Digital Genetic Information and the Idea of Access and Benefit Sharing

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Contents

1 The ethical question and its policy framework

2 Starting point

3 What is digital genetic information?

4 Digital genetic information and the idea of access and benefit sharing

5 Recommendations

1 The ethical question and its policy framework

Large collections of genetic information can be created by systematic screening and digitalisation of the DNA, RNA and nucleotides present in biological resources. These collections are both important for research and of interest for a wide range of applications. They can contribute to an understanding of molecular bases and evolutionary processes and could expedite the development of new therapies and medications. Because the genetics of living organisms and animal and plant-based products can be determined more precisely with such information, these data collections can also help to combat illegal trade, for example to give better protection to endangered species. The geographical origin of products could also be better established, making it easier to monitor the supply chain.[1]

In the debate about how to handle this digitally stored information, the first position taken is that everyone benefits from open access to it. A second argument maintains on a more pragmatical level that it is not subject to the regulation in the Nagoya Protocol[2], which only covers tangible genetic resources, not intangible digital information. Critics fear that this would nullify regulations already in existence such as the Nagoya Protocol and make them ineffective not just for digital information but for all information based on genetic resources. This is because digitalisation and databases would make it unnecessary to access the resources of the provider countries. By subverting the regulations of the Protocol, the associated objectives of biodiversity protection would also be ignored.

In this report, the question at issue for the ECNH is: How should digital genetic information be handled?[3] It specifically discusses whether the idea of access and benefit sharing (ABS) established in the Nagoya Protocol also covers *digital* genetic information. It goes beyond the Nagoya Protocol debate to look at other international agreements which also deal with the topic of handling digital genetic information. This information exists increasingly in digital form. Access to digital genetic resources and resource sharing are ethically relevant if they are a key factor in the achievement of morally significant conservation objectives. Among these objectives are contributions to the protection of human, animal and plant health, food security and conservation of the environment and biological diversity. The regulation on access to genetic information has been linked in various agreements with the concept of benefit sharing. This is intended to support the conservation of biodiversity and therefore the protection of genetic resources. As long as the handling of digital genetic information is not considered by all the parties to be within the scope of the Nagoya Protocol, access to that information remains unregulated and no right to benefit sharing exists.

In this context, the key ethical question is whether the carrier of the genetic information is relevant in terms of appropriate handling of that information. That debate is being conducted separately from the existing legislation. However, from an ethical perspective the existing legal and political context must be considered. Recommendations for implementation of principles for ethically justified handling of digital genetic information must therefore explore the options within that reality.[4]

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[1] On applications see e.g.: the German network-forum for biodiversity research (NeFo), Digital Sequence Information (DSI), NeFo Factsheet on Preparation in SBSTTA[*]-22. 28 June 2018. [*SBSTTA stands for Subsidiary Body on Scientific, Technical and Technological Advice of the CBD.]

[2] The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization was adopted in October 2010 at the 10th Conference of the Parties to the UN Biodiversity Convention in Nagoya. It entered into force in October 2014.

[3] The report is limited to information on genetic resources in the non-human domain, since this corresponds to the mandate of the ECNH. The handling of human genetic resources also raises other ethical questions.

[4] For a detailed ethical discussion on disposition and exclusion rights to digitalised gene sequences and genetic resources, see: Otto Schäfer, Digitale Sequenzinformationen. Ethische Fragen der Patentierung genetischer Ressourcen und des Eigentums an digitalisierten Sequenzinformationen, vol. 13 of the "Contributions to Ethics and Biotechnology" series, 2020.

2 Starting point

2.1 Issue for debate on international regulation

Digital genetic information is currently a subject for debate at the level of several international agreements and their implementation. To clarify the question of how genetic information should be handled, this report focuses principally on the Convention on Biological Diversity (CBD)[5] and the Nagoya Protocol based on it. Within this framework, the concept of "digital sequence information" is discussed. The Protocol implements one of the objectives of the Convention. It regulates access to genetic resources through a bilateral system.[6] In return for the countries of origin granting access to their genetic resources, the users share with the provider country part of the benefit this brings them (benefit sharing). The users negotiate the benefit sharing bilaterally with the provider countries. Indigenous communities and their achievements and knowledge of the functions and effects of genetic information developed within them and preserved and transmitted (often orally) by those groups or their representatives (called traditional knowledge) are to be included in this access and benefit sharing. The ABS instrument is intended to protect biological diversity, the central objective of the CBD.[7] The providers must therefore commit the benefit share, as "custodians of biodiversity", to sustainable use and conservation (in the widest sense). When these conventions came into being, the scope and pace at which genetic information can now be acquired and digitalised and the importance of digital databases of genetic resources could not have been foreseen, or at least not on such a scale. Whether or not digital sequence information is included in the Nagoya Protocol is therefore now under discussion.[8]

