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**Food and Agriculture
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The International Treaty
ON PLANT GENETIC RESOURCES
FOR FOOD AND AGRICULTURE

Item 4 of the Provisional Agenda

INTERNATIONAL TREATY ON PLANT GENETIC RESOURCES FOR FOOD AND AGRICULTURE

SECOND MEETING OF THE SCIENTIFIC ADVISORY COMMITTEE ON THE GLOBAL INFORMATION SYSTEM

Rome, Italy, 13 – 14 June 2017

ACCESS AND USE OF PGRFA INFORMATION THROUGH THE GLOBAL INFORMATION SYSTEM

I. INTRODUCTION

1. At its Sixth Session, the Governing Body of the International Treaty endorsed a vision of the Global Information System of Article 17. 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 related to access to, sharing and use of PGRFA information in the context of the Treaty's provisions, in particular Articles 12 and 13 on the Multilateral System.

2. With a view to setting in motion the policy and legal components of the vision and of the programme of work, the Secretariat introduced the subject of access to and use of genomics information at the first meeting of this Committee, through a background study paper and a working document synthesising the findings of the paper.¹ This Committee welcomed these inputs and decided to facilitate a dialogue with the *Ad Hoc* Open-Ended Working Group to Enhance the Functioning of the Multilateral System of Access and Benefit-sharing (Working Group), 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.

3. This document follows up on the deliberations of the Committee and, with regard to genomics information, updates the Committee on developments that occurred within the Working Group and within the Convention on Biological Diversity (CBD).

4. To further advance the above mentioned policy and legal components of the vision and programme of work in a practical way, the attention of the Committee is drawn to two additional definite topics of immediate relevance to the deployment of the GLIS DOI functions: (a) special considerations on the use of Digital Object Identifiers (DOIs) by breeders; and (b) the terms of access and use of the GLIS web-based platform.

¹ Available at: <http://www.fao.org/3/a-bq808e.pdf> and <http://www.fao.org/3/a-bq619e.pdf>

II. GENOMICS INFORMATION

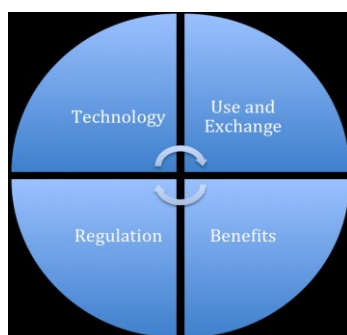
5. At the sixth meeting of the Working Group in March 2017, the consideration of issues regarding genetic information associated with material accessed from the Multilateral System was introduced, via a Note by the Co- chairs and an information event organized by the Secretariat.² The Co-Chairs noted, 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 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 implies 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 several international instruments, including the International Treaty.

6. 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 Standard Material Transfer Agreement (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 Seventh Session.³

7. In response to these developments and outcomes, the Secretariat has commissioned a multi-disciplinary scoping study on genomics information. The study will review literature and gather data, in the form of semi-structured interviews of selected stakeholders, on several relevant and interrelated dimensions of the production, manipulation and use of genomics information, such as:

- i). the technology dimension (e.g. the back and forth ‘map’ between material and data that synthetic biology induces);
- ii). the use-exchange dynamics (e.g. how data are stored, exchanged and shared within a community; what the specific characteristics/differences in exchange and use patterns in the academic and corporate contexts are);
- iii). the benefit dimension (e.g. at what point or points it is possible to assign value to information and what the spillovers are in relation to data production, exchange and use within the public and private research communities);
- iv). the regulatory dimension (e.g. to what extent researchers use self-regulatory instruments such as the Bermuda rules, the Fort Lauderdale agreement and the Toronto agreement, for data release).

Table: scoping study on genomics information



² See <http://www.fao.org/3/a-br438e.pdf>

³ See <http://www.fao.org/3/a-br666e.pdf>

8. The CBD has considered the issue of sequence data in relation to genetic resources, at the thirteenth Conference of the Parties (COP), also acting as Meeting of the Parties to the Nagoya Protocol on Access and Benefit-sharing, in December 2016. In the context of synthetic biology, the COP recognized the importance of addressing the matter in a timely manner and decided to consider any potential implications of the use of digital sequence information on genetic resources for the three objectives of the CBD, thus including benefit-sharing. The COP requested a fact-finding and scoping study to clarify terminology and concepts,⁴ and to assess the extent and the terms and conditions of the use of genetic sequence data. The COP also established an *ad hoc* technical working group to consider, among other matters, the technical scope, and legal and scientific implications of existing terminology, as well as to identify the different types of genetic sequence data that are relevant to the CBD and the Nagoya Protocol.

