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COMMISSION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE

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EXPERT GROUP ON MICRO-ORGANISM AND INVERTEBRATE GENETIC RESOURCES FOR FOOD AND AGRICULTURE

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DRAFT EXPLANATORY NOTES DESCRIBING, WITHIN THE CONTEXT OF THE ABS ELEMENTS,* THE DISTINCTIVE FEATURES OF MICRO-ORGANISM AND INVERTEBRATE GENETIC RESOURCES FOR FOOD AND AGRICULTURE

TABLE OF CONTENTS

*) The *Elements to Facilitate Domestic Implementation of Access and Benefit-sharing for Different Subsectors of Genetic Resources for Food and Agriculture* (ABS Elements) are available in all official UN languages at: http://www.fao.org/nr/cgrfa/cross-sectorial/abs/

I. INTRODUCTION

1. Sustainable Development Goal (SDG) Target 2.5 and SDG Target 15.6 require countries to "*promote access to and fair and equitable sharing of benefits arising from the utilization of genetic resources and associated traditional knowledge, as internationally agreed*".

2. In 2015, at its Fifteenth Regular Session, the Commission on Genetic Resources for Food and Agriculture (Commission), welcomed the *Elements to Facilitate Domestic Implementation of Access and Benefit-sharing for Different Subsectors of Genetic Resources for Food and Agriculture* (ABS Elements) and invited the Director-General of FAO to bring them to the attention of the Conference.[1] The FAO Conference, at its Thirty-Ninth Session in June 2015, welcomed the ABS Elements and invited Members to consider and, as appropriate, make use of them. The Conference also noted the complementarity between the work of the Commission and 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) in regard to access and benefit-sharing (ABS) for genetic resources.[2]

3. In 2017, at its last session, the Commission "*agreed to produce non-prescriptive explanatory notes describing, within the context of the ABS Elements, the distinctive features and specific practices of different subsectors of genetic resources for food and agriculture (GRFA), to complement the ABS Elements*".[3]

4. The Commission invited Members, observers and other stakeholders to provide relevant inputs for such explanatory notes by electronic means, including on their practical experiences in implementing national ABS measures related to GRFA, and the distinctive features and the specific practices of different subsectors of GRFA.[4]

5. The Commission also requested the Secretariat to convene, in collaboration with the Secretariats of the International Treaty on Plant Genetic Resources for Food and Agriculture (Treaty) and the Convention on Biological Diversity (CBD), an international workshop to assist countries to raise awareness of distinctive features and specific practices of subsectors of GRFA in the context of the ABS Elements. It requested that the open-ended workshop be attended by at least one representative per region of each of the Commission's intergovernmental technical working groups on plant, animal, forest and aquatic genetic resources and seven regionally representative experts from the subsectors of micro-organism and invertebrate GRFA.[5]

6. The International Workshop on Access and Benefit-Sharing for Genetic Resources for Food and Agriculture (Workshop) was held in Rome, Italy, from 10 to 12 January 2018. The Workshop considered inputs received from Members, observers and other stakeholders and provided a forum for participants to exchange information, experiences and views. As requested by the Commission, the Workshop provided outputs for subsequent elaboration into non-prescriptive explanatory notes describing, within the context of the ABS Elements, the distinctive features and specific practices of different subsectors of GRFA.[6] More information on the Workshop, including submissions received from Members, observers and other stakeholders, is available on the Commission's website. The outputs of the Workshop as well as the Proceedings have been made available to the Expert Group on Micro-organism and Invertebrate Genetic Resources for Food and Agriculture (Expert Group).[7]

7. This document proposes draft non-prescriptive explanatory notes describing, within the context of the ABS Elements, the distinctive features and specific practices of micro-organism and invertebrate genetic resources for food and agriculture (MIGR). It briefly introduces the ABS Elements (II) and presents the distinctive features of MIGR (III). It further identifies, taking into account the outputs of

[1] CGRFA-15/15/Report, paragraph 22(ii).
[2] C 2015/REP, paragraph 52.
[3] CGRFA-16/17/Report, paragraph 25 (iii).
[4] CGRFA-16/17/Report, paragraph 25 (iv).
[5] CGRFA-16/17/Report, paragraph 25 (v).
[6] CGRFA-16/17/Report, paragraph 25(v), e–g.
[7] CGRFA/EG-MIGR-1/18/Inf.3. Proceedings of the International Workshop on Access and Benefit-Sharing for Genetic Resources for Food and Agriculture (FAO, 2018).

the Workshop, areas where explanatory notes could further the aim of the ABS Elements to assist governments in taking into account, in the development, adaptation or implementation of ABS measures, the importance of MIGR, their special role for food security and the distinctive features of MIGR, while complying, as applicable, with international ABS instruments (IV).