In the context of the Treaty on Plant Genetic Resources, which is an international convention on the conservation and sustainable use of plant genetic resources for food and agriculture[9] of the United Nations Food and Agriculture Organization (FAO), the importance of digital information and the regulation of access and sharing is growing all the time. Digital information is increasingly used for cultivation and producing profit. The treaty regulates access to the global seed banks by a multilateral approach with a standard material transfer agreement.[10] It only covers a limited number of crops to date and important ones such as soya, tomatoes and peanuts are not included. All crops not shared by the material transfer agreement in the FAO Treaty are subject to the regulations of the Nagoya Protocol. Growers must then negotiate access bilaterally. Like the Nagoya Protocol, the Plant Treaty provides for a (small) part of the benefit to be fed back for the conservation and sustainable use of varietal diversity.[11, 12]

Similarly, the World Health Organisation (WHO) is focussing on an access and benefit sharing regulation for (digital) genetic information on influenza viruses, with the aim of combating pandemics.[13] This is intended to ensure quick and easy access to the genetic information. In return, those countries which make the information available will be given rapid and fair access to the vaccines, diagnostic tools and therapies developed on the basis of this information. A multilateral approach is being adopted to achieve these objectives. This means agreements which are not individually negotiated bilaterally between states and users but are concluded collectively on equitable principles between several states or subjects of international law and which apply to all in equal measure.

2.2 Lack of legal definition

The debate within the CBD and the Nagoya Protocol is being conducted under the concept of "Digital sequence information on genetic resources" (DSI). The parties have to date been unable to agree on a binding legal definition. They are only in agreement that the term needs clarification for implementation of the CBD objectives.[14]

The stakeholders participating in the debate do not even use the term consistently. It is also employed in different contexts for different types of data. In some cases it is just the DNA sequence, sometimes functions and behavioural data are also mentioned and sometimes there is also information on ecological contexts or terms of use.[15] When this knowledge is referred to in the context of the traditional knowledge of indigenous peoples, it is described in the Nagoya Protocol as traditional knowledge and cultural experience on the use of genetic resources.

5 SR 0.451.43.

6 Art. 1 of the Nagoya Protocol: “The objective of this Protocol is the fair and equitable sharing of the benefits arising from the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding, thereby contributing to the conservation of biological diversity and the sustainable use of its components”.

7 Under the CBD, this covers species diversity, the genetic diversity of species and the diversity of ecosystems.

8 Its inclusion is advocated by Kaspar Sollberger, Digital Sequence Information and the Nagoya Protocol, legal expert brief on behalf of the Federal Office for the Environment (FOEN), 7 April 2018, and Elizabeth Karger, Study on the use of digital sequence information on genetic resources in Germany in the project Scientific and technical support on implementing the Nagoya Protocol – Part 1 “Digital sequence information and ABS”. UFOPLAN 2017 R&D project (FKZ 3517810100) on behalf of the German Competent National Authority for the Nagoya Protocol in collaboration with the Institute for Biodiversity – Network: 1-80, 2018. A contrary legal line of argument follows the wording of Art. 2 of the CBD and Art. 2 of the Nagoya Protocol, stating that genetic resources mean genetic material (of actual or potential value). Genetic material is defined as material of biological origin containing functional units of heredity, generally genes. Genetic resources are therefore materials such as organisms or their components in which genes are present. Under this interpretation, the term can only cover genetic material that physically contains genes. It follows that digital sequence information is not a genetic resource within the meaning of the CBD and the Nagoya Protocol and is not subject to the benefit sharing obligation. Also, for example, in the Swiss submission to the CBD of 8 September 2017: “Government of Switzerland Submission in response to CBD Notification 2017-037 – Digital Sequence Information on Genetic Resources”. The view is expressed that benefit sharing between users and providers on the basis of agreements (called Mutually Agreed Terms MAT) is only to be arranged on the use of digital sequence information if the benefits of the DSI are obtained on the basis of a (physical) genetic resource. Another legal interpretation argues that even if the CBD and the Nagoya Protocol focused on material genetic resources, the use of these resources is always only about the information that is obtained from them on the basis of the genetic code.

