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“DIGITAL SEQUENCE INFORMATION” ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE AND ITS RELEVANCE FOR FOOD SECURITY

TABLE OF CONTENTS

	Paragraphs
I. Introduction	1–2
II. Background	3–6
III. The role of digital sequence information on genetic resources for food and agriculture	7–22
IV. The legal status of digital sequence information on genetic resources for food and agriculture	23–27
V. Developments in other fora	28–39
VI. Guidance sought	40

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CGRFA 17

I. INTRODUCTION

1. The Commission on Genetic Resources for Food and Agriculture (Commission), at its Sixteenth Regular Session, established a new work stream on “digital sequence information” (“DSI”) on genetic resources for food and agriculture (GRFA)¹ and requested the Secretariat to prepare, subject to the availability of the necessary resources, an exploratory fact-finding scoping study on “DSI” on GRFA (the Study) to provide information on, *inter alia*, terminology used in this area, actors involved with “DSI” on GRFA, and the types and extent of uses of “DSI” on GRFA, such as:

- characterization,
- breeding and genetic improvement,
- conservation, and
- identification of GRFA,

as well as on relevance of “DSI” on GRFA for food security and nutrition, in order to facilitate consideration by the Commission of the implications of the use of “DSI” on GRFA for the conservation and sustainable use of GRFA, including exchange, access and the fair and equitable sharing of the benefits arising from their use.²

2. The present document provides some background to the preparation of the Study and summarizes its key observations. It then discusses ways and means the Commission may wish to consider in further exploring the relevance of “DSI” on GRFA to the conservation and sustainable use of the different subsectors of GRFA and its implications for the sharing of benefits derived from GRFA and/or “DSI” on GRFA.

II. BACKGROUND

3. The Commission, at its Sixteenth Regular Session, requested the Secretary to invite Members to submit information on the use of “digital sequence information on GRFA” and potential implications for the conservation and sustainable use of GRFA, including exchange, access and the fair and equitable sharing of the benefits arising from their use, and to compile and submit this information to the Executive Secretary of the Convention on Biological Diversity (CBD), as a timely contribution to the process set by decision CBD COP XIII/16.³ The document *Submissions by Members and observers on “digital sequence information” on genetic resources for food and agriculture*⁴ compiles the submissions received, which were also made available to the Executive Secretary of the CBD.⁵

4. The Secretariat commissioned the University of Canterbury, Christchurch, New Zealand, to prepare the Study, which was developed in collaboration with the University of Basel, Switzerland. The report was peer-reviewed by two further experts independent of the authors. As requested by the Commission, the Bureau reviewed a preliminary draft of the Study. The Bureau invited the regions to provide, through their Bureau Members, comments on the document by 7 February 2018 and recommended that the document, as revised in the light of comments received would be first submitted, for comments, to the Commission’s intergovernmental technical working groups, the Expert Group on Micro-organism and Invertebrate Genetic Resources for Food and Agriculture and the Team of Technical and Legal Experts on Access and Benefit-sharing. The Bureau requested the Secretariat to submit the Study, as revised in the light of all comments received, to the Executive Secretary of the CBD, as a contribution to the CBD process set by decision CBD COP XIII/6 and to the Commission.

5. As requested by the Commission,⁶ the draft exploratory fact-finding scoping study on “DSI” on GRFA, as revised in the light of comments received from members of the Bureau, was reviewed by

¹ CGRFA-16/17/Report Rev.1 *Appendix C*.

² CGRFA-16/17/Report Rev.1, paragraph 86.

³ CGRFA-16/17/Report Rev.1, paragraph 88.

⁴ CGRFA-17/19/4/Inf.1.

