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منظمة  
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# COMMISSION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE

## Item 5 of the Provisional Agenda

### TEAM OF TECHNICAL AND LEGAL EXPERTS ON ACCESS AND BENEFIT-SHARING

#### Second Session

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### REVISED DRAFT ELEMENTS TO FACILITATE DOMESTIC IMPLEMENTATION OF ACCESS AND BENEFIT-SHARING FOR DIFFERENT SUBSECTORS OF GENETIC RESOURCES FOR FOOD AND AGRICULTURE

The Team of Technical and Legal Experts on Access and Benefit-Sharing (ABS Expert Team), at its first session in July 2014, considered the draft preliminary structure of *Draft Elements to Facilitate Domestic Implementation of Access and Benefit-Sharing for Different Subsectors of Genetic Resources for Food and Agriculture* (Draft Elements).<sup>1</sup> It reviewed the draft preliminary structure of the Draft Elements, discussed changes and requested the Secretariat to revise the Draft Elements accordingly, for review by the ABS Expert Team at its second session.<sup>2</sup>

This document contains the Revised Draft Elements, for consideration by the ABS Expert Team. The Revised Draft Elements do not necessarily reflect the views of FAO or its Members, nor have they been reviewed yet by the ABS Expert Team as a whole.

<sup>1</sup> CGRFA/TTLE-ABS-1/14/4, *Annex*.

<sup>2</sup> CGRFA/TTLE-ABS-1/14/Report, paragraph 13.

# REVISED DRAFT ELEMENTS TO FACILITATE DOMESTIC IMPLEMENTATION OF ACCESS AND BENEFIT-SHARING FOR DIFFERENT SUBSECTORS OF GENETIC RESOURCES FOR FOOD AND AGRICULTURE

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**REVISED DRAFT ELEMENTS**  
**TO FACILITATE DOMESTIC IMPLEMENTATION OF ACCESS AND BENEFIT-  
SHARING FOR DIFFERENT SUBSECTORS OF GENETIC RESOURCES FOR FOOD AND  
AGRICULTURE**

**I. BACKGROUND**

*Access and benefit-sharing and the Commission*

1. The Food and Agriculture Organization of the United Nations (FAO) and its Commission on Genetic Resources for Food and Agriculture (Commission) have a longstanding history of dealing with issues related to genetic resources for food and agriculture (GRFA), including access to them and the fair and equitable sharing of benefits derived from their utilization. In 1983, the FAO Conference adopted the *International Undertaking on Plant Genetic Resources for Food and Agriculture*, which provided a policy and planning framework for the Commission with respect to plant genetic resources. During the following years, the Commission negotiated further resolutions that interpreted the International Undertaking, and in 1994, started revising the International Undertaking. As a result of this process, the FAO Conference in 2001 adopted the *International Treaty on Plant Genetic Resources for Food and Agriculture* (Treaty), the first legally binding and operational international instrument on access and benefit-sharing for genetic resources.

*Convention on Biological Diversity*

2. The fair and equitable sharing of the benefits arising from the utilization of genetic resources is also one of the three objectives of the 1992 *Convention on Biological Diversity* (CBD) which states in its Article 15:

*Recognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.*

According to the CBD, access to genetic resources shall be subject to prior informed consent (PIC) of the Contracting Party providing such resources and, where granted, shall be subject to mutually agreed terms.<sup>3</sup>

*The Nagoya Protocol*

3. 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* (Nagoya Protocol) is a supplementary agreement to the Convention on Biological Diversity. It provides a legal framework for the effective implementation of the third objective of the CBD: the fair and equitable sharing of benefits arising out of the utilization of genetic resources.

*International Regime*

4. The Nagoya Protocol forms part of an International Regime that is constituted of the CBD, the Nagoya Protocol as well as complementary instruments, including the Treaty and the *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization*.<sup>4</sup>

*Special features of agricultural biodiversity*

5. The special nature of agricultural biodiversity, its distinctive features, and problems needing distinctive solutions is widely acknowledged. The Conference of the Parties to the CBD, at its fifth meeting in 2000, considered the distinctive features of agricultural biodiversity to include the following:

- (a) Agricultural biodiversity is essential to satisfy basic human needs for food and livelihood security;

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<sup>3</sup> CBD, Article 15.4;5.

<sup>4</sup> COP 10 Decision X/1.

- (b) Agricultural biodiversity is managed by farmers; many components of agricultural biodiversity depend on this human influence; indigenous knowledge and culture are integral parts of the management of agricultural biodiversity;
- (c) There is a great interdependence between countries for the genetic resources for food and agriculture;
- (d) For crops and domestic animals, diversity within species is at least as important as diversity between species and has been greatly expanded through agriculture;
- (e) Because of the degree of human management of agricultural biodiversity, its conservation in production systems is inherently linked to sustainable use;
- (f) Nonetheless, much biological diversity is now conserved *ex situ* in gene banks or breeders' materials;
- (g) The interaction between the environment, genetic resources and management practices that occurs *in situ* within agro-ecosystems often contributes to maintaining a dynamic portfolio of agricultural biodiversity.<sup>5</sup>

*The Nagoya Protocol and agricultural biodiversity*

6. The Nagoya Protocol, in its preamble, explicitly recognizes the importance of genetic resources to food security, the special nature of agricultural biodiversity, its distinctive features and problems needing distinctive solutions, as well as the interdependence of all countries with regard to GRFA and the special nature and importance of these resources for achieving food security worldwide and for sustainable development of agriculture in the context of poverty alleviation and climate change. In this regard, the Nagoya Protocol also acknowledges the fundamental role of the International Treaty and the Commission.

7. In its operational provisions, the Nagoya Protocol requires Parties to consider, in the development and implementation of their access and benefit-sharing legislation or regulatory requirements, the importance of GRFA and their special role for food security.<sup>6</sup> Parties shall also 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.<sup>7</sup>

8. The Nagoya Protocol leaves room for other international agreements in the field of access and benefit-sharing and it does not prevent its Parties from developing and implementing other relevant international agreements, including other specialized access and benefit-sharing agreements, provided that they are supportive of and do not run counter to the objectives of the Convention and the Nagoya Protocol.<sup>8</sup> Where a specialized international access and benefit-sharing instrument that is consistent with and does not run counter to the objectives of the Convention and the Nagoya Protocol applies, the Nagoya Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument.<sup>9</sup> One of the instruments explicitly acknowledged by the Nagoya Protocol is the Treaty which has been developed in harmony with the Convention. Beyond this openness to other international instruments, the Nagoya Protocol also states that due regard should be paid to “useful and relevant ongoing work or practices under such international instruments and relevant international organizations, provided that they are supportive of and do not run counter to the objectives of the Convention and this Protocol.”<sup>10</sup>

9. The Nagoya Protocol also requires Parties to encourage, as appropriate, the development, update and use of sectoral and cross-sectoral model contractual clauses for mutually agreed terms and of voluntary codes of conduct, guidelines and best practices and/or standards in relation to access and benefit-sharing.<sup>11</sup> The CBD COP serving as meeting of the Parties to the Nagoya Protocol shall

<sup>5</sup> COP 5 Decision V/5, *Appendix*, paragraph 2.

