Challenge session: "New legal landscape guiding access and benefit-sharing of animal genetic resources"

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I. The ABS challenge session

In 2016, at the EAAP meeting in Dublin, the EAAP Working Group on Animal Genetic Resources organized a challenge session (no 7) "New legal landscape guiding access and benefit sharing of animal genetic resources". The aim of the session was to discuss the potential impact of the Nagoya Protocol and implementing legislation at the EU level on animal breeding and research. The session included a number of invited lectures and a round table discussion with all speakers.

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (CBD, 2010) is an international treaty aimed at supporting implementation of the third objective of the Convention on Biological Diversity. It came into force on 12th October, 2014. The Nagoya Protocol has one objective: the fair and equitable sharing of the benefits arising from the utilization of genetic resources and associated traditional knowledge. This objective comes from the fact, that states have the sovereign right to exploit their own resources pursuant to their own environmental policies (Article 3 of the Convention). By 18th August, 2017, 100 countries ratified this treaty, including 39 countries from Africa and 25 countries from the European region as well as the EU.

The first presentation (Elzbieta Martyniuk, SGGW) provided information on the Nagoya Protocol and its three building blocks namely: access to genetic resources and associated traditional knowledge, sharing of benefits arising from their utilization, and compliance, both of the Parties to this treaty and of users of genetic resources.

Access to genetic resources for their utilization is subject to the prior informed consent (PIC) of the Party providing such resources (Article 6). Genetic resources are defined as any material of plant, animal, microbial or other origin containing functional units of heredity of actual or potential value. Parties requiring PIC should take the necessary legislative, administrative or policy measure to provide for legal certainty, clarity and transparency of their ABS legislation. They should establish clear rules and procedures for requiring and establishing PIC and MAT. MAT (mutually agreed terms) is a contract including benefit sharing arrangements. Parties may also decide not to regulate access and wave PIC requirements, as in the case of many European countries.

Traditional knowledge held by indigenous and local communities should be accessed with the prior and informed consent or approval and involvement of these indigenous and local communities, and the conditions should be established in the MAT (Article 7).

Sharing benefits with the provider country arising from utilisation of accessed genetic resources and associated traditional knowledge as well as from their subsequent applications and commercialization is the second key element of the Nagoya Protocol (Article 5). Utilisation of genetic resources, as defined in Article 2 of the Protocol, means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology. Benefits arising from the utilization of genetic resources shall be shared with the Party providing such resources in a fair and equitable way, according to the bilateral agreement, set in MAT.

Compliance is the last key component of the Nagoya Protocol. There is a number of compliance requirements for Parties to this treaty such as developing domestic ABS legislation; establishing competent national authority and checkpoint, issuing PICs, providing information to ABS Clearing House and monitoring utilisation of genetic resources. Users within their jurisdiction have to comply with domestic laws as well as the laws of a provider country.

The Nagoya Protocol is especially important in regard to genetic resources that have high potential to be developed into new commercial products and generate benefits to be shared with the provider country. Such resources include wild plant species or crops and associated traditional knowledge related to customary use of these species.

The next speaker (Alicja Kozłowska, DG Environment, European Commission) presented EU ABS legislation to implement the Nagoya Protocol. The EU Regulation No 511/2014 on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union (EU, 2014) entered into application on 12th October 2014, as the Nagoya Protocol itself. It regulates only one of three key elements of the Protocol: the compliance of users, as access to genetic resources rests with national governments and the benefit sharing is the subject of bilateral agreement (MAT) between provider country and the users.

The EU ABS Regulation is based on the concept of due diligence that has to be applied by users of genetic resources. According to Article 4 of the EU ABS regulation, users are under the obligation to ascertain that genetic resources and the associated traditional knowledge which they utilise have been accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements of the provider country, and that benefits are fairly and equitably shared on mutually agreed terms.

The EU ABS Regulation establishes two checkpoints, where users are expected to declare either that they exercised due diligence in accordance with Article 4, or that they have fulfilled the obligations under Article 4. One checkpoint is established at the stage of receiving research funding and the other one at the stage of final development of the product. The EU ABS Regulation provides for two voluntary mechanisms facilitating compliance with obligations of

the Regulation, namely best practices and registered collections. Furthermore, the EU ABS Regulation requires that Member States (MS) carry-on checks on user compliance based on risk-based implementation plans and to establish dissuasive and proportionate penalty system for infringement of the ABS rules.