II. ELEMENTS TO FACILITATE DOMESTIC IMPLEMENTATION OF ACCESS AND BENEFIT-SHARING FOR DIFFERENT SUBSECTORS OF GENETIC RESOURCES FOR FOOD AND AGRICULTURE

8. The Nagoya Protocol has been hailed as a giant step towards the implementation of the third objective of the Convention on Biological Diversity (CBD): the fair and equitable sharing of benefits arising out of the utilisation of genetic resources, including by appropriate access to them. Implementing this third objective should contribute to the conservation of biological diversity and the sustainable use of its components, the other two objectives of the CBD.

9. The Nagoya Protocol requires its Contracting Parties to consider, in the development and implementation of ABS measures, the importance of GRFA and their special role for food security.[8] It also explicitly recognizes the importance of genetic resources for food security, the special nature of agricultural biodiversity, its distinctive features and problems needing distinctive solutions, the interdependence of all countries with regard to GRFA as well as their special nature and importance for achieving food security worldwide and for sustainable development of agriculture in the context of poverty alleviation and climate change, and acknowledges in this regard the fundamental role of the Treaty.[9]

10. In 2011, the Commission initiated a process that ultimately led to the preparation of the ABS Elements. The Commission established an Ad Hoc Technical Working Group on Access and Benefit-sharing for Genetic Resources for Food and Agriculture that, *inter alia*, identified "relevant distinctive features of the different sectors and subsectors of genetic resources for food and agriculture".[10]

11. In 2013, the Commission replaced the Ad Hoc Working Group by the Team of Technical and Legal Experts on Access and Benefit-Sharing (ABS Expert Team) and mandated the latter to prepare, in collaboration with the Commission's Working Groups on plant, animal and forest genetic resources, draft ABS Elements, which would be "*voluntary tools to assist national governments, not new international access and benefit-sharing instruments*".[11]

12. In 2015, at its Fifteenth Regular Session, the Commission welcomed the ABS Elements. Subsequently, the FAO Conference, the highest Governing Body of FAO, at its Thirty-Ninth Session, welcomed the ABS Elements and invited Members to consider and, as appropriate, make use of them.[12]

13. The ABS Elements aim to assist governments considering developing, adapting or implementing ABS measures to take into account the importance of GRFA, their special role for food security and the distinctive features of the different subsectors of GRFA, while complying, as applicable, with international ABS instruments.

14. The ABS Elements recommend, in particular, to:

- Consider, in the development, adaptation or implementation of ABS measures, the distinctive features of the subsector of GRFA concerned, including its activities, socio-economic environment and use and exchange practices;
- identify and consult relevant governmental entities and non-governmental stakeholders holding, providing or using GRFA;

[8] Nagoya Protocol, Article 8(c).
[9] Nagoya Protocol, Preamble.
[10] CGRFA-14/13/6.
[11] CGRFA-14/13/Report, paragraph 40(xv).
[12] C 2015/REP, paragraph 52(c) & (d).

- integrate ABS measures with broader food security and sustainable agricultural development policies and strategies;
- consider and evaluate available options for ABS measures;
- integrate the implementation of ABS measures into the (existing) institutional landscape;
- communicate and raise awareness of ABS measures; and
- assess *ex ante* and monitor the effectiveness and impact of ABS measures for GRFA.

15. The ABS Elements also provide guidance with regard to issues of particular relevance to ABS for specific subsectors of GRFA, such as plant and animal genetic resources. While the ABS Elements thus address issues of particular relevance to GRFA, the Commission, at its last session, concluded that there is a need for more detailed explanatory notes describing, within the context of the ABS Elements, the distinctive features of GRFA.

III. DISTINCTIVE FEATURES OF MICRO-ORGANISM AND INVERTEBRATE GENETIC RESOURCES FOR FOOD AND ARGICULTURE

16. Starting in 2012, the Commission, in collaboration with its intergovernmental technical working groups on plant, animal and forest genetic resources, identified a list of distinctive features of genetic resources for food and agriculture, which is annexed to the ABS Elements. This work was based, inter alia, on studies commissioned by the Commission Secretariat, including on the use and exchange of MIGR.[13] While these distinctive features aim to reflect an equilibrium between all subsectors of food and agriculture, including MIGR, not every feature is necessarily applicable to each and every GRFA. Moreover, the features are distinctive, but not necessarily unique to GRFA.

17. Table 1, prepared on the basis of the outcomes of the Workshop[14], presents the distinctive features and highlights those features that are considered particularly relevant (marked in the table by plus signs [+]) or less (or not) relevant (marked in the table by minus signs [–]) to MIGR. In reviewing the table, features the Expert Group considers neutral or relevant only to parts of micro-organism or invertebrate genetic resources could be marked in the table by grey shades.

IV. DRAFT EXPLANATORY NOTES DESCRIBING, WITHIN THE CONTEXT OF THE ABS ELEMENTS, THE DISTINCTIVE FEATURES OF MICRO-ORGANISM AND INVERTEBRATE GENETIC RESOURCES FOR FOOD AND AGRICULTURE

18. The following draft explanatory notes aim to (i) provide relevant background information on MIGR to policy-makers developing, adapting or implementing ABS measures and (ii) clarify some of the issues raised in the ABS Elements as they are relevant to MIGR.