<sup>6</sup> Nagoya Protocol, Article 8(c).

<sup>7</sup> Nagoya Protocol, Article 8(a).

<sup>8</sup> Nagoya Protocol, Article 4.2.

<sup>9</sup> Nagoya Protocol, Article 4.4.

<sup>10</sup> Nagoya Protocol, Article 4.3.

<sup>11</sup> Nagoya Protocol, Article 19.1; 20;1.

periodically take stock of the use of the model contractual clauses, codes of conduct, guidelines and best practices and/or standards.<sup>12</sup>

*Development of the Elements to Facilitate Domestic Implementation of Access and Benefit-Sharing for Different Subsectors of Genetic Resources for Food and Agriculture (ABS Elements)*

10. The Commission, at its Fourteenth Regular Session, considered the need for and modalities of ABS for GRFA, taking into account relevant international instruments. The Commission put in place a process the output of which are these *Elements to Facilitate Domestic Implementation of Access and Benefit-Sharing for Different Subsectors of Genetic Resources for Food and Agriculture (ABS Elements)*.<sup>13</sup>

11. The Commission established a Team of Technical and Legal Experts on Access and Benefit-sharing (ABS Expert Team) consisting of up to two representatives from each of the seven FAO regions. As requested by the Commission, the ABS Expert Team:

- Coordinated, with the assistance of the Secretariat, by electronic means as appropriate, to help prepare the intergovernmental technical working group meetings, and based on input from their regions prepared written materials and proposed guidance for the intergovernmental technical working groups;
- Participated in the relevant portions of the meetings of the intergovernmental technical working groups, to help inform and shape the intergovernmental technical working group discussions and output on access and benefit-sharing; and
- Worked after each intergovernmental technical working group meeting with the Secretariat to compile the intergovernmental technical working group outputs into the *ABS Elements*, and communicated the *ABS Elements* to their regions for information.

12. The elaboration of the *ABS Elements* and the work of the Commission's intergovernmental technical working groups built upon and benefited from inputs received, at the Commission's invitation, from governments and relevant stakeholders<sup>14,15</sup>.

## II. OBJECTIVES OF THIS DOCUMENT

13. The overall objective of this document is to assist policy makers at the national level in reviewing their national ABS policy and, as relevant, in developing or adapting ABS measures so that these reflect the needs of the food and agriculture sector, while complying, as relevant, with international ABS instruments.

14. The central point of departure of this document is the need of countries to manage ABS for GRFA, taking into account the importance of GRFA and their special role for food security. The *ABS Elements* aim to assist policy makers in translating development and policy objectives into concrete domestic legislative, administrative or policy options for the different subsectors of GRFA. They raise relevant questions and aim to describe options for fine-tuning national ABS measures in line with the needs of the different subsectors of GRFA and existing international ABS instruments.

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<sup>12</sup> Nagoya Protocol, Article 19.2; 20.2.

<sup>13</sup> CGRFA-14/13/Report, paragraph 40.

<sup>14</sup> CGRFA/TTLE-ABS-1/14/Inf.2.

<sup>15</sup> CGRFA/TTLE-ABS-1/14/Inf.3.

### III. CONSIDERATIONS FOR DEVELOPING, ADAPTING AND IMPLEMENTING ABS MEASURES FOR GENETIC RESOURCES FOR FOOD AND AGRICULTURE

15. In developing, adapting and/ or implementing ABS measures addressing GRFA, governments may wish to consider taking the following steps:

#### 1. Assessment of the concerned subsectors of GRFA, including their activities, socio-economic environments and use and exchange practices

##### a. *Distinctive features of GRFA*

In a first step, governments may wish to analyse the distinctive features of their subsectors of GRFA<sup>16</sup>, as they present themselves in their countries. Attempts to identify the distinctive features of agricultural biodiversity have been made by the 5<sup>th</sup> meeting of the Conference of the Parties of the CBD<sup>17</sup> and by the Commission, at its Thirteenth Regular Session.<sup>18</sup> Both bodies stressed: the essential role of GRFA for food security; the dependence of many GRFA on human intervention or influence; the high degree of interdependence between countries for GRFA; the fact that many GRFA have been shaped, developed, diversified and conserved through human activities and practices over generations; the relevance of *ex situ* conservation to varying degrees depending on the subsector of the GRFA; the relevance of *in situ* conservation to the conservation of all GRFA to maintain a dynamic portfolio of agricultural biodiversity.

##### b. *Different forms of utilization of subsectors and variations within subsectors of GRFA*

Governments may also wish to take into account the different forms in which the different subsectors of GRFA make use of GRFA.

##### c. *Legal, policy and administrative measures, including existing practices*

Some subsectors of GRFA have developed specific practises for the use and exchange of genetic resources for research and development purposes; others, such as PGRFA falling under the Treaty's MLS, are covered by specific administrative or sometimes even legal measures. Analysing existing commercial and research practices as well as regulatory measures addressing the use and exchange of GRFA for research and development will assist policymakers in the preparation of ABS measures which make use of and are in line with existing practices and thus, avoid, to the extent possible and appropriate, the creation additional administrative procedures.

##### d. *Possible implications of the scope, including subject-matter and temporal scope, of ABS measures*

Governments may wish to analyse in some detail the implications of the scope, including the subject-matter and the temporal scope, of their ABS measures. With regard to the temporal scope of ABS measures, governments may wish to analyse, in particular, the implications of applying ABS measures to relevant "pre-existing materials", e.g. materials originating from other countries that have been collected prior to the entry into force of the ABS measures.

##### e. *Flows of germplasm, including transboundary flows, within the different subsectors*

<sup>16</sup> Throughout this document, "subsectors of GRFA" are understood as to mean the sectors of (1) plant genetic resources for food and agriculture (PGRFA); (2) animal genetic resources for food and agriculture; (3) forest genetic resources for food and agriculture; (4) aquatic genetic resources for food and agriculture and; (5) micro-organism and invertebrate genetic resources for food and agriculture.

<sup>17</sup> COP 5 Decision V/5, *Appendix*, paragraph 2.

<sup>18</sup> CGRFA-14/13/Report, *Appendix E*.

The extent of the historical and current exchange of germplasm and the proportion of exotic diversity used vary between subsectors of GRFA. While animal and plant genetic resources have extensively been exchanged, the situation in other subsectors, is mixed. While some of the most relevant species have been moved extensively throughout the world, others are just starting to be farmed in aquaculture or are only used within their natural habitat in native forests for the time being, and their exchange has been limited so far. In developing or adapting ABS measures, governments may wish to carefully consider the relevance of germplasm flows for the subsectors relevant to agriculture and food production in their countries and possible future changes of the germplasm flow due to climate change.