The Commission implementing Regulation (EU) 2015/1866 (EU, 2015) sets the application modalities concerning submission of due diligence declarations at checkpoints. Due diligence declaration at the stage of research funding is requested from all recipients of funding, either public or private. In the case of mixed sources or multiple recipients of funding, declaration is required only once. The declaration should be submitted to MS competent authorities, in the country where user is established. In the case of multinational research projects, declaration can be submitted by the project co-ordinator on behalf of all partners.

Due diligence declaration at the stage of final product development should be submitted prior to one of the following events: seeking market approval, submitting notification on placing product on the market, placing product on a market (developed via utilisation of GR), as well as when the result of utilisation is sold or transferred for the purpose the three situations above or when utilisation has ended in EU and its outcome is sold or transferred outside of the EU.

The Regulation (EU) 2015/1866 also provides details related to registered collections and best practices. The complementary measures to support implementation of the EU ABS Regulation is the ABS Consultation Forum (Article 5) and a number of Guidance documents prepared by the Commission.

The potential impact on exchange of animal genetic resources (AnGR) in research projects was discussed by Michele Tixier-Boichard (INRA). A number of practical examples provided understanding of the scope of ABS related issues to be addressed within multinational research projects where members of the consortium are coming from countries that have different ABS legislation and regulatory requirements, and their countries may have different status in regard to ratification of the Nagoya Protocol.

It has already been observed that complex administrative procedures for ABS have resulted in administrative burdens taking into account different legal circumstances, requirements and practices in countries of research projects' partners, and will require substantial staff training. It is expected that the time of collecting samples will increase, which will affect the time required for the completion of the research projects, and as result, reducing research. Also, the higher administrative costs may deplete resources that were intended to fund the research itself.

The next invited speaker (Jan Venneman, EFFAB) presented operations of the commercial breeding sector and current practices related to utilization of genetic resources of poultry, pigs, ruminant species and aquaculture species in genetic improvement programmes.

At present, there is no South-North movement of AnGR to contribute to commercial selection programmes, due to the low level of performance, as well as veterinary restrictions. Therefore, in the view of EFFAB, although the AnGR are in the scope of the Nagoya Protocol as well as the

EU ABS Regulation, at present the impact on both of them is not relevant for animal breeding sector. However, this could change in the future with the development of the New Breeding Techniques (NBT's) such as gene editing that could make genetic make-up of local breeds from the South interesting for the European breeding industry.

The next contributor from the United Nations Food and Agriculture Organization (FAO) presented activities of the Commission on Genetic Resources on Food and Agriculture being taken to support implementation of the Nagoya Protocol within the agriculture sector (Roswitha Baumung and Irene Hoffmann). The ABS related work was initiated by the Commission at its Eleventh Session in 2007, with the initial focusing on promoting the special needs of the agricultural sector and genetic resources for food and agriculture (GRFA) during international meetings where ABS issues were being discussed.

After adoption of the Nagoya Protocol, the Commission established the Ad Hoc Technical Working Group on ABS, which met in Svalbard, Norway in September 2012. In April 2013, the Commission established a Team of Technical and Legal Experts on ABS (TTLE-ABS) with the mandate to prepare *Draft Elements to Facilitate Domestic Implementation of Access and Benefit-Sharing for Different Subsectors of Genetic Resources for Food and Agriculture.*

This document (ABS Elements), adopted by the Commission (FAO, 2016), was meant as a voluntary tool to assist national governments to develop their domestic ABS legislation. The Commission decided to further elaborate subsector-specific elements for ABS, and requested its sectoral Intergovernmental Technical Working Groups (on plants, animal, forest, and aquatic genetic resources), to advance this work taking into account the role of traditional knowledge associated with GRFA and their customary use.

The final presentation analyzed practical examples of activities taking place within the animal breeding sector in the context of obligations arising from the EU ABS regulation (Sipke Joost Hiemstra, Martin Brink and Bert Visser, CGN). The presentation was based on case studies included in the draft Sectorial Guidance on Animal Breeding, which were contracted by the European Commission as a part of a set of guidance documents for all sectors of genetic resources to support implementation of the EU ABS Regulation.

These sectorial guidelines are meant to provide guidance to users of genetic resources in determining which activities qualify as research and development in the context of the Nagoya Protocol, and therefore, should be considered within the scope of the EU Regulation, assuming all other conditions have been fulfilled as well.

An important first matter was to clarify how the definition of utilization applies to animal breeding. Generally speaking animal breeding includes, elements of research and development and although some steps in the breeding process may focus on one of these processes, it is not very useful to separate individual steps in the breeding cycle.

