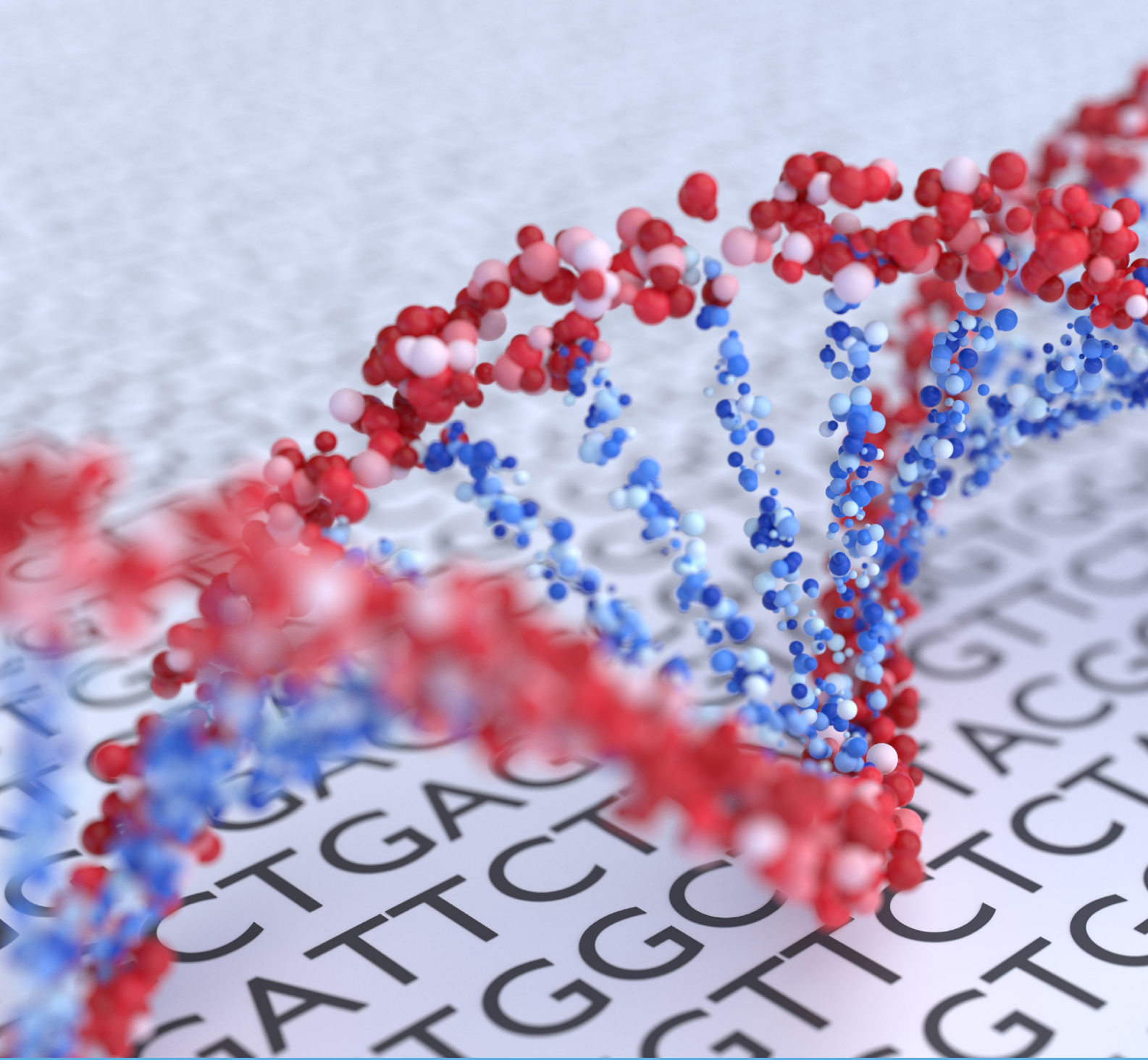

Digital Sequence Information (DSI)

Options and impact of regulating access and benefit sharing - stakeholder perspectives

