policy makers, academicians and for the international community in general.

The study was conducted as a collaborative initiative between the Centre for Biodiversity Policy and Law (CEBPOL) and the Norwegian Environment Agency (NEA). I would like to extend my gratitude to CEBPOL and NEA for accomplishing the task successfully. I sincerely thank the Ministry of Environment, Forest and Climate Change (MoEFCC), Government of India and the Royal Norwegian Embassy, New Delhi for encouragements and their support.

B. Meenakumari

Chairperson

National Biodiversity Authority

Executive Summary

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 (the Protocol) is an international legally binding agreement which aims at sharing the benefits arising from the utilization of genetic resources in a fair and equitable way. The Protocol calls upon Parties to take legislative, administrative or policy measures, as appropriate to implement this obligation domestically.

The study “Review of selected national legislations relating to access and benefit-sharing” is an inquiry into domestic regulations regulating access and benefit-sharing of genetic resources. It involves an examination of the national legislations on access and benefit-sharing enabling assessment on how far countries have met their commitments under the international agreement.

A report is prepared based on the findings of the study setting out the major factors influencing and shaping the access and benefit-sharing mechanisms of the selected countries. The report only covers countries with uploaded legislation on the ABS Clearing House mechanism, or other available legislation. As the selection only applies to a limited number of countries, global and regional trends can be identified, however it remains to be seen whether this also will apply subsequently, once more countries have ABS-legislation in place.

The report will be helpful and be utilized for comparing and contrasting the national ABS legislations. The study could indicate models and could thus serve as a tool kit for countries who intend to bring their legal frameworks in better compliance with the Protocol and for those who are interested to implement the Protocol in their domestic jurisdictions in future.

Acknowledgement

The authors are greatly indebted to both, the National Biodiversity Authority of India (NBA) and the Norwegian Environment Agency (NEA) for the opportunity and resources to inquire into the existing legislation on access and benefit-sharing. The Royal Norwegian Embassy in India is acknowledged for its support to the activities of the programme. Dr. B.Meenakumari, Chairperson, NBA, Shri. T.Rabikumar, Secretary, NBA and Dr. Rupam Mandal, Manager, CEBPOL are duly thanked for their guidance and mentorship during the course of the study. An expression of appreciation and gratitude is offered to Dr. Prabha S. Nair who contributed immensely to the matrix of legislation during her tenure at the Centre for Biodiversity Policy and Law. Much gratitude is extended to the Technical Committee and Dr. Sunniva Aagaard at the NEA for reviewing and providing valuable inputs to the report. The authors wish to acknowledge Shri N.Singaram, Information Technology Executive, CEBPOL for rendering technical assistance in organising and streamlining the contents of the matrix.

Contents

1. Introduction.....	1
a) Background.....	1
b) Selection of countries and choice of criteria for analysis	1
c) Methodology	3
2. Global and Emerging Trends on Access and Benefit Sharing	3
i) Subject matter of ABS (including exemption)	3
ii) Regulated activities (including exemption).....	5
iii) Prior informed consent (from State/ community/both).....	9
iv) PIC for traditional knowledge	12
v) Relationship between MAT and violation.....	13
vi) Nature of sanctions.....	16
vii) Special considerations under the Protocol	18
a) Non-commercial research purposes	19
b) Present or imminent emergencies.....	20
c) Plant Genetic Resources for Food and Agriculture	21
viii) User country measures as part of ABS legislation	22
ix) Designation of checkpoints under ABS legislation.....	23
3. General Observations	26
4. Conclusion	28



1. Introduction

a) Background

The report on review of national legislation is the outcome of a collaborative research study between the Centre for Biodiversity Policy and Law, India (CEBPOL)¹ and the Norwegian Environment Agency² within the framework of a bilateral agreement between the two countries. The bilateral agreement covers different subjects on biodiversity, inter alia access and benefit sharing (ABS) under the Nagoya Protocol³, which is a legally binding international agreement adopted pursuant to the Convention on Biological Diversity (CBD)⁴.

The Protocol entered into force on 12 October 2014. When the study of collecting data on national ABS legislations started in 2017, the Protocol was already in varying stages of implementation by several countries. To date, 110 States are Parties to the Protocol⁵. The Protocol received 114 ratifications and 92 signatures.

Prior to this report, a matrix covering information on the implementation of main articles of the Protocol in different ABS legislations, based on a set of criteria, was prepared. Based on the matrix, the report covers an analysis of the various national ABS legislations in connection with the Protocol's provisions. Lastly, it sets out general observations and a conclusion.

b) Selection of countries and choice of criteria for analysis

The national ABS legislations are chosen based on those countries who, within June 2017, had their national legislation uploaded on CBD's Access and Benefit-Sharing Clearing-House (ABS Clearing House)⁶. The legal basis for the establishment of the ABS Clearing House is the Protocol's Article 14⁷.

1. <http://nbaindia.org/content/332/31/1/cebpol.html>

2. <http://www.miljodirektoratet.no/en/>

3. <https://www.cbd.int/abs/doc/protocol/nagoya-protocol-en.pdf> and <https://www.cbd.int/abs/>

4. <https://www.cbd.int/>

5. <https://www.cbd.int/abs/>

6. Article 14, para 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 benefitsharing. In particular, it shall provide access to information made available by each Party relevant to the implementation of this Protocol.



Geographical representation is another factor that influenced the selection of countries. Four countries (Ethiopia, South Africa, Uganda and Kenya) are chosen from Africa, two from Asia (India and Viet Nam), three from Europe (Bulgaria, Croatia and Norway) and one representing America (Brazil).

In accordance with the format and guidelines laid down in decision NP-1/3⁸, the Protocol's Parties submitted their first Interim National Report by 1 November 2017 (Interim Report)⁹. Due to this obligation, some of the countries updated their information on the ABS Clearing House, and that information is, for the studied countries, included in the report where relevant.

