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The Alliance sees open access to digital sequence information at risk

Position paper from the Alliance of Science Organisations in Germany on the potential inclusion of digital sequence information¹ of genetic resources into the framework of the Nagoya Protocol and the Convention on Biological Diversity

The Alliance of Science Organisations in Germany strongly cautions against expanding the scope of the Convention on Biological Diversity (CBD) and the Nagoya Protocol (NP) to include digital sequence information (DSI). Such an expansion would have far-reaching negative consequences, which could severely damage scientific research progress in the fields of environmental and life sciences and biodiversity, and would particularly threaten international research cooperation within these fields. Furthermore, current efforts to make science more open and transparent (e.g. the European Open Science Cloud Declaration²) and initiatives to warrant open access to data from publicly funded research would be jeopardized.³

In principle, the Alliance supports the NP, which regulates access to genetic resources and the fair and equitable sharing of resulting benefits (Access and Benefit Sharing, ABS) as of October 2014. It is a central concern of the Alliance that its members respect good scientific practices (established by field-specific Codes of Conduct⁴) when cooperating with partners in a national or international context.

However, in 2013, the Alliance did publish a joint statement during the EU legislative process pointing out the foreseeable difficulties of implementing the NP for non-commercial research.⁵ Indeed, experience now confirms that, as a result of implementation of the NP, international cooperation in biodiversity research, the analysis of human and animal pathogen-vectors, and the investigation of plant diseases, among others, have been significantly obstructed. The main issues have been severe delays, bureaucratic barriers, difficulties

¹ The term "digital sequence information" was coined in political discussions within the context of the Convention on Biological Diversity and is not used uniformly. In short, digital sequence information refers to all information obtained through molecular-biological and biochemical methods.

² <https://ec.europa.eu/research/openscience/index.cfm?pg=open-science-cloud> (26 October 2017)

³ Further information on the CBD, the NP and the DSI process can be found at the end of this statement.

⁴ e.g. the Code of Conduct of the Consortium of European Taxonomic Facilities, CETAF

⁵ "Securing the access of research to genetic resources!" Statement of the Alliance of Scientific Organisations in Germany, 23 May 2013.

obtaining sampling permits from the respective authorities, and existing legal uncertainty.

Far-reaching negative consequences on international environmental and life science research

The massive increase of knowledge in natural and life sciences depends largely on the free and open availability of DSI. A restriction of access to DSI would significantly impair scientific progress, which depends on the analysis of large digital data sets. The Alliance anticipates the following consequences:

- In order to use digital data sets for subsequent analysis, researchers would need to obtain the approval of the genetic resource's provider country and notify the relevant national competent authority. The respective approvals for thousands of sequences would have to be obtained for every single set of DSI. This would constitute an insurmountable obstacle for a variety of research fields. For instance, evolutionary biology (e.g. calculation of genealogical tables from thousands of sequences), active-substance research (e.g. requiring the screening of immense amounts of DNA sequences), or infection research (e.g. investigation of new pathogens) would face tremendous difficulties. In the case of infection research, immediate tracking of global outbreaks would be impaired.
- Publication of scientific papers requires uploading of primary data (including DSI) into relevant databases as a condition of journal publication. If this requirement cannot be fulfilled due to usage restrictions, research results may not be published. This would threaten the fast reproducibility and validation of scientific results, directly obstructing scientific research and harming in particular Open Access journals and repositories.
- Research on domestic genetic resources in the countries of origin would be debilitated, as they could no longer benefit from Open Access. The Alliance worries that international research cooperation will focus increasingly on countries that have not ratified the NP.
- Substantial additional costs would arise for the operation and the use of digital databases and globally interconnected research and information infrastructures in order to fulfil the required criteria of each country. The latter would represent not only a substantial technical challenge, but, in practice, it is inconceivable how such changes would be feasible or financeable.

The impacts outlined above would not only harm scientific progress, but also contradict the goals of the CBD. Parties to the Protocol should respect article 8a of the NP and create conditions that facilitate access to DSI for non-commercial research.