*f. Cases of unauthorized/ denied access to GRFA*

Governments may wish to get an idea of the magnitude of the problems caused by unauthorized access to GRFA under their national sovereignty, on the one hand, and by denials of access to GRFA of other countries, on the other. Such knowledge may help to shape and fine-tune compliance measures, including monitoring. Information regarding possible difficulties to access GRFA of another country may be essential to enter consultations with them regarding the legal certainty, clarity and transparency of their domestic ABS measures.

*g. Possible gaps of ABS measures*

In reviewing existing ABS measures, governments may wish to identify regulatory gaps; such gaps may consist of, for example, genetic resources that are not covered by ABS measures; activities that are not covered although the Government may wish to address them through its ABS measures. The adoption of new or the review of existing ABS measures offers an opportunity to identify and close these gaps, as appropriate.

## **2. Identification and consultation of relevant governmental entities and non-governmental stakeholders holding, providing or using GRFA**

Prior to the development/ review of ABS measures, governments may wish to identify and consult relevant governmental and non-governmental stakeholders, providing or utilizing GRFA, including farmers and indigenous and local communities, genebanks and collections, research institutions as well as private sector entities. The purpose of such consultations may be manifold as they may: help raising awareness among stakeholders; allow policy and decision makers to get an insight into the specificities of the different subsectors GRFA and the current practices of using and exchanging genetic resources; inform potential users of traditional knowledge associated with genetic resources and of genetic resources that are held by indigenous and local communities about their obligations.

## **3. Consideration and evaluation of options for ABS measures and, based upon broad consultations, adoption of adequate ABS measures**

Based on an assessment of the concerned subsectors of GRFA, including their activities, socio-economic environments and use and exchange practices, and following consultations with relevant stakeholders, different options for ABS measures, may be considered and, based on a further round of consultations with regard to these specific options, governments may wish to adopt their ABS measures.

#### **4. Integration of ABS measures with broader food security and sustainable agricultural development policies and strategies**

ABS measures for GRFA may be considered in the wider context of sustainable agricultural development and food security. Not always will those being responsible for ABS also be in charge of sustainable agricultural development and food security strategies. Governments will therefore often face the challenge of coordinating different government policy areas and goals and integrating them into a broader and consistent strategy.

#### **5. Integration of implementation of ABS measures in institutional landscape**

ABS measures cut across different sectors of GR and GRFA for which often different ministries and competent authorities hold the responsibility. Governments may wish to consider using the existing infrastructure of the sectors and subsectors for the implementation of ABS measures, rather than creating new and additional administrative layers. Using and adapting, as appropriate, existing structures, administrative procedures as well as sectoral practises may facilitate the smooth and flawless operationalization and implementation of ABS measures.

#### **6. Communication of ABS measures to potential providers and users of GRFA**

Communicating ABS measures to potential providers and users of GRFA is essential. Various communication tools may be considered. Effective communication strategies will usually combine different communication tools and aim to provide stakeholder-specific information whenever necessary. It might also be important, especially during the initial phase of implementation, to provide individual advice and assistance.

#### **7. *Ex-ante* assessment as well as monitoring of the effectiveness and impact of ABS measures**

Possible implications, side effects and implementation difficulties may often be anticipated through scenario-based testing of policy measures. Given the many challenges and innovations ABS measures may pose, governments may wish to carry out such tests and/ or monitor the effects by agreeing on a set of relevant indicators.

### **IV. ABS FOR GRFA: THE LEGAL FRAMEWORK**

16. In framing their national framework on access and benefit-sharing for GRFA, governments need to be aware of their legal obligations. Essentially three instruments make up the global framework of access and benefit-sharing for genetic resources: the CDB, the Nagoya Protocol and the Treaty. The three instruments are legally binding for their Contracting Parties.<sup>19</sup>

#### *Convention on Biological Diversity*

17. The CBD requires its Contracting Parties to take legislative, administrative or policy measures, as appropriate, with the aim of sharing in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Contracting Parties providing such resources.<sup>20</sup> Access to genetic resources shall be subject to prior informed consent (PIC) of the Contracting Party that is country of origin of such resources or has

<sup>19</sup> For lists of Parties, see, for the CBD: <http://www.cbd.int/information/parties.shtml>; for the Nagoya Protocol: <http://www.cbd.int/abs/nagoya-protocol/signatories/default.shtml>; for the Treaty: [http://planttreaty.org/list\\_of\\_countries](http://planttreaty.org/list_of_countries).

<sup>20</sup> CBD, Article 15.7.



acquired them in accordance with the CBD.<sup>21</sup> Access, where granted, shall be on mutually agreed terms (MAT).<sup>22</sup> Potential benefits to be shared also include: access to and transfer of technology using genetic resources; participation in biotechnological research activities based on the genetic resources; and priority access to the results and benefits arising from biotechnological use of the genetic resources.<sup>23</sup>

*Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity*

18. The Nagoya Protocol is a supplementary agreement to the Convention on Biological Diversity and provides a legal framework for the effective implementation of one of the Convention's three objectives: the fair and equitable sharing of benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization. The Nagoya Protocol applies to genetic resources and to traditional knowledge associated with it. It aims to achieve the fair and equitable sharing of benefits, by setting out "access obligations" for Parties requiring PIC, benefit-sharing obligations as well as compliance obligations which require Parties to take measures to provide that genetic resources used within their jurisdiction have been accessed with PIC and that MAT have been established. More detailed information on the Nagoya Protocol will be provided throughout this document.

*International Treaty on Plant Genetic Resources for Food and Agriculture*

19. Like the CBD and the Nagoya Protocol, the Treaty is based on the premise that states have sovereign rights over their genetic resources and that the authority to determine access to these resources therefore lies with national governments. However, under the Treaty its Contracting Parties exercise their sovereign rights through the Multilateral System of Access and Benefit-sharing (MLS), by facilitating access and the sharing of monetary and non-monetary benefits arising from the use of plant GRFA through standardized conditions as set out in the Standard Material Transfer Agreement (SMTA). The ABS mechanism of the Treaty is thus different from the bilateral, case-by-case approach primarily envisaged by the CBD and the Nagoya Protocol. While the Treaty applies to all PGRFA, its MLS applies only to PGRFA set out in Annex I to the Treaty that are under the management and control of the Contracting Parties and in the public domain.

*Relationship between instruments*

20. The Nagoya Protocol foresees that where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and the Nagoya Protocol, the Nagoya Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument.<sup>24</sup> For PGRFA the Treaty exists. The Treaty, as a specialized international ABS instrument which is consistent with and does not run counter to the objectives of the CBD and the Nagoya Protocol, will take priority whenever PGRFA covered by the Treaty are exchanged for the purposes of the Treaty between Parties of the Treaty.