In addition to the countries covered by the ABS Clearing House, the Brazilian legislation on ABS was available. Although Brazil is not a Party but only a signatory to the Protocol, it was decided to include it in the study as it might reveal differences of a non-Party's legislation to that of the Parties'.

The European Union (EU) has regulations¹⁰ in place on ABS. However, this is not included in the report. Croatia and Bulgaria, both being EU Member States, have additional national legislation in place. With respect to the 2017 amendment of the Bulgarian ABS legislation, it is not yet available in English and thus not assessed in this report¹¹.

For Norway, the legislation on traditional knowledge, which entered into force on 1 January 2017, as well as the draft regulations on access and benefit sharing and the draft regulation on checkpoints are studied. It is to be noted that the draft regulations might change before entering into force and that the report only covers the current status.

8 <https://www.cbd.int/doc/decisions/np-mop-01/np-mop-01-dec-03-en.pdf>

9 <https://www.cbd.int/abs/NR.shtml>

10 Regulation (EU) No. 511/2014 on 16 April 2014 of the European Parliament and of the Council of 16 April 2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0511&from=EN>. More information: http://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation_en.htm and http://ec.europa.eu/environment/nature/biodiversity/international/abs/index_en.htm. See also its Guidance document: <https://www.naturvardsverket.se/upload/stod-i-miljoarbetet/vagledning/genetiskaresurser/scope-guidance-march2016.pdf>.

11 An update of the English text of the Act is being prepared following the amendments in SG No. 76/19.09.2017, see https://absch.cbd.int/api/v2013/documents/C0E4D846-4D94-755A-8556-E67261927A21/attachments/BIOLOGICAL_DIVERSITY_ACT_2017.pdf).



The choice of criteria for the study is based on the main articles in the Protocol as it is believed that such analysis might explore different solutions for implementation of the Protocol by observing how the same article is implemented under the ABS legislations of various countries.

Methodology

After having agreed on the selection of countries and the criteria for analysis, several parts of the national ABS legislations were tabulated in the form of a matrix. The matrix revealed the differences in the studied legislations making it easy to extract an analysis of the selected parts. Thus, this report constitutes a summary of the analysis of the matrix and additional information gathered through the Interim Reports of the studied countries.

2. Global and Emerging Trends on Access and Benefit-Sharing

i) Subject matter of ABS (including exemption)

The scope of application of the Protocol is set out in Article 3:-

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.

The subject matter of access and benefit-sharing is relatively similar in the studied ABS legislations, with only a few exceptions. Some legislations consider the unit of biodiversity at the level of biological resources and others genetic resources. India, South Africa, Uganda, Kenya, Ethiopia and Viet Nam include in-situ and ex-situ species, while Croatia and Bulgaria provides for native wild species. Norway's Nature Diversity Act manages the collection of genetic material directly from nature (*in situ*), retrieval of whole organisms, or smaller biobank samples (*ex situ*) or retrieval of information from publications (*in silico*) whereas the Marine



Resources Act covers management of wild living marine resources and genetic material derived from them. Microorganisms are protected under all of the studied legislations.

One of the major attributes of a biological resource under the Convention is “actual or potential value”¹². Care is taken to safeguard the potential use of a resource in the future. India, Ethiopia and Bulgaria recognize its significance and have offered protection to future use of resources within their jurisdiction.

Chapter VII of Norway’s Nature Diversity Act provides explicit scope for access to genetic material on, in and under land and water. Both genetic resources on land and freshwater, as well as marine bioprospecting, genetic material from the sea and sea areas as well as on and under the seabed, are covered.

As envisaged under the Protocol, access to traditional knowledge associated with genetic resources also forms the subject matter protected under national ABS-legislations, although addressed with different terminology. It is referred as community knowledge (in Ethiopia), knowledge associated (in India), intangible components (in Kenya) and associated traditional knowledge (in Brazil).

Among the ABS legislations observed, some define traditional knowledge (Brazil, Kenya and Norway). While Kenya’s Environmental Management and Co-Ordination Act, 1999 remains silent on it, the Kenyan Regulations that came into force in 2009 refers to traditional knowledge as “intangible components”¹³. Thereafter, in 2016, the Protection of Traditional Knowledge and Cultural Expressions Act was enacted particularly to regulate activities involving traditional knowledge and cultural expressions of Kenya.

In Croatia, access to traditional knowledge associated with genetic resources is not a subject matter of access and benefit-sharing in its legislation. However, the EU regulation, adopted by Croatia and Bulgaria, protects traditional knowledge associated with genetic resources¹⁴.

12. Article 2 of the Convention, definition of biological resources.

13. The Environmental Management and Co-ordination (Conservation of Biological Diversity and Resources, access to Genetic Resources and Benefit sharing) Regulations, 2006.

14. <https://absch.cbd.int/countries/HR>



The scope of legislation on genetic resources is nonetheless limited and does not apply to certain resources. Some common exemptions are human genetic material and genetic material covered under the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA). In India, value-added products are specifically kept outside the purview of the Act. In South Africa, indigenous biological resources excludes any exotic animals, plants or other organisms other than those exotic animals, plants or other organisms referred to in section 80 (2)(a)(iii)¹⁵. In the ABS-legislations of Ethiopia and Viet Nam, exemptions from subject matter are not specified. Bulgaria does not specify exemptions in its national legislation, but adopts that of EU's ABS Regulation as mentioned in its Interim Report.

ii) Regulated activities (including exemption)

Article 6, para 1 and Article 7 of the Protocol stipulate that national legal frameworks shall regulate both access to genetic resources and access to traditional knowledge associated with genetic resources. Article 6, para 1 states as follows:

*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.*

15. Any exotic animals, plants or other organisms, whether gathered from the wild or accessed from any other source which, through the use of biotechnology, have been altered with any genetic material or chemical compound found in any indigenous species or any animals, plants or other organisms referred to in subparagraph (i) or (ii).