III. DOIs FOR BREEDERS

9. The Secretariat recently attended a meeting of the CGIAR Excellence in Breeding Platform, where it was invited to present the on-going work on DOIs. The Secretariat received strong support from the meeting for the adoption of DOIs whenever a material is transferred to or from a breeding program. In this context, the Secretariat received a request from breeders of a CGIAR Center to explore the possibility of assigning DOIs that are not publicly accessible, for materials that are covered by confidentiality agreements. This would enable parties to such agreements to enjoy the functionality that GLIS offers during the period of the agreement, without the need to develop parallel systems. The value of this flexibility for breeders would be to apply the DOI system for material and data having different legal status (i.e. under development vs. released; confidential vs. non-confidential), without the need to resort to different identifier systems. Once it is determined that the confidentiality restrictions do not apply, the DOIs would then become public. Breeders would be able to render DOIs public in the appropriate sequence in order to document progenitors, once the resulting material is released.

10. The DOI system offers a grace-period mechanism before the actual publication of the DOI. This grace period is not pre-determined in time. It is granted at the request of the registrant and may also be revoked by the same registrant at any time. The grace period can be made coterminous with the confidentiality agreements and serve the breeders' needs. The question that arises is whether GLIS should provide a mechanism to furnish such "temporary private" DOIs.

11. The case above is the first concrete example of the need for practical legal protection of PGRFA information in the application of DOIs. Pending the comprehensive analysis of the legal protection of information, as suggested in the working document of the first meeting of this Committee in order to strategically deploy GLIS functions, a number of considerations could be made in relation to the above request.

12. There is no obligation, or expectation, to assign DOIs to every plant genetic resource for food and agriculture. The DOI system is entirely voluntary and, as such, incentive-based. The function of DOIs is to provide a service to the holders of the materials by identifying PGRFA and enabling the assignment of relations among materials and associated information resources ("targets") whose existence the holder wants to make public. The basic rule for when to obtain a DOI for PGRFA would be to assign a DOI to any PGRFA that the holder manages and whose present or past existence the same holder wishes to make known, at the level of detail the holder chooses. It follows from the above that in cases where the holder does not wish to make the existence of PGRFA publicly known, a DOI is not assigned.

13. It should also be recalled that, according to the latest version of the DOI guidelines under review by this Committee, the descriptors that are mandatory for obtaining a DOI from GLIS are:

⁴ For instance, while some State Parties used the terminology "digital sequence information on genetic resources" others referred to "genetic information" or "information arising from genetic resources".

- i). the organization/individual conserving the PGRFA;
- ii). the PGRFA identifier assigned locally by the holder;
- iii). the date on which the registering entity became holder of the material;
- iv). the method through which the material was acquired or created; and
- v). the genus or crop name.⁵

None of these descriptors describes the origin of the material and would not seem to interfere with the restricted legal status of breeding material and associated information, except in cases where the holder wants to keep the mere existence of the material confidential. In such cases, the recipient would simply not register the material in GLIS and therefore not associate a DOI to it.

14. However, it should also be noted that DOIs could be a useful tool to implement recipient's obligation under Article 6.9 of the SMTA (*"The Recipient shall make available to the Multilateral System, through the information system provided for in Article 17 of the Treaty, all non-confidential information that results from research and development carried out on the Material"*). An express reference to the confidentiality status of information is made in Article 6.9 although standards are not provided. Although the protection of undisclosed information may vary from country to country, the international standard of reference as to trade secrets is provided in Article 39(2) of the TRIPS Agreement, according to which the information shall:

- be secret in the sense that it is not generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;
- have commercial value because it is secret; and
- have been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret [e.g. through confidentiality agreements].

15. In the case of research and development information under Article 6.9 of the SMTA, the commercial value of information may not always be pre-determined at the time of the transfer of the germplasm. It is in the course of research and development of the material that the resulting information may acquire (or not acquire) commercial value. Applying the same DOI identification system to the transferred germplasm and to the information resulting from research and development would be a practical advantage. In this sense, the flexibility of "private" DOIs would be an incentive for the use of such identifier system for reporting under Article 6.9. Technically, this is possible at no additional costs, considering that the Secretariat has already implemented technical protocols and standards to protect SMTA information that is not publicly available.

