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Digital Sequence Information and the Nagoya Protocol

Legal expert brief on behalf of the Swiss Federal Office for the Environment (FOEN)

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Executive Summary

Modern biotechnology has advanced at a very high pace in the last few years. Research and development activities using genetic resources are more and more substituted by computerised, automated activities with digital information of genetic resources. These developments have made it an indispensable condition for research and development today to exchange such information via open access databases. This again has increased the potential for conflict with the objectives of the Nagoya Protocol – regulated access to genetic resources, and fair and equitable benefit-sharing.

The negotiation background of the Nagoya Protocol leaves no doubt that sequencing activities on genetic resources must be considered as research and development, or as utilisation of genetic resources by the terms of Art. 2 lit. c of the Protocol. An activity with a genetic resource must be considered as research and development if it creates new insight into characteristics of the genetic resource which is of potential benefit to the further process of product development. Such a potential added value is generated not only by sequencing, but also by screening activities, as far as the latter result in a «hit list» of genetic resources or sequence information with certain traits of interest.

The use of digital sequence information is not covered by the term *utilisation of genetic resources* of Art. 2 lit. c of the Nagoya Protocol; such information is also not a *derivative* according to Art. 2 lit. e. The historical interpretation of the Protocol however leads to the conclusion that the use of sequence information is not per se excluded from the scope of the Protocol. The negotiations were rather marked by an understanding that the sharing of benefits resulting from the use of information of genetic resources can be covered by Art. 5 of the Protocol and be managed via mutually agreed terms.

The teleological interpretation of the Protocol equally suggests that the use of sequence information can lead to benefits which must be shared by the terms of the Nagoya Protocol. Under the concept of «benefits arising from the utilisation of genetic resources as well as subsequent applications and commercialisation» (Art. 5 Para. 1 NP), and considering the spirit and purpose of the Protocol, it cannot make a difference whether a commercialised product contains genetic resources or is based on a synthetic substance which goes back to the utilisation of information gained when sequencing the original genetic resource. It can also not be relevant whether the product is entirely developed by one person or organisation, or if different actors are involved, who might only be connected indirectly via their use of a publicly accessible database. This means that the Nagoya Protocol and the Swiss implementation legislation also apply to the use of digital sequence information.

There have been multiple reasons brought forward against the Nagoya Protocol being applicable to instances where digital sequence information is accessed from open access databases: practical difficulties, negative implications on research and development, lack of traceability, and inherent benefits for the conservation and sustainable use of biodiversity. The first three aspects present a particular challenge for the implementation the Nagoya Protocol in the dynamic field of modern biotechnology. However, arguments *de lege lata* and arguments *de lege ferenda* must not be mixed up.

The Nagoya Protocol, as applicable today, is based on a bilateral approach. Potential solutions for the challenges relating to digital sequence information could include governing its use already at the time of access to genetic resources via PIC/MAT, uploading sequence information only to databases with certain conditions of use, and enhancing tracking options by way of marking DNA sequences.

There are good reasons to assume that a multilateral sharing of benefits arising from the use of digital sequence information could be more practical and result in greater added value for all actors involved. A multilateral solution would have to be achieved via a specialised international ABS instrument (Art. 4 Para. 4 NP), a global multilateral benefit-sharing mechanism (Art. 10 NP) or an amendment of the Nagoya Protocol itself.

1. Question

1

According to the contract of 18 September 2017, the author submits several legal expert briefs on matters related to the Nagoya Protocol. The present brief deals with the following topics:

- Digital sequence information: this topic is relevant both internationally and nationally for the implementation of the Nagoya Protocol[1], the Federal Act on the Protection of Nature and Cultural Heritage[2], and the Nagoya Ordinance.[3] The brief examines in particular if and how the topic of digital sequence information has been dealt with during the negotiation of the Nagoya Protocol, and if and how digital sequence information is addressed by the Nagoya Protocol. It is of particular interest if and to what extent the Nagoya Protocol and the implementing Swiss legislative framework are applicable in cases where digital sequence information is accessed without direct access to genetic resources.
- Sequencing: The term «utilisation of genetic resources» of the Nagoya Protocol raises questions about its interpretation both within industry and research sectors. There is a particular need for clarification of this term for sequencing activities and for the utilisation of the resulting digital sequence information.
- Screening: Both industry and research sectors also raise questions about the interpretation of the term «utilisation of genetic resources» of the Nagoya Protocol with regard to screening activities.

2. Concept and relevance of digital sequence information

2

Digital sequence information in its broadest sense is immaterial, electronically saved data on genetic resources. As the Convention on Biological Diversity (CBD[4]) defines genetic resources as genetic material containing functional units of heredity (Art. 2), digital sequence information is qualified as genetic sequence data for the purpose of this brief. The term *genetic* refers to the physical carrier of hereditary information, i.e. the deoxyribonucleic acid (DNA) and the ribonucleic acid (RNA). The digital shape of this information is insignificant for the legal evaluation of the topic of this brief and is simply reflecting the fact that such information is generally very voluminous and, realistically, can only be saved and used in a digital shape. The term *sequencing* refers to the process of determining and documenting the order of nucleotides or nucleobases on a given fragment of DNA or RNA, which are the building blocks of the chromosomes of organisms. The sequencing activity is generally performed for a particular series of genes, i.e. for a specific genotype. The identification of genotypes is of particular relevance because genotypes are the determining factor for an organism's observable characteristics (phenotype).[5]

3

The topic of digital sequence information under the Nagoya Protocol is mainly relevant because it is possible to have access to such data independent from access to genetic resources. There is no need to travel to a country providing a particular resource if the coded characteristics of this resource can be downloaded from an electronic database. It is of particular interest to know which rules apply under the

1 Nagoya Protocol of 29 October 2010 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; SR 0.451.432); the German and Italian translations have no legal force.

2 Federal Act of 1 July 1966 on the Protection of Nature and Cultural Heritage (NCHA; SR 451). German, French and Italian are the official languages of the Swiss Confederation. The English translation of certain acts (such as the NCHA) and ordinances is provided for information purposes only and has no legal force.

3 Ordinance of 11 December 2015 on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation (Nagoya Ordinance, NagO; SR 451.61); English translation without legal force (cf. fn. 2).

4 Convention of 5 June 1992 on Biological Diversity (CBD; SR 0.451.43); the German and Italian translations have no legal force.

5 For more detail about the term (including further need for clarification) and the utilisation of digital sequence information, see LAIRD/WYNBERG, pp. 8 ff. and pp. 19 ff.; in relation to the CBD and the negotiation of the Nagoya Protocol, also see SCHEI/TVEDT (UNEP/CBD/WG-ABS/9/INF/1), passim.

Nagoya Protocol when sequence information uploaded by researchers into open access databases are freely downloaded by users of such information. Sequence databases provide an immense wealth of information that research can build on. These databases also facilitate the publication of research related to sequencing activities as journal articles can simply include a reference number of an open access database and don't need to replicate sequence codes over several pages. Journals mostly even require including such a reference number to publish research dealing with sequences. Most database hosts don't verify if uploaded data may lawfully be shared and used by others, but simply refer users to their due diligence requirement. Some databases though request or allow the upload of metadata such as the source (*in situ* or *ex situ*), which facilitates recognising aspects that are relevant in relation to the Nagoya Protocol.[6]

The three main open access databases are affiliated through the *International Nucleotide Sequence Database Collaboration* (INSDC) and include:

- *GenBank* at the *U.S. National Center for Biotechnology Information* (NCBI);
- *European Nucleotide Archive* (ENA) at the *European Molecular Biology Laboratory's European Bioinformatics Institute* (EMBL-EBI);
- *DNA Data Bank of Japan* (DDBJ).