Article 7 reads as hereunder

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.

Access to genetic resources and access to traditional knowledge associated with genetic resources are regulated under the respective national ABS laws commonly for the following purposes –

- i. research;
- ii. commercial utilization; and
- iii. obtaining intellectual property rights (IPR) for inventions using biological resources.

South African law on genetic resources bifurcates bioprospecting into two stages, the discovery phase and/or commercialization phase, and regulates both the stages¹⁶. Brazil's law classifies the regulated activities on the following basis – access to genetic resources and traditional knowledge, shipment¹⁷ abroad of genetic heritage samples, and economic exploitation of finished products¹⁸ or reproductive material obtained through access to genetic resources or from associated traditional knowledge¹⁹. Bulgaria regulates access depending on whether they form natural flora and fauna, agricultural and forest genetic resources, or genetic

16 Discovery phase means any research or development or application of indigenous biological resources where the nature and extent of any actual or potential commercial or industrial exploitation in relation to the project is not sufficiently clear or known to begin the process of commercialization. Commercialization phase includes filing of any complete IP application whether in South Africa or elsewhere; obtaining or transferring IPR or other rights; commencing clinical trials and product development including the conducting of market research & seeking pre-market approval for the sale of resulting products; or multiplication of indigenous biological resources through cultivation, propagation or cloning or other means to develop and produce products such as drugs, industrial enzymes, food flavours, fragrance, cosmetics, emulsifiers, oleoresins, colours and extracts.

17 "Shipment" is defined as the transfer of a sample of genetic heritage, intended for access, to an institution located abroad, in which responsibility for the sample is transferred to the recipient institution (Article 2 of Brazil's Law No 13,123).

18 "Finished product" is defined as a product originating from access to genetic heritage or associated traditional knowledge that does not need any additional processing, in which the genetic heritage or the traditional knowledge component is a key main element of value adding to the product, being it ready for use by the final consumer, whether a natural or a legal person (Article 2 of the Law No 13,123).

19 Article 11 of Brazil's Law No 13,123.



resources of industrial microorganisms, viruses and cell cultures. Viet Nam grants license to access genetic resources for purposes of research for non-commercial purposes; research for commercial purposes and commercial product development²⁰.

In general, consent is not required if the access for genetic resources and/ or traditional knowledge associated with genetic resources are used for private and non-commercial purposes. Predominantly, conventional practices by local communities fall outside the regulatory framework.

In India, the Biological Diversity Act empowers the Central Government, in consultation with the National Biodiversity Authority, to notify that the provisions of this Act shall not apply to any items, including biological resources normally traded as commodities²¹. Apart from Annex I crops regulated under the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)²², other exemptions are activities constituting:

- i) conventional breeding, traditional practices in use in agriculture, horticulture, poultry, dairy farming, animal husbandry or bee keeping²³, and
- ii) collaborative research projects involving transfer or exchange of biological resources or information relating thereto between institutions if such projects are approved by Central Government²⁴.

A similar trend of free access for conventional practices is found in Ethiopia, Uganda, Kenya and Brazil. Croatia and Norway exempt non-commercial research. In the Norwegian Act, non-commercial research is limited to public collections²⁵. A public collection means a collection of genetic material managed by, or on behalf of, the state and to which any person has access on specified conditions. As this is limited to public collections, private collections are not to be covered. In Bulgaria and Vietnam, no exemptions from regulated activities are specified.

20 See article 3 no. 7 of Viet Nam's Decree on the Management of Access to Genetic Resources and the Sharing of Benefits Arising from their Utilization.

21 Section 40 of India's Biological Diversity Act, 2002. Biological resources, normally traded as commodities are notified by the Central Government under section 40 of the Biological Diversity Act. The notification can be found at http://nbaindia.org/uploaded/pdf/Notification_of_Normally_Tradeded_Commities_dt_7_April_2016.pdf

22 <http://www.fao.org/plant-treaty/en/>

23 Sec. 2(f) of India's Biological Diversity Act, 2002.

24 Sec. 5 of India's Biological Diversity Act, 2002.

25 Norwegian Nature Diversity Act, Section 59.



Special rule for foreigners

In India, the procedure does not differentiate foreign applications. However, there is a distinction with regard to the authority before which application has to be filed – foreign applications are required to be filed before the National Biodiversity Authority whereas domestic applications at the State Biodiversity Boards of the State where the resources have been procured. The Croatian legislation prescribes for equal treatment of all applications²⁶.

Contrastingly, in certain other studied countries, access by foreigners is strictly monitored or prohibited unless the foreign applicant collaborates with a national of the respective country. In Ethiopia, a foreign access applicant shall present a letter from the competent authority of his national state or that of his domicile assuring that it shall uphold and enforce the access obligations of the applicant²⁷. Collection of genetic resources/ community knowledge shall be undertaken only if accompanied by the personnel of the Institute of Biodiversity Conservation or the personnel of the relevant institution designated by the Institute of Biodiversity Conservation. Where research based on genetic resource accessed is permitted to be carried out abroad, the institution sponsoring and/or hosting the research shall give a letter of assurance that they shall observe the access obligations attached thereto²⁸.

South Africa follows a similar regime for foreign ABS applicants. A foreign entity or individual need apply jointly with, either a juristic person under South African ABS law or a citizen / permanent resident of South Africa²⁹. Viet Nam's decree imposes special procedures for foreigners where the foreign individual / organization is required to register and request an access license for any purpose. The same procedure is followed when any domestic individual / organization transfers genetic resources abroad³⁰.