⁵ <https://www.cbd.int/abs/dsi-gr/ahteg.shtml#submissions>

⁶ CGRFA-16/17/Report Rev.1, paragraphs 90, 91.

the intergovernmental working groups on animal,⁷ aquatic,⁸ forest⁹ and plant¹⁰ genetic resources for food and agriculture, and by the Expert Group on Micro-organism and Invertebrate Genetic Resources for Food and Agriculture nominated by the Commission's Bureau Members.¹¹ A newly revised version of the Study was then discussed by the Team of Technical and Legal Experts on Access and Benefit-sharing which provided comments on the study.¹² The Study is contained in the document *Exploratory fact-finding scoping study on "digital sequence information" on genetic resources for food and agriculture*, for information of the Commission. As requested by the Commission, the document was shared with the Executive Secretary of the CBD, as a contribution to the process set by decision CBD COP XIII/16.¹³

6. Given the enormous speed with which developments in this area of research occur, an area in which, in fact, two technological innovations coalesce, the Study takes into account possible future developments, a dimension which stakeholders and policy-makers alike may wish to take into account in addressing "DSI" on GRFA. The Study examines how "DSI" on GRFA is being used currently, how it might be used in the future and what the implications of its use are and might be in the future for the food and agriculture sector. Its aim is to assist with discussions about whether, and in what ways, "DSI" now or in the future may substitute for genetic material to carry out research and development on GRFA, and to create value from genetic resources through "DSI". It is also intended to assist policy-makers in adapting to the scientific changes brought about by both quantitative and qualitative changes in information collection, transmission, applications and inherent value even when it may be uncoupled from the original biological genetic material. The study covers:

- terminology used in this area;
- current status of biotechnologies (including identification, characterization, breeding and genetic improvement and conservation of GRFA) in the management of GRFA and agroecosystems and possible future developments;
- the types and extent of current and possible future uses of "DSI" on GRFA in biotechnologies; and
- actors involved with "DSI" on GRFA, and the relevance of "DSI" now and in the future on GRFA for food security and nutrition.

III. THE ROLE OF "DIGITAL SEQUENCE INFORMATION" ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE

7. There is no universally agreed definition for "DSI". This is reflected in relevant decisions taken under the CBD and its Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya Protocol) and the decision of the Commission to establish a new work stream on "DSI". There is recognition that "there are a multiplicity of terms that have been used in this area (including, *inter alia*, "genetic sequence data, "genetic sequence information", "genetic information", "dematerialized genetic resources", "*in silico* utilization" and that further consideration is needed regarding the appropriate term or terms to be used".¹⁴ The CBD COP/XIV noted that "the term 'digital sequence information' may not be the most appropriate term" and used the term therefore as a "placeholder". CBD COP/XIV also established a "science and policy based process on digital sequence information on genetic resources"¹⁵ to, *inter*

⁷ CGRFA/WG-AnGR-10/18/Report.

⁸ CGRFA/WG-AqGR-2/18/Report.

⁹ CGRFA/WG-FGR-5/18/Report.

¹⁰ CGRFA/WG-PGR-9/18/Report.

¹¹ CGRFA/EG-MIGR-1/18/Report.

¹² CGRFA-17/19/3.1, paragraphs 6–11.

¹³ CBD/COP/14/INF/29.

¹⁴ CGRFA-16/17/Report Rev.1, paragraph 87.

¹⁵ Decision 14/20, paragraph 8.

alia, “clarify the concept, including relevant terminology and scope, of digital sequence information [...]”¹⁶

8. Not everyone using the various terms associated with “DSI” therefore means the same thing by them. The Study found that the scientific community notably does not use the term “DSI” and points out that science is constantly evolving, making precise definitions potentially arbitrary or prescriptive.

9. The Study therefore uses an illustrative definition of “DSI”: ““DSI” refers to the kind of information in or that might be added to databases of the kind currently in use and collated by the scientific journal *Nucleic Acid Research (NAR)*”.¹⁷ The Commission may therefore wish to continue using “DSI” as a “placeholder” for the time being.

10. “DSI” on GRFA currently in use includes multiple kinds of information usually kept in electronic databases about various biological materials found in GRFA, used to manage GRFA, or to derive value from GRFA. Some but not all “DSI” on GRFA is DNA (or RNA) composition information, usually presented as a sequence of nucleotides. “DSI” may sometimes be sufficient to synthesize a trait without needing access to biological genetic material. “DSI” on GRFA that is not DNA or RNA will often be essential to identify or synthesize some traits; in other cases “DSI” on DNA or RNA may not be required to identify or synthesize traits.

