sfam
society for applied microbiology

Executive Secretary

Secretariat of the Convention on Biological Diversity

United Nations Environment Programme

413 Saint-Jacques Street, Suite 800, Montreal, QC, H2Y 1N9, Canada

07 September 2017

Dear Ms. Palmer,

Society for Applied Microbiology Position on Digital Sequence Information and the Nagoya Protocol

On behalf of the Society for Applied Microbiology (S*f*AM), I am delighted to present the Society's position on the use of Digital Sequence Information on Genetic Resources, within the context of the Convention on Biological Diversity and the Nagoya Protocol. Specifically, we are grateful for the opportunity to detail some of the implications for microbiology that ought to be considered.

Please find attached a copy of our position statement, which outlines the Society's stance and recommendations. If you require clarification on any of the points therein, please do not hesitate to contact the Society.

Once again, may I express our gratitude for the opportunity to contribute the Society's views on the behalf of applied microbiologists.

Yours sincerely,

Professor Mark Fielder

President, Society for Applied Microbiology

Society for Applied Microbiology Position on Digital Sequence Information and the Nagoya Protocol

September 2017

Introduction and position

1. 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.

2. 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:

   2.1. 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 *utilisation* and hence should not trigger the Nagoya Protocol.

   2.2. 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 recognised 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.

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

Considerations from a microbiological perspective

3. There are a number of considerations relevant to microbiology, regarding the generation, publication and utilisation of DSI. Whilst many of these will be addressed by the recommendations made above, they should still be considered in the wider context of how DSI is treated.

The use of Digital Sequence Information

4. 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.

    4.1. 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.

5. 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).

    5.1. Depending on the provenance of each genetic component, this raises the issue of requiring multilateral arrangements for utilisation, which have the potential to slow the pace of research whilst an agreement is reached.

    5.2. 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.

6. 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:

    6.1. Potential legal disagreements over the geographical origin of a genetic sequence, which will be difficult to prove.

    6.2. 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 NP (regardless of origin) could help mitigate this risk, but may impinge on the sovereign rights of Party countries.

Publishing

7. All DSI which is generated from organisms should be provided alongside full provenance details under an appropriate Material Transfer Agreement, 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]

8. 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.

9. 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.

10. 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 disincentivise basic (i.e. descriptive) research, as researchers would be expected to pay a subscription fee without expecting any return.

Training and capacity

11. 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.

12. 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 utilisation. In addition, microbiologists working in these areas should be sufficiently trained in best practice measures when generating and accessing DSI.

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[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

About the Society for Applied Microbiology

The Society for Applied Microbiology (S*f*AM), the oldest microbiological society in the UK, aims to advance the science of microbiology in its application to the environment, human and animal health, agriculture and industry. S*f*AM is the voice of applied microbiology, with members across the globe, and works with sister organisations to support policy-makers world-wide to put in place practical and implementable regulations and policies.