26 Article 88.4 of the Nature Protection Act, Croatia provides that access and utilization of genetic material, depending on the purpose and manner of utilization, shall be permitted to all under equal conditions in a manner prescribed by this Act or a special regulation.

27 Art.12.4 of Ethiopia's Proclamation No. 482/2006.

28 Art.12 of Ethiopia's Proclamation No. 482/2006.

29 Regulation 9.1 of South Africa's National Environmental Management: Biodiversity Act, 2004: Regulations on Bio-prospecting, Access and Benefit-sharing.



In Brazil, access to genetic resources or access to associated traditional knowledge by foreign natural persons is prohibited while foreign legal persons shall associate with a public or private Brazilian entity for the purpose of scientific and technological research. Uganda, Norway, Bulgaria and Kenya do not set out any specific rules for foreigners. In Norway, this means that all applicants are to be treated equally. If this is not the case for all the other countries without specific rules for foreigners, it can also be true that the issue has not been considered by their legislations.

iii) Prior informed consent (from State/ community/both)

Article 6, paragraph 1 of the Protocol, as stated above, specifies that access to genetic resources shall be subject to the prior informed consent (PIC) of the provider of such resources. Article 6, paragraph 2 provides that:

This requirement is reflected in national ABS legislations of the respective Parties. In some countries, PIC needs to be obtained from the competent national authority and some others

*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.*

from the community directly; and under certain occasions, from both.

In India, PIC is granted by the National Biodiversity Authority with the involvement of local people and communities following a process of consultation with them through the established institutional mechanism of State Biodiversity Boards at provincial levels, which in turn consult the Biodiversity Management Committees at the local level. In Ethiopia, access to genetic resource shall be subject to the PIC of Ethiopian Biodiversity Institute³¹.

30 Accessor of genetic resources who are foreign individuals or organizations are allowed access to genetic resources only when licensed by the competent national authorities (Article 4.2 of the Decree on the Management of Access to Genetic Resources and the Sharing of Benefits Arising from their Utilization).



In South Africa, similar to India and Croatia, issuance of access permit for genetic resources is a pre-requisite for carrying out the regulated activities. The applicant must disclose all material information relating to the bioprospecting to the relevant stakeholders³² and based on that disclosure, has to obtain prior consent of the stakeholder to use any of the stakeholder's knowledge of or discoveries about the indigenous biological resources for the proposed bioprospecting. Further, the applicant and stakeholder involved must negotiate and conclude material transfer agreement and benefit sharing agreement and the Minister has to approve both these agreements³³. In such cases, the issuing authority may facilitate negotiation between applicant and stakeholder and ensure that negotiations are conducted on an equal footing. Permits differ with the type of activity regulated – bioprospecting permit, integrated export and bioprospecting permit and lastly, the export permit. The authority by whom these permits for access to genetic resources are issued also differ – the first two permits by the Minister whereas for the last, by the MEC (MEC for Environmental Affairs refers to a member of the Executive Council of a province who is responsible for the conservation of biodiversity in the province).

In Uganda, permit for access to genetic resources is consequential to an accessory agreement and material transfer agreement³⁴. A person intending to access or collect genetic resources shall obtain PIC and enter into an accessory agreement³⁵ with the lead agency, local community or owner of the genetic resource. PIC or the accessory agreement do not entitle the applicant to access genetic resources, but only enables the applicant to proceed with the application for access permit³⁶. The applicant shall, after obtaining the PIC and entering into the accessory agreement, enter into a material transfer agreement with the lead agency³⁷.

31 Article 12, Sub-Article 1 of Access to Genetic Resources and Community Knowledge, and Community Right Proclamation No. 482/2006 (from the Interim Report).

32 "Stakeholder" refers to (a) a person, an organ of state or a community providing or giving access to the indigenous biological resources to which the application relates or (b) indigenous community - i) whose traditional uses of the indigenous biological resources to which the application relates have initiated/or will contribute to or form part of the proposed bioprospecting, ii) whose knowledge of or discoveries about indigenous biological resource to which application relates are to be used for proposed bio-prospecting.

33 Section 82 of the Act. Article 1 of the Act: "Minister" means the Cabinet member responsible for national environmental management.

34 The lead agency/ local community/ owner shall, before granting PIC, enter into an accessory agreement with the applicant with such terms and conditions agreed between the parties.

35 Accessory agreement is any facilitating agreement relating to PIC and includes a letter of exchange, a memorandum of understanding, or an academic or research agreement.



In Brazil, a registration system is followed instead of access permit. Registration is required before carrying out any of the regulated activities³⁸. The Norwegian draft regulation on ABS includes permit requirements both to grant a written permission and a permission for access and/or utilization of genetic resources as such which are to be issued based on a prior, complete application. Depending on what kind of genetic material needs to be accessed, the application has to be filed either to the Norwegian Environment Agency or the Norwegian Directorate of Fisheries³⁹. In the draft regulation on extraction and utilization of genetic material, the Agency is given the authority to grant access on land and freshwater, whereas the Directorate is given the same authority covering access in the marine environment⁴⁰.

In Bulgarian ABS law, the coordinating authority issues a written permission for access and use of genetic resources⁴¹ after a filed request from the applicant⁴². Access to genetic resources may be provided for use based on advance agreement in writing on the terms and manner of sharing the benefits arising from such transfer under mutually advantageous terms (MAT)⁴³.

Under Viet Nam's biodiversity law, organizations and individuals are assigned to manage the access to genetic resources⁴⁴. Right to access is granted by following a five-step process, also involving participation of the local communities⁴⁵.

In Kenya, the application for a permit for the access of genetic resources shall be accompanied by evidence of PIC from interested persons and relevant lead agencies as well as a research

36 Regulation 12 of the National Environment (Access to Genetic Resources and Benefit Sharing) Regulations, 2005.

37 A lead agency is any ministry, department, parastatal, local government system or public officer in which or whom any law vests functions of control or management of any segment of the environment (from the Interim Report)

38 The procedure for registration as well the registering authority are yet to be notified through a separate regulation.