Background information on micro-organism and invertebrate genetic resources for food and agriculture

19. ABS policy-makers may find it useful to receive some background information on the use and exchange of MIGR. Explanatory notes could therefore explain that:

> Micro-organism genetic resources (MGR) and invertebrate genetic resources (IGR) have been used as tools for the production of products for millennia.
>
> *Micro-organism genetic resources*[15]
> The number of MGR currently used for food or agriculture applications is small relative to the huge number of species potentially useful, in part because of technical limitations to the culturing of many living micro-organisms. Agriculture applications of MiGR are nevertheless quite diverse: soil fertility improvement and plant growth promoting agents; biological control;

[13] Background Study Paper No. 46; No. 47 and No. 59.
[14] CGRFA/EG-MIGR-1/18/Inf.3, pp.11-12.
[15] This section draws on Background Study Paper No. 59, pp.9-10.

TABLE 1: DISTINCTIVE FEATURES OF MICRO-ORGANISM AND INVERTEBRATE GENETIC RESOURCES FOR FOOD AND AGRICULTURE[16]

		MGR	IGR
A. Role of GRFA for food security	A.1 GRFA are an integral part of agricultural and food production systems and play an essential role for achieving food security and the sustainable development of the food and agriculture sector.	+	+
	A.2 Plant, animal, invertebrate and micro-organism GRFA form an interdependent network of genetic diversity in agricultural and aquatic ecosystems respectively.	+	+
B. Role of human management	B.1 (a) The existence of most GRFA is closely linked to human activity. (b) Many GRFA can be regarded as human-modified forms of genetic resources.	(a): - (b): +	-
	B.2 The maintenance and evolution of many GRFA depend on continued human intervention, and their sustainable utilisation in research, development and production is an important instrument to ensure conservation.	-	-
C. International exchange and interdependence	C.1 Historically, GRFA have been widely exchanged across communities, countries and regions over often long periods of time, and a relevant part of the genetic diversity used in food and agriculture today is of exotic origin.	+	+
	C.2 Countries are interdependent with regard to GRFA and act both as providers of some GRFA and as recipients of others.	+	+
	C.3 The international exchange of GRFA is essential to the functioning of the sector, and its importance is likely to increase in future.	+	+
D. Nature of the innovation process	D.1 The innovation process for GRFA is usually of incremental nature and the result of contributions made by many different people, including indigenous and local communities, farmers, researchers and breeders, in different places and at different points in time.	-	-
	D.2 Many GRFA products are not developed out of an individual genetic resource, but with the contributions of several GRFA at different stages in the innovation process.	-	-
	D.3 Most products developed with the use of GRFA can in turn be used as genetic resources for further research and development, which makes it difficult to draw a clear line between providers and recipients of GRFA.	+	+
	D.4 Many agricultural products reach the market place in a form in which they may be used both as biological resources and as genetic resources.	+	+
E. Holders and users of GRFA	E.1 (a) GRFA are held and used by a broad range of very diverse stakeholders. (b) There are distinct communities of providers and users with respect to the different subsectors of GRFA.	(a): - (b): +	(a): - (b): +
	E.2 The different stakeholders managing and using GRFA are interdependent.	-	-
	E.3 A significant amount of GRFA is privately held.	+	-
	E.4 An important part of GRFA is held and can be accessed *ex situ*.	+	-
	E.5 An important part of GRFA is conserved *in situ* and on farm under different financial, technical and legal conditions.	+	+
F. GRFA exchange practices	F.1 The exchange of GRFA takes place in the context of customary practices and existing communities of providers and users.	+	+
	F.2 An extensive transfer of genetic material between different stakeholders along the value chain occurs in research and development.	+	-
G. Benefits generated with the use of GRFA	G.1 (a) While the overall benefits of GRFA are very high, (b) it is difficult to estimate at the time of the transaction the expected benefits of an individual sample of GRFA.	(a): + (b): +	(a): - (b): +
	G.2 The use of GRFA may also generate important non-monetary benefits.	+	+
	G.3 The use of GRFA may lead to external effects going far beyond the individual provider and recipient.	+	+

[16] As proposed by the experts on micro-organism and invertebrate genetic resources during the *International Workshop on Access and Benefit-Sharing for Genetic Resources for Food and Agriculture* (Rome, 10–12 January 2018): CGRFA/EG-MIGR-1/18/Inf.3.

beneficial symbiosis in the digestive tracts of livestock; production of chemicals of direct benefit to agriculture; catalysts in agro-industrial processes; understanding and surveillance of microbial plant and animal (including fish) pathogens. Food applications are also quite varied: traditional fermentation (fermented foods); industrial fermentation of alcohol and wines; dairy production; probiotics; feed additives; production of chemicals of benefit to food production, including vitamins and organic acids; environmental damage remediation and purification of soils and water; and understanding and surveillance of health-hazardous micro-organisms such as food toxins and food-borne pathogens.

Use of MGR is mainly done by screening vast quantities of naturally occurring microbes or microbial resources conserved in purified form in *ex situ* collections. Synthetic biology may involve genetic improvement, but this remains a marginal phenomenon although it may grow in the future.