## V. RATIONALE OF ABS MEASURES FOR GRFA

21. Considering that GRFA are an integral part of agricultural and food production systems and therefore play an essential role for achieving food security and sustainable agricultural development, and that the international exchange of GRFA is essential to the functioning of the sector, ABS measures may be instrumental in furthering the achievement of food security and improving nutrition. There is general consensus that food and nutrition security requires effective conservation of GRFA

<sup>21</sup> CBD, Article 15.5; 15.3.

<sup>22</sup> CBD, Article 15.4.

<sup>23</sup> CBD, Articles 15.7; 16; 19; 20; 21.

<sup>24</sup> Nagoya Protocol, Article 4.4.

and that the effective conservation of GRFA requires their continued use by farmers, including smallholders, indigenous and local communities, research institutions, plant breeders and other stakeholders. Therefore, ABS legislation aiming at achieving food security and the conservation of GRFA needs to aim at facilitating and actively encouraging the continued use and exchange of GRFA.

22. There is also agreement that the conservation and sustainable use of GRFA are essential to the sustainable development of agricultural production. Productivity, adaptability and resilience of agro-ecosystems depend on the diversity of GRFA.

## VI. ELEMENTS OF ABS MEASURES FOR GRFA

23. According to the Nagoya Protocol, Parties shall consider, in the development/ adaptation and implementation of their access and benefit-sharing regulatory requirements, the importance of GRFA and their special role for food security.<sup>25</sup> However, the Nagoya Protocol does not provide guidance as to how Parties may translate the importance of GRFA and their special role for food security into specific legislative, administrative or policy measures or reflect them in their implementation. The *ABS Elements* for national ABS measures for GRFA highlight those areas of ABS policy which deserve particular attention from the perspective of research and development in food and agriculture.

24. National measures on ABS should be simple and flexible. *Simplicity* is a challenge given the complexity of the matter and given the variety of situations in which GRFA may be accessed, transferred to others, further improved and used for research and development. *Flexibility* is therefore a must to allow administrators to adjust the implementation of ABS measures to new and newly identified situations and challenges. ABS legislation should leave sufficient flexibility to accommodate new and newly identified situations without having to revise the legislation as such. Administrators and stakeholders alike will learn implementing ABS by implementing ABS measures; ABS measures should therefore allow for an evolutionary implementation approach which allows to improve the operation of the ABS system through practice, self-perfection and innovation. Developing and implementing ABS measures is *work in progress* and so is the development of these *ABS Elements*.

25. National measures on ABS may come with considerable transaction costs and governments may wish to assess these costs prior to the adoption of the measures.

26. In designing legislative, administrative or policy measures for ABS that reflect the special needs of GRFA, policy makers may wish to address a wide range of issues to facilitate the domestic implementation of ABS for the different subsectors of GRFA:

- (1) Institutional arrangements;
- (2) Access to GRFA;
- (3) Access to traditional knowledge associated with GRFA;
- (4) Fair and equitable sharing of benefits;
- (5) Monitoring and compliance.

### 1. Institutional Arrangements

27. ABS measures will often specify the institutional arrangements for the management of ABS. Depending on the structure of a state, the form of government and, where relevant, the jurisdictional division of responsibility and depending on the ABS measures chosen, one or several competent authorities may be tasked with the administration of ABS measures. These can be either existing or

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<sup>25</sup> Nagoya Protocol, Article 8(c).

new authorities. Several authorities within one country may also share the responsibility according to the geographical origin of the resource, the purpose for which it is to be accessed and utilized, the involvement of traditional knowledge associated with the genetic resource, the rights indigenous and local communities may have over the resource or any other criteria that seem appropriate and practical.

- Under the Nagoya Protocol, Parties have to designate one or more competent authorities, which shall be responsible, *inter alia*, for granting access and advising on applicable procedures and requirements for obtaining PIC and entering into MAT.<sup>26</sup> In addition, Parties to the Nagoya Protocol have to designate national focal points on ABS, which shall be responsible for liaison with the Secretariat and provide relevant information to applicants.<sup>27</sup> One and the same single entity may fulfil the functions of both, the focal point and the competent national authority.<sup>28</sup>
- While the Treaty does not explicitly require its Contracting Parties to designate competent national authorities, it does require that facilitated access be provided “pursuant to a standard material transfer agreement,” as adopted by the Treaty’s Governing Body.<sup>29</sup> As the Treaty and the Standard Material and Transfer Agreement (SMTA), define the conditions of access as well as the benefit-sharing obligations conclusively there is no role under the Treaty for bilateral negotiations, e.g. between the genebank providing access and a recipient. However, it is of course understood that the institution(s) actually providing access to MLS material should do so only upon acceptance of the SMTA by the recipient of the material.

28. Whatever institutional arrangements are chosen, it is of pivotal importance that the institutional arrangements are clear and transparent. Users of genetic resources need to know whom they have to ask for PIC and with whom they may negotiate MAT, if this is what the ABS measures require. Where several, e.g. federal and state, authorities are involved in one and the same decision, the authorization procedure may quickly become complicated, time-consuming and transaction costs may increase considerably. To avoid overly burdensome institutional arrangements, existing arrangements may perhaps be used to address PIC and MAT. Governments may consider using existing authorization procedures, e.g. marketing approval procedures, and make ABS requirements part of them. Where several authorities are involved in the approval procedures, governments may wish to consider designating one lead authority or national clearinghouse to oversee the whole chain of partial approvals, communicate with the applicant and ultimately grant one cumulative authorization, once all relevant authorities have given their green light.

## 2. Access to genetic resources

29. ABS measures usually address access and benefit-sharing separately. Access to a genetic resource may require an access permit but no benefit-sharing, for example where a country has agreed to require PIC, but no benefit-sharing, for taxonomic research. ABS measures may provide “unrestricted” access to certain categories of genetic resources (and thus exempt them from the access provisions) and, at the same time, provide that the utilization of these resources requires benefit-sharing along the lines of a pre-defined set of terms and conditions (which users accept, for example, by utilizing the resource or commercializing a product derived from it). This section therefore deals with issues related to access only.

30. Parties to the Nagoya Protocol requiring prior informed consent shall take, in accordance with the Nagoya Protocol, the necessary legislative, administrative or policy measures, as appropriate to:

- (a) *Provide for legal certainty, clarity and transparency of their domestic access and benefit-sharing legislation or regulatory requirements;*

<sup>26</sup> Nagoya Protocol, Article 13.2.

<sup>27</sup> Nagoya Protocol, Article 13.1.

<sup>28</sup> Nagoya Protocol, Article 13.3.

<sup>29</sup> Treaty, Article 12.4.