IV. TERMS OF ACCESS AND USE OF THE GLIS WEB-BASED PLATFORM

16. As presented at the first meeting of this Committee, the Secretariat is developing a prototype of the GLIS web-based platform for presentation at the next Session of the Governing Body. Analogously to the Easy-SMTA portal, legal terms of access and use for the services of the platform will be developed.⁶

17. The main concept underpinning the platform is to provide a global entry point to scientific, technical and environmental matters related to PGRFA. In order to promote interoperability among existing information systems, the platform will essentially host links to systems maintained by the holder of the material, FAO and third parties. The platform will also provide a set of tools to address specific needs, the first of which will be the DOI registration service.

18. In order to develop the terms of access and use, a number of general principles and criteria will be followed.

⁵ See <http://www.fao.org/3/a-br574e.pdf>

⁶ See <https://mls.planttreaty.org/itt/index.php?r=site/page&view=terms>

- a) The terms of access and use will explain the main functions performed and services offered by the platform.
- b) The terms will provide incentives for the maximum use of content and functions of the platform. FAO may place database-protected content and functions as completely as possible in the public domain, so that any subsequent user may freely build upon, enhance and reuse the works for any purposes without restriction. FAO may also grant a public domain-type of license, i.e. it will hold the copyright in the platform and will grant registered users a license to: i) share (i.e. copy and redistribute in any medium or format); and ii) adapt (i.e. remix, transform and build upon) for any lawful purpose. The permitted uses will be subject to: iii) attribution (users will have to give appropriate credit, provide a link to the license and indicate if changes are made, in any reasonable manner but without any explicit or implied suggestion that the licensor endorses the user or the use); and iv) a no-additional-restriction clause (i.e. users may not apply legal terms or technological measures that legally restrict others from doing anything that the license permits).
- c) Privacy issues will be clarified. IP addresses of computers accessing the platform will be tracked with login attempts and stored in access logs, for the exclusive purpose of analyzing use and use trends.
- d) FAO will apply reasonable measures to maintain the security and integrity of information, including for any confidential information that the platform may deal with.
- e) FAO will reserve the right to make future changes to the platform and the use of the DOI system as well as to the terms of access and use, subject to immediate notice of those changes on the homepage.
- f) Warranties and disclaimers as to the quality or accuracy of data and information will still be set forth. Along the same lines, standard provisions for the exclusion of liability will be made.
- g) The terms of use will contain standard clauses on termination of rights in case of breach, privileges and immunities, applicable law, entire agreement and severability.

19. The above general principles and criteria, once drafted as terms of access and use, will be applied to the platform as a whole. Regarding the DOI registration service, the relevant parts of the platform will be subject to specific terms and conditions.

- h) FAO will assert no claims of ownership to user contributed content, individual items of metadata (e.g. the descriptors associated to the DOI, including targets) and associated DOIs acquired through the use of the DOI system. Individual items of metadata and associated DOIs may be incorporated into the user's content and systems.
- i) Additional provisions for exclusion of FAO's liability will be made with reference to external links (targets). As the content of these links is not under FAO's control, FAO will assume no liability for such external content. In all cases, the provider of information of the linked websites will be liable for the content and accuracy of the information provided.
- j) FAO will hold DOI name data or any metadata solely for the purpose of permitting look-up from a DOI name to the declared metadata (resolution) and vice-versa (discovery) by any user.
- k) Usage statistics and information as to the aggregate activity of the DOI system may be developed and published. Records of resolution activity by DOI name will not be made available. In case of system performance analysis and optimization, all data will be rendered un-interpretable and un-resolvable.

V. ADVICE SOUGHT

20. With regard to genomics information, the Committee is invited to:
- a) appraise in the future (i.e. should the Committee be reconvened by the Governing Body) the information management-related findings of the scoping study that the Secretariat has commissioned, with a view to addressing the aspects that the Committee may find of significance to the GLIS vision and programme of work;
 - b) recommend the further continuous monitoring of policy and legal developments within the Treaty and in other relevant fora, which may affect the deployment and operation of GLIS functions.
21. With regard to special considerations on the use of DOIs by breeders, the Committee is invited to advise as to:
- a) whether the Secretariat should develop the DOI system so to enable the registration of “private” DOIs i.e. allowing registrants to temporarily make the DOI descriptors not visible to the public;
 - b) how to keep the issue under further consideration in the future, e.g. through a small test case study or the collection of further views from the breeding community.
22. With regard to the terms of access and use of the GLIS web-based Platform, the Committee is invited to consider and, as it may deem appropriate, endorse principles and criteria for drafting those terms.