Microbial culture collections (MCCs) are at the heart of the sector. All known culture collections with major holdings in food and agriculture belong to the public sector or are non-profit organizations with major governmental funding. They fulfil several objectives: procurement of cultures and *ex situ* conservation of micro-organisms; provision of authentic microbial cultures to industries and academic and research institutes; provision of identification, freeze-drying and other microbiology-related services; depository of cultures deposited for patent purposes; and research on microbial diversity, taxonomy and related areas. The majority of large MCCs are situated in OECD countries, where the majority of deposits, distribution and exchange also occur. However, many countries are actively involved in collecting and exchanging micro-organisms internationally, and microbial collections from non-OECD countries represent an important and growing subset in the overall network of culture collections. MGR currently used in agriculture and food systems have been collected both from tropical and subtropical species-rich agro-ecosystems and from non-tropical areas.[17]

Because each MCC contains an important set of unique strains (an average of 40 percent of the strains in each collection are unique), collaboration and exchange among MCCs is common.[18] These exchanges, as well as flows from *in situ* to *ex situ*, occur in all geographical directions. Whereas historically these exchanges were quite informal, there has been a noticeable evolution towards formalization in recent decades.[19] In particular, MCCs are moving increasingly towards the use of legal instruments: acquisition agreements when acquiring materials and MTAs when distributing them. Some important limitations, especially on further distribution to third parties, generally apply even for non-commercial research purposes, mainly for quality management purposes and to address biosecurity issues. When commercial development is involved, additional agreements with the MCC, the initial depositor and/or the country of origin are required, with the general understanding that recipients of materials hold the responsibility to take all step necessary for compliance with ABS measures as they may apply to the material, including with regard to prior informed consent from the country of origin. Exchange between qualified MCCs may involve simplified procedures. Both OECD and non-OECD collections include clauses related to legitimate/legal exchange in their MTAs, which allow public culture collections that comply with strict quality-management criteria to further distribute microbial research material that they have received from other public MCCs (so-called legitimate exchange). European Biological Resource Centres Network (EBRCN) and Asian Consortium of Microbiological Resources (ACM) are making efforts to make the cultures available within the networks with few restrictions. However, in response to growing commercial opportunities and to financial restrictions on government spending on culture collections in some countries in the 1990s, this club model is threatened. Some MCCs have departed from the sharing and collaborating practices and have introduced restrictive MTAs even for exchange between MCCs.[20]

[17] Background Study Paper No. 46, chapter II.
[18] Ibid.
[19] Ibid.
[20] Ibid.

The culture collection community has developed a distinct body of codes of conduct, standards for best practices and model documents addressing specific aspects of access and benefit-sharing.[21]

Invertebrate genetic resources[22]

Invertebrates play a key role for agricultural systems. They participate in essential soil processes, provide biological control of crop pests and provide pollination from which many of the world's most important crops benefit in terms of yield and/or quality.[23]

For the purpose of these Explanatory Notes, only invertebrate biological control agents are considered under the term IGR. Invertebrate pollinators are covered by the notes relating to animal genetic resources.

The biological control (BC) of pests plays an important role in integrated pest management approaches in the food and agriculture sector. It is based on the use of natural enemies of pests, often referred to as BC agents. These are predators, parasitoids and pathogens of invertebrate pests, and herbivores that attack weed pests.

There are two main categories of BC. Classical BC is the introduction of one or more BC agents, usually from a pest's area of origin, to control the pest in an area it has invaded. Once introduced, the BC agent becomes established, reproduces and spreads. The BC agent then continues to have its effect on the target pest without the need for any further interventions. Augmentative BC involves the production and release of BC agents – indigenous or exotic – into specific crop situations, where they cause mortality in the target pest, but are not expected to persist from one cropping cycle to the next.[24]

The research and development process leading to the use of a new BC agent involves various steps that require access to genetic resources. The largest number of exchanges of genetic material takes place in the early stages of research and development, when it is necessary to study the target pest and its natural enemies. Preliminary surveys of the target pest and its natural enemies will often need to be carried out in several countries, and specimens of pests and natural enemies normally need to be exported for identification and taxonomic studies. Detailed studies on natural enemies to assess their potential as BC agents can, in part, be carried out in the source country, while host-specificity studies involving plants or animals not naturally occurring in the source country are best carried out in quarantine in the target country or in a third country. Overall, only a small fraction of all the species found and studied will actually be recommended for use and released as BC agents. Once a specific BC agent has been identified and is being applied for biological control purposes, there is little need for further exchange of genetic material.[25]

The type of genetic material used in BC consists primarily of living organisms used as BC agents. Organisms are mostly collected *in situ* and exported as live specimens. Product development does not normally include genetic improvement of the BC agent as such. At most, it sometimes entails discrimination between populations in terms of biological characteristics that affect their adaptation to the target country or target pest. While most of the genetic diversity used in BC can consequently be regarded as wild, it is at the same time closely linked to agricultural production environments.