- (b) *Provide for fair and non-arbitrary rules and procedures on accessing genetic resources;*
- (c) *Provide information on how to apply for prior informed consent;*
- (d) *Provide for a clear and transparent written decision by a competent national authority, in a cost-effective manner and within a reasonable period of time;*
- (e) *Provide for the issuance at the time of access of a permit or its equivalent as evidence of the decision to grant prior informed consent and of the establishment of mutually agreed terms, and notify the Access and Benefit-sharing Clearing-House accordingly;*
- (f) *Where applicable, and subject to domestic legislation, set out criteria and/or processes for obtaining prior informed consent or approval and involvement of indigenous and local communities for access to genetic resources; and*
- (g) *Establish clear rules and procedures for requiring and establishing mutually agreed terms. Such terms shall be set out in writing and may include, inter alia:*
  - (i) *A dispute settlement clause;*
  - (ii) *Terms on benefit-sharing, including in relation to intellectual property rights;*
  - (iii) *Terms on subsequent third-party use, if any; and*
  - (iv) *Terms on changes of intent, where applicable.<sup>30</sup>*

31. In developing or adapting ABS provisions dealing with access to genetic resources it is useful to specify:

- (i) the categories of genetic resources covered by the access provisions;
- (ii) intended purposes of use triggering the application of access provisions;
- (iii) the types of authorization procedure applicable, depending on the category of genetic resource and the purpose for which the resource is to be used.

*(i) Categories of genetic resources covered by access provisions*

32. “Genetic resources” are defined by the CBD as “genetic material of actual or potential value” and genetic material means “any material of plant, animal, microbial or other origin containing functional units of heredity.”<sup>31</sup> This definition is also mirrored in the Treaty, which defines “plant genetic resources for food and agriculture” as any genetic material of plant origin of actual or potential value for food and agriculture.<sup>32</sup>

Genetic resources covered by other specialized international instruments

33. The Nagoya Protocol foresees that where a specialized international access and benefit-sharing instrument applies that is consistent with, and does not run counter to the objectives of the Convention and the Nagoya Protocol, the Nagoya Protocol does not apply for the Party or Parties to the specialized instrument in respect of the specific genetic resource covered by and for the purpose of the specialized instrument.<sup>33</sup> The Treaty, currently the only specialized international ABS instrument, will take priority whenever PGRFA covered by the Treaty are exchanged for the purposes of the Treaty between Parties of the Treaty. Parties to the Treaty should therefore exclude from their access and, in fact, benefit-sharing provisions, PGRFA covered by and for the purpose of the Treaty’s MLS.

34. It should be noted that, according to the Nagoya Protocol, the Nagoya Protocol shall also be implemented in a mutually supportive manner with other international instruments relevant to the Nagoya Protocol. Due regard shall also be paid to useful and relevant on-going work or practices under such international instruments and relevant international organizations, provided they are supportive of and do not run counter to the objectives of the CBD and the Nagoya Protocol.<sup>34</sup>

<sup>30</sup> Nagoya Protocol, Article 6.3.

<sup>31</sup> CBD, Article 2.

<sup>32</sup> Treaty, Article 2.

<sup>33</sup> Nagoya Protocol, Article 4.4.

<sup>34</sup> Nagoya Protocol, Article 4.3.

#### Genetic resources accessed before entry into force of ABS measures

35. The absence of clear and unambiguous rules in the Nagoya Protocol on its temporal scope has stirred a debate regarding the temporal scope national ABS measures could or should have. At the outset, it seems important to note that the Nagoya Protocol, in the absence of any rules to the contrary, does not prevent its Parties from applying their national ABS measures to genetic resources or utilizations that fall outside the temporal scope of the Nagoya Protocol. However, with regard to resources outside the scope of the Nagoya Protocol, Parties cannot rely on the support of user country compliance measures, as set out in Articles 15 – 18 of the Nagoya Protocol. The implications of applying ABS measures to GRFA accessed prior to the entry into force of the Nagoya Protocol will be further considered below, in the context of benefit-sharing.<sup>35</sup>

#### Genetic resources provided by countries of origin/ countries which acquired them in accordance with the Convention

36. Countries will usually apply their access measures to genetic resources for which they are the country of origin or which they have acquired in accordance with the CBD. “Country of origin of genetic resources” means the country which possesses those genetic resources in *in situ* conditions.<sup>36</sup> “*In situ* conditions” means conditions where genetic resources exist within ecosystems and natural habitats, and, in the case of domesticated or cultivated species, in the surroundings where they have developed their distinctive properties.<sup>37</sup>

37. In the case of GRFA, it will often be difficult to determine with certainty or beyond reasonable doubt the country of origin. GRFA have been widely exchanged across regions, countries and communities over often long periods of time. Many different stakeholders, including indigenous and local communities, farmers, researchers and breeders have contributed to the development of GRFA, in different places and at different points in time. In fact, the maintenance and evolution of many GRFA depend on continued human intervention, and their sustainable utilization in research, development and production is an important instrument to ensure their conservation.

38. ABS measures could provide clarity as to which GRFA are considered to have developed their distinctive properties in the surroundings of the country and are therefore covered by the relevant access provisions. It is currently unclear whether in case of GRFA that developed distinctive properties in the surroundings of several countries access has to be approved by several “countries of origin”.

39. Finally, ABS measures could clarify whether their access and/ or benefit-sharing provisions also apply to GRFA for which the country is not the country of origin and which have not been acquired in accordance with the CBD or the Nagoya Protocol.

#### Privately versus publicly held genetic resources

40. While the Treaty’s Multilateral System addresses only plant GRFA “that are under the management and control of the Contracting Parties”<sup>38</sup> as well as materials brought within the purview of the Treaty by other holders,<sup>39</sup> the Nagoya Protocol does not make the distinction between genetic resources which are under the management and control of government and other categories of genetic resources.

41. ABS measures need to be clear as to whether they apply only to publicly or also to privately or collectively held genetic resources. Given that a significant amount of GRFA is privately held, in particular in sectors like the livestock sector, ABS measures covering privately held GRFA may have a significant impact on the exchange of such GRFA, in the sense that they may limit the freedom of resource holders to exchange resources with, for example, other plant or animal breeders. Such laws may also raise complex questions as to the hierarchy or relationship of different proprietary, including intellectual property, and quasi-proprietary and other rights related to genetic resources.

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<sup>35</sup> See paragraph 67-70.

<sup>36</sup> CBD, Article 2.

<sup>37</sup> CBD, Article 2.

<sup>38</sup> Treaty, Article 11.2.

<sup>39</sup> Treaty, Articles 15; 11.3.