11. The Study points out that “DSI” on GRFA contributes to food security and nutrition as a fundamental tool for characterization of GRFA, selection and breeding, creation of new products, food safety and traceability, and management of GRFA, including optimization for environmental context. It underlines that “DSI” is an essential component of technologies used for the characterization, conservation and sustainable use of GRFA. “DSI”, according to the Study, underpins technology for the synthesis of DNA and some kinds of genetic material. Such technologies could possibly one day allow all kinds of genetic or biological material to be synthesized using “DSI”.

12. “DSI” makes it easier to get value from a genetic resource without possessing it or its DNA. The Study did not find significant actual or potential differences in the characteristics of technologies as they are applied in the different subsectors of GRFA. The Study found that “DSI” was used extensively in all subsectors of GRFA. “DSI” is a routine component of nearly all research in the biological sciences. The Study concludes that “DSI” on GRFA is central to product development and expected to increase in importance especially as an increasing number of “DSI” for relevant GRFA will become available.

13. “DSI” also plays an important role in food safety governance systems, including product labelling, and identification of food components, which can be important for the conservation of threatened species. It is used to both diagnose diseases in all forms of GRFA and to design therapeutics for treatment.

14. “DSI” in the form of species surveys contributes to species conservation. “DSI” is frequently used for identification of species and for assessing genetic diversity within species. It is also used to select material for storage, and can be used to test for viability (via metabolomics analysis) and ensure purity over time. However, it can also be used to select material for different activities, such as breeding, artificial insemination, oestrus synchronization, *in vitro* fertilization and cloning, but may also be used to monitor or test progeny.

15. “DSI” also contributes to sustainable use on many levels, from direct application to GRFA to genetic resource management through the discovery and design of new pesticides, biofertilizers and probiotics.¹⁸ It also contributes to economic sustainability of use. New products from GRFA increase both income security and the financial sustainability of farmers. “DSI” is a critical element in new product development.

16. “DSI” is used to provide value disconnected from biological material to support characterization, conservation and sustainable use of GRFA. In some cases, the value comes from re-

¹⁶ Decision 14/20, paragraph 9(a), see also below section V.

¹⁷ Background Study Paper No. 68, p. 10.

¹⁸ See Background Study Paper No. 52.

coupling the “DSI” with biological material, such as in its use of metagenomics to identify probiotic bacteria to add as soil amendments. The inability to detect a species of bacteria in soil might be the trigger for seeking a probiotic amendment, or to add a nutrient that could amplify the species from undetectable to biologically relevant levels. Table 1 contains some examples of the current uses of “DSI” in the different subsectors of genetic resources. The original study¹⁹ should be consulted for further details.

17. With increases in the global capacity to generate DNA sequences and to share them, “DSI” is sufficient to make significant use of the information from GRFA for characterization of biodiversity and improvement of GRFA through breeding. Moreover, using only “DSI” it is possible today or in the foreseeable future to obtain, transfer and re-construct significant parts of the genetic information from organisms without having possessed the organism or transferred its DNA from one place to another.

18. It is evident that “DSI” can be and is being generated from all kinds of GRFA: microbes, plants and animals. It contributes to conservation and a variety of value chain activities that rely upon taxonomic description, trait identification, breeding, certification, raw materials and new products. The examples in the Study are distributed across microbes, plants and animals to reveal the sector independence of how much “DSI” is applied.

19. The value of a genetic resource is also no longer restricted to its biology. The scale and speed of information gathering about organisms can generate future uses and revenue independently of the organism that originally provided the genetic material. “DSI” has achieved the scale of what is called “big data”. The use of big data can create value to GRFA quite distinct from possession, use or management of GRFA, while also providing assistance and products to those who do possess, use and manage GRFA.