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

10 Art. 12.3 d) of the FAO Plant Treaty does not expressly exclude patenting of plant genetic resources from the multilateral system, but does attach conditions. Access is only granted if the recipients do not claim rights which restrict the easier access to the plant genetic resources for food and agriculture which originate from the multilateral system. (For more information on interpretation of the regulation see P. 92 IUCN Explanatory Guides to the Treaty.)

11 The system of the standard conditions n the Plant Treaty for use and benefit sharing still has many weaknesses: Many collections of genetic resource collections are not yet integrated, there is no monitoring of patents granted unlawfully and very few mandatory payments have yet been made to the fund. In September 2013 the governing body decided to start negotiations on reforming the multilateral system. Those negotiations are still ongoing.

12 On the debate about further development of multilateral approaches under the FAO Plant Treaty, see Sylvain Aubry: The Future of Digital Sequence Information for Plant Genetic Resources for Food and Agriculture, Frontiers in Plant Science, Vol 10, Article 1046, August 2019.

13 WHO Pandemic Influenza Preparedness Framework (PIP), adopted unanimously at the World Health Assembly in May 2011.

14 See decision 14/20 of the CBD Conference of Parties in Sharm El Sheik, Egypt, of November 2018 on “Digital sequence information on genetic resources”.

15 See for example: the german network-forum for biodiversity research (NeFo), Digital Sequence Information (DSI), NeFo Factsheet on Preparation in SBSTTA-22, 28 June 2018. This lists how, in the current SBSTTA-22 document, DSI is associated with very different topics and data types.

3 What is digital genetic information?

Because the term digital DNA sequence information is not precisely defined at present, it is helpful to apply the more common term "genetic information".

Terms such as "information", "code", "transcribing" and "language" have been used since the 1950s to refer to the activity of the genes. The term genetic information covers the "information" stored in the form of DNA molecules (or more rarely RNA molecules).[16] But epigenetic modifications of DNA which are also recorded by new sequencing methods are also genetic "information" of this kind. This "information" is a natural phenomenon existing independently of humans. The extent to which it is appropriate to use the term information or whether this has introduced a misleading metaphor[17] cannot be discussed here. Using the customary terminology, genetic information is in any case conveyed in a specific "code" – a specific arrangement of three nucleotides. The nucleotides of DNA and RNA are the carriers of the information, the information transfer media. Since other DNA segments and their epigenetic modifications are responsible for regulation of the copying process, this does not just involve syntax (i.e. the arrangement of the characters) – even if talking of "code" suggests this – but also semantics (i.e. the meaning of those characters). The metaphor of "Book of Life" is used for the genome as a whole.

The "code" active in the biological process is only relevant to human practice if knowledge of the activity of the genes exists. The DNA or RNA sequence has no informative value for humans without it. Without this knowledge it is even impossible to determine which segments of the DNA carry specific information. In order to generate relevant handling information, it is necessary to identify functional elements of the genome or transcriptome and characterise their functions. The biological "code" active in the biological process must be rendered in human language. The second understanding of genetic information relates to the rendering of knowledge about gene activity. Here, the information medium is not the DNA or RNA, it is a human language spoken about a biological process. As with the usual use of the term in human genetics and medical ethics, "genetic information" covers all types of information providing knowledge of the genetic predisposition of humans and other organisms.

The objection could be raised that the same information is always involved and the biological genetic information is simply translated into human language while transmitted in characters (e.g. CTG). But this would assume that information is spoken of here not purely in the metaphorical sense. That meaning would also have to be translatable into human language. Both are challenging hypotheses which are not to be advocated here. It is more logical to assume that the term genetic information is used in two different ways. The first interpretation refers to a "code" which is active in biological processes and exists in the world independently of humans, and the second to human knowledge of the activities of the genes which can be captured in linguistic form and communicated to other people.

By making a distinction between genetic information as a natural phenomenon and as human knowledge, the concept of digital genetic information (and digital sequence information) can also be further clarified.