### Genetic resources vs. biological resources

42. The Nagoya Protocol covers “genetic resources”, i.e. genetic material of plant, animal, microbial or other origin containing functional units of heredity provided the material is of actual or potential value.<sup>40</sup> However, some ABS laws cover genetic as well as “biological resources” and usually mean by the latter specific *uses* of or activities performed with genetic resources that are not considered “research and development on the genetic and/or biochemical composition of genetic resources”, for example the use of material for the extraction of specific compounds. The distinction between genetic and biological resources is, thus, not a distinction between different resources, but a distinction between different uses of a resource, the use for research and development (“genetic resource”) and the use of the resources as a commodity for extracting chemical components or producing food (“commodity”). This distinction will be addressed in the section on intended uses.<sup>41</sup>

### Genetic resources held by indigenous and local communities

43. The Nagoya Protocol also addresses, as a special case, genetic resources held by indigenous and local communities. The Protocol requires Parties in such case to take measures, in accordance with domestic law, 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<sup>42</sup>.

44. ABS measures implementing the Nagoya Protocol may therefore foresee two PIC procedures: the PIC granted by the state and the PIC, approval or involvement of the indigenous and local communities where they have the established right to grant access to such resources. The community PIC, as such, is a challenging, even though not completely new concept. The Protocol does not provide guidance as to how “PIC or approval or involvement of the indigenous and local communities” may be obtained. In the case of GRFA, additional difficulties may arise as several communities will often share the genetic resources and the communities concerned may not always be known.

### *(ii) Intended purpose of use triggering the application of access provisions*

#### Research and development on the genetic and/ or chemical composition of genetic resources

45. Many countries limit the scope of their ABS measures to specific uses of genetic resources, i.e. to their use in research and development. Under the Nagoya Protocol, only “access to genetic resources for their utilization shall be subject to PIC by the country providing such resources that is the country of origin of such resources or that has acquired the genetic resources in accordance with the Convention (...)”<sup>43</sup>. “Utilization of genetic resources” means “to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology (...)”<sup>44</sup>

46. Other ABS measures use a wider definition of intended purpose of use that triggers the application of access provisions. Under those measures, the acquisition of genetic resources for certain purposes other than research and breeding may require PIC, for example the use of genetic resources for the extraction of specific compounds. The measures often refer to “biological resources”, meaning that the resources are not used for their genetic composition, but as an end product or commodity. The rationale for such broad definition is the experience that compounds used in the pharmaceutical and cosmetic industry are often extracted from agricultural products sourced through intermediaries from local markets at local prices which at times do not reflect the actual market value of the extracted compounds.

47. A broad definition of purposes that would capture a whole range of activities that typically and regularly happen with agricultural commodities in the course of food production, will obviously

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<sup>40</sup> CBD, Article 2.

<sup>41</sup> See paragraph 46.

<sup>42</sup> Nagoya Protocol, Article 6.2.

<sup>43</sup> Nagoya Protocol, Article 6.1.

<sup>44</sup> Nagoya Protocol, Article 2(c).

imply that access provisions would apply to a possibly large number of transactions where for the time being the assumption in most countries might be that in such cases the sales contract manifests the ABS agreement.

#### Development of genetic resources in the course of agricultural production

48. If the activities triggering access provisions are limited to “utilization” within the meaning of the Nagoya Protocol, certain typical uses of GRFA, for example the growing of seeds for subsequently using the harvested products for human consumption do clearly not qualify as utilization and therefore do not trigger the application of access provisions.

49. Other activities regularly performed with respect to GRFA are more difficult to classify. The question may arise whether selection and reproduction of plant genetic resources by a farmer or farming community based on phenotypical traits and not entailing any genetic methods, qualify as “utilization”. Similarly, fish farming while serving the purpose of producing fish for human consumption may simultaneously, through natural selection due to the hatchery environment, contribute to the genetic development and, in fact, domestication of the fish. Provenance trials which help to identify tree seedlings best adapted to the conditions of a specific planting site may simply serve the purpose of reforestation and the production of timber on sites that are similar to the test environment; on the other hand provenance research is also important for the planned breeding within and between species. The use of cattle embryos or bovine semen for reproduction and, ultimately, dairy or meat production may be considered as falling outside the boundaries of “utilization”. However, the selection of semen-donor bulls and the selection of offspring for multiplication may entail aspects of research and development. Currently, the assumption of stakeholders when selling genetic material in the form of semen, embryos, etc., is that its value as a genetic resource is already reflected in its price, and that the buyer will be free to use it for further research and breeding.<sup>45</sup> If, however, the planned use of such material qualifies as “utilization” access requirements would apply.

50. Many GRFA are being shaped, developed and improved through their continued use in agricultural production. Where “research and development” and agricultural production occur in tandem, it may be difficult to distinguish “utilization” from activities related to the production of agricultural products for sale and human consumption. ABS measures could provide guidance as to the treatment of these cases, for example by listing examples of activities/ purposes of use that fall under “utilization” and other examples which fall outside the definition of “utilization”.

#### Research and development for food and agriculture

51. In the light of Article 4.3 of the Nagoya Protocol, policy makers could consider to treat the utilization of genetic resources differently if it is intended to contribute to food and agricultural research and development. In this case special procedural requirements or benefit-sharing standards could apply or a special authority could, for example, be responsible for ABS. ABS measures making this distinction, could consider whether “agriculture” should or should not include non-food/ feed agricultural products.<sup>46</sup> However, a distinction between food/ feed and non-food/ feed agricultural products faces the difficulty that at the stage of research and development it will often be unknown for which purpose the outcome will end up being used. Many agricultural products may be and are used for both, food and non-food purposes. Still ABS measures could, for example, exempt from “research and development for food and agriculture” research and development that is intended to exclusively serve non-food/ feed purposes.

#### Commercial/ non-commercial research and development

52. ABS measures may distinguish between commercial and non-commercial utilization of genetic resources. Non-commercial utilization often benefits from softer authorization requirements and simpler authorization procedures. PIC is often required for both forms of utilization. However, in the case of non-commercial utilization, recipients are sometimes given the option not to negotiate the

<sup>45</sup> Background Study Paper No. 43. 2009. The use and exchange of animal genetic resources for food and agriculture, p. 28.

<sup>46</sup> See Treaty, Article 12.3(a).

sharing of monetary benefits immediately, if they agree to get back to the provider and negotiate monetary benefit-sharing, should their intent change.

53. The distinction between commercial and non-commercial utilization, which is particularly important for taxonomic research and encouraged by the Nagoya Protocol,<sup>47</sup> might be of little value in the case of agricultural research and development which typically aim at improving agricultural and food production and therefore might qualify, in most cases, as commercial utilization.

#### Exemption of specific research and development activities

54. ABS measures may also provide exempt certain utilizations of genetic resources from any ABS authorization. Pre-existing and on-going utilizations of genetic resources by (small-scale) farmers, for example, the exchange of genetic resources for research and development within and among local and indigenous communities as well as exchange practices within intergovernmental research networks could be exempted from any access requirements and, possible, the ABS measures as such.