3. Wording of the Protocol, negotiation background and latest developments with regard to digital sequence information

3.1. Wording of the Nagoya Protocol

4

The Nagoya Protocol does not explicitly refer to digital sequence information. However, the following of its provisions are particularly relevant to determine the extent the Protocol and the Swiss implementation legislation apply to the use of digital sequence information:[7]

- Art. 1, Objective: When interpreting the Protocol, it is important to keep its underlying purpose in mind, i.e. the fair and equitable sharing of the benefits arising from the utilisation of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies.
- Art. 2, Use of Terms: A core element for the interpretation is the definition of *utilisation of genetic resources* as the conduct of research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention (lit. c). The CBD definition of *biotechnology* is recapitulated in lit. d and refers to any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use. Lit. e defines a *derivative* as a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.
- Art. 4, Relationship with International Agreements and Instruments: Para. 3 states that the Nagoya Protocol shall be implemented in a mutually supportive manner with other relevant international instruments. Para. 4 provides that the Protocol does not apply where a specialised international access and benefit-sharing (ABS) instrument applies that is consistent with, and does not run counter to the objectives of the Convention and the Protocol.
- Art. 5, Fair and Equitable Benefit-Sharing: Para. 1 requires that benefits arising from the utilisation of genetic resources as well as subsequent applications and commercialisation shall be

6 For more detail about the establishment, the significance and the policy of these databases, see LAWSON/ROURKE, pp. 8 ff.; LAIRD/WYNBERG, pp. 27 ff.

7 This brief does not specifically address access to genetic resources held by indigenous and local communities and to their traditional knowledge associated with genetic resources, and the respective sharing of benefits. However, its conclusions can be applied mutatis mutandis also in those situations.

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. Such sharing shall be upon mutually agreed terms (MAT).

- Art. 6, Access to Genetic Resources: In the exercise of sovereign rights over natural resources, and subject to domestic ABS legislation or regulatory requirements, access to genetic resources for their utilisation shall be subject to the prior informed consent (PIC) 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, unless otherwise determined by that Party (Para. 1).
- Art. 17, Monitoring the Utilisation of Genetic Resources: Parties must designate one or more effective checkpoints which collect and provide relevant information, and must take appropriate measures to address situations of non-compliance. Checkpoints should be relevant to the utilisation of genetic resources, or to the collection of relevant information at, inter alia, any stage of research, development, innovation, pre-commercialisation or commercialisation (Para. 1 lit. a).

3.2. Negotiation background

5

The issue of how to treat information on genetic resources has been part of the negotiations of the Bonn Guidelines on ABS already and later of the Nagoya Protocol. As early as 1999, a panel of experts established by the fourth CBD Conference of the Parties referred to the growing role and problem of «intermediary» entities offering specialised services such as the collection, screening and provision of genetic-resource samples, extracts and associated information.[8] During the negotiations of the Bonn Guidelines on ABS in 2002, some experts believed that a definition of the term *derivative* should include information.[9] Hence the context of the discussion was already the same as today, even though the term *digital sequence information* was not yet used as such. In the end, the term *derivatives* was taken up in the Bonn Guidelines,[10] but was not defined.

6

When the Nagoya Protocol was negotiated in 2006, the discussion on the use of terms was first deferred to a later time when negotiations would be more advanced.[11] Two years later, the ninth CBD Conference of the Parties decided to establish three distinct groups of technical and legal experts, one of them to deal with concepts, terms, working definitions and sectoral approaches under the future international regime on ABS.[12] This expert group convened at the end of 2008. On the one hand, the expert group considered that the renegotiation of the CBD definitions – i.a. of the terms *genetic resources* and *biotechnology* – was not practical.[13] On the other hand, it held a detailed conversation on various terms, including:

- *Uses of genetic resources*: In a non-exhaustive list, the expert group included genetic modification, biosynthesis, breeding and selection, propagation and cultivation, conservation, characterisation and evaluation (including sequencing and phenotyping) as well as production of compounds naturally occurring in genetic material (including screening and extraction of metabolites) as uses of genetic resources.[14]
- *Derivatives*: Without reaching a common understanding, the expert group compiled a list of varying concepts, from very general to very specific. The concepts mentioned included

8 UNEP/CBD/COP/5/8, Annex II. The panel of experts was mandated to, inter alia, contribute to the development of a common understanding of basic ABS concepts.

9 UNEP/CBD/COP/6/INF/40, Annex I, Para. 60 (Nigeria). The experts were tasked to develop draft elements of a decision on the use of terms in the Bonn Guidelines on ABS.

10 Cf. Bonn Guidelines on ABS, Para. 36 lit. l, Para. 44 lit. i and Appendix 1 Para. B.2, <https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf> (accessed 7 April 2018).

11 UNEP/CBD/COP/8/6, Para. 102–104.

12 UNEP/CBD/COP/DEC/IX/12, Para. 11 and Annex II.

13 UNEP/CBD/WG-ABS/7/2, Annex, Para. 6.

14 UNEP/CBD/WG-ABS/7/2, Annex, Para. 13.

information or knowledge derived from genetic materials in general, or a specific gene sequence in particular.[15] Some experts indicated that derivatives, including information about genetic resources, may be considered to be in the public domain, while some experts also suggested that this issue would need specific consideration during the negotiations, without offering a solution for it.[16]

7
During the following rounds of negotiation, the various proposals for the material scope of the draft protocol correlated with the differing opinions of the experts. The so-called Paris Annex, elaborated at the seventh meeting of the ABS Working Group in April 2009 and almost illegible due to the abundance of square brackets,[17] mentioned derivatives and «genetic sequences regardless of their origin» as potential elements for the material scope.[18] The eighth ABS Working Group meeting in November 2009 did not deal with the material scope and the use of terms.[19] In their endeavours to facilitate a negotiation breakthrough, the Co-Chairs of the ABS Working Group made a written statement in the run-up to the ninth meeting in March 2010. They stated that it was recognized that derivatives resulting from the expression or characterisation of genetic resources were a key issue for the future international ABS regime (i.e. the Nagoya Protocol), and that there was a growing understanding that this regime should ensure sharing of benefits from derivatives. They further stated that derivatives could be addressed through «use of genetic resources» and benefit-sharing arising from their use in mutually agreed terms (MAT).[20]

8
Drawing on their guidance note, the Co-Chairs produced a new draft of the Nagoya Protocol at the ninth meeting of the ABS Working Group. This non-paper provided for the «sharing of the benefits arising from the utilisation of genetic resources, including from derivatives produced through techniques such as expression, replication, characterisation or digitalisation».[21] It included an Annex II that featured a list of «typical uses» of genetic resources which largely corresponded to the list of the expert group mentioned above.[22] With this draft, the Co-Chairs attempted to reflect the progress the negotiations had made to date, but did not identify sections where consensus had not yet been reached. At the least they managed to reduce the length of the negotiation text to approximately one third of the previous draft. On this basis, the meeting tried to address key issues on a conceptual level without amending the text with square brackets, however, got caught in procedural disagreement. These controversies temporarily stalled the negotiations and resulted in a footnote in the revised draft protocol stating that the document – i.e. its wording – had not been negotiated.[23]