Sipke Joost Hiemstra, Martin Brink, Theo van Hintum

CGN Report 42

WAGENINGEN
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With the 'genomic revolution' a continuously increasing amount of data is being generated. The Convention on Biological Diversity refers to this type of data as "Digital Sequence Information (DSI)". Innovation in different domains and subsectors, ranging from agriculture and biodiversity conservation, to biotechnology and human health, depends on the use of DSI. Access to DSI and related technologies is crucial for any stakeholder and country, in order to reach long term food security objectives, to be able to adapt to climate change, to deal with human health issues, and to contribute to the conservation and sustainable use of biodiversity. Stakeholder consultations in the Netherlands indicate that fair and equitable benefit sharing arrangements - related to the use of DSI - should possibly only be dealt with in a multilateral context.

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Summary

With the ‘genomic revolution’ a continuously increasing amount of data is being generated. The Convention on Biological Diversity refers to this type of data as “Digital Sequence Information (DSI)”. Innovation in different domains and subsectors, ranging from agriculture and biodiversity conservation, to biotechnology and human health, depends on the use of DSI. Access to DSI and related technologies is crucial for any stakeholder and country, in order to reach long term food security objectives, to be able to adapt to climate change, to deal with human health issues, and to contribute to the conservation and sustainable use of biodiversity. Stakeholder consultations in the Netherlands indicate that fair and equitable benefit sharing arrangements - related to the use of DSI - should possibly only be dealt with in a multilateral context.

1 Introduction

The costs of DNA sequencing and DNA synthesis have dropped dramatically over the past 15 years. Increasingly, cost-effective genetic sequence-based techniques are being used by researchers. The amount of so-called "Digital Sequence Information" (DSI) in international, public or dedicated databases is exponentially increasing, as is the use of that type of data. Organisms, genetic material or genes can be sequenced relatively cheaply, and data can be exchanged rapidly between researchers, institutions, countries and databases.

DSI is used both in public research and in commercial research and development, in a wide range of applications. Bioinformatics has grown alongside genomic technologies in order to store, retrieve, and analyse the vast and growing amounts of information. With synthetic biology, one of the most recent advances, organisms can be created or altered synthetically on the basis of DSI only. Another revolutionary technique is genome editing (such as CRISPR/Cas) that will make it possible to change the genetic makeup of individuals without the use of other genetic resources.

1.1 International fora

The Nagoya Protocol (NP) on Access and Benefit Sharing (ABS) under the Convention on Biological Diversity (CBD) regulates the global exchange of genetic resources and is the global regulatory framework for access and benefit sharing arrangements, related to the "utilization" of genetic resources.

The three objectives of the CBD – conservation, sustainable use and access and benefit sharing - are interlinked and mutually supportive. Access to DSI and use of DSI should contribute to all three objectives of the CBD, and are crucial for reaching the UN Sustainable Development Goals (SDG) and the targets of the UN Climate Agreement.

Until recently, ABS discussions were focussed on the physical genetic resources (themselves), but more recently developing countries raised the issue whether digital sequence information (DSI) related to genetic resources should also fall under relevant international agreements dealing with ABS. Discussions on ABS in relation to DSI came on the agenda parallel to discussions related to synthetic biology.

Since the 13th Conference of the Parties to the CBD (COP13) / 2nd Meeting of the Parties to the Nagoya Protocol (MOP2), in 2016, discussions related to DSI are on the agenda of a variety of relevant international fora[1].

In general there is consensus that access to and use of DSI is extremely important to reach common global (Sustainable Development) goals. However, there are divergent views whether currently the access to DSI and benefits from the use of DSI are fair and equitable. Parties to the CBD/NP and various stakeholder groups have different opinions on whether and how to regulate access to DSI and benefit sharing.

One central element in the discussions on DSI is whether access to DSI should be open or not. At present, DSI is either accessible through public databases or in the hands of private parties. Private parties generally own their DSI data, and decide about access to their data.

[1] The Convention on Biological Diversity; the Nagoya Protocol on Access and Benefit Sharing; the Commission on Genetic Resources for Food and Agriculture of Food and Agricultural Organisation of the United Nations; the International Treaty on Plant Genetic Resources for Food and Agriculture; International Union for the Protection of New Varieties of Plants (UPOV), the Trade Related Intellectual Property Rights System van de WTO (TRIPS), United Nations Convention on the Law of the Seas (UNCLOS), the Pandemic Influenza Preparedness (PIP) Framework of the World Health Organisation.