39 Art. 5 of the draft Norwegian ABS regulation.

40 See Section 5 of Norway's proposed regulation.

41 As per the Interim Report of Bulgaria, Ministry of Environment and Water (MOEW) is the coordinating authority for genetic resources from wild species; Ministry of Agriculture Food and Forests (MAFF) the coordinating authority for agricultural and forest GR and the Ministry of economics (ME) the coordinating authority for industrial microbiological GR.

42 In the Interim Report, it has been mentioned that the detailed terms and provisions are in advanced drafting stage.

43 Article 66.3 of Bulgaria's Biological Diversity Act.

44 Article 56 of Vietnamese Biodiversity law.

45 The process involves registering with the competent national authority, negotiating and entering into written contracts on access to genetic resources and benefit sharing with organizations, households or individuals assigned to manage genetic resources under Articles 58 and 61, requesting certification from Communelevel People's Committee, requesting access license from the competent national authority and to provide any additional information to finalize the grant of access.



clearance certificate from the National Council for Science and Technology⁴⁶.

iv) PIC for traditional knowledge

Article 7 of the Protocol, as mentioned above, provides that, in accordance with domestic law, traditional knowledge associated with genetic resources that is held by indigenous and local communities is accessed with prior and informed consent or approval and involvement of these communities.

In Ethiopia, upon giving PIC, the Institute of Biodiversity Conservation shall negotiate and conclude genetic resources access agreement. Where community knowledge is involved, the Institute shall negotiate the access agreement based on the PIC of the concerned local community, by following a special procedure⁴⁷. The application must be filed to the Institute, which shall identify the community to be consulted and submit the application for the respective representative committee of such community. Such committees shall communicate the consent to the Institute.

As per Norway's regulation on traditional knowledge, access to and use of traditional knowledge associated with genetic material is unique to or characteristic of an indigenous people or local community or that is linked to the traditional way of life of the community requires consent from a representative or decision-making body that is entitled to represent and make commitments on behalf of the indigenous people or local community⁴⁸.

Brazil provides a distinctive process for access to associated traditional knowledge based

46 Part III of Kenya's Environmental Management and Co-ordination Act.

47 Article 14.3 of Ethiopia's Proclamation No. 482/2006.

48 Norway's Interim Report. Consent is not required if the traditional knowledge is used for private and noncommercial purposes, is reproduced or used for the purposes of citation or education, and the source is disclosed, is used in connection with research or experimentally in a way that concerns the knowledge itself, with the purpose of confirming or disproving the objective basis of the knowledge, or has over a reasonable period of time been generally known or available outside the indigenous or local community in question (Section 3 of the Regulations relating to the protection of traditional knowledge associated with genetic material).



on whether it is of identifiable or unidentifiable origin. Access to associated traditional knowledge of identifiable origin shall be subject to securing PIC. Proof of PIC may be obtained by the following ways: at the discretion of the local people, traditional community or traditional farmer in the form of signature of prior consent, audio-visual recording of the consent, opinion of the competent official body or adherence to the provisions set forth in the community protocol. Access to associated traditional knowledge for genetic resources from unidentifiable origin does not require PIC ⁴⁹.

No special procedure is laid in the legislations of Uganda, Bulgaria, Viet Nam for access to traditional knowledge associated with genetic resources and in Croatian legislation (where traditional knowledge is not covered under its national legislation).

v) Relationship between MAT and violation

Article 5 of the Protocol states the need for mutually agreed terms when regulating access to genetic resources and traditional knowledge.

The requirement for MAT is reflected in the domestic ABS laws of the studied countries. The

*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

49 Article 9 of Brazil's Law No 13,123, dated May 20, 2015.



*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.***

terms are incorporated in either the access permit granted or the agreements concluded prior to the permit. In South Africa, MAT is reflected in the material transfer agreement and benefit sharing agreement which are concluded prior to the grant of permit. In India and Kenya, these terms form part of the access permit (which is in the form of agreement in India). Some of the common elements of MAT are –

1. Type of the biological resources and traditional knowledge including quantitative description;
2. Particulars of the provider and exporter / recipient of the biological resources;
3. Location of the resources / traditional knowledge to be collected or person providing them;
4. Intended uses of the biological resources;
5. Duration of the access agreement;
6. Obligations of the permit holder;
7. Quantum of monetary and other incidental benefits including benefits in case of change of intent
8. Regular review of the agreement by parties as the bioprospecting progresses / furnishing



of quarterly or annual reports on the status of research;

9. Restrictions / conditions on third-party transfer without consent of the competent authority.

One of the significant terms is revocation of the access permit on occasion of non-compliance. Violation or failure to comply with the law in force, or MAT / conditions upon which the access is granted is a common ground for revocation of permit.

Other grounds include the purported access causing risk of damage to genetic resources, environment or affecting overriding public interest. In India, carrying out any of the regulated activities without prior approval of the National Biodiversity Authority including attempt and abetment constitutes violation⁵⁰. In South African ABS law, the issuing authority may cancel the permit if it was issued as a result of misleading or false representations by the applicant or if the permit-holder has contravened any foreign law governing the permitted activity⁵¹.

According to the draft regulation on access and utilization of genetic material, the Norwegian Environment Agency or the Norwegian Directorate of Fisheries (depending on whether the access related to resources on land or water) might revoke access of permits granted. Such revocation will only be possible in case of “severe breach” of the regulation’s provisions or duties laid down in the regulation⁵².

In Viet Nam, from the date that the decision for withdrawal of license is issued, the individual or organization that granted the license must obey the following requirements: a) they shall not be allowed to continue access or utilize genetic resources as previously licensed, b) they must continue to fulfil the agreement on benefit-sharing of the accessed genetic resources stipulated under the contract signed; c) they must pay compensation for damage and restoration of the environment and biodiversity⁵³.