9
Due to lack of progress the ninth meeting of the ABS Working Group had to be formally suspended and was reconvened in July 2010. After another nine days of negotiation, the Working Group adopted a draft protocol which was based on the one provided by the Co-Chairs in March 2010, but was again amended with various alternatives, options and provisos in square brackets. In particular, the paragraph mentioned above on the «sharing of the benefits arising … from derivatives» including the reference to Annex II was bracketed.[24] Developing countries tended to request an explicit reference to derivatives in the provision on benefit-sharing, while developed countries tended to express reservations in this regard.[25] Observers of the

15 UNEP/CBD/WG-ABS/7/2, Annex, Para. 19 lit. e.
16 UNEP/CBD/WG-ABS/7/2, Annex, Para. 24.
17 Square brackets in negotiated text identify alternative options or lacking agreement.
18 UNEP/CBD/WG-ABS/7/8, Annex, Para. II.1.
19 Cf. UNEP/CBD/WG-ABS/8/8.
20 Cf. Revised Co-Chairs' Guidance Note, Para. 58 f., <https://www.cbd.int/doc/?meeting=ABSWG-09> (accessed 7 April 2018).
21 UNEP/CBD/WG-ABS/9/3, Annex I, Art. 4 Para. 2.
22 Cf. Point 6, first bullet point.
23 Also see the analysis of the Earth Negotiations Bulletin, Vol. 9, No. 503, pp. 14 ff., <http://enb.iisd.org/download/pdf/ enb09503e.pdf> (accessed 7 April 2018).
24 UNEP/CBD/COP/10/5/Add.4, Annex, Art. 4 Para. 2.; also see the fn. in Art. 4 Para. 1.
25 Cf. the various statements made by delegations and negotiation groups in UNEP/CBD/COP/10/5/Add.4 and the Earth Negotiations Bulletin, Vol. 9, No. 527, pp. 6 f., <http://enb.iisd.org/download/pdf/enb09527e.pdf> (accessed 7 April 2018).

meeting could at least detect a convergence towards a common understanding of the utilisation of genetic resources, which included both the uses of «genetic information» as well as that of «naturally occurring compounds».[26]

10
As the draft protocol was still far from ready to be adopted three months before the CBD Conference of the Parties in Nagoya, two further «interregional» negotiation meetings took place. At the first of these meetings, the definition of the term *utilisation of genetic resources* was transferred from Art. 4 Para. 1 and 2 (*Fair and Equitable Benefit-Sharing*) to Art. 2 (*Use of Terms*) of the draft protocol, and Annex II, so far mentioned in Art. 4 Para. 2, was deleted.[27] In Art. 2, the terms were grouped in a pyramid-like structure, as the term *utilisation of genetic resources* incorporates the term *biotechnology* as defined in Art. 2 CBD, which again covers the term *derivative*. In the context of the *utilisation of genetic resources* «through the application of biotechnology», the definition of *derivative* was reduced to «naturally occurring biochemical compounds». Even though still bracketed at the time, this definition was not changed in substance anymore.

11
As several key issues of the draft protocol were still lacking agreement towards the end of the CBD Conference of the Parties in Nagoya, the Japanese Presidency felt compelled to present a last-minute «take it or leave it» proposal.[28] There was no opposition against this compromise proposal, even though many half-satisfied delegations and negotiation groups criticised the last phase of the negotiation process as non-transparent.[29] For the terms *utilisation of genetic resources*, *biotechnology* and *derivative*, the pyramid-like solution as mentioned above was confirmed. For the term *utilisation of genetic resources*, the prevailing option refers to the «conduct of research and development on the genetic and/or biochemical composition of genetic resources».

3.3. Latest developments

12
Biotechnology has further advanced since the adoption of the Nagoya Protocol on 29 October 2010 and its entry into force on 12 October 2014, making the issue of how to deal with digital sequence information under the Protocol more and more prominent. The issue was also discussed at length at the latest Conference of the Parties for the CBD and the Nagoya Protocol in December 2016, where it was agreed to first have a technical expert group look into the matter before taking a decision. In consideration of submissions by Parties and other stakeholders, as well as a fact-finding and scoping study,[30] the expert group has commented on a number of technical, scientific and legal aspects.[31] Based on the conclusions of the expert group, the Subsidiary Body on Scientific, Technical and Technological Advice (SBSTTA) will make recommendations to the Conference of the Parties meeting in November 2018.[32]

26 Cf. the analysis in the Earth Negotiations Bulletin, Vol. 9, No. 527 (fn. 25), p. 15.

27 UNEP/CBD/WG-ABS/9/ING/1, Annex, Art. 2 Para. c; for the thorny negotiations see the Briefing Note of the International Institute for Sustainable Development (IISD), pp. 2 f., <http://enb.iisd.org/biodiv/absing/brief/absing_briefe.pdf> (accessed 7 April 2018).

28 UNEP/CBD/COP/DEC/X/1, Annex I.

29 For an analysis of the negotiations in Nagoya, see MORGERA/BUCK/TSIOUMANI, pp. 21 ff.; GREIBER/PEÑA MORENO ET AL., pp. 22 f.; BUCK/HAMILTON, pp. 50 f.; Earth Negotiations Bulletin, Vol. 9, No. 544, pp. 3 ff. and 26 f., <http://enb.iisd.org/download/pdf/enb09544e.pdf> (accessed 7 April 2018).

30 Cf. LAIRD/WYNBERG; the draft study was made available for peer review at <https://www.cbd.int/abs/dsi-gr/ahteg.shtml> (accessed 7 April 2018).

31 CBD/DSI/AHTEG/2018/1/4.

32 Cf. decisions CBD/COP/DEC/XIII/16 and CBD/NP/MOP/DEC/2/14.

4. Status of digital sequence information in related fora

4.1. International Treaty on Plant Genetic Resources for Food and Agriculture

13

Other fora also discuss how international ABS provisions are to be interpreted and applied in relation to the utilisation of digital sequence information. This question is particularly relevant for the Multilateral System of the International Treaty on Plant Genetic Resources for Food and Agriculture[33] (Art. 10 ff., Annex I), which is to be considered as a specialised international ABS instrument for the intended use of food crops and forages, taking precedence over the Nagoya Protocol (Art. 4 Para. 4 NP).[34]

The priority of the International Treaty can be deducted from the preambular text of the Nagoya Protocol, which recognises the Treaty to be «in harmony» with the Convention.[35] In November 2018, the third Conference of the Parties of the Nagoya Protocol will consider a study that looks into criteria that could be used to identify what constitutes a specialised international ABS instrument, and what could be a possible process for recognising such an instrument.[36] However, as Art. 4 Para. 4 NP is not conditional in this respect, its application cannot depend on a formal recognition of such an instrument, e.g. on a decision of the Conference of the Parties, even though such a recognition would definitely benefit the consistent application of the Protocol by Parties.