1.2 Terminology and definitions

The term "digital sequence information" (DSI) was introduced in recent decisions within the CBD and the Nagoya Protocol. However, terms more commonly employed by the scientific community and databases include "genetic sequence data", "nucleotide sequence data", "nucleotide sequence information", and "genetic sequences". Differences in terminology reflect differences in the material referred to, as well as technological developments.

Terminology also varies between international policy processes. In ABS policy discussions, differences in terminology often reflect divergent political views of what should or could fall within the scope of the regulatory framework on Access and Benefit Sharing and related national laws.

In 2018, the Ad Hoc Technical Expert Group of the CBD on DSI[2] did not come to an agreement about the definition of DSI. Participants expressed very divergent views and possible definitions ranging from nucleic acid sequence reads to information on phenotypes and even environmental information.

The 2018 Conference of the Parties of the CBD and the Nagoya Protocol[3] recognized the need to better define the terminology. In the meantime, DSI will continue to be used as a "working definition" in international negotiations.

1.3 Data repositories

Many types of DSI are stored in either public (national and international) or private data repositories. The European Nucleotide Archive, GenBank in the USA and the DNA Data Bank of Japan are the principal public repositories for sequence data. Scientific journals increasingly require to make data available in publicly accessible databases or journal repositories as supplementary materials

Some public databases have implemented conditions for using DSI, including notifications from users on the database/websites, signing (clicking through) access agreements or memoranda of understanding, or they have implemented more specific user agreements. Use conditions may also include benefit sharing provisions.

1.4 Generating new DSI

Some research is based on sequences accessed through public and private databases only, but more often physical samples will be sequenced and analysed. It is common practice that both samples and data are shared between (research) collaborators.

A wide and varied range italic collections are held by public entities, non-profit organisations and scientific research institutions, universities, companies and others. A further increasing part of the same collections will be digitized in the near future.

Although science is moving towards more extensive use of genetic sequence information, physical material is still necessary and important for research projects. Physical samples can provide information on the relationship of genotype to phenotype, and interactions between organisms and their environments. Sequence information alone cannot deliver this type of information.

[2] CBD, 2018. Report of the Ad Hoc Technical Expert Group on Digital Sequence Information on Genetic Resources. Montreal, Canada, 13-16 February 2018.

[3] COP/MOP3, 2018. Conference of the Parties to the Convention on Biological Diversity serving as the meeting of the Parties to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization. Third meeting. Sharm El-Sheikh, Egypt, 17-29 November 2018.

2 Relevance of DSI for different subsectors

Recent fact finding or scoping studies on DSI have been published by the CBD[4], the FAO Commission on Genetic Resources for Food and Agriculture (CGRFA)[5], and the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA)[6].

The CBD study describes the use of DSI in different sectors, including synthetic biology research, industrial biotechnology, healthcare biotechnology and agriculture. Moreover, the authors discuss the use of DSI related to the identification and characterization of biodiversity, conservation genetics and genomics, invasive species, understanding pollinators, monitoring environmental change, ex situ conservation, tracking trade and wildlife tracking, developing new and improved crops, minimizing genetic erosion, and to pathogens and health emergencies.

Despite differences between sectors and domains, the authors of the CTB study state that "distinctions between academic, governmental, or industry research using genetic sequences have become blurred as partnerships increase, and academic institutional policies increasingly require the assertion of intellectual property rights or generation of economic value from research. Distinctions between different industrial sectors are also increasingly blurred …".

The authors of the CGRFA study did not discuss differences between sectors and domains regarding the use and value of DSI. However, a variety of examples are presented about the use of DSI in different subsectors and domains.[7]

2.1 Stakeholder views

National stakeholder consultations in the Netherlands indicated that different subsectors and domains have in common that the access to and the use of DSI is very important for research and innovation, in particular in the context of global food security and human health, and climate change challenges. As a result, access to DSI and the use of DSI has a tremendous economic and societal value. The annual turnovers of R&D in industry and scientific research are high, and DSI is increasingly used.

