Society *for* Applied Microbiology

POSITION STATEMENT

Nagoya Protocol

Digital Sequence Information and the Nagoya Protocol

The Society *for* Applied Microbiology fully supports the principles behind ensuring the fair and equitable use of genetic resources, as stipulated under the Convention on Biological Diversity (CBD). However, it is our view that careful considerations need to be made for Digital Sequence Information (DSI) to be included within the scope of the Nagoya Protocol. Due to the scale and disparate nature in which DSI is gathered, stored and accessed, there ought to be clear recommendations on when the guidelines within the Nagoya Protocol should apply.

We view DSI as an expression of a genetic resource and therefore believe that it should, in principle, be subject to Access and Benefit-Sharing (ABS) arrangements in the spirit of the CBD. However, for DSI to be brought within the scope of the Nagoya Protocol, we would recommend that the following considerations apply:

The generation and publication of DSI should be considered as a descriptive act. Basic research that leads to descriptive knowledge should *not* be regarded as *utilization* and hence should not trigger the Nagoya Protocol.

Under the spirit of the CBD, publication of DSI (i.e., the description of the genetic resource) as publicly available electronic data alone should be sufficient to satisfy equitable benefit-sharing. However, it is recognized that a country has the right to control access to such data, but this should not be to the extent that it impedes innovative science.

Subsequent use of published DSI for the development of a product or tool ought to be considered as utilization, which would then trigger the need to arrange specific ABS agreements between the User and Provider.

Nagoya Protocol

The use of Digital Sequence Information

- Sequence data from microorganisms is generated (i.e., described) on a large scale, with varying degrees of complexity, and at an ever-increasing rate. It would be unfeasible to agree and regulate different benefit-sharing arrangements each time DSI is generated.
    - *Example: environmental samples, for instance soil, contain thousands of different microorganisms. Metagenomic analysis of these samples produces data on small fragments of each organism's genome, each piece different. These data are different in nature to Whole Genome Sequence (WGS) data, which describes the entire genome of one particular organism.*
- Microbiologists enjoy an unprecedented ability to engineer novel genetic sequences, due to the breadth of DSI available and an increasingly sophisticated array of genetic modification techniques. In practice, such engineered sequences may be composed of genetic components from several organisms (including plants, animals, microorganisms and invertebrates).
- Depending on the provenance of each genetic component, this raises the issue of requiring multilateral arrangements for utilization, which have the potential to slow the pace of research whilst an agreement is reached.
- Electronic databases which contain information on novel engineered sequences ought to describe the geographical origin of the genetic components it comprises. Ensuring traceability will enable subsequent Users to draw up new ABS agreements, as necessary.
- Many microorganisms have very similar genetic sequences, yet differ in geographical origin. Online databases are frequently used to find microorganisms which contain matching genetic sequences of interest. In relation to ABS legislation, the following issues could arise:
    - *Potential legal disagreements over the geographical origin of a genetic sequence, which will be difficult to prove.*
    - *If a User is interested in a genetic sequence belonging to an organism from one particular country, online databases may be used to find a similar sequence which originates from a different country with underdeveloped (or less restrictive) ABS legislation. This could result in certain countries being purposefully exploited. Treating all DSI equally under the Nagoya Protocol (regardless of origin) could help mitigate this risk, but may impinge on the sovereign rights of Party countries.*

Publishing

- All DSI which is generated from organisms should be provided alongside full provenance details under an appropriate Material Transfer Agreement (MTA), which provides all relevant information on Mutually Agreed Terms (MAT) and Prior Informed Consent (PIC). In electronic databases, these provenance details should be included as metadata alongside the sequence data to ensure transparency and traceability.[1]
- Published journal articles include information on the genetic sequences studied in a particular research project, often linking to publicly available databases. However, it should not be made mandatory for academic journals to make such publications freely available to satisfy benefit-sharing. The description of the genetic resource, through its publication in an electronic database should be viewed as sufficient. Nevertheless, academic journal articles which refer to DSI ought to contain a reference to the database that contains the sequence information and its associated provenance metadata. This will boost transparency and traceability for any potential subsequent Users, whilst not proving too burdensome for the publishing industry.
- Microbiologists often freely share data on genetic resources in the spirit of academic collaboration. If the transfer of DSI is treated in the same way as genetic resources are, then the DSI would need to be accompanied with a MTA (see paragraph 7), defining how the material can and cannot be used. This will provide legal clarity to the recipient and improve traceability, whilst not stifling the exchange of information.
- The establishment of a 'Multilateral subscription system', similar to that being considered by the FAO,[2] may be viewed as an appropriate method to control the use of DSI. However, we view that this would be very costly (in terms of time and money) to set up and maintain, especially in light of the number of free publicly available online databases. Furthermore, this measure would significantly disincentivize basic (i.e., descriptive) research, as researchers would be expected to pay a subscription fee without expecting any return.

[1] For reference, see the Global Genome Biodiversity Network (GGBN) Best Practice Guidance for ABS

[2] IT/OWG-EFMLS-6/17/Inf.8 para 9

Training and Capacity

- Researchers across academia, industry and the public sector are frequent consumers and contributors of DSI data. Appropriate training would be required to ensure that such researchers, across all experience levels, are sufficiently aware of ABS requirements, and are trained in compliance measures relating to DSI.
- The ability to rapidly access, generate and share genomic data is crucial to public health surveillance and ensuring food safety. This applies to routine monitoring exercises, as well as to responses in emergency situations (e.g., disease outbreaks). Data storage and sharing systems should be coordinated so that information can be readily shared and unrestricted by different interpretations of what constitutes utilization. In addition, microbiologists working in these areas should be sufficiently trained in best practice measures when generating and accessing DSI.

EU Regulations

- We recommend that basic research leading to the generation and publication of DSI should be considered as a descriptive act and not utilization. However, current guidance on implementing the existing EU Regulation is confusing and will lead to conflicting interpretations of what constitutes utilization.
- Relying on the descriptions of "research and development (R&D)" and "utilization" from the OECD's 2002 Frascati Manual is confusing as it encompasses basic research (i.e., experimental or theoretical work undertaken primarily to acquire new knowledge of the underlying foundation of phenomena and observable facts, without any particular application or use in view).
- The draft EU Regulatory Guidance which refers to Articles 5.4, 8(a) and 17 of the Nagoya Protocol and Article 7 of the EU ABS Regulation, implies that each type of R&D is considered to constitute utilization. Under the Frascati interpretation, this will mean that all basic (descriptive) research will be viewed as utilization under the EU Regulation, regardless of whether research is aimed at products or tools for the market (or similar).
- In order to achieve clarity, we believe that all research leading to descriptive knowledge should not be regarded as utilization, but within the spirit of the CBD it will require the benefits to be shared. Equitable benefit-sharing, from the generation of knowledge and descriptive output, should be satisfied by making such information available to the Provider country, either directly, or through the publication of research data in publicly available databases.

About S*f*AM

S*f*AM is the oldest microbiology society in the UK, serving microbiologists around the world. As the voice of applied microbiology, S*f*AM works to advance, for the benefit of the public, the science of microbiology in its application to the environment, human and animal health, agriculture and industry. It works in collaboration with other organizations to ensure evidence-based policymaking and, in partnership with Wiley, publishes five internationally acclaimed journals.
Value for money and a modern, innovative and progressive outlook are the Society's core principles. A friendly society, S*f*AM values integrity, honesty and respect, and seeks to promote excellence and professionalism and to inspire the next generation of microbiologists.

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