14

In early 2017, the Commission on Genetic Resources for Food and Agriculture (CGRFA), a permanent forum according to Art. VI.1 of the Constitution of the Food and Agriculture Organization of the United Nations (FAO)[37], has established a new work stream on «digital sequence information on genetic resources for food and agriculture». It requested the Secretariat of the International Treaty to prepare an exploratory fact-finding scoping study on this topic and to collaborate with the relevant CBD bodies in this regard.[38] This study shall consider i.a. terminology, actors, types and extent of uses of such information as well as relevance for food security and nutrition, in order to facilitate consideration by the Commission. In particular, there is a need to know if the ABS provisions, including the *Standard Material Transfer Agreement*, apply when transferring digital sequence information on plants covered by the Multilateral System. A resolution of the Governing Body (equivalent to the Conference of the Parties) of the International Treaty made in November 2017 reflects the decision of the CGRFA on digital sequence information and invites Parties and other stakeholders to provide relevant information for consideration by the Governing Body at its next meeting in late 2019.[39] At the same time, the Governing Body has welcomed the voluntary use of digital object identifiers and the publication of descriptors and guidelines for their use.[40] These identifiers help to increase transparency in the Global Information System according to Art. 17 of the International Treaty, to make different information systems interoperable and to facilitate the discovery, identification and monitoring of information on genetic resources.[41] Hence they support the implementation of the Treaty.

15

DivSeek should also be mentioned in this given context. *DivSeek* is an initiative of 68 research and other partner organisations that aims to use digital data to unlock the societal and economic potential of crop and

33 SR 0.910.6.

34 Cf. GREIBER/PEÑA MORENO ET AL., pp. 80 f.; MORGERA/BUCK/TSIOUMANI, pp. 98 ff.; BUCK/HAMILTON, p. 58; SOLLBERGER/GONSETH, in: Legal Commentary of the Federal Act on the Protection of Nature and Cultural Heritage (*draft 2nd edition*), preliminary notes for Art. 23n–23q and 25d, point 10.

35 Para. 19; also see Para. 16 and MORGERA/BUCK/TSIOUMANI, p. 98, who consider that the International Treaty is meeting the criteria of Art. 4 Para. 4 NP since 2010 (i.e. the time of adoption of the Nagoya Protocol).

36 Cf. CBD/NP/MOP/DEC/2/5, Para. 3.

37 SR 0.910.5.

38 Cf. CGRFA-16/17/Report, Para. 86 ff., <http://www.fao.org/3/a-ms565e.pdf> (accessed 7 April 2018).

39 Cf. IT/GB-7/17/Res13, Para. 4 ff., <http://www.fao.org/3/a-mv176e.pdf> (accessed 7 April 2018).

40 Cf. IT/GB-7/17/Res5, Para. 2, <http://www.fao.org/3/a-mv103e.pdf> (accessed 7 April 2018), with links to the publications mentioned.

41 Cf. the FAQs at <http://www.fao.org/plant-treaty/areas-of-work/global-information-system/faq/en> (accessed 7 April 2018).

related wild plants stored around the globe for food and nutritional security.[42] The initiative promotes best practices in sequencing and phenotypic analysis of genetic resources and in the exchange of such information. Hence *DivSeek* is also relevant for the Nagoya Protocol when it deals with plants other than the crops covered by the Multilateral System of the International Treaty. Non-government organisations have cautioned that the generation and propagation of digital data supported by *DivSeek* could lead to commercial uses without respecting ABS requirements.[43] The activities undertaken by *DivSeek* are followed and regularly discussed by the bodies of the International Treaty.[44]

4.2. WHO Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits

16

The Pandemic Influenza Preparedness (PIP) Framework for the sharing of influenza viruses and access to vaccines and other benefits was adopted by the World Health Organisation (WHO) in 2011.[45] With its benefit-sharing mechanism, the PIP Framework also establishes a specialised international ABS instrument taking precedence over the Nagoya-Protocol (Art. 4 Para. 4 NP).[46] The main objectives of the PIP Framework are to ensure the sharing of influenza viruses with human pandemic potential, and to improve access to vaccines and sharing of other benefits in and with developing countries. The PIP Framework requires the sharing of genetic sequence data for risk assessment, research, monitoring and risk response in order to prevent and contain pandemic influenza outbreaks.

17

Pharmaceutical companies receiving PIP candidate vaccine viruses or their genetic sequence data are urged to take a number of specific benefit-sharing measures.[47] Adequate monitoring measures are supposed to ensure the sharing of benefits and to prevent the use of such viruses and data outside the PIP Framework. WHO established a Technical Working Group to shape these monitoring measures and to make recommendations via the PIP Advisory Group.[48] The Working Group has identified optimal characteristics and best practices of an influenza genetic sequence data sharing system,[49] recommending that providers first submit sequence data to an open source database with controlled access. Unlike open access databases, open source databases register the data users and require them to accept specific terms and conditions before having access to data.[50] Sequence data should be uploaded together with minimal metadata such as the name of the originating laboratory and of the organism, the geographic location of the specimen collection and a unique specimen identification number. When later uploading the data to an open access database, a reference should be made that the PIP Framework is applicable. To monitor if data use is in harmony with the PIP Framework, WHO is collaborating with the *World Federation for Culture Collections* (WFCC) and the *World Data Centre for Microorganisms* (WDCM) to establish a search engine which would retrieve information on the use of genetic sequence data from publicly available downstream documents, such as scientific publications, patents, research trial documentation, and regulatory files.[51]

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42 Cf. <http://www.divseek.org/faqs-1/> (accessed 7 April 2018); the *World Food System Center* of *ETH Zurich* is among the *DivSeek* partners.

43 Cf. the brief prepared by *The International Civil Society Working Group On Synthetic Biology* in the run-up to the 2016 CBD/NP Conference of the Parties at <https://www.boell.de/sites/default/files/2016-11-icswgsb_synbio_brief_cop13_.pdf>, p. 6 (accessed 7 April 2018).

44 Cf. the synthesis report informing the 7th session of the Governing Body at <http://www.fao.org/3/a-mt955e.pdf> (accessed 7 April 2018).

45 Cf. <http://www.who.int/influenza/pip/en> (accessed 7 April 2018).

46 Cf. MORGERA/BUCK/TSIOUMANI, pp. 102 ff. (with further references); SOLLBERGER/GONSETH, in: Legal Commentary of the Federal Act on the Protection of Nature and Cultural Heritage (*draft 2nd edition*), preliminary notes for Art. 23n–23q and 25d, point 10; see point 13 above for the recognition of specialised international ABS instruments.

47 Cf. Chapter 6 PIP Framework.

48 Cf. <http://www.who.int/influenza/pip/advisory_group/gsd/en> (accessed 7 April 2018).

49 Cf. <http://www.who.int/influenza/pip/advisory_group/twg_doc.pdf?ua=1> (accessed 7 April 2018).

50 On open source databases, also see point 34 below, second bullet point.

51 Cf. <http://www.who.int/influenza/pip/advisory_group/gsdoptionspaper_revised.pdf?ua=1> and <http://www.who.int/influenza/pip/

5. Interpretation with regard to different circumstances

5.1. Concept of utilisation in general

18

As mentioned above, Art. 2 NP defines the term *utilisation of genetic resources* as the conduct of research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention (lit. c). The term *biotechnology* encompasses any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use (lit. d). A *derivative* is defined as a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity (lit. e).