There is substantial variation between subsectors and domains to what extend they generate DSI, and how they use and exchange DSI. Across stakeholder groups typical uses of DSI include characterization of species and genetic diversity within species, genome association studies and diagnostic tests for pathogen surveillance. A growing amount of data is being generated for a wide range of uses. For many users it would be impossible to carry out their work without generating or using DSI.

Dutch breeding companies (plant and animal) are global players. Breeding industry is dependent of the continued availability of genetic resources and data for breed development. Genetic improvement and development of new varieties is based on the effective use of both genomic and phenotypic data.

[4] Laird, S.A. & Wynberg, R.P., 2018. 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. 77 pp.

[5] Heinemann, J.A., Coray, D.S. & Thaler, D.S., 2018. Draft Exploratory Fact-Finding Scoping Study on "Digital Sequence Information" on Genetic Resources for Food and Agriculture. 77 pp.

[6] Welch, E.W., M.J.D. Bagley, T. Kuiken and S. Louafi. Potential implications of new synthetic biology and genomic research trajectories on the International Treaty for Plant Genetic Resources for Food and Agriculture (ITPGRFA). Scoping report. October 2017.

[7] Animal genetic resources management (Box II.1); animal breeding (Box II.2; Vignette III.3.1; Vignette III.3.2); plant breeding (Box II.2; Vignette III.1.1; Vignette III.3.2); microbiology (Vignette III.1.2; Vignette IV.1.1); forestry (Vignette III.1.3); conservation of plant genetic diversity Vignette III.2.1); conservation of animal genetic diversity (Vignette III.2.2); food (Vignette III.3.3; Vignette III.3.6; Vignette III.3.7); public health (Vignette III.3.4); plant and animal health (Vignette III.3.4; Vignette IV.1.2).

Key research areas include genome association studies, better understanding of evolution, and genetic diversity studies for effective and efficient conservation and sustainable use.

Access to data (DSI) and free exchange of DSI is important for early detection and diagnosis of infectious diseases. Diagnosis of diseases is increasingly carried out on the basis of sequence data (DSI). This development is also particularly relevant for developing countries, that often do not have diagnostic labs, but they can particularly benefit from international exchange of pathogens and data for diagnostics and detection of emerging diseases. Recent outbreaks of MERS-CoV, Ebola and ZIKA showed the importance of rapid development of diagnostics at global level, using state of the art techniques and rapid exchange of pathogens and data. Limiting access to pathogens and/or DSI, and hampered global exchange between countries, hospitals and labs would hinder epidemic preparedness and response efforts, in any country and region.

3 Potential impact of regulating access and use of DSI

Any change in access arrangements for DSI or any restrictions on sequencing of genetic resources and/or publication of the resulting DSI could potentially affect a very large number of individual researchers, institutions and industry actors. There are strong concerns amongst stakeholders that any future restriction could potentially hinder their work, make it more costly or even make it impossible."[8] A large variety of public and private sector organisations, academic and scientific institutions, data repositories and collections, representing a broad range of stakeholders, recently presented a joint statement[9] emphasizing the importance of access to DSI and expressed their concern about potential barriers for access and use of DSI.

Limiting the availability of DSI will hamper innovation for future food security and adaptation to climate change. Reaching sustainable Development Goals (Agenda 2030) and objectives of the Paris Climate Agreement would become more difficult.

3.1 Plant breeding

Representatives of Dutch plant breeding companies stressed that innovation in plant breeding and the economic position of the sector would be negatively affected, when exchange, access and use of DSI is hampered. Limiting exchange of data would more often result in 're-inventing the wheel' and will negatively affect international cooperation and capacity building. This will be harmful in the context of global food security and climate challenges. Moreover, plant breeders also stress the need to minimize the administrative load.

3.2 Animal breeding

From the Dutch animal breeding perspective, access to DSI in the public domain is crucial for scientific research and knowledge development in animal breeding and genomics. Although private breeding industry will generally not deposit DSI related to their breeding stock and breeding lines in the public domain, public-private partnerships between research and breeding industry are key for scientific research and innovation programs.

3.3 Biological research

Biological research benefits from open access to DSI. Any access restriction is expected to have potentially large negative consequences. For some research areas it may even be impossible to continue the work. It may slow down progress and scientific output, or researchers may decide to take alternative approaches, so that a large part of global diversity will not be studied and understood.