50 Section 55 of India’s Biological Diversity Act, 2002.

51 Article 93 of South Africa’s National Environmental Management: Biodiversity Act, 2004.

52 Section 13 of the Draft Norwegian regulation on access and benefit sharing of genetic material.

53 Article 18, paragraph 3 of Viet Nam’s Decree on the Management of Access to Genetic Resources and the Sharing of Benefits Arising from their Utilization.



In Kenya, where the National Environment Management Authority suspends, cancels or revokes a permit, it shall publish the order suspending, cancelling or revoking the permit in the Gazette and in at least one newspaper with nationwide circulation⁵⁴. In Croatia, Brazil and Bulgaria, there are no specific provisions dealing with revocation.

vi) Nature of sanctions

Article 15 of the Protocol covers compliance with domestic legislation or regulatory requirements on access and benefit-sharing and states the following:

- 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.*

As stated in Article 15, the Parties are to decide what measures are “appropriate, effective and proportionate”. Thus, the nature of sanctions differ among the countries studied in this report and also varies from civil, criminal to administrative sanctions depending upon the offence, for example, in the Ugandan legislation⁵⁵, the applicable sanctions vary and might cover administrative or criminal sanctions, or both.

⁵⁴ Section 16, Part III of Kenya’s Environmental Management and Co-ordination Act (No. 8 of 1999).

⁵⁵ Regulation 25, 26 and 27 of Uganda’s National Environment (Access to Genetic Resources and Benefit Sharing) Regulations, 2005.



Administrative sanctions can range from warning, fine, seizure, temporary suspension of the manufacture and sale of the final product or reproductive material obtained through access, prohibition of specific activity related to the offence, partial or total prohibition of the establishment activity or enterprise, suspension of certificate of authorization under the regulation, cancellation of certificate of authorization. The actions above are possible administrative sanctions as regards to Brazil's ABS regulation .

Fines seem to be the most commonly used tool of sanction amongst the countries covered under the report. Bulgaria seems only to impose fine whereas Croatia, has not specified any sanctions. In case of no sanctions being mentioned under the law, it is somewhat unclear if the country does not have any sanctions in place or if possible criminal or administrative sanctions, or both are covered by other acts or regulations, like general criminal acts.

The Ethiopian and the Vietnamese legislation are examples of ABS legislations where the loss of rights, for instance the termination of an access permit, is covered ⁵⁷.

For those ABS legislations punishing non-compliance with criminal sanctions, such violations are considered to constitute an offence. Criminal sanctions might also cover imprisonment, for instance in India⁵⁸.

India, South Africa and Norway are examples of countries having criminal and administrative sanctions that is, imprisonment or / and fine⁵⁹ . The Norwegian regulation on traditional knowledge also covers specific sanctions in these cases.

The quantum of penalty is not specified in all ABS regulations studied. However, a pointer on the threshold of imprisonment is possible with available information. Criminal sanctions in South Africa involves imprisonment not exceeding five years whereas in Norway, it is limited

56 Article 27 of Brazil's Law No 13,123.

57 Article 21.2 of Ethiopia's Proclamation No. 482/2006 and Vietnamese Decree No. 155/2016/ND-CP (Article 44 on sanctioning violations of regulations on the management, access to genetic resources and sharing of benefits from genetic resources).

58 Sec. 55 of India's Biological Diversity Act.

59 Sec. 55 of India's Biological Diversity Act and Regulation 21 of the South Africa's Regulations, 2008.



to one year of imprisonment for willful or negligent contravention and three years for gross contravention for genetic resources on land, hereunder lakes and waterways as well as territorial waters. For marine species, the sanctions are laid down in the Norwegian Marine Resources Act. In Uganda and Kenya, both the measure of imprisonment and the level of fine are given, that is imprisonment shall not exceed eighteen months, and in some cases along with fine of not less than one hundred and eight thousand Uganda shillings and not exceeding eighteen millions Uganda shillings. In Kenya⁶⁰, sanctions include imprisonment that shall not exceed eighteen months, or fine, which shall not exceed three hundred and fifty thousand shillings, or both. In India, punishment varies depending on whether the contravention is committed by a domestic or foreign applicant. In the former case, imprisonment may extend up to three years or fine up to five lakh Indian rupees or for latter applicants, up to five years' imprisonment or fine up to ten lakhs Indian rupees⁶¹.

In Viet Nam, disputes over or complaints about access to genetic resources and benefit-sharing shall be settled under Vietnamese law and treaties to which the Socialist Republic of Vietnam is a contracting party⁶².

vii) Special considerations under the Protocol

Some cases are given special considerations under the Protocol and those are laid down in its Article 8:

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;*

60 Part V – No. 24 of Kenyan Environmental Management and Co-ordination Act.

61 Sec. 55, paras 1 and 2 of India's Biological Diversity Act.

62 See Article 58, paragraph 5 of the Vietnamese Decree.



*(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.*

a) Non-commercial research purposes

All the countries covered under this report, except Brazil and Viet Nam, seem to provide special consideration for non-commercial purposes. For instance, the Croatian legislation has non-commercial utilization as an excepted activity⁶³. Although majority of countries studied have simplified procedures for such activity, who is covered under Article 8, paragraph (a) of the Protocol differs.

In India, both Indian researchers and government institutions who intend to carry / send the biological resources outside India are covered⁶⁴. In the Bulgarian legislation, gratuitous provision of genetic resources may be agreed when the said resources are intended for non-commercial purposes: scientific research, education, conservation of biological diversity, or public health⁶⁵.