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The term *research and development* is not defined in the Nagoya Protocol. It should be interpreted in accordance with its ordinary meaning (Art. 31 Vienna Convention on the Law of Treaties[52]). Relying on the negotiation language, the Oxford Dictionary defines *research* as «the systematic investigation into and study of materials and sources in order to establish facts and reach new conclusions». *Development* includes applied research, i.e. the creation of innovations and practical applications.[53] The German Duden Dictionary again defines *research* as «working to gain scientific knowledge or rather examining a scientific problem». The guidance document of the European Commission refers to «a type of litmus test» where an activity with a genetic resource is to be considered research and development if it creates new insight into characteristics of the genetic resource which is «of (potential) benefit to the further process of product development». The EU guidance document also refers to the OECD Frascati Manual which states that «research and experimental development comprise creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications».[54]

20

The Frascati Manual is the acknowledged worldwide standard for collecting and reporting internationally comparable statistics on the financial and human resources devoted to research and experimental development.[55] For an activity to be a research and development activity, the Manual asks for five cumulative core criteria to be satisfied:[56]

- Novel: The activity must be aimed at new findings, which can mean different things in different research sectors and institutions. In the commercial sector for example, copying, imitating or reverse engineering do not qualify as research and development.
- Creative: The activity must be based on original, not obvious, concepts and hypotheses. This excludes from research and development any routine change to products or processes as well as sole data processing, unless new methods are developed to perform common tasks.
- Uncertain: At the outset of a research and development project, the kind of outcome, the cost and the time needed cannot be precisely determined relative to the goals. This means it must be uncertain to which degree the objectives can be achieved.
- Systematic: The activity must be conducted in a planned way, with records kept of both the process followed and the outcome, and of the human and financial resources allocated.

AG_Nov2017.pdf?ua=1>, Para. 27–32 (both accessed 7 April 2018); for the developments regarding genetic sequence data under the PIP Framework, also see LAWSON/ROURKE, pp. 31 ff.

52 Vienna Convention on the Law of Treaties, concluded on 23 May 1969, SR 0.111.

53 Cf. GREIBER/PEÑA MORENO ET AL., p. 65; EUROPEAN COMMISSION, Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014, OJ C 313, 27 August 2016, p. 8.

54 ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT (OECD), Frascati Manual 2015: Guidelines for Collecting and Reporting Data on Research and Experimental Development, point 1.32.

55 Cf. OECD, Frascati Manual 2015, point 1.1.

56 Cf. OECD, Frascati Manual 2015, point 1.2, 2.7, 2.14 ff. as well as sector-specific comments.

- Transferable and/or reproducible: The activity needs to allow other researchers to reproduce the new knowledge (peer review). This means the results of a research and development activity cannot remain tacit, but must be codified.

5.2. Sequencing

21

As mentioned above, sequencing refers to the process of determining and documenting the order of nucleotides or nucleobases on a given fragment of DNA or RNA. The characterisation of a genetic resource can serve numerous purposes, i.a. the identification of genes that have useful or undesirable traits, the analysis of evolutionary relations between different species, or the examination of interrelationships between environmental impacts such as from fertilisers, pesticides or other pollutants, and the development of biodiversity.[57] Most importantly, the documentation of base sequences also facilitates numerous other – automated and computerised – research and development activities.[58] Thus the decoding of the genome of organisms like animals, plants and microbes is to be considered a new insight which, according to the EU guidance document, is of (potential) benefit to the further process of product development. This added value is illustrated by various cases of patent applications for gene sequences which have eventually been denied by judicial decisions.[59] Accordingly, the group of legal and technical experts established during the negotiation of the Nagoya Protocol has considered sequencing genes or genomes as uses of genetic resources.[60]

22

Going by the core criteria of the Frascati Manual though, it is debatable if sequencing activities are to be qualified as research and development. Considering the various ways gene sequence information can be used and developed, sequencing activities are clearly aimed at new findings. It is less clear though if the same activities are creative: On the one hand, sequencing activities result in a substantial advancement of knowledge and are not a simple change to an existing product or a mere data processing exercise. On the other hand, today's routine sequencing techniques are often automated, lacking a genuine human input, and can be performed by low-cost, portable and real-time instruments, even by small kits for rudimentary use via smartphone.[61] The sequencing activity does also not seem uncertain, as the necessary investment of time and money can often be determined beforehand. It seems obvious though that the activity is planned, systematic and reproducible. After all, the Frascati Manual explicitly includes big data projects such as the *Human Genome [Decoding] Project* in research and development activities.[62] Other, less complex sequencing activities however do not seem to fulfil the creativity and uncertainty criteria.

23

In conclusion, it is not clear-cut if sequencing DNA or RNA qualifies as *utilisation of genetic resources* according to Art. 2 lit. c NP. For historical and teleological reasons though, the interpretation provided by the EU guidance document must prevail: Firstly, as elaborated in point 6 above, a group of legal and technical experts established under the CBD has explicitly equated sequencing genetic resources with their utilisation, which has not been challenged in the remaining course of the negotiations. Secondly, we would deny the spirit and purpose of the Nagoya Protocol if we used a standard for collecting internationally comparable statistics – the Frascati Manual – to conclude that sequencing activities are not research and development. Such a conclusion would logically exempt the subsequent utilisation of sequence information – an important aspect of modern biotechnology – from the application of the Nagoya Protocol.

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57 Cf. the Report of the Meeting of the Group of Legal and Technical Experts on Concepts, Terms, Working Definitions and Sectoral Approaches of the future international regime on ABS (i.e. the present Nagoya Protocol), UNEP/CBD/WG-ABS/7/2, Annex, Para. 13, Sub-Para. 6; also see in greater detail LAIRD/WYNBERG, pp. 12 f., 22 ff. and 39 ff.

58 Cf. e.g. REICHMAN/UHLIR/DEDEURWAERDERE, pp. 319 ff.

59 Cf. UNCTAD Handbook, p. 78; BAGLEY 2015, pp. 5 f.

60 UNEP/CBD/WG-ABS/7/2, Annex, Para. 13, Sub-Para. 6.

61 Cf. LAIRD/WYNBERG, p. 33 and their reference to <https://nanoporetech.com/products> (accessed 7 April 2018).

62 Cf. OECD, Frascati Manual 2015, point 2.93.

This would conflict with the notion of access and benefit-sharing as perceived by the international community when negotiating and concluding the Nagoya Protocol.

5.3. Screening

24

As elaborated in Chapter 5.2, decoding genetic resources into nucleobase sequences and publishing them in a database can serve numerous purposes. The large amount of gene sequence information in a database allows the search for a specific sequence of nucleobases with a trait of interest. The search activity is called *screening* and, from a layperson's perspective, comparable to a Google search on the internet. As opposed to a physical screening, the digital screening does not require direct access to genetic resources. This is why physical screening is replaced by digital screening whenever feasible. The physical screening – the application of *high-throughput screening techniques* – is much more expensive and is often undertaken by using validated assays run in laboratory robotics set-ups. Both kinds of screening depend on searching a large amount of either information or genetic resources in order to increase the likelihood of finding the traits of interest.[63]

25

Screening activities have come to play a very important role in biotechnological research and development.[64] Applying the «litmus test» of the EU guidance document referenced above, the screening of genetic resources and sequence information must be considered research and development where traits of interest are identified («hits»). This identification must be considered a new insight with a «potential benefit to the further process of product development», at least if this insight is documented and reusable later on. In other words, the screening activity is generating added value by identifying genetic resources or sequence information with specific traits that can later be accessed without further search activity. In contrast, the screening activity cannot be considered research and development where it is applied to the large majority of genetic resources and sequence information for which those traits are not identified, because there is no added value compared to the situation before the screening. In practice, this discrepancy must mean that the Nagoya Protocol applies to the «hits» resulting from the screening as long as the «hit list» of genetic resources or sequence information with specific traits is saved, transferred and/or reused. As for the digital screening, monitoring compliance with national ABS requirements is not feasible before the search anyway, as the wealth of sequence information to be searched is not manageable at this point.