3.4 Human health

Access to DNA sequence information related to pathogens is extremely important for national and global human health. Diagnostic tests, for example to distinguish between the Zika and Dengue viruses, have been developed on the basis of sequence data. Virology experts from research institutes

[8] Karger, E., 2018. Study on the use of digital sequence information on genetic resources in Germany. 80 pp.
[9] Promoting sustainable use and conservation of biodiversity through open exchange of Digital Sequence Information. Joint statement by public and private sector organisations, academic and scientific institutions, data repositories and collections representing a broad range of stakeholders. 2018.

in the Netherlands play a leading role in international networks, in which pathogens and data are exchanged between countries, labs and databases, in order to be able to adequately respond to emerging and acute health threats. For seasonal influenza the Pandemic Influenza Preparedness (PIP) Framework of the World Health Organization (WHO) is an important framework for exchange of pathogens and data[10].

Hampered access to DSI would seriously challenge national and international biosecurity and public, animal and plant health responses by impeding international research and surveillance activities relating to existing and emerging global health threats[11]. Research organisations state that it will affect the development of effective state of the art diagnostics and vaccines, and it would result in a dramatic reduction of scientific output and impact.

3.5 Micro-organisms

Stakeholders working with micro-organisms and invertebrates are also very concerned about the negative impact of regulating exchange of organisms and data. Research organisations working with micro-organisms and invertebrates have a long tradition of international collaboration and free exchange of species, samples and data. Scientific research and international collaboration would become much more difficult, and it would seriously affect the further development of international, public reference databases.

3.6 Biotech

According to biotech industry, the administrative load would become enormous. For example, the food industry is developing enzymes using a large diversity of sequences, originating from many different organisms and different "countries of origin". Tracking and tracing is impossible in this case. The consequence would be that companies will only work with "in house" samples, strains and data. Hampered international exchange will subsequently generate less global benefit sharing. Moreover, industry indicated that it would also result in a decreasing number of biotech start-ups and less innovation.

[10] WHO, 2018. Consultation to discuss the draft Analysis on approaches to seasonal influenza viruses and GSD under the PIP Framework. 15-16 October 2018. https://www.who.int/influenza/pip/WHA70_10_8_b/en/

[11] Submission of Royal Biological Society (UK).

4 Possible scenarios for regulating ABS related to DSI

In the Netherlands, stakeholder representatives[12] discussed four possible scenarios for regulating DSI towards the future, and their potential impact:

- Base Scenario: DSI out of scope of NP (BASE-OUT)
- DSI within scope of NP (ALT-IN)
- DSI out of scope of NP + Multilateral Benefit Sharing Mechanism for DSI (ALT-OUT-MBSM)
- DSI within scope of NP + Coalition of the willing for access and exchange of DSI (ALT-IN-CoW)

4.1 Base Scenario: DSI out of scope of NP (BASE-OUT)

This scenario implies that DSI is not considered to be equivalent to genetic resources and that DSI is out of scope of the Nagoya Protocol (NP). Countries can implement national access legislation for genetic resources, requiring Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) in case of access to genetic resources. Although DSI is out of scope of the Nagoya Protocol in this scenario, countries may include conditions for generating and publishing DSI in their access legislation, and providers could include provisions on the generation and further use of DSI in the MAT agreed upon before giving access to the genetic resources.

4.2 DSI within scope of NP (ALT-IN)

In this scenario, DSI would be included in the scope of the Nagoya Protocol, and become equivalent to genetic resources. This would mean that countries could develop and implement access and compliance legislation for both genetic resources and DSI. For many provider countries this would probably lead to PIC and MAT being required for both genetic resources and DSI.

4.3 DSI out of scope of NP + Multilateral Benefit Sharing Mechanism for DSI (ALT-OUT-MBSM)

This alternative scenario implies that DSI is not considered to be equivalent to genetic resources and that DSI is out of scope of the Nagoya Protocol. However, Parties of the CBD may recognize the need for a multilateral benefit sharing mechanism related to the use of DSI. A multilateral benefit sharing mechanism could include non-monetary (capacity building, technology transfer, development aid, free access to DSI from public databases) and/or monetary (taxing, user fees, membership) benefit sharing elements.

