

Digital Sequence Information on Genetic Resources

Submission by the Secretariat of the International Treaty on Plant Genetic Resources for Food and Agriculture

With reference to the notification published on 25 April 2017 by the Executive Secretary of the Convention on Biological Diversity, the Secretary of the International Treaty on Plant Genetic Resources for Food and Agriculture is pleased to inform about on-going activities within the International Treaty related to genetic information. The activities may be considered of relevance to the process established by the thirteenth meeting of the Conference of the Parties to the Convention on Biological Diversity (COP 13) and the second meeting of the Conference of the Parties serving as the meeting of the Parties to the Nagoya Protocol on Access and Benefit-Sharing (ABS COP-MOP 2). The relevance of the activities presented below may be appraised when considering the implications of digital sequence information for the objectives of the Convention and the Nagoya Protocol, which are germane to those of the International Treaty.

The information below is submitted to the attention of experts convened in inter-sessional processes of the Convention and the Nagoya Protocol, without prejudice to any past, present and future guidance that the Governing Body of the International Treaty may give within the remit of the same Treaty.

Genomic Information in relation to the process for the enhancement of the functioning of the Multilateral System of Access and Benefit-Sharing

At its Sixth Session in 2015, the Governing Body of the International Treaty specifically requested the *Ad Hoc* Open-Ended Working Group to Enhance the Functioning of the Multilateral System of Access and Benefit-Sharing (Working Group), to consider genetic information associated with the material accessed from the Multilateral System. At the sixth meeting of the Working Group in March 2017, the consideration of issues regarding genetic information associated with material accessed from the Multilateral System was introduced, through a Note by the Co-Chairs and an information event organized by the Secretariat. The Co-Chairs noted, in particular, that the generation and publication of genomics information obtained from PGRFA accessed from the Multilateral System in open source public databases are becoming increasingly common, in line with conditions set by funding agencies and scientific journals alike. Being that the Standard Material Transfer Agreement (SMTA) is silent on this issue, third parties can access the information freely, and use it to adapt their own genetic resources (including commercial varieties) and create new traits by technological means. In the view of the Co-Chairs, this would imply that it is not known which (natural or legal) persons use the information, and that, under current conditions, such use does not entail any benefit-sharing obligations. Therefore, these technological developments impact on the benefit-sharing arrangements, which are part of the International Treaty. The Working Group recognized the importance of this emerging issue and the need for further study and awareness raising, focusing on the objectives of the International Treaty as well as its implications for the ongoing negotiations to enhance the functioning of the Multilateral System, in particular the proposed revised SMTA and the Subscription System. Some members of the Working Group took the position that it would not be possible to finalize the revised SMTA until this matter has been satisfactorily addressed. However, in the view of the Working Group, this matter merits a thorough analysis by the Governing Body, at its forthcoming Seventh Session in October 2017.

In response to these developments and outcomes, the Secretary has commissioned in July 2017 a scoping study to explore how current technologies and practices related to the exchange and use of genetic information are relevant for the International Treaty. A multi-disciplinary team of scientific experts under the leadership of the Center of Science, Technology and Environmental Policy Studies at Arizona State University, is conducting the study, which, at the time of this submission, is in the final phase for submission. This initial scoping study has a broad focus, i.e. on the potential implication(s) of new synthetic biology and genomic research trajectories for the International Treaty. Specifically, it will provide an introductory examination of how the evolving technological, legal and institutional context surrounding the exchange and use of information for synthetic biology and genomic research affect the principles and framework of the International Treaty. Seen broadly, the report will address the phenomenon of dematerialization which suggest that ‘the information and knowledge content of genetic material [could increasingly be] extracted, processed and exchanged in its own right, detached from the physical exchange of the plant genetic material’ (FAO, IT/GB-5/13/4).

The report, which will be based substantially on background information, literature and expert interviews aims to provide a useful resource for the Treaty community as it seeks to determine how it should begin to address the new and evolving technological context. Analytically, the scoping study has selected questions of enquiry based on key principles and structural dimensions of the International Treaty. The questions revolve around three dimensions: science and technology; legal; and opportunities for benefit-sharing. Questions investigated include:

- Science and technology dimension: what are the characteristics of the technological change, how are data different from material? How are sequence data stored, exchanged and shared? What are the documentation practices? Can data be traced to material?
- Legal dimension: how are actors addressing ownership, property rights, and tracking for data? What are the emerging IP practices? To what extent have researchers experienced regulatory or IP constraints?
- Opportunities for benefit-sharing: what are the different ways actors assign value to genetic information? How accessible is such information to individuals, institutions and countries with different levels of scientific and technical capacity? What investment options exist for developing scientific and technical capacity in synthetic biology and genomics?

The study will be published online by mid-October 2017 and communicated to all interested stakeholders via an-online notification by the Secretariat of the International Treaty. Some preliminary findings for each of the three dimensions are presented below.

