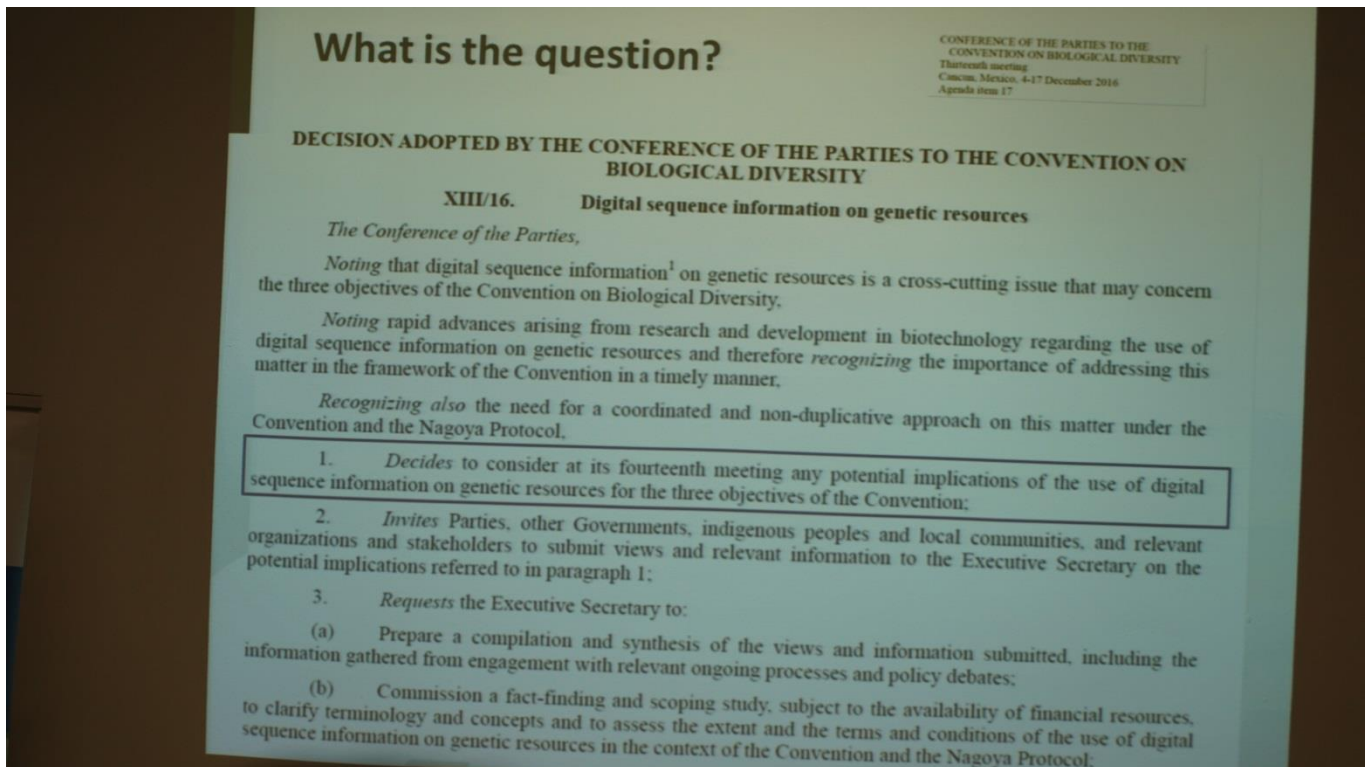


# Synthetic Biology, Open Science and the Nagoya Protocol

Key insights from a science-policy workshop 9.1.2018 in Berlin



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## Synopsis

At a workshop held in Berlin on January 9<sup>th</sup> 2018<sup>1)</sup> hosted by the Network-Forum for Biodiversity Research Germany (NeFo), stakeholders and network representatives from science and policy discussed the linkage between synthetic biology and open science under specific considerations of the decisions of the Conferences of the Parties (COP) to the Convention on Biological Diversity (CBD) and to the Nagoya Protocol (NP) to consider any potential implications of the use of digital sequence information (DSI) for the three objectives of the CBD, i.e. the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, where the third objective (Access and Benefit Sharing – ABS) is addressed specifically in the NP (decisions XIII/16<sup>2)</sup> and NP-2/14, respectively<sup>3)</sup>). Although participants and their discussions are neither complete nor representative, it might be of interest to make this documentation available to a broader public.