Mechanisms could be (partly) sector specific, such as possible arrangements under the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) or the WHO (PIP Framework).

Stimulating (open) access is an important objective of this scenario, as access to DSI can be seen as benefit sharing in itself, and facilitating access and use of DSI will contribute to the global Sustainable Development Goals.

[12] Representatives of DSM, KNAW, Ministry of I&M, Ministry of EZ, CGN-WUR, RIVM, Oxfam Novib, Godan, Wageningen University, Wageningen Research, Naturalis, VSNU, NWO, Ministry of VWS, Koppert, NVWA, Plantum, EFFAB/animal breeding industry, Westerdijk Institute.

4.4 DSI within scope of NP + Coalition of the willing for DSI (ALT-IN-CoW)

The key assumption for this fourth scenario is that DSI is within scope of the Nagoya Protocol. In this scenario, provider countries may decide to implement national access legislation for DSI. In order to facilitate exchange and use of DSI among themselves, countries could decide to form a "Coalition of the Willing" allowing free exchange of DSI, and possibly the associated genetic resources, amongst themselves, restricting access to others.

5 Assessment of scenarios and stakeholder views

Despite typical differences between sub-sectors, the general conclusion from Dutch national stakeholder consultations was that further regulating access to and use of DSI will negatively impact all subsectors and different domains.

5.1 What if DSI would be IN scope of Nagoya Protocol?

Including DSI in the scope of the Nagoya Protocol may result in decreased access to DSI. This will ultimately negatively affect all three objectives of the CBD (conservation, sustainable use and ABS).

The global research community is very concerned about the potential negative impact of DSI being included in the scope of the Nagoya Protocol[13]. It would be counterproductive, and would put increased administrative and financial pressure on research institutions, and it could make certain future research projects unaffordable, unappealing or impossible. Any restriction on sharing and accessing DSI from public databases and extra bureaucracy would create a major barrier to research and innovation and would delay scientific progress in many subsectors and research areas.

International research collaboration, including capacity building and technology transfer, will be hampered, and stakeholders believe that large companies and developed countries might benefit even more from such a change, so that further imbalance would be created between developed and developing countries.

Regulating ABS for DSI through bilateral MAT would make it difficult to maintain and further develop global reference databases for public research purposes and global needs.

5.2 Towards a multilateral benefit sharing mechanism?

DSI being out of scope of the Nagoya Protocol could go hand in hand with the development of a multilateral benefit sharing mechanism. Such a multilateral system should find a proper balance between promoting access to DSI and equitable benefit sharing related to the use of DSI by a variety of countries of stakeholders.

Generally there seems to be agreement between countries and regions that further capacity building and technology transfer is needed to better use, generate and analyse DSI, in order to contribute to conservation and sustainable use of biodiversity (non-monetary benefit sharing).

Respondents to a German survey[14] see potential benefits of open access for scientific development, agricultural development and human health. They support non-monetary benefit-sharing (e.g. funding for research, knowledge & technology transfer), and there was some support for benefits of commercial use of DSI flowing to provider countries.

An important form of (non-monetary) benefit sharing is access to publicly available databases. Generating and sharing DSI, hosting global data repositories, and providing funds, expertise and technological capacity to generate, store, analyse and manage DSI, should be considered as benefit sharing.

[13] Submission of Royal Society Biology (UK) to the CBD.
[14] Karger, E., 2018. Study on the use of digital sequence information on genetic resources in Germany. 80 pp.

5.3 Specialized multilateral instruments by subsector or domain

The CBD and NP may recognize specialized instruments such as the ITPGRFA and the PIP framework of the WHO. The ITPGRFA might serve as a model developing a multilateral system for access and benefit sharing.

The World Health Organisation (WHO) has developed the Pandemic Influenza Preparedness (PIP) Network, a dedicated multilateral benefit sharing mechanism. A future PIP framework without incorporating DSI might result in a potential "loophole", as the use of unregulated DSI instead of regulated physical genetic resources, may result in drastic reduction of the total amount of benefit sharing within the PIP framework.