Science and technology

Genetic materials are sourced and used including for: mining plant genomic information for gene editing purposes in agriculture; mining for use outside of agriculture; and using the plant as a ‘work horse’ to produce other products. The new digitization era is producing a large amount of sequence data that is widely available and easily exchanged. The high number of decentralized data libraries and organizations raises significant challenges to the Treaty ABS logic of identification and expectations of benefits from commercialized products. Technological changes have accelerated the dematerialization revolution. Even though many researchers still require or prefer to have the physical material for their work, there is an increasing separation between material and data in the research enterprise.

Monitoring of genetic resources based on DSI is a challenging prospect. But even if a robust tracking system were possible, other factors including partial sequence combinations and the fact that the same sequence may occur in multiple organisms poses further challenges.

Legal

The development and use of DSI in synthetic biology projects poses a challenge to the ABS structure embedded in the Treaty. Researchers can use genetic information (DNA sequences) from MLS material (obtained through DSI in publicly accessible databases) in research without such usage being monitored, and can obtain value from it. Even though scientists working on DSI may be using sequence information from identifiable published material, the chain of transmission is often not transparent nor easily documented. As such, it may be difficult to assess benefits from uses of Treaty material or DSI.

While some patents obtained for inventions incorporating DSI may provide geographic origin information, others may not, or the information may be hidden if a particular sequence could be obtained from more than one kind of organism. In addition, patents may not always be necessary to extract value from DSI, as trade secret protection can be a viable alternative under certain conditions.

Opportunities for benefit-sharing

From data that the scoping study generated and analysed, four conceptualizations of value emerged: innovation; sequence and part functionality; plant system understanding; education and exploration. With regard to the requisite infrastructure for undertaking synthetic biology research, three general perspectives were identified: high-cost infrastructure, low-cost infrastructure and flexible infrastructure. The recognition of the diverse sources of value and different approaches to infrastructure informed study findings. The study identifies five different strategies employed by researchers that are currently in place: 1) *ex ante* investment to facilitate access; 2) grant-based funding for hard infrastructure investment; 3) facilitated access for research community building; 4) structured research collaboration; and 5) education and training. These different strategies can be linked to the values framework and investment approaches above and could be considered by the Treaty as it addresses benefit sharing and DSI.

Genomic information in relation to the Vision and Programme of Work for the Global Information System of Article 17 of the International Treaty

At its Sixth Session in 2015, the Governing Body of the International Treaty endorsed a vision of the Global Information System under Article 17 of the Treaty (GLIS). One component of the vision is the promotion of transparency of rights and obligations related to accessing, sharing and using information associated with germplasm, and the establishment of ways to exercise those rights and obligations within the Global Information System. A 6-year programme of work complements the vision. The programme of work foresees the analysis of the institutional, organizational, policy and legal factors for access, sharing and use of PGRFA information in the context of the International Treaty's provisions, in particular Articles 12 and 13 on the Multilateral System.

With a view to setting in motion the policy and legal component of the vision and in order to begin implementing the programme of work, the Secretariat commissioned a background study paper on the legal status of genomics information in the International Treaty and in the wider international

framework of access and benefit-sharing.¹ The Secretariat prioritized this sub-category of information in the light of the growing attention by the International Treaty community to the importance of genomics information for advancing the objectives of the Treaty, and of developments occurring in the global ABS landscape that International Treaty stakeholders should be informed of when operating under the GLIS.

The background study paper was appraised by the Scientific Advisory Committee on the GLIS in November 2016. The Committee welcomed these inputs and decided to facilitate a dialogue with the Working Group (see above) on issues regarding genetic information associated with the material accessed from the Multilateral System. The Committee also decided to continue monitoring relevant international forums and processes and to keep the members of the Committee informed. In addition, the Committee began considering issues regarding the impact of information management on access and benefit sharing, and decided to await further analysis before making any specific suggestions. At its second meeting, the Committee recognized the importance of access to genetic sequence information to the GLIS vision and functions, and sought the guidance of the Governing Body of the International Treaty on how to further address the topic.

On-going coordination among Secretariats

Following the deliberations of COP 13 and ABS COP-MOP 2, the Secretariats of the International Treaty and the Convention on Biological Diversity are promoting coordination on the technical inputs into the respective policy processes and dialogue between those processes. So far, such coordination has resulted in the following practical initiatives:

- Dialogue between the experts preparing the scoping study for the International Treaty and those responsible for the fact-finding and scoping study commissioned by the COP 13 to clarify terminology and concepts and to assess the extent and the terms and conditions of the use of digital sequence information;
- Invitations to the CBD Secretariat and the experts responsible for the Convention/Nagoya Protocol fact-finding and scoping study, to the Special Event on Genomic Information, which will be held on 28 October 2017, in the context of the Seventh Session of the Governing Body (more information on the special event is available at this link: <http://www.fao.org/plant-treaty/meetings/meetings-detail/en/c/1026007/>).

The Secretariat of the International Treaty will inform the *Ad Hoc* Technical Expert Group on Digital Sequence Information on Genetic Resources, at its meeting of February 2018, of the relevant outcomes of the Seventh Session of the Governing Body of the International Treaty, and will continue close cooperation with the Secretariat of the Convention in order to ensure mutual support and coherence between the respective work tracks and stimulate continuous dialogue between the constituencies.

¹ The background study paper is available at: <http://www.fao.org/3/a-bq620e.pdf>.