Workshop participants strongly re-affirmed the goals of the CBD and the ensuing NP for the protection and sustainability of biodiversity as well as access and benefit sharing. It is important to implement the already existing regulations of NP in a feasible way. The participants discussed that it is helpful to keep the big picture in mind and that until now an industrialized North often profits more from benefits arising from genetic resources than the Global South does.

However, expanding the NP to include DSI into the framework may not be the right solution and indeed may even aggravate the progress of biodiversity protection and research as well as successful implementation of ABS. As the speakers and participants pointed out repeatedly, DSI is used in a broad array of scientific activities, including supporting food security and nature conservation, sustainable use of biodiversity, species mapping and basic taxonomic assessments. Without research necessary for understanding, characterization and potential use, genetic resources hardly have any monetary and non-monetary benefits. The inclusion of DSI into the Nagoya Protocol would impede basic and applied research, and hinder social and technical innovation. Strategically, it is important to broaden the intellectual and technical basis for scientific participation and benefit sharing in poorer countries. Here, the global open science movement provides many entry points which should be explored further.

And, importantly, providing DSI itself represents a prime example of benefit sharing, as billions of sequences have been published free-of-charge for the entire world to use in open databases such as the three largest databases of the International Nucleotide Sequence Databases (INSD)<sup>4)</sup>.

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## DSI, synthetic biology, and the role of real organisms

A key discussion topic was how DSI (here roughly defined as sequence information) is made use of in synthetic biology. Indeed, there is a wide variety of scientific techniques and fields related to synthetic biology where DSI is utilized. For example, DSI can be used to implement novel genetic input into so-called chassis organisms ('domesticated' model organisms), where the DSI can be copied from real DNA sequences or even newly designed sequences. These new sequences can also be integrated into existing genomes using new gene editing tools. However, it was frequently reiterated that the utilization of DSI cannot currently be done without the presence of the real genetic organism. The reason is that gene regulation and expression remains an important and complicated issue, which requires iterative trial-and-error experimentation on the real organism in order to achieve the desired scientific outcome. Furthermore, these attempts are very difficult to understand, technically challenging, and costly and time consuming. For basic research, e.g. in the area of chemical genetics, and in order to understand mechanisms, it could be that the genetic components of a designed cells have their origin in different organisms and organelles<sup>5)</sup> and that it is very challenging to integrate these systems together for a successful functional outcome.

Three hundred and fifty research scientists from Germany recently participated in a survey on the use of DSI in Germany, which was conducted on behalf of the German Federal Agency for Nature Conservation (BfN). The majority of the scientists who participated in this exploratory study were biologists who conduct research in a wide range of fields, including more classical fields, e.g. taxonomy, phylogeny or physiology, the newer "omics" fields, and other more applied fields, e.g. health, food, biotechnology, plant breeding etc. The study mostly attracted participation by non-commercial researchers. The results indicate that DSI is generated, accessed, used and shared in various ways by these researchers and that DSI is an important tool for them.

Last but not least, a recent legal analysis by a Prof. Dr. iur. Dr. rer. pol. Tade Matthias Spranger, Bonn, based on decades of international, adjudicated law is that genetic resources as defined in the CBD relate only to tangible material<sup>6)</sup> – which DSI is not – and as such an extension of the NP to include DSI would require re-negotiation and re-ratification.

## Scientific “reality check”

The scientific community highlights that the inclusion of DSI into the NP may further complicate the already existing practical difficulties of implementing the NP. There are strong concerns that adding DSI “on top” may hamper scientific endeavors and cooperation with provider countries, and may ultimately counteract the goals of the CBD and its vision that science contributes substantially to sustain biodiversity as a foundation for global wealth and well-being.

Indeed, scientists may be unable to cope with an increasing bureaucratic burden and have, in some cases, already either changed research direction or countries with which they cooperate.