26

The position paper provided by industry applies the core criteria of the Frascati Manual and concludes that screening activities are not to be considered research and development. The paper argues that these activities are executed in a largely automated manner and do not require a creative, substantial human input. It is also stated that screening activities are not uncertain in relation to the cost and time required. One can easily relate to industry's interpretation, however, the same points could very well be made with regard to sequencing activities which are just as little creative and uncertain, as demonstrated above. The growing automation and predictability in the research sector illustrates in fact a general development in modern biotechnology.[65] Hence for screening and sequencing activities alike, the notion of research and development can be understood in different ways. And again, it aligns with the spirit and purpose of the Nagoya Protocol – the sharing of benefits – to favour the interpretation that looks at the (potential) value added by the screening activity. In contrast to sequencing activities, the difference between the two interpretations is of little practical significance though, as both consider the further use of the screening «hit list» to qualify as utilisation according to the Nagoya Protocol. This is also recognised in the position paper provided by industry.

63 See the position paper provided by industry as background for this legal brief.

64 Cf. REICHMAN/UHLIR/DEDEURWAERDERE, pp. 21 (fn. 119) and 110.

65 Cf. e.g. REICHMAN/UHLIR/DEDEURWAERDERE, pp. 319 ff.

27

Despite the pivotal criterion of the added value, it will not always be obvious if a specific physical screening activity qualifies as research and development in the sense of Art. 2 NP. The following scenarios tend to speak against the applicability of the Nagoya Protocol and the due diligence requirement of Art. 23n of the Swiss NCHA:

- The screening applies to a large amount of candidate genetic resources (*high throughput*), which are de-selected by a large factor.
- The screening is executed in a relatively short time, in which the candidate genetic resources are assessed for specific traits of interest in one or few steps. The more steps necessary, the more we need to assume a research and development activity.
- The screening applies to candidate genetic resources from an existing ex-situ collection of samples from multiple provider countries.

If, for the purpose of screening, genetic resources are accessed directly in a provider country, e.g. via bioprospecting, it is understood that all domestic access requirements must be complied with. The territoriality principle makes these requirements directly applicable, irrespective of the due diligence requirement according to Art. 23n of the Swiss NCHA.

5.4. Utilisation of digital sequence information without access to open access databases

28

We need to first examine the applicability of the Nagoya Protocol in the relatively less complex case where digital sequence information is used without access to open access databases. We hereby assume that there is no transfer of digital sequence information between different actors. Rather we suppose it is the person or organisation that had initial access to a specific genetic resource in its country of origin that develops a drug with a synthetic substance. It is further assumed that the manufacture of the synthetic substance goes back to the utilisation of information gained when sequencing the original genetic resource. Whether sequencing was allowed and on what conditions is dependent on PIC/MAT negotiated with the provider country. The Bonn Guidelines' indicative list of typical MAT explicitly includes «provisions regarding the sharing of benefits arising from the commercial and other utilisation of genetic resources and their derivatives and products».[66] However, it is not the term *derivative* – defined in Art. 2 lit. e NP and not including information on genetic resources – which makes the Nagoya Protocol applicable to the scenario just described, but rather the concept of «benefits arising from the utilisation of genetic resources as well as subsequent applications and commercialisation» (Art. 5 Para. 1 NP). Teleological considerations about the sharing of benefits strongly suggest not to make a distinction depending on whether the genetic resource utilised can still be detected in the final product, i.e. the drug in our case, or not.[67] For Art. 5 Para. 1 NP to be applicable though, there would have to be an adequate causality between the initial utilisation (e.g. sequencing) of the genetic resource and the attributes of the product commercialised in the end. For our example, the synthetic substance would have to significantly contribute to the effect of the drug.

5.5. Utilisation of digital sequence information from open access databases

29

Building on the above, we have to ask ourselves how the Nagoya Protocol is to be applied to the same example of a drug with a synthetic substance if different actors are involved, which are not in direct contact with each other, but are connected indirectly via a publicly accessible database. This means that the information gained from sequencing the original genetic resource is uploaded to an open access database, with or without explicit or implicit authorisation by MAT. It is then screened and downloaded by an interested user. Subsequently the information contributes to the manufacture of the synthetic substance, possibly together with other digital sequence information.

66 Cf. Para. 44 lit. i Bonn Guidelines on ABS, <https://www.cbd.int/doc/publications/cbd-bonn-gdls-en.pdf> (accessed 7 April 2018).

67 Also see the example for «subsequent applications and commercialisation» given by GREIBER/PEÑA MORENO ET AL., p. 85; SPRANGER, pp. 52 f., is drawing the conclusion that «subsequent applications and commercialisation» must exclusively refer to genetic resources or «physical substances», which seems a too narrow perspective from a teleological point of view.

5.5.1. Implementation difficulties and objections against the application of the Nagoya Protocol

30

There have been multiple reasons brought forward against the Nagoya Protocol being applicable to instances where digital sequence information is accessed from open access databases and subsequently utilised. In particular:[68]

- *Practical difficulties*: In state-of-the-art biotechnology and bioinformatics, information on hundreds to thousands of different sequences may be used to develop a particular product. This makes it difficult – if not impossible – to determine the relative value of one individual sequence. Also, genetic sequences can be common to several species.
- *Negative implications on research and development*: If digital sequence information from open access databases were not freely available and useable, research activities on genetic resources and respective publications would decrease and the development of innovative products would be less likely. This would result in a substantial loss of socio-economic benefits for society as a whole.
- *Lack of traceability*: It is often not possible – or not possible anymore – to determine the origin or the source of digital sequence information and to reconstruct the user chain. The tracking and monitoring of such information is even more difficult than it is with genetic resources. The same is true for the enforcement of PIC and MAT.

31

Beyond the reasons above, the argument is made that sequencing genetic resources and utilising the resulting data provides a vital resource for the conservation and sustainable use of biodiversity. It is pointed out that digital databases help increase and spread knowledge and technologies, as pursued by the 2020 Aichi Biodiversity Target 19,[69] and often benefit from public funding by their country hosts.[70] Hence free access to those databases would already represent an adequate form of benefit-sharing.[71]

5.5.2. Debate about the objections against the application of the Nagoya Protocol

32

Before examining the reasons and arguments just presented, we must acknowledge that biotechnology does indeed advance at breathtaking speed, while the measures of biodiversity policy lag behind, both nationally and internationally.[72] The dynamic scientific developments make it particularly challenging to implement the Nagoya Protocol and domestic ABS regulations. As biotechnology further advances, the international community will have to consider enhancing and adapting the Nagoya Protocol or developing other specialised international ABS instruments as provided for by Art. 4 Para. 4 NP. This is illustrated by a significant number of submissions on digital sequence information made by Parties and stakeholders that do not seem to make a distinction between existing applicable regulations and mechanisms desirable from their perspective.