A particular feature of classical BC is the public good nature of its activities. As classical BC agents establish and reproduce themselves in the target environment and from that point on are freely available, it is not possible to make any profit from their production and release. Consequently, classical BC is exclusively run by the public sector, mainly through national and

[21] For an overview: McCluskey K *et.al.*. 2017. The U.S. Culture Collection Network responding to the requirements of the Nagoya Protocol on Access and Benefit Sharing. mBio 8, Table 1.
[22] This chapter draws on Background Study Paper. No. 59, pp. 9-12.
[23] Matthew J.W. Cock et.al. 2012. The positive contribution of invertebrates to sustainable agriculture and food security. CAB Reviews.
[24] Background Study Paper No. 47.
[25] Ibid.

international research institutions paid by governments or development agencies. Augmentative BC, in turn, is a relatively recently developed activity. The history of commercial mass production and sale of natural enemies spans less than 50 years. It is carried out by a relatively small number of companies worldwide, of which most are located in developed countries and the majority are medium or small-sized. Even though augmentative BC agents are mainly produced for high-value crops such as greenhouse vegetables and ornamentals, the average profit margin is usually quite low. While the development of rearing, distribution and release methods is mainly carried out by commercial producers, public research institutions and universities sometimes play an important role in the early stages of research and development.

The international exchange of genetic resources relevant for BC plays a critical role in the functioning of the sector. The importance of exchange can easily be understood by looking at the case of classical BC. The introduction of a new classical BC agent is always linked to the use of exotic genetic material, as it follows the movement of target crops and pests around the world. In fact, the great majority of classical BC transfers are intercontinental, which is to be expected as the target pests are themselves introduced species, often of intercontinental origin. Once a BC agent has been used successfully in one country, the opportunity is often taken to repeat the success in other countries through redistribution of the agent. Consequently, the international flow of genetic resources related to BC has been quite significant, involving several thousand BC agent species from more than a hundred countries, and introductions into an even higher number of countries.[26]

As the BC sector is composed of a small number of actors, exchanges of genetic material have essentially been regulated through informal means, mainly by professional networks, which may be institutionalized or simply operate at a personal level. However, the informal character of exchange practices does not necessarily mean that no terms and conditions apply. Established "customary" practices for use and exchange may, for example, foresee the sharing of results obtained from the use of the material or, in the case of research, the joint publication of results. In addition, in the augmentative BC sector, exchange practices are also regulated through classical commercial practices such as licensing production (i.e. larger augmentative BC companies license production to smaller companies as a way of facilitating the establishment of new companies in new countries to supply new markets) and intercompany supply (i.e. commercial augmentative BC companies sometimes buy BC agents from each other).[27]

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

20. The ABS Elements recommend consulting government entities and non-governmental stakeholders holding, providing or using GRFA.[28] Explanatory notes could explain that:

It is important to note that research and development on MIGR lies in most countries in the hands of very different stakeholders. These include academic researchers, the private sector, and business associations representing specific stakeholders. All these stakeholders should be consulted in the development and implementation of ABS for MIGR. Their involvement will

be important to allow policy-makers and regulators to gain insight into the diversity and specificities of MIGR and related research and development activities.Existing use and exchange practices should be taken into account as well as best practices that are either already in use or have been proposed by stakeholders.

MIGR play an important role for sustainable agriculture: as plant growth promoting agents; for biological control; in the digestive tracts of livestock; for the production of chemicals of direct benefit to agriculture; as catalysts in agro-industrial processes; for understanding and surveillance of microbial plant and animal (including fish) pathogens; and environmental damage remediation and purification of soils and water. MGR may also be used for food processing, such as traditional or industrial fermentation, the production of alcohols, dairy

[26] Ibid.
[27] Ibid.
[28] ABS Elements, paragraph 15.II.

products, probiotics and feed additives; the production of chemicals of benefit to food and feed production (vitamins, organic acids, etc.) and understanding and surveillance of health-hazardous micro-organism, such as food toxins and food-borne pathogens. IGR are essential for important soil processes, provide biological control of crop and animal (incl. fish) pests and provide pollination.

Integration of ABS measures with broader food security and sustainable agricultural development policies and strategies

21. The ABS Elements recommend considering ABS for GRFA in the wider context of sustainable agricultural development and food security.[29] Explanatory notes could therefore explicitly refer to policies and legislation in the areas of, for example, food security, pollination, and biological control, which could either integrate or refer to relevant provisions for ABS for MIGR:

> In many countries ABS measures have been or are being developed as stand-alone legislation or policy. It is, however, important to develop ABS measures in harmony with other related policies and to integrate them with these policies, such as regulatory frameworks for biological control, pesticides and food safety and policies, such as food security strategies. It is likewise important to involve from the outset the different communities behind the different functional groups of MIGR in the development and implementation of ABS measures to ensure that policy-makers have a full understanding of the taxonomic complexity and multiplicity of functions of the sector, of its current use and exchange practices and of potential effects ABS measures may have on research and development of MIGR.