Clear and simplified framework conditions for Open Access to digital sequence information

Considering the issues outlined above, the Alliance of Science Organisations in Germany calls on policymakers in Germany and the European Union as well as the CBD secretariat **not to extend the scope of the Nagoya Protocol to cover the use of digital sequence information**. Non-commercial research on the exploration and protection of biodiversity and the environment, on human health, nutrition, and livelihood must be ensured. Research organisations and scientists must be able to continue to engage in international cooperation without having to face insurmountable hurdles.

The Alliance of Science Organisations in Germany is a union of the most important German research organisations. It regularly issues statements relating to research policy and funding and the structural development of the German research system. Members of the Alliance include the Alexander von Humboldt Foundation, the German Academic Exchange Service, the German Research Foundation (DFG), the Fraunhofer-Gesellschaft, the Helmholtz Association of German Research Centres, the German Rectors' Conference (HRK), the Leibniz Association, the Max Planck Society, the German National Academy of Sciences Leopoldina, and the German Council of Science and Humanities (Wissenschaftsrat). In 2018, the Fraunhofer-Gesellschaft is chair of the Alliance of Science Organisations in Germany.

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Attachment

Background information – Nagoya Protocol and digital sequence information

The Nagoya Protocol, which came into force on 12 October 2014, is one of a number of measures to implement the Convention of Biological Diversity. The NP establishes a framework for the access to genetic resources (and associated traditional knowledge) and the sharing of benefits resulting from the use of genetic resources (*Access and Benefit Sharing*, ABS). Since the implementation of the NP in the European Union by Regulation EU Nr. 511/2014⁶, specific obligations to support compliance with domestic legislation and regulatory requirements apply to bio- and geo-scientific as well as for basic medical research concerning the use of biological material from countries that are Party to the Protocol. In Germany, the Federal Agency for Nature Conservation (Bundesamt für Naturschutz, BfN) as a departmental research agency, which reports to the German Environment Ministry (BMUB), is in charge of implementation.

As a result of the 13th Conference of Contracting States (COP 13) of the CBD and at the second meeting of the Nagoya Protocol Parties in December 2016, an open-ended process was set up⁷ in order to scrutinize whether the use of digital sequence information should be subject to the CBD and NP regulations. So far, the Nagoya Protocol is confined to the use of *genetic material*.⁸

The decision whether or not DSI will fall within the scope of the NP is expected to be made at the COP 14 in late November 2018. In preparation, a panel of experts was appointed by the CBD to provide advice to the SBSTTA⁹. The panel will meet from 13 to 15 February in Montreal. In addition, a scoping study was commissioned by the CBD Secretariat.¹⁰ The NP Parties, along with all potentially affected stakeholders were invited to comment on this study by 8 September 2017. Many countries and interest groups from all over the world have already published their positions.¹¹ The German Research Foundation (DFG) contributed to the discussion on DSI as well.¹² In preparation for the COP 14, the SBSTTA¹³ – the advisory board of the CBD – will discuss the DSI issue between 2 and 7 July 2018 and will most likely issue a conclusive recommendation for COP 14.

⁶ Download: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0511&from=DE>

⁷ Notification 2017-037: <https://www.cbd.int/doc/notifications/2017/ntf-2017-037-abs-en.pdf>

⁸ According to the NP, “genetic material” refers to any material of plant, animal, microbiological or further origin containing functional units of heredity, thus including water or soil samples. Human genetic material or genetic resources are excluded, as they are subject to special international ABS regulations.

⁹ Subsidiary Body on Scientific, Technical and Technological Advice

¹⁰ Peer Review of Fact-finding and Scoping Study on Digital Sequence Information on Genetic Resources: <https://www.cbd.int/doc/notifications/2017/ntf-2017-115-abs-en.pdf>

¹¹ An overview of the statements can be found here: <https://www.cbd.int/abs/dsi-gr/ahteg.shtml>

¹² Download: <https://www.cbd.int/abs/DSI-views/DFG-DSI.pdf>

¹³ Subsidiary Body on Scientific, Technical and Technological Advice