33

As mentioned above, the term *derivative* as defined in Art. 2 lit. e NP does not include digital sequence information. This means that such information is – per se – also not included in the terms *biotechnology* and *utilisation of genetic resources* according to Art. 2 lit. c and d NP. This is not essential though. The

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68 See the various submissions to the Executive Secretary from Parties, other Governments, relevant organisations and stakeholders based on decisions CBD/COP/DEC/XIII/16 and CBD/NP/MOP/DEC/2/14, accessible at <https://www.cbd.int/abs/dsi-gr/ahteg.shtml> (accessed 7 April 2018). They were invited to address any potential implications of the use of digital sequence information on genetic resources for the three objectives of the Convention. In particular, see the submission from the International Chamber of Commerce (ICC). Also see SPRANGER, pp. 14 ff., 29 ff. and 55 ff., who considers intellectual property rights and «human rights standards» at stake. For the most significant limitations of the bilateral approach in general, see REICHMAN/UHLIR/DEDEURWAERDERE, pp. 106 ff. and LAIRD/WYNBERG, pp. 13 ff. and 51 ff.

69 See the joint submission from Natural History Museum London, Royal Botanic Gardens Kew and Royal Botanic Garden Edinburgh (fn. 68).

70 Cf. LAIRD/WYNBERG, pp. 13 and 44.

71 Cf. LAIRD/WYNBERG, pp. 44 ff.

72 Cf. WYNBERG/LAIRD, pp. 1 ff.

crucial question is rather if the utilisation of digital sequence information can lead to «benefits arising from the utilisation of genetic resources as well as subsequent applications and commercialisation» (Art. 5 Para. 1 NP). If the manufacture of the synthetic substance is not possible without initial access to specific sequence information, and if the same substance is significantly contributing to the effect of the drug, the chain of causality suggests that the respective benefit is a result of the original utilisation of the corresponding genetic resource, i.e. the sequencing activity. This interpretation has to be confronted with the above arguments against the applicability of the Nagoya Protocol, particularly with regard to a potential disruption of the chain of adequate causality. It has to be anticipated that the objections are to some extent similar to the ones made against an international ABS regime as such, and are therefore aimed at the core elements of the Nagoya Protocol.

34
The above reasons and arguments against the applicability of the Nagoya Protocol are examined as follows:

- *Practical difficulties*: The fact that the development of an individual product often requires the use of information from hundreds to thousands of genetic sequences is – in general terms – not sufficient to disrupt the chain of adequate causality between the use of an original genetic resource when it is sequenced and the benefits that result from the commercialisation of an individual product. If the Nagoya Protocol was to be considered not applicable due to the high volume of genetic sequence data involved, one would have to define a certain threshold limiting the scope of the Protocol to a manageable number of sequences used. Such a threshold does not seem defendable, even though it is admittedly difficult to determine the relative value of one individual sequence if information on multiple sequences is used at the same time. In all events, there are no objective criteria for the kind and the extent of benefit-sharing which depends on the negotiation between parties in particular circumstances.[73] Neither is the applicability of the Nagoya Protocol challenged by the fact that genetic sequences can be common to several species. This is in essence comparable to a situation where a genetic resource is found in more than one country, which enables the user to choose the provider country with the «lowest» ABS requirements. Finally, it would make little sense to declare the Nagoya Protocol not applicable in cases where genetic resources and/or digital sequence information is passed on between a defined number of actors. It rather matters whether – in an individual situation – applicable ABS requirements have been researched and respected with regard to specific sequence information for which the development of a product is dependent on.
- *Negative implications on research and development*: A decline in research activities can not only result from ABS-specific restrictions for the use of digital sequence information from open access databases, but also from domestic ABS regulations on access to and use of genetic resources altogether. Both constraints essentially go back to the paradigm shift relating to the third objective of the CBD, which acknowledges the Parties' sovereign rights to genetic resources.[74] Both uses however benefit from special considerations in favour of non-commercial research and emergency situations (Art. 8 NP). Potential negative implications on research and development can therefore not lead to a general exclusion of digital sequence information from the Nagoya Protocol.
- *Lack of traceability*: It is indeed very challenging to determine the origin or source of digital sequence information and to monitor its transfer. However, this is also true for genetic resources, which means that monitoring is a generic challenge when implementing the Nagoya Protocol and national ABS legislation. Even where genetic resources are found in products, the sole existence of checkpoints (Art. 17 NP) will in many cases not suffice to make sure that PIC/MAT requirements of provider countries are respected. For such products as well, the respect of ABS

73 For the term *fair and equitable benefit-sharing*, see SOLLBERGER/GONSETH, in: Legal Commentary of the Federal Act on the Protection of Nature and Cultural Heritage (*draft 2nd edition*), Art. 23n, point 11.

74 Cf. SOLLBERGER/GONSETH, in: Legal Commentary of the Federal Act on the Protection of Nature and Cultural Heritage (*draft 2nd edition*), preliminary notes for Art. 23n–23q and 25d, point 2.

requirements depends on elaborate monitoring technologies and – most of all – the willingness of users to integrate the key elements of the Nagoya Protocol into their organisational structures and business models. We surely need to consider implementation and enforcement challenges when interpreting the Nagoya Protocol and when potentially developing it further. These challenges however cannot justify exempting the use of digital sequence information accessed in open access databases from the Protocol altogether.

- *Conservation and sustainable use of biodiversity*: The argument that using open access databases is contributing to the conservation and sustainable use of biodiversity, and is therefore already representing an adequate form of benefit-sharing, could also be made for many cases of traditional access to genetic resources and their subsequent (non-commercial) utilisation. This argument ignores that it is up to each provider country to make use of its sovereign rights and to decide how it is «creat[ing] conditions to promote and encourage research which contributes to the conservation and sustainable use of biological diversity» (Art. 8 lit. a NP). The regulatory approach of the Nagoya Protocol is based on a bilateral concept, which requires a provider country to explicitly agree if general biodiversity gains were to be recognised as benefit-sharing. However, it would amount to a multilateral concept to consider benefit-sharing to be inherent when using open access databases, or – for example – to introduce a licensing scheme or a minimal «ABS fee» for consulted sequence information.[75] A multilateral mechanism would have to be further elaborated and recognised as a valid alternative to the bilateral approach by the Parties of the Nagoya Protocol. This would need to be achieved via a specialised international ABS instrument (Art. 4 Para. 4 NP), a global multilateral benefit-sharing mechanism (Art. 10 NP) or an amendment of the Nagoya Protocol itself.

5.5.3. Approaches to overcome implementation and enforcement challenges

35

The considerations set out above suggest that, in principle, the Nagoya Protocol is also applicable to access to and utilisation of digital sequence information, as long as this information significantly contributes to the delivery of benefits which relate to genetic resources from Parties with ABS requirements. Potential solutions to overcome or mitigate the obvious implementation and enforcement challenges have not yet been addressed though, and are briefly[76] presented below. On the one hand, they illustrate that it is possible to utilise digital sequence information from publicly accessible databases while taking the objectives of the Nagoya Protocol into account. On the other hand, they demonstrate the necessity to consider further developing the Nagoya Protocol, e.g. towards a multilateral approach.

- *Conditions of use in PIC/MAT*: The most obvious solution could be to govern the use of sequence information via PIC/MAT at the time of access to the original genetic resource. Such conditions (e.g. «no commercial use») can be included in the metadata of databases where sequence information is uploaded. They ensure transparency for subsequent use, but there is of course no guarantee that the conditions are accessible, potentially transferred and respected in individual cases.