Integration of implementation of ABS measures into the institutional landscape

22. The ABS Elements recommend "using and adapting, as appropriate, existing structure administrative procedures and sectoral practices [as they] may facilitate the smooth identifying existing operationalization and implementation of ABS measures.[30] Explanatory notes could explain that:

> The responsibility for the national ABS framework is often with one single competent authority. In fact, national interim reports on the implementation of the Nagoya Protocol show that many countries have chosen to select a single competent authority for ABS, rather than taking a sector or subsector-specific approach. However, several authorities within one country may share the responsibility for ABS and thus the different functionalities of MIGR could fall within the competence of a specialized authority responsible for a specific application/function of MIGR. Whether such sharing of ABS competences is useful will depend on the institutional landscape and other country-specific circumstances.

Communication of, and awareness-raising regarding, ABS measures for potential providers and users of GRFA

23. The ABS Elements stress the importance of communicating ABS measures to potential providers, holders and users of GRFA.[31] Explanatory notes could explain that:

> The global distribution and exchange of micro-organisms that are publicly available for research is mainly in the hands of MCCs. Various initiatives of MCCs, such as MOSAICC, the Micro-Organisms Sustainable use and Access regulation International Code of Conduct[32], have led to an increased awareness of MCCs of the potential implications of access and benefit-sharing for the distribution and use of MIGR.
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> Material Transfer Agreements (MTA), nowadays used by most MCCs, usually impose the responsibility for complying with applicable ABS measures on the recipient of materials. In other words, receiving material from an MCC does usually not imply that the material can be freely used. Commercial uses of the material are often prohibited, unless explicitly authorised.

[29] ABS Elements, paragraph 15.III.
[30] ABS Elements, paragraph 15.V.
[31] ABS Elements, 3.VI.
[32] http://bccm.belspo.be/projects/mosaicc

It is furthermore the recipient's sole responsibility to obtain necessary intellectual property licenses and ABS permits, as applicable.[33]

Raising the awareness and improving relevant knowledge of recipients of materials from MCCs, for example on the occasion of scientific conferences and workshops, might nonetheless be useful to increase the awareness of ABS measures. More specifically, it will be important to guide and possibly assist stakeholders as to how they may obtain the information necessary to initiate the necessary approval procedures.

Access and benefit-sharing for genetic resources for food and agriculture: the international legal framework

24. The ABS Elements refer to three international instruments, which are part of the global framework for ABS for genetic resources: the CBD, the Nagoya Protocol and the Treaty.[34] Explanatory notes could explain that:

In addition to the Treaty, the Convention and the Protocol, other instruments relevant to certain MIGR should be taken into account in the development, adaptation and implementation of ABS measures.

The FAO Conference, its 39th session in 2015, adopted the *Revised World Soil Charter* which states:

> "Soils are a key reservoir of global biodiversity, which ranges from micro-organisms to flora and fauna. This biodiversity has a fundamental role in supporting soil functions and therefore ecosystem goods and services associated with soils. Therefore it is necessary to maintain soil biodiversity to safeguard these functions."[35]

While the Charter does not specifically address access and benefit-sharing issues, it can be concluded from it that access to soil micro-organisms is of pivotal importance to the delivery of soil functions and the ecosystem services associated with soils.

The *Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms*, adopted in 2005 by the 7th session of the Interim Commission on Phytosanitary Measures, recommend phytosanitary measures for the safe usage of biological control agents and other beneficial organisms. Although the Guidelines are focussed on risk assessment and management, the administrative procedures National Plant Protection Organization's (NPPOs) should follow, as recommended by the Guidelines, prior to the import and export of biological control agents or other beneficial organisms resemble to some extent the ABS procedures of the Nagoya Protocol.[36]

Rationale of access and benefit-sharing measures for genetic resources for food and agriculture

25. According to the ABS Elements, "ABS measures may be instrumental in furthering the achievement of food security and improving nutrition. (…) Therefore, ABS measures aimed at achieving food security and the conservation of GRFA should aim to facilitate and actively encourage the continued use and exchange of GRFA for research and development and benefit-sharing".[37] Explanatory notes could explain that:

While the importance of access to plant and animal genetic resources is obviously indispensable for the improvement and adaptation of crops and livestock and, thus, for food security, the importance of MIGR for food security may be less obvious to some. The reason might be that for a long time the service of pollinators and soil micro-organisms, to name just a few, has been taken for granted and therefore received little attention in agricultural management. ABS

[33] See, for example, the BCCM Material Transfer Agreement.
[34] ABS Elements, Chapter I.
[35] Revised World Soil Charter, paragraph 8.
[36] IPPC. ISPM 3 - Guidelines for the export, shipment, import and release of biological control agents and other beneficial organisms. Published in 2017.
[37] ABS Elements, Chapter 5.

measures aimed at achieving food security and the conservation of MIGR could therefore, as an objective, also mention the facilitation of exchange, sustainable use and conservation of MIGR as an important contribution to food security.