20. “DSI” on GRFA is stored in electronic/digital media. The amount of privately held “DSI” on GRFA is unknown. Publicly accessible “DSI” includes the content and functionality of approximately 1 700 online databases with infrastructure mainly in developed countries. However, due to the large data volumes and the bioinformatic skills that are required to access “DSI,” public availability of “DSI” does not necessarily imply accessibility.

21. Through “DSI”, different kinds of industries and actors become involved with the characterization, conservation and sustainable use of GRFA. Value chains are developing for everything from bionanotechnologies through synthetic biology and biological computing to on-farm hand-held sequencers and customized management advice. The decreasing cost of sequencing and synthesis will facilitate access to tools by researchers, the public and farmers.

22. Despite the decreasing cost of DNA sequencing and synthesis, the cost of working with other kinds of biological material, and the high cost of electronic infrastructure and specialist training, will continue to make it difficult for some countries to use or fully benefit from the use of “DSI”.

IV. THE LEGAL STATUS OF “DIGITAL SEQUENCE INFORMATION” ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE

23. According to the Nagoya Protocol, “benefits arising from the utilization of genetic resources as well as subsequent applications and commercialization shall be shared in a fair and equitable way with the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention”.²⁰

24. Different views are held as to whether “DSI” may be considered a “genetic resource”. Opinions also differ as to whether or under which conditions DNA sequencing, i.e. the process or determining the order of nucleotides in DNA or RNA, and screening activities, qualify as “utilization”. The legal implication of understanding “DSI” as equivalent to a genetic resource could be obligations for prior informed consent, mutually agreed terms and benefit-sharing. The legal implication of

¹⁹ See Background Study Paper No. 68.

²⁰ Nagoya Protocol, Article 5.1.

understanding “DSI” as only the product of utilization of a genetic resource could be obligations for the sharing of benefits arising from the “DSI” or subsequent applications and commercialization of “DSI”.²¹ “DSI” also raises the question whether the right to the sharing of benefits exhausts at some “cut-off” point or extends to every subsequent re-use that generates benefits.

TABLE 1: EXAMPLES OF CURRENT USES OF DIGITAL SEQUENCE INFORMATION ON GENETIC RESOURCES FOR FOOD AND AGRICULTURE

Animal genetic resources
<ul style="list-style-type: none"> • An example of the use of “DSI” for characterization of animal genetic resources is genomic selection, using genome-wide markers for predicting breeding value of individual animals. The shortened generation interval speeds up the breeding process. • “DSI” is being used for disease diagnosis and prevention. • The gene editing tool CRISPR/Cas9 guided by “DSI” of the BCO2 gene was used on the one cell stage of Tan sheep zygotes creating either biallelic or monoallelic BCO2 disrupted modified animals. Biallelic animals (those with both BCO2 genes mutated) had significantly more yellow colour in fat. • “DSI” of the rumen biome and its use in management of animal genetic resources. Several significant metagenomic surveys of the rumen microbiome have been completed, creating “DSI” that is applied to the dual challenges of increasing feed efficiency and reducing greenhouse gas emissions.
Aquatic genetic resources
<ul style="list-style-type: none"> • “DSI” is used to characterize genes that contribute to phenotypic plasticity in fish. • “DSI” contributes to cryopreservation of sperm and to a lesser degree fish ova and embryos and some invertebrate larvae, reproductive technologies and detection of hybrids, and disease diagnosis and prevention. • Product labeling verification using “DSI” can both be used for traceability and compliance with laws that promote the conservation and sustainable use of aquatic genetic resources.
Forest genetic resources
<ul style="list-style-type: none"> • “DSI” is used to provide species, sub-species and hybrid identification as well as to select genetic material for storage or micropropagation. • “DSI” used in predictive genomics may help in the conservation of trees by identifying the environment suited to the genotype and assisting their migration. • “DSI” has powerful potential for breeding of forest trees, helping to reduce the challenges resulting from their high levels of heterozygosity, large number of undomesticated species and long generation times.
Plant genetic resources
<ul style="list-style-type: none"> • “DSI” underpins marker-assisted selection in genomics-assisted breeding programmes. By providing improved tools for breeding, “DSI” contributes to food security and nutrition. • “DSI” supports the use of molecular markers, omics, cryopreservation, in vitro slow growth storage, wide crossing, somatic hybridization, micropropagation and biotechnologies for disease diagnosis. • “DSI” is used for pest management. “DSI” from genomic and metagenomic profiles is being used to design DNA or RNA pesticides, often referred to as types of “biologicals” or “agricultural biologicals” to distinguish them from synthetic chemical pesticidal active ingredients.
Micro-organism and invertebrate genetic resources
<ul style="list-style-type: none"> • “DSI” is used to generate molecular markers and for omics analysis in the characterization of micro-organism and invertebrate genetic resources, as well as for the detection of pathogens and spoilage agents in food. • “DSI” is used for molecular marker development, omics, cryopreservation and pathogen detection.