In the case of importing genetic resources for research and development from countries having access legislation, it is important so that first users obtain PIC and negotiate with provider benefit sharing arrangements in a way that potential obligations towards the providing country of the subsequent users /purchasers of next generations are clearly defined.

The round table discussion, including all speakers focused on three key questions:

- What activities in the breeding sector can be considered as utilization as defined by the Nagoya Protocol?

This part of discussion was very much related to the last presentation. There was a general feeling that at this point of time, it is difficult to have a final view on this issue, as the EU guidance document was still under discussion and a number of cases were considered as unresolved.

However, the more advanced EU guidance document of 11th October 2016, suggests that *out* of the scope of the EU ABS regulation are activities such as: acquisition of AnGR by genebanks to enhance their collection, taxonomic characterization, development and application of reproductive technologies (e.g. IVF, semen sexing) to increase reproduction efficiency, trading genetic material, buying semen for production purposes, exchange of genetic material of rare and traditional breeds between breeders within breed associations or networks, exchange of genetic material within the same company, using genetic resources as testing/reference tools, using sequencing data from the public domain and import of commodities.

However, it has to be stressed that any acquisition of genetic resources should be done in line with the ABS legislation and regulatory requirements of the country of collection, means with PIC and MAT if given country is regulating access to genetic resources.

Contrary, the following activities: genotypic and phenotypic characterization of breeds, breeding lines and individual animals, basic scientific research on the genetic background of traits, identification of causal mutations, breeding activities using germplasm from external sources aimed at the genetic improvement of breeding material for the purpose of commercial sales, breeding of genetic resources newly introduced from the wild for the purpose of aqua farming, genome editing and use of molecular information for breeds/animal traceability are currently considered to be within the scope of the EU ABS regulation.

It is important to underline that the guidance document for breeding sector has not been adopted yet with the discussions continuing, and interpretation of some activities may change.

- What is and potentially might be the impact of the new law on exchange of biological material for research purposes?

Participants of the session agreed that the Nagoya Protocol and the EU ABS legislation might affect the exchange of genetic material for scientific research and collaboration. New laws may affect exchange practices for AnGR at the global level, as access to genetic resources from developing countries and obtaining PIC may require long procedures. Planning and executing research projects might become difficult as the duration and outcomes of legislative procedures in provider countries could become unpredictable, especially in the early phase of national implementation of the Nagoya Protocol.

It was underlined that if availability of AnGR for research is hampered, global benefits resulting from undisturbed gene flow to support research and further development of animal breeding sector, which benefits humankind, could be adversely affected.

It was also mentioned that development of animal gene banking worldwide is an important step to ensure availability of animal genetic diversity for research to enable an effective response to future needs of livestock sector and facilitating access to AnGR.

- What is, and potentially might be, the impacts of new laws on the trade of live animals and their reproductive material?

While there was agreement that in general, the ABS legislation is relevant for animal breeding sector in the EU, short term impacts might be very limited in the EU. Introduction of breeding material from countries that have established or are developing ABS access legislation has been negligible, and examples of commercially successful introgression of exotic genotypes to mainstream breeds are almost none. It was also recognized that gene flows may change in the future driven by technology (genomic research, genome editing) and driven by climate change (increase of interest in adaptive traits of AnGR from the South).

The global interdependency of food production should promote access to AnGR for research and breeding among all countries, both developed and developing. The Parties to the Nagoya Protocol, while developing domestic ABS legislation, may apply different access measures for GRFA, considering the importance of genetic resources for food and agriculture and their special role for food security. (Article 8c of the Protocol). A number of European countries have excluded livestock from their ABS legislation to facilitate unhampered trade of AnGR.

II. International developments as regards ABS

In December 2016, in Cancun, Mexico, the Parties to the Nagoya Protocol met for the second time. A number of decisions were adopted. Two of the decision are addressed here. The first is Decision 2/10. The need for and modalities of a global multilateral benefit-sharing mechanism (Article 10) (CBD, 2016a).

Article 10 of the Nagoya Protocol provides for Parties to consider the need for and modalities of a global multilateral benefit sharing mechanism. Such mechanism might address the fair and equitable sharing of benefits derived from the utilization of genetic resources and associated traditional knowledge in two situations: in transboundary situations or when it is not possible to grant or obtain prior informed consent. Then, the benefits shared by users through this mechanism shall be used to support the conservation of biological diversity and the sustainable use of its components globally.