Flows of germplasm, including international flows and possible gaps in ABS measures

26. The ABS Elements recommend that in developing, adapting and implementing ABS measures, the relevance of germplasm flows should be considered.[38] Explanatory notes could explain that:

> *Micro-organism genetic resources*
> Most micro-organisms can easily be spread by host organisms, wind and water, or attached to any organic material. However, the "ubiquity" of micro-organisms does not mean that every strain can be found everywhere. There is growing recognition that microbes can exhibit biogeographical patterns in spite of their widespread availability. This means that certain micro-organisms are only available in specific habitats and cannot be found elsewhere.[39]
>
> Besides this interdependence in access to *in situ* MGR, there is interdependence with regard to material stored *ex situ* in MCCs. The largest MCC, with approximately 25,000 strains, holds less than 2 per cent of the total number of strain holdings in the collections united under the World Federation of Culture Collections (WFCC) and only an estimated 1.5 per cent of the total biodiversity of unique strain holdings in the WFCC collections. Many collections have specialized in various areas of microbial research and it is this specialization and the resulting creation of internationally recognized reference culture collections used and referred to in most follow-up research that has led to close international collaboration and exchange of materials and, thus, to a situation that has been considered "*functional interdependency in access to ex situ strains on a global scale*."[40]
>
> *Invertebrate genetic resources*
> Similarly, throughout the history of BC, BC agents that proved effective in one country have been forwarded to other countries effected by the same pest problem. The international exchange of genetic resources relevant for BC plays, thus, a critical role in the functioning of the BC sector. The great majority of classical BC transfers are intercontinental, which is to be expected as the target pests are themselves introduced species, often of intercontinental origin. The international flow of genetic resources related to BC has therefore been quite significant, involving several thousand BC agent species from more than a hundred countries, and introductions into an even higher number of countries.[41]

Categories of genetic resources use covered by ABS measures

27. The ABS Elements stress that ABS measures need to be clear as to which GRFA are covered by relevant access provisions and which are not.[42] This consideration applies likewise to the temporal and the subject-matter scope of ABS measures. Explanatory notes could explain that:

> IGR, such as insects, snails, molluscs or crustaceans, made available for direct use, e.g. for trade, consumption or multiplication, can often also be used for research and development, including breeding. There is a concern that genetic resources that have been originally accessed for direct use could end up being used for research and development. Some laws therefore require PIC and MAT for access to genetic resources for both research and development and direct use.
>
> However, regulating access to IGR for direct use may have an unwanted impact on trade of IGR, such as fingerlings and broodstock. If ABS measures refrain from regulating access to IGR that may be directly used, they could still require PIC and benefit-sharing where the

[38] ABS Elements. paragraph 15 I.e.
[39] Background Study Paper No. 46, p. 31.
[40] Background Study Paper No. 46, pp. 32.
[41] Background Study Paper No. 47, Annex I.
[42] ABS Elements, paragraph 36.

intention of the recipient changes and IGR originally intended for direct use are being used for research and development.

Most MCC require nowadays depositors to indicate the country of origin of materials they wish to deposit. It appears that most MCC also require information regarding the prior informed consent of the country of origin of the material.[43] Many MCC also require recipients of material to comply with the relevant ABS provisions of the country of origin, often irrespective of whether or not the material has been collected and deposited prior to or after the entry into force of the Nagoya Protocol. This means that MTAs of MCC might at times require PIC and MAT for materials which are excluded from the scope of ABS measures under the jurisdiction under which the MCC operates. ABS measures and MCC MTAs should therefore be clear as to whether PIC and MAT are required for research and development on pre-Nagoya MGR.

MIGR provided by countries of origin/ countries that acquired them in accordance with the CBD

28. Under the Nagoya Protocol, "[…] 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 […]." The ABS Elements refer to difficulties "to determine with certainty the country of origin" of GRFA as many GRFA have been widely exchanged across regions countries and communities and often over long period of time.[44] Explanatory notes could suggest:

The Nagoya Protocol requires PIC of the Party providing genetic resources "that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention." ABS measures should clarify whether PIC (and MAT) are also required where genetic resources have been received from a country other than the country of origin and have been collected prior to the entry into force of the Nagoya Protocol ("indirect acquisition of genetic resources"). ABS measures could point out that irrespective of national ABS laws recipients of genetic resources have to comply with conditions they accepted under bilateral agreements, such as MTAs.

Utilisation of micro-organism and invertebrate genetic resources

29. "Access to genetic resources for their utilisation", is subject to prior informed consent under the Nagoya Protocol. "Utilization" means "to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the use of biotechnology".[45] The ABS Elements point out that it may be difficult in some cases to decide whether a GRFA is utilized within the meaning of the Nagoya Protocol.[46] Explanatory notes could explain that:

There is a need to clearly identify activities related to MIGR that are considered "utilisation" and those which are not. It is important to note that there are certain 'upstream' activities which are related to (or carried out in support of) research on MIGR but are as such not "utilisation", e.g. the maintenance and management of collections for conservation purposes, including storage, rearing, multiplication, identification and evaluation of MIGR. Similarly, the mere description of genetic resource in phenotype-based research, such as morphological analysis might normally not qualify as utilisation. One question ABS measures could address is whether such 'up-stream' activities, if carried out for the purpose of research and development, qualify as "utilisation" or whether as each of them by itself does not imply research and development does not constitute "utilization", even if their ultimate purpose is to feed into research and development on the biological or chemical composition of MIGR.