#### *(iii) Types of authorization procedures*

55. The Nagoya Protocol provides that access to genetic resources for their utilization shall be subject to the PIC 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 on Biological Diversity, unless otherwise determined by that Party.<sup>48</sup>

#### Prior informed consent

56. Countless variations of authorization procedures exist and policymakers may therefore wish to consider advantages and disadvantages of the different options and adapt procedures to the different categories of genetic resources and the different purposes for which they are intended to be used. The Nagoya Protocol does not provide in any detail how PIC should be granted and thus leaves its Parties, within the boundaries of Article 6.3 of the Nagoya Protocol, considerable flexibility as to how the authorization procedure may be designed. Parties to the Nagoya Protocol ABS measures may also provide for different types of authorization procedures depending on the user. The selection of different types of authorization procedures given below does not claim to be exhaustive.

#### Standard and fast-track PIC

57. Governments may wish to establish standard procedures and, in addition, fast-track procedures for certain situations, e.g. for access to certain materials; for materials which are to be used for certain purposes, e.g. research and development for food and agriculture; for access by certain stakeholders, e.g. farmers; or for combinations of these constellations.

#### Implicit prior informed consent

58. ABS measures may also provide for implied informed consent procedures for specific materials, purposes, stakeholders or other situations. In this case, access to and utilization of genetic resources could proceed without an explicit PIC by the competent authority. Implicit PIC does not rule out the possibility of benefit-sharing. Relevant ABS measures could provide, for example, that in the case of implicit PIC, the recipient has to agree with the competent authority on the terms and conditions of benefit-sharing prior to the commercialization of a product derived from the genetic resource.

#### Standardization of PIC (and MAT)

59. A typical regulatory response to the high number of transfers of GRFA and the recurrent exchange events in the food and agriculture sector could be the standardization of access procedures, terms and conditions. The Treaty already establishes a fully functioning precedent for this approach through its standard material transfer agreement.

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<sup>47</sup> Nagoya Protocol, Article 8(a).

<sup>48</sup> Nagoya Protocol, Article 6.1.



60. A good starting point for the use of standardized procedures and conditions could be already existing pools of GRFA, for instance in the form of collections and genebanks, provider and user communities and networks. Their established exchange practices may offer useful models to build upon, as they often include the use of an agreed set of conditions and modalities, sometimes even formalized in the form of codes of conduct, guidelines or MTAs.

61. ABS measures may establish standard ABS conditions for specific materials, purposes, stakeholders or other standard situations. Recipients accessing and using specified genetic resources, for example, for specified research/ development purposes, would have to abide by a set of access and benefit-sharing conditions pre-defined in the ABS measures. Given the variety of resources, the variety of purposes for which they may be used and the variety of stakeholders, standardization of ABS may not work as an overall solution for all GRFA. However, for specific types of utilization of genetic resources which usually generate a similar scale of benefits, standardization of ABS may be a viable option and, in addition, a powerful instrument to attract recipients who prefer abiding by a set of pre-defined ABS standards over having to negotiate bilateral ABS agreements on a case-by-case basis.

62. The standardization of PIC (and MAT) procedures may, if the agreed standards are adequate and have been developed in line with existing practices and upon consultation of relevant stakeholders, help to reduce transaction costs considerably, and may also help to speed up the administrative decision-making processes.

#### Framework PIC

63. As the international exchange of genetic material is a longstanding practice in the food and agriculture sector, many stakeholders rely on it and business practices have been structured accordingly, often characterized by transnational specialization and division of labour. The different stakeholders managing and using GRFA are interdependent and GRFA are often exchanged in the framework of close working collaborations and partnerships, with many stakeholders acting rather as intermediaries in the value chain, i.e. being neither the original provider nor the end user of a specific GRFA.

64. ABS measures may accommodate these practices by providing for the possibility to conclude framework agreements which authorize access to and utilization of a specified range of genetic resources, possibly limited to specific purposes, provided benefits are shared as and when agreed. In this case users would not have to request access for each genetic resource separately and could still notify every accession they actually accessed and used for research and breeding to facilitate monitoring of compliance with the framework agreement. The framework PIC may be particularly appropriate for sectors which exchange large numbers of germplasm among the different stakeholders along the value chain during research and development.

### **3. Access to traditional knowledge associated with GRFA**

65. According to the Nagoya Protocol, 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.<sup>49</sup> It is important to note that the Protocol requires PIC and MAT for access to traditional knowledge associated with genetic resources irrespective of whether genetic resources are being made available at the same time.

66. The Protocol does not provide guidance as to how “prior and informed consent, approval and involvement by indigenous and local communities” should be obtained. In the case of traditional knowledge associated with GRFA some additional difficulties may arise: much of this knowledge may be shared by several, if not many, communities and thus the question may arise how in such cases a

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<sup>49</sup> Nagoya Protocol, Article 7.

fully valid approval may be obtained, how one proceeds if all except one community have approved access etc.

#### 4. Fair and equitable sharing of benefits

##### (i) *Scope of benefit-sharing obligations*

67. Many GRFA have been collected long before the entry into force of the Nagoya Protocol. For these resources the question is no longer whether or under which conditions they may be accessed as access has already occurred. However, one may raise the question whether the Nagoya Protocol requires the sharing of benefits arising from new or continued uses of genetic resources or associated traditional knowledge accessed prior to the Protocol's entry into force.

68. As mentioned above, the absence of a provision on the temporal scope in the Nagoya Protocol has caused some debate. As has been pointed out, there is nothing in the Nagoya Protocol that would prevent its Parties from applying their national benefit-sharing obligations to (the utilization of) genetic resources that fall outside the scope of the Nagoya Protocol. However, such resources or utilizations would of course not benefit from Articles 15 to 18 of the Nagoya Protocol.

69. In the absence of a provision on the temporal scope, the Protocol's provisions, according to the principle of non-retroactivity of treaties, do not bind a Party in relation to any act or fact which took place or any situation which ceased to exist before the date of the entry into force of the Protocol with respect to that Party.<sup>50</sup> This suggests that the Protocol's access obligations do not apply to genetic resources accessed prior to the Protocol's entry into force. The Protocol also does not seem to require the sharing of benefits arising from (new or continued) uses of genetic resources or associated traditional knowledge accessed prior to the Protocol's entry into force. This is because the relevant provisions of the Protocol relate to genetic resources *provided by a Party to the Protocol* and thus require benefit-sharing only for genetic resources provided at a time when the Nagoya Protocol is in force for the providing country. However, as has been pointed out before, nothing in the Protocol prevents its Parties to adopt national ABS measures which go beyond the obligations set out in the Nagoya Protocol.

70. The temporal scope of the Protocol is a controversial matter and there are voices calling for a decision of the Conference of the Parties acting as Meeting of the Parties to the Protocol in accordance with Article 26.4(a).<sup>51</sup>

71. Governments may wish to consider carefully the implications of expanding the scope of their ABS measures to previously accessed GRFA or traditional knowledge. As most countries are using GRFA originating from other countries, ABS measures covering previously accessed GRFA could lead to considerable uncertainty regarding the status of such resources and, more importantly, severely discourage potential users from utilizing such GRFA for research and development.