If genetic information is conceived as a natural phenomenon, it seems obvious that the term digital genetic information refers to the nucleotide sequence rendered digitally. To sequence

[16] Paradigmatically, to cite a quotation from Francis Crick: "In its simplest form [the sequence hypothesis] assumes that the specificity of a piece of nucleic acid is expressed solely by the sequence of its bases, and that this sequence is a (simple) code for the amino acid sequence of a particular protein. [The central dogma] states that once 'information' has passed into protein it cannot get out again. In more detail, the transfer of information from nucleic acid to nucleic acid, or from nucleic acid to protein may be possible, but transfer from protein to protein, or from protein to nucleic acid is impossible. Information means here the precise determination of sequence, either of bases in the nucleic acid or of amino acid residues in the protein." (Crick, Francis, On Protein Synthesis, Symposium of the Society of Experimental Biology, 12, 1958: 152–153.

[17] cf Christina Brandt, Metapher und Experiment. Von der Virusforschung zum genetischen Code. Göttingen: Wallstein Verlag 2004 and generally on the meaning of genetic information: Elisabeth Hildt & Lasslo Kovasc, Was bedeutet genetische Information?, Berlin: De Gruyter 2009.

the DNA of an organism, it would be enough to convert the resultant sequence of nucleotides to digital formats as a character string and process them in a digital system. But this only means that the nucleotide sequence is copied to a different medium and the "code" – the information – is copied with it. This would be like drawing a copy of the inscription on the Rosetta Stone before deciphering the Egyptian hieroglyphs. It would have been known at the time that information lay hidden in the images. But no-one would have known whether each image carried information or whether specific character strings had a meaning (and if so what), let alone knowing what information has been copied. A coded text has simply been represented in a new medium. Book illustrations of the *kohau rongorongo* tablets have precisely this status now, because the Easter Island glyphs have not yet been deciphered. As long as genes are neither identified nor characterised, digitalisation of the DNA sequence will transfer information which is currently incomprehensible to humans. Even identification of the genes alone would not make a difference if the function which those genes have is still not understood. If it is a case of genetic information as a natural phenomenon, a code not yet deciphered is transferred to a new medium by the digitalisation. This is the first potential interpretation of digital genetic information.

If genetic information is viewed in a practical sense, knowledge of the activity of the genes is necessary as well as the sequence. Ultimately, this ranges from information on gene expression and functions to data on the phenotype through to relevant knowledge of environmental factors and modalities of use – for an understanding of the action of the genes. The term digital genetic information covers both digitalisation of the biological "code" and digitalisation of the knowledge of the function of the gene in linguistic form. In this case data which may have direct practical human significance is digitalised and stored.

This does not alter by changing "digital gene information" to "digital sequence information". Either it involves the information stored in the (DNA or RNA) sequence and conveyed by it, i.e. genetic information as a natural phenomenon. Or it involves the knowledge of the action of the genes or the DNA sequence, i.e. genetic information in a practical sense.

What significance does this have for ethical considerations in general and the idea of ABS set out in the Nagoya Protocol in particular? The Commission starts with this specific question in order to clarify these general points in the debate.

4 Digital genetic information and the idea of access and benefit sharing

4.1 The Nagoya Protocol and the debate about digital sequence information

The objective of the bilateral ABS regulation of the Nagoya Protocol is to reconcile the many and diverse interests in the use of genetic resources with the conservation objectives of the CBD. Countries rich in biodiversity decide for themselves whether and how they grant access to their genetic resources. This presupposes the disposition rights of sovereign states over the genetic resources in their territories.[18] In return for access, the states negotiate benefit sharing with the users. This defines how the users share a commercial benefit obtained by them from exploiting the genetic resources with the provider countries.[19]

Fairer distribution in the sense of development aid for countries of the Global South was not a central objective of the regulation. As mentioned, the focus is on conservation of biological diversity. The sovereign rights of the countries of origin are restricted to an extent because they must use the benefit sharing obtained under the ABS system for the purpose of conservation and sustainable use of their biodiversity. The compensation payments may however be used for purposes other than conservation of biodiversity in the narrower sense, such as poverty alleviation projects.

International regimes like the Nagoya Protocol are the result of negotiation processes in which diverse political and economic interests are reconciled. Factors other than these particular interests generally also play a part and can be interpreted as the expression of ideas of fairness and justice. The Committee debates below in the knowledge that despite the inadequacies of the Protocol, it has to be acknowledged as the political reality, and also from an ethical perspective, in the absence of realistic alternatives at present. The Nagoya Protocol itself is not being called into question in this debate on digital sequence information, instead the issue of whether “digital sequence information” is subject to the ABS regulation is discussed. Similar discussions are taking place on ABS regimes for digital genetic information, as mentioned above, including under the FAO Treaty on Plant Genetic Resources.