As a type of 'litmus test', it has been suggested, users should ask themselves whether what they are doing with the genetic resources creates new insight into characteristics of the genetic resource which is of potential benefit to the development of a product. If this is the case, the

[43] Background Study Paper No. 46, p. 49.
[44] ABS Elements, pargraph 35.
[45] Nagoya Protocol, Article 2.
[46] ABS Elements, paragraph 46–48.

> activity would go beyond mere description, should be considered research and therefore fall under the term "utilisation."[47]

Research and development for food and agriculture

30. The ABS Elements refer to Article 8(c) of the Nagoya Protocol, which calls upon Parties to consider the importance of GRFA and their special role for food security in the development of ABS legislation or regulatory requirements. Explanatory notes could explain that:

> To acknowledge the special role of MIGR for food security, governments could consider treating access to and utilisation of them differently if they are intended to contribute to food and agricultural research and development. It is important to note that no country is under an obligation to restrict access to genetic resources within its jurisdiction.

Commercial/non-commercial research and development

31. ABS measures sometimes distinguish between commercial and non-commercial utilisation of genetic resources.[48] Explanatory notes could explain that:

> Many activities related to MIGR for food and agriculture ultimately aim at the development of a product and might therefore be considered "commercial". Depending on the definition of the term "commercial" the sectors using MIGR for research and development might not greatly benefit from a distinction between commercial and non-commercial activities and simplifications granted by ABS measures for the latter. However, policymakers could consider to exclude certain research and development activities from the application of ABS measures, in particular the research and development on genetic resources for classical biocontrol which due to its nature defies commercialization.

Standard and fast-track procedures

32. The ABS Elements recognize that governments may wish to establish fast-track procedures for certain situations, e,g. for access to certain materials or materials to be used for certain purposes. Explanatory notes could explain:

> Fast-track procedures could be foreseen in ABS legislation (as well as MTA and material acquisition agreements, MAAs) for cases of emergency, for example for MIGR required for biocontrol or plant and animal health.[49]

Standardization of PIC and MAT

33. The ABS Elements encourage governments to consider the different options of authorization procedures, including the option of standardizing procedures, terms and conditions. The ABS Elements explicitly refer to the Standard Material Transfer Agreement of the Treaty, as a "fully functioning precedent" for standardization of PIC and MAT.[50] Explanatory notes could explain:

> Best practices, model MTAs and MAAs have been developed for various subsectors of MIGR.[51] These models may inspire the development of MTAs and MAAs stakeholders of the relevant sub-sectors may agree on with a view to facilitate access and benefit-sharing and avoid the need to conclude bi-lateral agreements on a case-by-case basis. ABS measures could allow for and, in fact, encourage the use of MTA and MAAs for MIGR.

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[47] Commission notice — Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union (2016/C 313/01)

[48] ABS Elements paragraph 50.

[49] See, for example, MOSAICC, section I.2.

[50] ABS Elements, paragraph 57.

[51] For an overview: McCluskey K *et.al.*. 2017. The U.S. Culture Collection Network responding to the requirements of the Nagoya Protocol on Access and Benefit Sharing. mBio 8, Table ; Mason, G. et al. 2018. Best practices for the use and exchange of invertebrate biological control genetic resources relevant for food and agriculture. Biocontrol: 63. pp. 149-154. Supplementary information.

Benefit-sharing through cooperation agreements

34. The ABS Elements stress the importance of sharing monetary and non-monetary benefits and note that the terms and conditions of such benefit-sharing will often depend on the particularities and specificities of the subsector, the species, the concrete intended use, etc.[52] The ABS Elements note that GRFA are often exchanged in the framework of working collaborations and partnerships. ABS measures could therefore allow for benefit-sharing arrangements tailor-made to the subsector's collaboration and partnership practices.[53] Explanatory notes could explain that:

> ABS measures could encourage stakeholder to address ABS issues, where possible and appropriate, as part of scientific partnership agreements and within existing informal and formal networks. It has been argued that "informal cooperative networks of biological control practitioners around the world, involving scientists working with government agencies, intergovernmental organizations, international agricultural research centres, universities, industries, etc, are best suited to assist biological control practitioners for the free multilateral exchange of invertebrate biological control agents."[54]

V. GUIDANCE SOUGHT

35. The Expert Group is invited to:

- review and revise, as appropriate, the relevance of distinctive features of GRFA, as indicated in Table 1 of this document, to MIGR; and
- review and revise, as appropriate, the explanatory notes contained in this document, and suggest additional explanatory notes, for submission to the Commission.

[52] ABS Elements, paragraph 73.
[53] ABS Elements, paragraph 74.
[54] Mason, G. et al. 2018. Best practices for the use and exchange of invertebrate biological control genetic resources relevant for food and agriculture. Biocontrol: 63. p. 151