²¹ See Report of the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources (CBD/DSI/AHTEG/2018/1/4), Annex, paragraph 7(f).

25. Concerns have been expressed that “DSI” due to technological advances may challenge the implementation of ABS arrangements by obviating the need for users to seek access to the original biological resources, thus potentially enabling users to bypass procedures for access and benefit-sharing. On the other hand, it has been noted that under Article 5 of the Nagoya Protocol also benefits arising from “subsequent applications and commercialization” of genetic resource utilization have to be shared.

26. Some fear that any additional compliance or subscription costs for “DSI” could slow the distribution of assets for upstream research, as the information would be either not generated or kept secret. Others argue that failure of a legal framework for access to and the sharing of benefits derived from “DSI” could tempt countries to restrict the use of “DSI” extracted from genetic resources they provide.

27. Notwithstanding the differences in opinion, there seems to be agreement that the issue of “DSI” and its impact on the conservation, sustainable use of genetic resources and the fair and equitable sharing of benefits deserve further consideration.

V. DEVELOPMENTS IN OTHER FORA

Convention on Biological Diversity/ Nagoya Protocol

28. The Conference of the Parties (COP) to the CBD, at its Thirteenth Meeting, and the COP serving as the meeting of the Parties to the Nagoya Protocol at its Second Meeting adopted decisions on “DSI” in which they recognized the need for a coordinated and non-duplicative approach on this matter under the CBD and the Nagoya Protocol (decisions CBD COP XIII/16 and NP-2/14, respectively). They decided to consider at their forthcoming meetings any potential implications of the use of digital sequence information on genetic resources for the three objectives of the CBD and for the objective of the Nagoya Protocol, respectively.

29. The Parties also agreed on a process to facilitate consideration of this matter, including: consultations with governments, indigenous peoples and local communities and relevant organizations and stakeholders;²² the preparation of 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” in the context of the CBD and the Nagoya Protocol;²³ and the establishment of an hoc technical expert group to consider, *inter alia*, the technical scope and legal and scientific implications of existing terminology related to “DSI”.²⁴

30. In considering the matter at the Fourteenth Meeting of the COP, Parties, noting “a divergence of views among Parties regarding benefit-sharing from the use of digital sequence information on genetic resources” committed to working towards resolving this divergence through a “science- and policy-based process”²⁵ with the aim of “strengthening the fulfilment of the third objective of the CBD and Article 15, paragraph 7, without prejudice to the circumstances to which this article applies”.²⁶ The process includes consultations, the establishment of an extended Ad Hoc Technical Expert Group and the preparation of four peer-reviewed studies, on:

- (i) the concept and scope of digital sequence information on genetic resources and how “DSI” on genetic resources is currently used, building on the existing fact-finding and scoping study²⁷;

²² See *Synthesis of views and information on the potential implications of the use of digital sequence information on genetic resources for the three objectives of the Convention and the objective of the Nagoya Protocol* ([CBD/SBSTTA/22/INF/2](#) & [CBD/DSI/AHTEG/2018/1/2/Add.1](#)).

²³ See *Fact-finding and scoping study on digital sequence information on genetic resources in the context of the Convention on Biological Diversity and the Nagoya Protocol* ([CBD/DSI/AHTEG/2018/1/3](#)).