The exclusion of digital sequence information is advocated by those arguing that the Nagoya Protocol only refers to genetic resources and therefore *tangible* entities are meant, not intangibles (such as digital sequence information). This argument also stresses that it is to everyone’s benefit not to make DSI subject to ABS. If it were to come under the ABS regime, research, scientific cooperation and scientific publication activity would be adversely affected. And free sharing of DSI is essential for research on biological diversity, scientific and technical education and technology transfer and to promote cooperation and knowledge building. The concern of both the private and public research sectors is that an ABS regulation for DSI would involve high financial and administrative hurdles and monitoring and control of compliance with the regulations would be extremely complex or even impossible. This would make benefit sharing for DSI impracticable and would ultimately undermine the overall objectives of the CBD.

The opposing argument states that the overall objectives of the Nagoya Protocol actually require DSI to be subject to the ABS regime. If the regime were allowed to be circumvented through screening and digitalisation of genetic resources, it would simply become meaningless. The achievements to date of the people of the

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[18] C.f. Otto Schäfer (2020).

[19] In addition to the ABS regulation, the CBD provides for other instruments to achieve its conservation objective – conservation of biological diversity and its sustainable use. These are identification and monitoring of biodiversity, its conservation *in situ,* i.e. locally in the ecosystem, and *ex situ,* e.g. through gene banks and other options for storage and preservation of genetic information. Other important elements are support for technology transfer, scientific cooperation and information sharing.

countries of origin would not be recognised and their present and future function as custodians of biodiversity, as enshrined in the Protocol, would not be honoured. The crucial point is that the digital information is obtained from genetic resources and that these come from countries rich in biodiversity. This argument clearly places DSI within the scope of the Nagoya Protocol.[20]

4.2 The connection between genetic resources and genetic information

There is agreement between advocates of both inclusion and exclusion of DSI that the term genetic resources refers to biological material containing functional units of heredity. Those in favour of excluding digital genetic information further argue, as described, that the Nagoya Protocol only covers tangible entities and intangible material such as DSI cannot be meant.

But is this correct? To test it, a closer look is needed at what the term genetic resources refers to, i.e. whether only to purely tangible entities or also to intangibles. What a tangible or intangible entity might be is also a philosophical question. Therefore, the Committee consciously selects a philosophical approach.

Two arguments militate against an interpretation that the Nagoya Protocol only covers tangible entities.

Firstly, the term genetic resource refers to biological material containing units of heredity. Therefore, as in the terminology of the Nagoya Protocol genetic resources have two components: biochemical and genetic. It is now hardly disputed that DNA as a whole is a tangible entity, nor does anyone doubt that this is the case for the individual nucleotides. What needs examination is the classification of genes or units of heredity. These cannot be referred to without also meaning genetic information conceived as a natural phenomenon. But information in general is not a tangible entity. With Morse code and other forms of human information, it is clear that the information transferred (such as SOS) is not tangible. This is equally true of the inscription on the Rosetta Stone (abbreviated: “Ptolemy V is a god and benevolent ruler.”) The detailed warning calls of the black-fronted titi monkey have a meaning in themselves and are “intangible” as information (“There is a bird of prey over us”). But what about genetic information conceived as a natural phenomenon?

Units of heredity or genes are DNA segments which are carriers of specific “information” based on a specific sequence of nucleotides and which therefore have a functional meaning. Just as in Morse code the string “three short, three long, three short” signals an emergency, the specific sequence of nucleotides – let us say “AAC TGA ACT” – has a “meaning” in the biological process. Although the material nature of the sequence changes in transcription from the source to a complementary RNA strand, a specific sequence or “information” is transferred from one medium to another. If the metaphorical use of “information”, “code”, “transcribe”, “matrix” etc. is reasonable, this “information” is something “intangible”. Morse code signs and genes then unite in that they are tangible entities (a specific sequence of electromagnetic waves or nucleotides), but something “intangible” (the meaning of the specific sequence) is transferred at the same time. The metaphor could be misleading or wrong, but if so, genetics would have to be rethought from scratch. Molecular genetics would then have gone astray due to their imagery.

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[20] The objection that the fullest possible access to digital genetic information would then be more difficult could be countered in the Nagoya Protocol by appropriate exemptions for research dedicated to the common good.