Discussion on the need for a new global financial mechanism is ongoing since adoption of the Protocol, with contributions from two meetings of the Ad Hoc Expert Group. So far, no agreement has been achieved.

Therefore, the COP/MOP 2 set in place a process to further investigate this issue and invited Parties, other Governments, indigenous peoples and local communities and stakeholders, including holders of *ex situ* collections, to submit information, including practical experiences if any, on situations in which it is not possible to grant or obtain prior informed consent in relation to *in situ* or *ex situ* genetic resources and associated traditional knowledge.

The Executive Secretary was requested to compile this information for consideration by the Subsidiary Body on Implementation and by the third meeting of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol.

If such global multilateral benefit sharing mechanism were ever to be established, it might be relevant for the animal breeding community.

The second decision is important for the research community: Decision 2/14. Digital sequence information on genetic resources (CBD, 2016b)**.**

During the COP/MOP 2 the issue of utilisation of digital sequence information (DSI) was discussed in length and created a lot of controversy. There was no agreement on if DSI should be treated as genetic resources and if use of DSI on genetic resources without the resources themselves, should trigger benefit sharing obligations.

As DSI is a cross-cutting issue, both for the Convention on Biological Diversity and for the Nagoya Protocol, Parties to both agreements recognized rapid advances arising from research and development in biotechnology regarding the use of DSI have occurred, and established a process to further analyse this issue (CBD/COP XIII, Decision 16. Digital sequence information on genetic resources).

The process includes inviting Parties, other Governments, indigenous peoples and local communities, and relevant organizations and stakeholders to provide their views and relevant information on the use of DSI, as well as commissioning by the Executive Secretary a fact-finding and scoping study to clarify terminology and concepts and to assess the extent and the terms and conditions of the use of DSI on genetic resources in the context of the Convention and the Nagoya Protocol.

Both submissions and the study will provide a background information for the work of the Ad Hoc Expert Group, and the outcome of its meeting will be considered by the Subsidiary Body on Scientific, Technical and Technological Advice in order to make recommendations on the potential implications of the use of DSI on genetic resources for the objective of the Nagoya Protocol, for consideration of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol at its third meeting.

The outcome of this discussion at CBD COP 14 and NP COP/MOP 3 might have substantial impact on access to DSI and conditions related to use of DSI both in research and in animal breeding.

The parallel work on ABS related issues relevant for GRFA is carried-out by the FAO Commission on Genetic Resources for Food and Agriculture. In January 2017, the Commission convened its 16th regular session. The ABS discussion both in the plenary and within the

contact group, resulted in a set of decisions that are being implemented in the intersessional period (FAO, 2017).

The most important elements include an invitation to Members, observers and other stakeholders to provide inputs on their practical experiences in implementing national ABS measures related to GRFA, as well as on the distinctive features and the specific practices of different subsectors of GRFA. These submissions will support preparation of non-prescriptive explanatory notes describing the distinctive features and specific practices of different subsectors of GRFA. Another source of information for this purpose would be the outcome of an international workshop scheduled for 10-13 January 2018, with the aim to assist countries and raise awareness of specific circumstances of subsectors of GRFA.

The Team of Technical and Legal Experts on ABS was charged with preparation of the draft explanatory notes for the different subsectors of GRFA for further consideration and elaboration by the Working Groups. When the draft is reviewed by all four Working Groups, and experts on microorganisms and invertebrates, the TTLE-ABS will reconvene to consolidate and finalize the draft explanatory notes for consideration of the Commission at its next session in 2019.

Another development was the establishment by the Commission of a new work stream on "digital sequence information on GRFA". The Secretariat was requested to prepare, an exploratory fact-finding scoping study on DSI on GRFA to provide information on terminology used in this area, actors involved, the types and extent of uses of DSI on GRFA such as identification and characterization of GRFA, breeding and genetic improvement, conservation as well as on relevance of DSI on GRFA for food security and nutrition. The study will facilitate consideration by the Commission the implications of the use of DSI on GRFA, including exchange, access and the fair and equitable sharing of the benefits arising from their use at the next session of the Commission in February 2019.

A preliminary draft of the exploratory fact-finding scoping study, after review by the Bureau, will be submitted to the Executive Secretary of the CBD, as a contribution to the process set by decision CBD COP XIII/16 described above.

It is clear, that developments at international fora over the next two years will be very important for animal research and livestock breeding activities and may further change the current ABS landscape.

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