²⁴ See *Report of the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources* ([CBD/SBSTTA/22/INF/4](#)).

²⁵ Decision 14/20, paragraph 8.

²⁶ Decision 14/20, paragraph 6.

²⁷ *Fact-finding and scoping study on digital sequence information on genetic resources in the context of the Convention on Biological Diversity and the Nagoya Protocol* ([CBD/DSI/AHTEG/2018/1/3](#)).

- (ii) ongoing developments in the field of traceability of digital information, including how traceability is addressed by databases, and how these could inform discussions on "DSI" on genetic resources;
- (iii) public and, to the extent possible, private databases of "DSI" on genetic resources, including the terms and conditions under which access is granted or controlled, the biological scope and the size of the databases, numbers of accessions and their origin, governing policies, and the providers and users of the "DSI" on genetic resources, and encouraging the owners of private databases to provide the necessary information; and
- (iv) how domestic measures address benefit-sharing arising from commercial and non-commercial use of "DSI" on genetic resources and address the use of "DSI" on genetic resources for research and development.²⁸

31. The outcomes of the extended Ad Hoc Technical Expert Group will be considered by an open-ended intersessional working group established by the COP to support the preparation of the post-2020 global biodiversity framework.²⁹ The open-ended intersessional working group is to make recommendations to the fifteenth meeting of the COP on how to address DSI on genetic resources in the context of the post-2020 global biodiversity framework.³⁰ The open-ended intersessional working group is also requested to submit the outcome of its deliberations for consideration by the fourth meeting of the COP serving as the meeting of the Parties to the Nagoya Protocol.³¹

International Treaty on Plant Genetic Resources for Food and Agriculture

32. The International Treaty on Plant Genetic Resources for Food and Agriculture (Treaty) convened a special event on genomic information prior to its Seventh Session on 28 October 2017 in Kigali, Rwanda. A study on *Potential implications of new synthetic biology and genomic research trajectories on the International Treaty on Plant Genetic Resources for Food and Agriculture*,³² commissioned by the Treaty Secretariat, was presented at the special event.

33. The Governing Body of the Treaty, at its Seventh Session, considered "DSI" in the context of the Draft Multi-Year Programme of Work for 2018–2025. The Governing Body decided to consider at its Eighth Session the potential implications of the use of "digital sequence information" on genetic resources for the objectives of the Treaty, and to consider it for inclusion in its Multi-Year Programme of Work at that meeting. The Governing Body also invited Contracting Parties, other governments, relevant stakeholders and individuals with relevant expertise on the matter to provide information to the Governing Body on, *inter alia*, terminology used in this area, actors involved with "digital sequence information" on plant genetic resources for food and agriculture (PGRFA), the types and extent of uses of "digital sequence information" on PGRFA, such as characterization, breeding and genetic improvement, conservation, identification of PGRFA as well as on relevance of "digital sequence information" on PGRFA for food security and nutrition, in order to facilitate consideration by the Governing Body, at its Eighth Session, of the potential implications of the use of "digital sequence information" on PGRFA for the objectives of the International Treaty, including exchange, access and the fair and equitable sharing of the benefits arising from their use.³³

34. With regard to the Multilateral System of Access and Benefit-Sharing, the Governing Body set up a Contact Group to make progress on the enhancement of the Multilateral System. The Open-Ended Working Group to Enhance the Functioning of the Multilateral System of Access and Benefit-sharing, whose mandate was extended by the Governing Body for the 2018–19 biennium, is expected to consider issues regarding genetic information associated with material from the Multilateral System, including in the context of the Standard Material Transfer Agreement.³⁴

35. With regard to the Treaty's Global Information System (GLIS), the Governing Body decided to include in the terms of reference of the Scientific Advisory Committee on the Global Information

²⁸ Decision 14/20, paragraph 11.

²⁹ See Decision 14/34.

³⁰ Decision 14/20, paragraph 12.

³¹ Decision NP-3/12, paragraph 3.