##### (ii) *Fair and equitable*

72. The fair and equitable sharing of benefits arising from the utilization of genetic resources is a key component of ABS measures. Benefits may include monetary and non-monetary benefits. According to the Nagoya Protocol, 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 CBD.<sup>52</sup> The Nagoya Protocol requires Parties in addition, to "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

<sup>50</sup> Vienna Convention on the Law of Treaties, Article 28.

<sup>51</sup> According to Article 26.4(a) the Conference of the Parties acting as Meeting of the Parties to the Protocol may "make recommendations on any matters necessary for the implementation of the Protocol".

<sup>52</sup> Nagoya Protocol, Article 5.1.

indigenous and local communities over these genetic resources, are shared in a fair and equitable way with the communities concerned, based on mutually agreed terms.”<sup>53</sup> Moreover Parties “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.”

73. Thus, under the Nagoya Protocol:

- the benefits arising from the *utilization of genetic resources* shall be shared with the Party and, if applicable, with the indigenous and local communities holding the genetic resources and
- the benefits arising from the *utilization of traditional knowledge* associated with the genetic resources shall be shared with the indigenous and local communities holding such knowledge.

The Nagoya Protocol provides no guidance as to what “fair and equitable” is nor does it indicate how benefits should be shared between several beneficiaries if several are eligible, e.g. the country of origin, the indigenous and local communities holding the resources and the indigenous and local communities holding the traditional knowledge associated with the genetic resources.

### (iii) *Beneficiaries*

74. Identifying the proper beneficiary or beneficiaries may be particularly difficult in the case of GRFA. The innovation process for many GRFA, in particular plant and animal genetic resources, is usually of incremental nature and based on contributions made by many different people in different places at different points of time. Most products are not developed out of an individual genetic resource, but with the contributions of several genetic resources at different stages in the innovation process.

75. Sharing the benefits in a fair and equitable way and sharing the benefits with the proper beneficiary may therefore become a major challenge for most subsectors of GRFA, including aquatic and forest genetic resources where breeding technologies play an increasingly important role. The more genetic resources and traditional knowledge associated with them contribute to a final product, the more difficult it may become to share the benefits fairly and equitably with the different countries and indigenous and local communities that contributed genetic resources and/ or traditional knowledge. For some GRFA it may also be difficult to determine their country of origin and the question may arise whether several countries may be considered the country of origin of a genetic resource where the genetic resource has acquired its distinctive properties in the natural surroundings of these countries.

76. Various options may be considered to accommodate the incremental nature of the innovation process typical to many GRFA. Benefits could, for example, be decoupled from individual providers or accessions, pooled in a national benefit-sharing fund or other cooperative arrangements and be distributed in line with agreed policies and disbursement criteria. This option could be considered, in particular, for the distribution of benefits among different beneficiaries at national level (e.g. the state and various indigenous and local communities). However, where the genetic resources originate from different countries, benefit-sharing models would need to go beyond national ABS measures of individual countries and would need to reflect the interests and views of the countries involved.

### (iv) *Monetary and non-monetary benefits*

77. Considering the important non-monetary benefits of GRFA, such as characterization data, research results, capacity-building and technology transfer, ABS measures for GRFA may identify non-monetary benefits which are of particular relevance to the food and agriculture sector. The Nagoya Protocol lists research directed towards food security, taking into account domestic uses of

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<sup>53</sup> Nagoya Protocol, Article 5.2.

genetic resources in the country providing genetic resources, as well as food and livelihood security benefits as possible non-monetary benefits.<sup>54</sup>

78. The terms and conditions of benefit-sharing will often depend on the particularities and specificities of the subsector, the species, the concrete intended use etc. However, access to GRFA will always be a benefit in itself, as is stated for PGRFA in Article 13(1) of the Treaty. Exchanging GRFA for other GRFA may therefore be a model governments may wish to consider as it would allow for access to GRFA without having to negotiate the sharing of monetary benefits and yet offers substantial benefits to both sides.

(v) *Sharing benefits through partnerships*

79. As the international exchange of genetic material is a longstanding practice in the food and agriculture sector, many stakeholders rely on it and business practices as well as scientific collaboration partnerships have been structured accordingly. The different stakeholders managing and using GRFA are interdependent and GRFA are often exchanged in the framework of close working collaborations and partnerships, with many stakeholders acting in the value chain being neither the original providers nor the end users of a the GRFA. To manage the sharing of benefits arising from the utilization of genetic resources and associated traditional knowledge, ABS measures may allow for benefit-sharing arrangements to be part of broader research partnerships agreements. Such framework agreements (see above, paragraph 63), may allow to agree on ABS for a whole range of genetic resources as a package in one framework agreement.

## 5. Monitoring and compliance

80. User country measures, *i.e.* measures that aim to ensure that users of genetic resources within the jurisdiction of a country have accessed the resources in accordance with PIC and that MAT have been established are at the core of the Nagoya Protocol. These measures have to be taken by all Parties of the Nagoya Protocol, whether they are predominantly user or provider countries.

81. The Nagoya Protocol requires each Party to 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 PIC and that MAT have been established, as required by the domestic ABS legislation or regulatory requirements of the other Party. Parties to the Nagoya Protocol shall also take measures to address non-compliance with user country measures and cooperate in cases of alleged violations.<sup>55</sup> To support compliance, Parties to the Nagoya Protocol shall also take measures, as appropriate, to monitor and to enhance transparency about the utilization of genetic resources, which shall include the designation of one or more checkpoints.<sup>56</sup>

82. User country compliance measures, as required by the Nagoya Protocol may in practice pose significant challenges to the food and agriculture sector. A particular problem some sectors of GRFA may face is that the status of many GRFA, including the status of GRFA that may have contributed to them, may be unknown to potential users. The use of such genetic resources as initial source of variation for breeding a new plant, animal, fish or tree may therefore entail the risk that the status of one or more genetic resources used is unknown and that, therefore, the product ultimately bred does not pass the ABS compliance test. Initially, this problem may be relatively small if GRFA accessed prior to the entry into force of the Nagoya Protocol are exempt from the ABS measures. However, as time goes by and more and more products that include material accessed in accordance with PIC and MAT are available, the information regarding the genetic pedigree of the products as well as the relevant ABS agreements will not be necessarily divulged to third parties. Using these products for further breeding, as is quite common in animal, plant, fish as well as tree breeding, would not be a

<sup>54</sup> Nagoya Protocol, Annex, sections 2(m); 2(o).

<sup>55</sup> Nagoya Protocol, Article 15.

<sup>56</sup> Nagoya Protocol, Article 17.

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feasible option for breeders unless they manage to find out which countries provided the material and to agree on MAT with them.