Specific subsectors could also organise sector specific benefit sharing arrangements on a voluntary basis, in line with the economic value, turnover or profit of the subsectors and the value of exchange of DSI.

Dutch stakeholders suggested that discussing the issue of DSI would be better placed at a "higher" UN level than the CBD only, because the relevance of DSI goes far beyond the CBD, including discussions at WHO, FAO and WTO.

5.4 Promoting open science and open data

Further regulating access to DSI and use of DSI would be against the principles of Open Science and Open Data, that is promoted by the global research community and supported by the government of the Netherlands and other EU countries. Sharing research and data could be considered as an important benefit sharing element.

5.5 Public and private DSI

In line with a statement made in the CBD Scoping Study on DSI that distinction between commercial and non-commercial use becomes increasingly blurred, Dutch stakeholders pointed at the potential negative effect of separating commercial and non-commercial use of DSI. Although different treatment of commercial and non-commercial use of DSI could also contribute to solutions, there is a large 'grey area' between the two and should therefore be avoided.

5.6 Coalition of the willing

Further implementation of the Nagoya Protocol may result in hampered access and exchange of genetic resources and/or DSI. For that reason a subset of countries and/or stakeholders may decide to establish a "coalition of the willing", committing themselves to share genetic resources and data within the coalition. Such a model already exist in Asia, coordinated by Japan. The EU could decide to join other regions in a coalition, with the aim to increase the size of the coalition. On the other hand, such initiatives may negatively impact other (related) international collaborations, processes or negotiations.

5.7 Feasibility and administrative costs

Access and benefit sharing arrangements for DSI, similar to those for genetic resources under the Nagoya Protocol, would result in a very complex situation. DSI is often 're-used' and transferred to other users, even more frequently than physical genetic resources. This is particularly true for DSI in the public domain and DSI deposited in public databases.

Tracking and tracing of DSI for the purpose of benefit sharing obligations will not be feasible. Individual sequences are not unique, and uniqueness cannot be proven. The origin of DSI cannot be traced back easily to specific organisms, or even to 'countries of origin'. This will have impact on the enforceability of ABS regulations. Therefore, benefit sharing arrangements related to the use of DSI, if any, additional to the ones already in place, could best be dealt with at multi-lateral level.

The majority of stakeholders involved in the process fear, apart from the huge impact on their work, the bureaucracy related to regulating access to DSI. By nature, DSI is used in research and industry for genetic analysis and comparisons, combining information from different sources. ABS arrangements for DSI would result in an unforeseeable administrative burden, which consequently leads to large costs, delays in research and slowing down of scientific progress and innovation.

Finally, it was felt by Dutch stakeholders that the value of individual genetic resources or DSI is over-rated or overestimated in international discussions. This may result in unrealistic expectations regarding levels of benefit sharing.

6 Conclusions

- DSI is not equivalent to Genetic Resources.
- Promoting open access and use of DSI should be continued, as it benefits mankind, globally
- Potential additional benefit sharing arrangements for DSI could be best dealt with in a multilateral context.
- Free access to information, capacity building, technology transfer and research collaboration are key benefit-sharing elements of a multilateral approach.

7 Follow-up

CBD CoP14 decision 14/20 on Digital sequence information on genetic resources, decided to establish a science and policy-based process on digital sequence information on genetic resources (DSI) inviting Parties, other Governments, indigenous peoples and local communities, relevant stakeholders and organizations to submit their views and information.

The Conference of Parties also decided to establish an extended Ad Hoc Technical Expert Group, including the participation of indigenous peoples and local communities, and requests the Executive Secretary to fulfil a large number of assignments, including three peer reviewed studies.

Based on its national consultations and experience in this field the Netherlands is keen on participating in the extended Ad Hoc Technical Expert Group, that will submit its outcomes for consideration by a meeting of the open-ended working group on Post-2020, and make recommendations to the Conference of the Parties at its fifteenth meeting on how to address digital sequence information on genetic resources (DSI) in the context of the post-2020 global biodiversity framework.

At the same time the Netherlands is pro-actively involved in this matter and cooperating with other intergovernmental organizations (especially the ITPGRFA working group for enhancing the multilateral system), taking into account the work, approaches and outcomes that these organizations generate in the area in question.

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