Secondly, the Nagoya Protocol awards a huge benefit to genetic resources. In the preamble it goes as far as to emphasise the importance of genetic resources "for food security, public health, biodiversity conservation and mitigation of and adaptation to climate change". But what is the basis for this high instrumental value of genetic resources which is not disputed in the debate? Is it in the tangible entity or the information? Independently of the genetic information, the biological material alone would scarcely have such a great instrumental value. It has a value of this kind, but whatever use is considered, the material only has a high value in exceptional cases, perhaps as a rare material component in medicines. In general however, this cannot be said, and certainly not that these biochemical substances could be central to the above conservation objectives. If genetic resources are awarded this high value, it is as information carriers. What matters is the potential value which the information may have, or its already known actual high value.

When the Protocol stresses the importance of genetic resources, it is referring to the information rather than the material. Here again, genetic resources are similar to other information media. We can use the Rosetta Stone again to illustrate this. Considered materially, it is a heavy slab of granodiorite weighing 762 kg. A stone like that has a price and could be used in different ways. But the Rosetta Stone has particular importance and special benefit because it is also a carrier of information. It conveys information for priests, officials and rulers in three inscriptions. Its benefit as an information carrier is greater than that of the material itself. When we talk about the Rosetta Stone nowadays, we are always referring to the information carrier. Only this has great importance and has brought benefits. Similarly for genetic resources, the benefit and importance of the biological material is very limited. The information is crucial.

When benefit is mentioned, it cannot just concern genetic information as a natural phenomenon. It must be about genetic information in a practical sense. Benefit is only obtained through an understanding of the action of genes and through knowledge.

As with digital genetic information, it could be argued that the Protocol never mentions genetic information. This is certainly true, but alluding to units of heredity necessarily includes genetic information as a natural phenomenon. By invoking the importance of the benefit of genetic information, the Protocol is inevitably referring to that information in a practical sense. Both are something "intangible". Despite the fact that reference to a genetic resource implies genetic information and the importance and benefit of the genetic resources is based on the genetic information, the further objection may be raised that the Protocol is only concerned with genetic and not digital information. Digital genetic information has a different status and must be distinguished from it.

4.3 What difference does it make that digital information is involved?

Is the digitalisation of information gained on the basis of tangible genetic resources morally relevant inasmuch as the status of the genetic information changes due to the digitalisation? The answer is no. Digitalisation means that information is translated into a different language – a binary code – and is conveyed via a different medium. If information is transferred via a different medium, the message remains the same. The information that the federal councillors have been re-elected does not change, whether someone communicates it by telephone, email or website via the internet. The message is always that the federal councillors have been re-elected. Equally, the information does not change by being translated into Spanish or English. Or to be precise: the aim of a translation is always for the information to stay the same. If the Spanish or English translation does not report that the federal councillors have been re-elected, there is a translation error.

There may be specific moral rules relating to the medium,[21] but the moral imperatives covering the information remain the same for a translation or change of medium. If, for example, the message is confidential, the status of the confidentiality obligation does not change because the message is translated from German to Ancient Greek. Likewise, the medium used does not change the confidentiality obligation. If the information is confidential, it is confidential regardless of whether it is communicated verbally, by smoke signals, by telephone or by email. This is because the obligation relates to the information and not to the language or medium. The same moral obligations exist for the same information in whatever language or via whatever medium it is conveyed. If this hypothesis is correct, it follows from an ethical perspective that genetic information rendered in different languages or via different media is to be treated equally. The digitalisation of the information is morally irrelevant.

This is clear for genetic information as human knowledge. It is only translated from one human language to another by digitalisation, and a different medium is also used. The information remains the same, which also means that digitalisation does not change its ethical status. It follows from a legal perspective that it is subject to the same legal regime.[22] If, on the other hand, genetic information is referred to as a natural phenomenon, a biological "code" not yet understood is rendered digitally. But here too there is no change in the moral status of the genetic code. Once again, the medium and format in which it is rendered are irrelevant. It remains the same code. We can use the Rosetta Stone as an illustration again and assume that the hieroglyphs are known to be signs and that the images which are a sign have been identified. And again: photographing the Rosetta Stone changes the format in which the signs are rendered. But its moral and legal status has not changed. If the physical Rosetta Stone belongs to country A and that country has a legitimate right to ensure that the information is not deciphered, the confidentiality requirement also prohibits use of the photography to decipher the information.