- *Conditions of use for databases*: The most promising solution could be to solely upload sequence information subject to ABS-relevant restrictions to databases with corresponding terms and conditions. Such open source databases are publicly accessible as well, but require the identification of the parties uploading and downloading data, and the consent to specific conditions of use such as disclosure of source or compliance with ABS requirements. The controlled access to the database and the consent to terms and conditions represent a major difference to open access databases, and are more likely to ensure that ABS requirements are known and respected.

75 Cf. LAIRD/WYNBERG, p. 48; BAGLEY 2015, p. 13.

76 An extensive discussion of the approaches to find solutions would be beyond the scope of this legal brief; for further detail, see in particular LAWSON/ROURKE, pp. 35 ff.; LAIRD/WYNBERG, pp. 43 ff.

- *Marking and tracking*: A biotechnological solution could be to make DNA sequences traceable by providing them with a water mark. However, the watermarking technique is currently not considered feasible for large quantities of DNA sequences; watermarks may also be susceptible to degradation, or may be identified and removed by users.[77] We still need to keep an eye on potential technological solutions though, considering that the PIP Framework focuses on the ex-post identification of sequence information which had been used unlawfully.[78] Also, watermarking could prove useful for specific scenarios or in combination with other measures.

36
There are also other potential solutions which would require developing the current legal situation further. One suggestion is to create a multilateral regime for facilitated exchanges of microbial genetic resources and information (called *Microbial Research Commons*) which would apply to research on, sequencing of and utilisation of microorganisms. Similar to the regime of the International Treaty on Plant Genetic Resources for Food and Agriculture, exchanging genetic resources would require a *Standard Material Transfer Agreement*.[79]

Conclusions

37
The decoding of the genome of genetic resources through sequencing activities has become easier, faster and cheaper. The number of organisms with available digital sequence information increases rapidly. Given the various ways such information can be used and developed, we must consider that sequencing activities are creating new insights which are of – at least potential – benefit to the further process of product development. This means sequencing activities qualify as research and development, which makes them come under the concept of utilisation of genetic resources according to Art. 2 lit. c of the Nagoya Protocol. The same conclusion of a potential added value must apply to screening activities with genetic resources and digital sequence information for which certain traits of interest have been identified, and which can be saved in a «hit list», transferred and reused.

38
In principle, the Nagoya Protocol and the Swiss implementation legislation also apply to digital sequence information. While sequencing activities qualify as utilisation of genetic resources, the subsequent use of sequence information must count as «benefits arising from the utilisation of genetic resources as well as subsequent applications and commercialisation» (Art. 5 Para. 1 NP). This holds true as long as there is an adequate causality between the initial utilisation of the genetic resource – i.e. the sequencing activity – and the benefits accrued, e.g. the proceeds of the commercialisation of a product with certain attributes.

39
There have been multiple reasons brought forward against the Nagoya Protocol being applicable to instances where digital sequence information is accessed from open access databases: practical difficulties, negative implications on research and development, lack of traceability, and inherent benefits for the conservation and sustainable use of biodiversity. The first three aspects present a particular challenge for the implementation of the Nagoya Protocol in the dynamic field of modern biotechnology. However, arguments *de lege lata* and arguments *de lege ferenda* must not be mixed up. We must rather pursue and substantiate existing approaches to overcome the challenges, both within the boundaries of today's Nagoya Protocol and in consideration of options according to Art. 4 Para. 4 and Art. 10, or of an amendment of the Nagoya Protocol. In essence, there needs to be a balance between the interest in an open and free access to information on genetic resources and the interest in a fair and equitable sharing of benefits with countries and communities providing those genetic resources which do not necessarily benefit from the results of research and development activities.[80]

77 Cf. BAGLEY 2017, p. 94.
78 See above point 17.
79 Cf. REICHMAN/UHLIR/DEDEURWAERDERE, pp. 270 ff.
80 Cf. LAWSON/ROURKE, p. 41.

Cited references

BAGLEY Margo A., Digital DNA: The Nagoya Protocol, Intellectual Property Treaties, and Synthetic Biology, Washington 2015

BAGLEY Margo A., Towering Wave or Tempest in a Teapot? Synthetic Biology, Access & Benefit Sharing, and Economic Development, in: Frankel Susy/Gervais Daniel (eds.), Intellectual Property and the Regulation of the Internet, Wellington 2017, pp. 85–111

BUCK Matthias/HAMILTON Clare, 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, RECIEL 2011, pp. 47–61

EUROPEAN COMMISSION, 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, OJ C 313, 27 August 2016

GREIBER Thomas/PEÑA MORENO Sonia/ÅHRÉN Mattias/NIETO CARRASCO Jimena/KAMAU Evanson Chege/CABRERA MEDAGLIA Jorge/OLIVA Maria Julia/PERRON-WELCH Frederic in cooperation with ALI Natasha/WILLIAMS China, An Explanatory Guide to the Nagoya Protocol on Access and Benefit-sharing, IUCN Gland/Bonn 2012

LAIRD Sarah A./WYNBERG Rachel P., A 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, study undertaken for the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources, CBD/DSI/AHTEG/2018/1/3, 2018

LAWSON Charles/ROURKE Michelle, Open Access DNA, RNA and Amino Acid Sequences: The Consequences and Solutions for the International Regulation of Access and Benefit Sharing, Journal of Law and Medicine 2016, pp. 96–118

MORGERA Elisa/BUCK Matthias/TSIOUMANI Elsa, Unraveling the Nagoya Protocol, A Commentary on the Nagoya Protocol on Access and Benefit-sharing to the Convention on Biological Diversity, Leiden 2014

OECD (Organisation for Economic Co-operation and Development), Frascati Manual 2015: Guidelines for Collecting and Reporting Data on Research and Experimental Development, The Measurement of Scientific, Technological and Innovation Activities, Paris 2015

REICHMAN Jerome H./UHLIR Paul F./DEDEURWAERDERE Tom, Governing Digitally Integrated Genetic Resources, Data, and Literature: Global Intellectual Property Strategies for a Redesigned Microbial Research Commons, Cambridge 2016

SCHEI Peter Johan/TVEDT Morten Walløe, «Genetic Resources» in the CBD: the Wording, the Past, the Present and the Future, study undertaken for the Ad Hoc Open-ended Working Group on Access and Benefit-sharing, UNEP/CBD/WG-ABS/9/INF/1, Oslo 2010

SOLLBERGER Kaspar/GONSETH Noémie, in: Keller Peter M./Zufferey Jean-Baptiste/Fahrländer Karl Ludwig (eds.), Legal Commentary of the Federal Act on the Protection of Nature and Cultural Heritage (*draft 2nd edition*), commentary on Art. 23n–23q and 25d, Zurich 2018 (*forthcoming*)

SPRANGER Tade Matthias, Gutachterliche Stellungnahme zur Anwendbarkeit des Übereinkommens über biologische Vielfalt und des Nagoya-Protokolls auf digitale Sequenzdaten *(= Legal expert brief on the applicability of the Convention on Biological Diversity and the Nagoya Protocol on digital sequence data*), Bonn 2017

UNCTAD (United Nations Conference on Trade and Development), The Convention on Biological Diversity and the Nagoya Protocol: Intellectual Property Implications, Handbook on the Interface

between Global Access and Benefit Sharing Rules and Intellectual Property, United Nations New York 2014

WYNBERG Rachel/LAIRD Sarah A., Fast Science and Sluggish Policy: The Herculean Task of Regulating Biodiscovery, in: Trends in Biotechnology (TIBTEC) 1/2018, pp. 1–3