³² http://www.fao.org/fileadmin/user_upload/faoweb/plant-treaty/GB7/gb7_90.pdf

³³ Resolution 13/2017.

³⁴ Resolution 2/2017.

System Committee, for the 2018–2019 biennium, the consideration of scientific and technical issues of relevance to genetic sequence information, as far as it is generated from the use of PGRFA and related to the implementation of GLIS.³⁵

World Health Organization

36. The Pandemic influenza preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits (PIP)³⁶, adopted in 2011 by the World Health Assembly, aims to improve pandemic influenza preparedness and response and strengthen the protection against pandemic influenza, with the objective of creating a fair, transparent, equitable, efficient and effective system for, on an equal footing, sharing of influenza viruses with human pandemic potential and access to vaccines and sharing of the benefits.

37. The PIP Review Group established in 2016 in accordance with the PIP Framework, while noting that the principles of the Framework remained as relevant as they were in 2011, concluded that “there are key issues that must urgently be addressed for the PIP Framework to remain relevant, including the issue of how [genetic sequence data] should be handled under the PIP Framework”.³⁷

38. While the PIP Framework makes reference to “genetic sequence data”³⁸ and encourages all countries to share these data in a rapid, timely and systematic manner,³⁹ genetic sequence data are not included in the definition of PIP Biological Materials. The benefit-sharing regime applicable under the PIP Framework to PIP Biological Materials does therefore not fully include genetic sequence data. The PIP Review Group therefore concluded that clarity is urgently required on the handling of genetic sequence data under the PIP Framework to ensure that it is guided by the same principles as the sharing of PIP Biological Materials.

39. In May 2017, the World Health Assembly requested, in response to the PIP Review Group’s report⁴⁰, the Director General of WHO to, *inter alia*, conduct a thorough and deliberative analysis of the issues raised by the PIP Review Group, including with regard to genetic sequence data. Following intensive consultations, and following the publication of a draft analysis in September 2018, the World Health Organization published the analysis on 14 December 2018.⁴¹ The analysis presents potential implications of possible approaches to seasonal influenza and genetic sequence data under the PIP Framework. The Executive Board of WHO will consider a draft decision on this matter at its forthcoming 144th Session, for consideration of the Seventy-second World Health Assembly.⁴²

VI. GUIDANCE SOUGHT

40. The Commission may wish to :

- i. consider the need for further analysis of “DSI” in preparation of its next session;
- ii. request that “DSI” and its implications on the conservation and sustainable use of, and the sharing of benefits derived from GRFA, including subsector-specific dimensions of DSI, be addressed by the Commission’s subsidiary bodies and the Commission at their next sessions;

³⁵ Resolution 5/2017, paragraph 9. See also the [Invitation to submit views and other information on “Digital sequence information”](#) of 3 December 2018.

³⁶ http://apps.who.int/iris/bitstream/handle/10665/44796/9789241503082_eng.pdf?sequence=1

³⁷ PIP Framework Review Group. 2016. [Review of the Pandemic Influenza Preparedness Framework, Report by the Director General. Geneva: World Health Organization](#), p.13.

³⁸ “Genetic sequences” means the order of nucleotides found in a molecule of DNA or RNA. They contain the genetic information that determines the biological characteristics of an organism or a virus (PIP Framework, section 4.1).

³⁹ PIP Framework, section 5.2.1.

⁴⁰ PIP Framework Review Group. 2016. [Review of the Pandemic Influenza Preparedness Framework, Report by the Director General. Geneva: World Health Organization](#).

⁴¹ World Health Organization. 2018. [Approaches to seasonal influenza and genetic sequence data under the PIP Framework](#).

⁴² http://apps.who.int/gb/ebwha/pdf_files/EB144/B144_23-en.pdf

- iii. invite countries and relevant stakeholders to provide capacity-building and financial support to allow all countries, especially developing countries, to make use of and benefit from “DSI”; and
- iv. request FAO to address the status and use of “DSI” on GRFA in future reports on the state of the world’s genetic resources and biodiversity for food and agriculture.