This means in relation to the ABS: If country A is the owner of a genetic resource, it has a claim to benefit sharing if others in country B obtain a commercial gain on the basis of that genetic information conceived as a natural phenomenon. It is irrelevant whether the sequence is in natural or digitalised form. It is the information that is central, not the information medium. If knowledge is used which is gained on the basis of and in relation to genetic resources, it is also irrelevant that the knowledge is in digital form.

It may be argued that a morally relevant difference exists if the digital genetic information that plays a part in synthetic biology is involved. This is not digitalisation of genetic information present in natural DNA or RNA or relating to them. It is rather a case of nucleotide sequences being digitally designed which do not exist in that form in nature. There may be good reasons for assessing designed and

[21] For instance, if information is tattooed on the body, the moral rules applicable to access to the information carrier are different from those where the information is written on the wall of a telephone box.

[22] There are historical cases where precisely this was not considered and which seem absurd in retrospect. IT specialists will recall Phil Zimmermann and the e-mail encryption software PGP (Pretty Good Privacy). The US customs authorities took the view that export of software was banned. To get around the export restrictions, Phil Zimmermann published the complete source code in a book called "PGP Source Code and Internals" which could be freely exported. The typewritten code led to internationally available software.

natural genetic information differently in moral terms. But this does not change the general point of relevance here that it is irrelevant that the information is digital. If designed genetic information is used to produce nucleotides physically, the moral status of the information does not change. If the result of designing genetic information is intellectual property in respect of the information, that intellectual property remains in existence even if it is stored physically in biological material. It is always the same information. Just as the moral status of information is not changed by digitalisation, so it is not changed by "materialisation".

It would be a fallacy to conclude from the (possibly) specific moral status of digital genetic information created in connection with synthetic biology that all digital genetic information has the same status. The relevance lies not in digitalisation but (at best) in the fact that sequences are created which do not occur in that form in nature or at least have an unknown natural occurrence. But this means specifically that the creation and use of these sequences – not developed on natural models – are not subject to the Nagoya Protocol. Because the Protocol covers naturally occurring resources.

4.4 Should digital genetic information not be excluded anyway?

Apart from arguments based on particular interests, ethical arguments advocating the removal of digital genetic (or sequence) information from the ABS regime are also raised. According to the consequentialist argument already mentioned in the introduction, this exclusion would improve the situation for all, including the people of countries rich in biodiversity.

It may well be that the Nagoya Protocol is not the best possible solution for reconciling the interests in the use of genetic resources with the goals of biodiversity conservation. But on the assumption that the Nagoya Protocol is valid, which even the advocates of DSI exclusion accept, then a purely consequentialist argument cannot be put forward. The great benefit of genetic resources is recognised and highlighted in the Protocol. If we consider the ethical arguments acknowledged by the parties, they are indeed always consequentialist. But the parties also acknowledge solidarity and justice arguments. The achievements for biodiversity in the countries rich in resources are explicitly recognised and those which conserve and maintain that biodiversity are to be compensated for their contributions. They include cultural achievements such as maintaining the traditional knowledge of ecological correlations and effects of genetic information and collaborative work for biodiversity conservation. Those which benefit commercially from the knowledge of context and use that communities develop and maintain and keep that benefit private should pay compensation.

The Protocol is not just the result of a negotiation of particular interests, it also represents an attempt to reconcile two ethical demands. It is intended to result in maximum benefit in terms of meeting conservation objectives and at the same time to achieve solidarity and justice. Like other international treaties, the Nagoya Protocol embodies an ethical compromise between (partly) conflicting ethical demands.

By digitalisation of genetic information, the benefit underlined in the Nagoya Protocol may have become even greater and achievable even more quickly. The fact that the benefit of genetic resources has increased through digitalisation strengthens the consequentialist argument advocating open access. But this is no reason to ignore the solidarity and justice commitments made through the Nagoya Protocol. A compromise between consequentialist considerations and solidarity and justice considerations has been formulated in the Protocol. The signatories cannot now simply abandon this compromise because the benefit might be greater than thought. That would need a completely new negotiation of the particular interests and relevant ethical demands. This is not an issue for debate at present and it would be unwise to start one. Solutions and improvements must be found within the scope dictated by the Nagoya Protocol; and its regulation must adopt a consistent approach and include digital genetic information or digital sequence information as well as genetic information or sequence information.