In Viet Nam, the time to evaluate an application is shorter for non-commercial research and there are shortened procedures of licensing applied for the transfer of genetic resources abroad for study and research purposes, not for commercial purposes submitted by Vietnamese

63 See Article 89, paragraph 3 of the Croatian Nature Protection Act.

64 See Regulation 13 of the Indian ABS Guidelines (2014).

65 See Bulgarian Biodiversity Act Art. 66 para 4.



pupils, students, doctoral students and scientific and technological organizations⁶⁶.

In Kenya, approved research activities intended for educational purposes within recognized Kenyan academic and research institutions, which are governed by relevant intellectual property laws are allowed without want of consent. In India, Indians who seek to access bio-resources for non-commercial purposes do not require consent.

Separate forms or permits for non-commercial purposes are present in most of the studied ABS-laws and regulation under this report. For instance, the Form B application in India is disposed of expeditiously within a specified timeframe through simplified measures. Most countries do not seem to require any fee for the proceeding or issuance of applications for non-commercial research purposes. In Norway, a change of intent from research to other uses may require a new permit⁶⁷. Similar provision exists in the Bulgarian Biological Diversity Act wherein any use that is not mentioned in the permit would demand the possible new terms of use of samples and new benefit sharing provisions shall be negotiated⁶⁸. Even in India, change in the purpose of utilization requires the applicant to reapply using appropriate form as given under its law.

b) Present or imminent emergencies

For present or imminent emergencies, India seems to be the only studied country covering this aspect in their ABS regulation⁶⁹.

Other countries, for instance Norway and Viet Nam, refer back to corresponding provisions in their general biological diversity laws or other acts and regulations regulating emergency issues.

66 See Article 20 of the Vietnamese Decree on the Management of Access to Genetic Resources and the Sharing of Benefits Arising from their Utilization.

67 See Article 58 of Norway's Nature Diversity Act. A proposal for access regulations has been on public hearing and the Norwegian Government aim to clarify the issue of change of intent as part of the work on these regulations.

68 See Bulgarian Biodiversity Act Art. 66 para 4.

69 See Rule 13.2. of the Indian ABS Guidelines (2014).



Some countries, like Ethiopia and South Africa, do not seem to have sufficient regulations in place for ABS-specific emergencies and are revising their existing ABS law to harmonize with the Protocol on this point⁷⁰.

According to their Interim Reports, most countries seem, either in their national ABS regulations or other national acts or regulations related to ABS, to regulate emergencies. Several countries, for instance Norway, are also looking into the possibility to include this into their ABS legislation.

c) Plant genetic resources for food and agriculture

In order to implement Article 8, paragraph c of the Protocol and in consonance with the objective of the international agreement to secure sustainable agriculture and food security, the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), plant genetic resources covered by this treaty are exempted from the national rules on ABS in all of the countries surveyed except Viet Nam⁷¹.

Some countries, like India and Ethiopia, refers specifically to Annex 1 of ITPGRFA whereas others like South Africa refers to ITPGRFA as such. Others address exemptions more generally for food and consumption as well as plant breeding and plant varieties, and those covered by other national legislation.

Brazil and Bulgaria both specifically mention forest genetic resources and forestry. This is not a requirement as per the above-stated provision.

70 Stated in the named countries' Interim Reports.

71 Stated in Viet Nam's Interim Report Question 35.



viii) User country measures as part of ABS legislation

In addition to Article 15, the requirement for user country measures as part of national ABS legislation is given under Article 16 of the Protocol, which reads as follows:

- 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.*

Most of the countries covered under the study do not regulate compliance with the domestic ABS regulatory frameworks of other countries to date. However, steps to develop appropriate user country measures in, for instance India, Ethiopia and South Africa, are taken. Ethiopia and South Africa are revising their ABS legislation in order to accommodate the Protocol's obligations⁷².

In Norway, genetic material from other countries is regulated⁷³. Import for utilization in Norway of genetic material from a State that requires consent for collection or export of such

72 See the countries' Interim Report on ABS.

73 See section 60 of the Norwegian Diversity Act.



material may only take place in accordance with such consent. The person in control of the material is bound by the conditions that have been set for consent. The Norwegian regulation applies to traditional knowledge relating to genetic material developed, used, sustained and passed on by indigenous peoples and local communities in other countries, provided that access to or use of such knowledge requires consent under the legislation of the state in question⁷⁴.

In Uganda, any person transporting or responsible for the movement of genetic resources in transit through the country shall declare the genetic resources in his / her possession or control to the customs control. They shall provide evidence of lawful acquisition from the country of origin at the point of entry and exit and in any other part of the country as may be required.

For Kenya, users intending to commercialize genetically modified organisms (GMO) within its jurisdiction are supposed to provide certificate in line with the requirements of the Protocol. All imports for utilization are to comply with the provisions of the Protocol as per the domestic legislations⁷⁵.

ix) Designation of checkpoints under ABS legislation

The designation of checkpoints is laid down in the Article 17, para. 1 of the Protocol:

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:

74 Regulations relating to the protection of traditional knowledge associated with genetic material were adopted by Royal Decree of 25. November 2016 under section 61a of the Act of 19 June 2009 No. 100 relating to the management of biological, geological and landscape diversity, also mentioned in the Interim Report.

75 See point 24 of the Kenyan Interim Report.



(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.



The checkpoints shall follow up on a range of different tasks under the Protocol and are thus important for the functioning of the ABS framework.

Not all countries' profiles at the ABS Clearing-House have updated information on the designation of checkpoints. However, some countries included in the study have given updated information on this aspect in their 2017 Interim Reports. According to the named reports some of them, inter alia Ethiopia, is considering the possibility to harmonize their existing ABS legislation with the Protocol and thus be able to designate national checkpoints. India is in the process of consultation with various concerned government agencies, which have functions relevant to the utilization of biological resources or collection of relevant information at different stages of research, development, innovation, pre-commercialization or commercialization for designating checkpoints⁷⁶.