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Furthermore, including DSI into the NP might lead to the use of the most accessible information rather than the best usable ones, which leads to a reduction of scientific progress.

In short, the participants strongly argued that the focus of German and European biodiversity research should be on effective and efficient implementation of the NP regulations in force. Any discussion of an expansion of the Protocol is entirely premature. Moreover, there are very compelling scientific reasons (in addition to legal reasons) why DSI is not equivalent to the real genetic resource:

- In order to officially describe new microbial species it is required that the organism is in culture (physically present and pure). Pure DSI has limited applications other than taxonomic differentiation.
- In contrast, sequence information (microbial nametags or barcodes for macroorganisms) are necessary for taxonomic surveys (i.e. mapping biodiversity). If DSI were included indiscriminately in the NP, these basic taxonomic surveys would be negatively impacted having a counterproductive effect on the goals of the CBD.
- Microorganisms are ubiquitous and cosmopolitan therefore it is difficult to apply the provisions of the NP which follows a bilateral approach. Strains with 99% genome sequence identity have been found halfway around the world raising the question who can legitimately claim sovereign rights over such identical sequences when there is no physical material to differentiate them?
- It is difficult, if not impossible, to identify the origin of DSI because sequence variation within is infinite but not geographically defined.

## Ways forward and possible solutions

It was discussed that it is important to differentiate between (political) positions and (justified) interests, and also distinguish between and within different countries. Three lines for possible solutions were addressed in the debate, 1) increase scope and intensity of capacity building, 2) develop governance models of global (scientific) commons, and 3) explore options of multilateral networks which should be explored in more detail in future:

### Capacity Building

- Analyze best practices of the implementation of the NP and promote its application. This refers to the national focal points in provider countries but also to the international research community which is not necessarily aware of the NP and its implications.
- Support initiatives such as the internationally organized ABS Capacity Development Initiative<sup>7)</sup>

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- Assess the long-term effectivity of capacity building and technology transfer activities.
  - Increase national and international cooperation with universities and other research institutes; e.g. empower and support student teams to contribute to iGEM<sup>8)</sup> or other learning opportunities.

## Open Science and the Governance of global (scientific) commons

- Develop incentives which allow sharing scientific insights; the European Commission (as part of its "3-Os" strategy: "Open Science, Open Data, Open to the World") and other funding institutions follow the rule that results achieved with public money should be made publically accessible. This strategy will be compromised if in the future DSI falls under the scope of the NP. Scientists will be trapped between contradictory demands.
- The databases of the International Nucleotide Sequence Database Collaboration (INSDC) are a key part of scientific integrity and provide central mechanisms in scientific peer review publication since primary data (sequences) must be deposited in the databases (freely and unconstrained) as a prerequisite for publication. The three open access databases of the INSD Consortium are managed and financed by USA, Japan, and the European Union although the data is available for free to the whole world. Thus, through the high quality service, provision of analysis tools, tutorials, curation, and access to billions of sequences, these countries provide the scientific and world community with a large monetary and non-monetary benefit.
- Intensify research on the governance of DSI as a global scientific commons<sup>9)</sup>.

## Development of networked implementation

- What can be learned from the experience gained from existing well-established and acknowledged networks and treaties such as the International Treaty on Plant Genetic Resources for Food and Agriculture (IT-PGRFA)<sup>10)</sup>?
- The instruments provided by EU Regulation 511/2014 - Best Practises (art. 8) and registered collections (art 5) - and their fulfillment of due diligence requirements on behalf of a community of users needs to be more widely understood, recognized and incorporated. At present, CETAF (Consortium of European Taxonomic Facilities) is in the process of getting its Code of Conduct accredited as "best practice"<sup>11)</sup>. At the same time, the Leibniz Institute DSMZ – German Collection of Microorganisms and Cell Cultures<sup>12)</sup> is actively working towards status as the first registered collection.
- Explore the links – synergies and trade-offs – with different IPR regimes including patent laws and licensing practices. Initiatives such as the Open Source Seeds Movement<sup>13)</sup> may give some insights.

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