4.5 The benefit of a multilateral approach

The Committee emphasises that there is currently no realistic alternative to the Nagoya Protocol, but recognises its inadequacies. As far as the requirement for a just and equitable benefit from the use of genetic information is concerned, there are already means of gaining access to natural genetic resources without being obliged to pay a benefit share in return. And not all countries have ratified the Nagoya Protocol. If they possess resources which also occur in other countries, either *in situ* or in collections, access to them is also possible in those countries. A benefit sharing agreement only applies in relation to the country from which the genetic resources are obtained, even if the same resources occur in several countries or possibly are only conserved thanks to the efforts of several countries. Furthermore, the bilateral approach currently adopted by the Nagoya Protocol includes the possibility of denying access to the information or making it subject to conditions which cannot be met by the party.

One alternative to be examined would be the extent to which the Nagoya Protocol could be expanded to a multilateral system in order to guarantee access to genetic information which is linked to morally relevant conservation objectives such as human, animal and plant health, food security and environmental and biodiversity conservation. These options for a multilateral approach are already established in the Protocol. Art. 4 and 10 introduce them as a further development of the bilateral regime. Art. 10 provides for the possibility of setting up a multilateral global mechanism requiring any benefit which is generated from the use of transnationally occurring genetic resources or for which prior consent for use cannot be issued or obtained to be dedicated to the conservation of global biodiversity.[23]

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[23] See Sylvain Aubry (2019).

5 Recommendations

1. Analysis of the concept of "digital genetic information". The ECNH recommends a conceptual analysis, which is essential to clarify the status of digital genetic information. Those who argue that this information is not covered by the Nagoya Protocol cite Art. 2 CBD, according to which "genetic resources" are material of actual or potential value and "genetic material" is any material of plant, animal, microbial or other origin containing functional units of heredity. To deduce from the term "material" that "intangible" digital genetic information is not covered misjudges the fact that the Protocol constantly mentions *genetic* rather than just biochemical material. It deliberately distinguishes explicitly between biochemical and genetic components of genetic resources. To exclude genes by restriction to biochemical material is an erroneous interpretation of the Nagoya Protocol. Genetic resources are more than just biochemical material. They are also information in a practical sense. The conceptual analysis submitted demonstrates that the term "genetic material" not only necessarily includes the information, it actually means the information first and foremost. This is also in line with the purpose of the Nagoya Protocol.

2. Legal equitable treatment of natural and digital genetic information. The act of digitalising genetic information does not change its moral status. The information medium is changed but not the information itself. For consistency, natural genetic information should be treated equally with digital genetic information in law.[24]

3. No undermining of the Nagoya Protocol. Digitalisation certainly may have made the benefits of genetic information underlined in the Nagoya Protocol even greater and maximum open access to it even more important. But the result must not be to ignore the commitments to solidarity and justice. The Nagoya Protocol represents the outcome of negotiation of particular interests, but it is also an attempt to make the conservation objectives of the Convention on Biological Diversity (CBD) and the concepts of solidarity and justice a reality. Yet developments in digitalisation are expanding the potential to circumvent the benefit sharing on natural genetic resources which already exists. The ECNH is aware of the inadequacies of the Nagoya Protocol, but also maintains that there are no realistic alternatives to it at the present time. To exclude digital genetic information from the scope of the Nagoya Protocol would undermine it. In the opinion of the ECNH, this should be prevented.

4. Promote multilateral mechanisms. The ECNH is aware of the problems of the Nagoya Protocol bilateral regime, which are being compounded by digitalisation, and recommends that the multilateral mechanisms established in the Protocol be promoted and further developed. These mechanisms should also make allowance for traditional knowledge of the characteristics and uses of the genetic information.

5. Contribute to the negotiations at international level. Based on the conceptual analysis and consistency considerations, the ECNH considers it ethically imperative for Switzerland to be committed at international level to including digital genetic information under the Nagoya Protocol and to the multilateral mechanisms being further developed.

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[24] This is different for digital information from genetic material created using synthetic biology. What is relevant here is not the act of digitalisation but that the genetic material is not built on natural models and the Nagoya Protocol only regulates access to, and use of, natural genetic resources.

March 2020

Publisher:
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Translation: Linguistic services FOEN

Graphic design: Atelier Bundi AG
Typography: zwei.null, Simone Zeiter

This report is available also in French and German at www.ekah.admin.ch.