According to the study, the status on the designation of checkpoints appears to vary from one country to another. Some countries, such as Kenya, have a range of checkpoints covering different agencies at both ministerial and lower levels whereas other countries, like South Africa, Bulgaria and Viet Nam, have designated checkpoints at the ministerial level. In all these cases, the designated checkpoint is also either the national focal point or competent authority, or both. For the time being, the checkpoint in Norway is at the ministerial level. However, there are discussions if this should also be the case in future or not and thus move the checkpoints to a lower level.

In the Interim Report of Uganda, the need for capacity building on the Protocol before designating checkpoints is stated as vital in order to have better knowledge and understanding of the Protocol.

⁷⁶ India's Interim Report, point No.9.



3. General Observations

The compilation and study of national legislations relating to ABS is conducive to assess the status of various countries on a selected set of criteria. Although these countries have implemented the Protocol within their jurisdictions through domestic laws, they have altered them to suit their national demands and situations. Hence, the differences. The observation makes visible those aspects where each of the studied country varies from each other and what lessons can be drawn to fix any inconsistency with the objectives and provisions of the Protocol.

It is noted that Croatia does not include traditional knowledge as a subject matter of ABS in its domestic law. However, the ABS Clearing House indicates that the EU's ABS regulation applies to it⁷⁷. It is believed that a sufficient framework is available for protection of traditional knowledge in Croatia.

Most countries recognize the continuance of traditional practices among the local communities as it is a matter of their livelihood and subsistence. Hence, it is appreciable that such practices are left undisturbed.

It is also observed that countries like Ethiopia, Vietnam, South Africa and Brazil have stringent rules for foreign applicants. Foreigners are either restricted (by not being allowed to undertake independent access but only in collaboration with a local individual or institution) or prohibited from access to genetic resources and traditional knowledge associated with these resources available in these countries.

It is noted that in most of the observed legislations, PIC is obtained with involvement of local communities (where relevant) in line with the requirements of the Protocol. However, there is a variation in whether PIC is covered by the permit granted for access or in one of the agreements signed prior to the permit.

77 <https://absch.cbd.int/countries/HR>



There is a strong commitment observed among majority of the States to promote food security and comply with related international instrument, that is, ITPGRFA. The high number of countries having special provisions on plant genetic resources might be because ITPGRFA existed prior to the Protocol. For many countries, the regulations around food and agriculture are very important to their sustenance and economy. Further, the relationship between the two international legal instruments were debated and formed a significant part during the negotiations of the Protocol. Therefore, the relationship of the Protocol and ITPGRFA is popularly recognized in all regions.

The sanctions imposed by the observed countries range from administrative, civil to criminal. It reflects the legal systems prevalent in these countries and the treatment of violations relating to ABS under their respective jurisdictions.

The promotion and encouragement of research is paramount to the health of people and economic development. It is noteworthy that the need for special consideration to access and utilization undertaken for non-commercial purposes seems to be well recognized among the Parties to the Protocol covered by the survey.

User country measures are one aspect, which is still in its infancy. Although Norway, Uganda and Kenya have some mechanism in place, much needs to be developed in order to meet the standards prescribed under the Protocol.

The designation of checkpoints might be an area where there will be changes over time. The level of designation of checkpoints will be decisive for its role. Furthermore, how the work of checkpoints are being structured and the number of national checkpoints will be crucial on how this is being followed up at a national level. This can be a strength, but also requires a consistent and close cooperation between the agencies in order to function optimally.



4. Conclusion

The comparative analysis of national legislations reveals the status of implementation of the Protocol at the domestic levels. The commonalities among legislations representing different legal systems and geographical locations of the world suggest that the Protocol has been nationally recognized and due significance is granted under their ABS-laws.

The studied ABS legislations in the selected ten countries aim to comply with their international legal obligations under the Protocol and are tailored to meet the local trends and needs. Some areas in the studied regulations where stark deviation from the objectives of the Protocol is found, could be more streamlined to harmonize their legislation with the Protocol.

Conclusively, it is believed that the report will be helpful and be utilized for comparing and contrasting the national ABS legislations. The study could indicate models for countries who intend to bring their existing legal frameworks in better compliance with the Protocol and for those who are interested to implement the Protocol in their domestic jurisdictions in future.

About CEBPOL

Government of India in collaboration with the Norwegian Government has established "Centre for Biodiversity Policy and Law (CEBPOL)" at the National Biodiversity Authority (NBA), an autonomous and statutory body of the Ministry of Environment Forest and Climate Change towards strengthening of expertise in Biodiversity Policy and Law in India. This programme is executed by the NBA in collaboration with Norwegian Environment Agency through the Royal Norwegian Embassy, New Delhi, India.

The Centre aims to provide advice and support to the Government of India and Norway on Biodiversity Policy and Law related issues including complex negotiations on Access and Benefit Sharing and Traditional knowledge as well as governance issues relating to biodiversity at the National and International level. The Centre proposes to help NBA in the effective implementation of International agreements on conservation, sustainable use and the associated access and benefit sharing components of it.

CEBPOL is set up as a specialized Centre of Excellence in Biodiversity Policy and Law to network, organize and consolidate expertise on issues of Biodiversity Policy and Law in India and Norway. The Centre, located at NBA, would function as an independent think tank on Biodiversity Policy and Law. In addition, CEBPOL aims to contribute to the effective implementation of the Biological Diversity Act 2002 and Rules 2004.

Contact:

The Secretary

Centre for Biodiversity Policy and Law

National Biodiversity Authority

5th Floor, TICEL BIO PARK, CSIR Road
Taramani, Chennai-600 113, Tamil Nadu

Email: secretary@nba.nic.in

Website: www.nbaindia.org/cebpol



Norwegian Embassy

