

Summary of Microbiology Society member comments regarding Digital Sequence Information (DSI) and the Nagoya Protocol

1. Background

In July 2017 DEFRA issued a call for comments to the Access and Benefit Sharing Stakeholder Forum relating to proposals to consider the inclusion of Digital Sequence Information (DSI) within the scope of the Nagoya Protocol on access and benefit sharing of genetic resources.

The Microbiology Society *does not* currently have a formal position on this issue. However, to inform DEFRA's input to international discussions on this issue, and given potential implications for microbiology, the Society invited members to submit views and comments, which are summarised below. Ten responses were received from the Society's Council, Policy Committee, Open Research Data Working Group and general membership. As a Member Organisation of the Royal Society of Biology (RSB), our comments were also informed the RSB's response.

2. Summary of Microbiology Society Members' comments

2.1 Concerns about hindering research and workability

Most respondents were very clear that extending the Nagoya Protocol to include DSI would likely impede microbiological research, and raised concerns about the workability of regulating access to DSI from microbial resources under the terms of the Nagoya Protocol.

2.1.1 Potential hindrances to the pace of research, collaboration, open access and addressing global health challenges

- Some respondents indicated experiences of microbiological research having been impeded or inhibited under the current terms of Nagoya, or due to related restrictions and concerns; it was suggested this was likely to increase with any extension to DSI, due to the widespread use of this data. For example, one respondent noted that they were aware of scientific publications that have been effectively blocked due to hold ups in host countries who fear missing out on commercial income – even simple taxonomic and descriptive papers, with no commercial implications, have been inhibited due to restrictions on overseas data by some host countries. There is a risk that inclusion of DSI in the Nagoya Protocol would lead to the formation of national silos of sequencing data less easily accessible to outside researchers. If the usage of DSI becomes contingent on collaboration with an academic in that country or approval from a national regulatory body, the pace of scientific research will drastically decrease. One respondent noted the frustration of acquiring bacterial strains and plasmids via Material Transfer Agreements, which often take months of jumping through bureaucratic hoops. If this were to become the norm for obtaining DSI the fear is that research would become increasingly limited as genetic and genomic analyses have become such an integral part of day to day lab work.
- Respondents highlighted that any additional complexity and delay obtaining permissions to use DSI may cause some researchers and their institutions to think twice before collaborating and sharing resources. This may be truer for microbiology than for other areas

of research, with greater uncertainty over origins and ownership of microbial genetic resources (see 2.1.2 below).

- Respondents were also concerned that including DSI within the Nagoya Protocol would conflict with the principle of open access and sharing of data. Many microbiology studies rely on the ability to compare gene sequences obtained from different studies and available in public databases. Any restrictions to open access would potentially run counter to increasing demand for open data. For example, the Microbiology Society's journals operate policies that help to ensure that authors of papers in our journals deposit DSI in public databases so that all may benefit from the research without the need to consider national borders. Additionally, online repositories are not the only sources of DSI: this material also appears in the pages of journals and in supplementary files linked to published papers. Technical measures that aim to control and/or to police access to DSI are likely to be inhibitory to the freely-flowing, collaborative and cross-border nature of modern research in microbiology.
- A member raised concerns that including DSI under the Nagoya Protocol would be extremely damaging to global efforts to track and control microbial pathogens and antimicrobial resistance determinants. It is clear that the generation of, and access to, comprehensive databases of genetic sequences for both pathogenic organisms and antimicrobial determinants will be necessary to track pathogens and AMR determinants globally, providing early alerts for the emergence of new pathogenic lineages and AMR determinants and their spread between countries. Such databases will necessarily require the combination of data from a very large number of different countries, and the free re-use of such data. Building such a database through individual negotiation with every country would be very difficult. However, subjecting the database to the Nagoya protocol's requirements for tracking benefit sharing and controlling re-use would make actually using these databases entirely impractical.

2.1.2 Concerns about the workability of regulating access and sharing of DSI

- Several respondents were concerned about the workability of implementing and policing regulations for DSI under Nagoya, and that it could lead to considerable legal complexity, which might impede research while not delivering on proposed benefits.
- Respondents highlighted that attributing origin and/or ownership of microbial DSI for micro-organisms, and determining what level of precision sequences should be 'protected', is challenging for several reasons, including:
 - Microbial strains and species readily cross international borders and exchange genes.
 - Microbes exhibit extensive genetic diversity. When a microbial genetic sequence with a useful function is identified in one place, this may readily lead to the discovery of similar but different genetic sequences, but with the same function of interest in other places.
 - Micro-organisms are transferred between different hosts (e.g. people and animals) and environments, and their functions are modified by (and in turn modify) the microbiome of the host. For example, if a person travels to a foreign country, is unknowingly colonised by a microbe, returns home and then cultures it with commercial purpose, it is unclear who should own the microbial genetic resource and associated DSI – especially in cases where the utility of the DSI may only be apparent in the context of the host's microbiome.

2.2 Potential benefits of extending the Nagoya Protocol to include DSI

Given very careful consideration, consultation and implementation, a few respondents tentatively agreed DSI should perhaps be covered by the Nagoya Protocol.

- While acknowledging difficulties and likely hindrances to research, respondents variously suggested that: this extension may nonetheless be the right thing to do; it would seem illogical to exclude DSI from the scope of an agreement on genetic resources; and it might effectively keep legislation up-to-date with the current state of research.
- One respondent, who is familiar with difficulties encountered with international sharing and usage of microbial DSI during recent outbreaks of influenza, MERs and Ebola, argued that although there would be hindrances to research and development, including DSI under Nagoya might be beneficial and a stable way forward, as it might provide a clear international framework within which host countries and researchers could operate and in which the practical issues (see below) could be negotiated. Outside of Nagoya, it is likely (and in places already happening) that some countries will develop their own rules on access to DSI, and increasingly become less willing to share DSI as risks of exploitation are more apparent, which could more greatly impede research.

2.3 Further considerations

Some respondents highlighted considerations, should the DSI proposal progress further:

- Ensure that DSI remained open access without restriction, but with Nagoya requirements being triggered by commercialisation. This would still have the effect of slowing down development and business, but would be less inhibitory of basic research.
- Careful consideration should be given to the level of precision of DSI that any regulations would apply to. For example, regulations might be appropriate for some whole genome sequence data of possible commercial value, but not for individual genes and sets used for taxonomy and variation studies. As outlined under 2.1.2, microbial gene flow and genetic diversity makes determining the level of precision sequences should be 'protected' challenging.
- Implementing this policy for digital data while maintaining open access needs clear leadership, careful explanation and clear guidance to all parties, easy paperwork, and possibly some resource. Without this, researchers and their institutions will see it as 'too hard' and may think twice before collaborating and resource sharing.

3. About the Microbiology Society

The Microbiology Society is a membership organisation for scientists who work in all areas of microbiology. It is the largest learned microbiological society in Europe with a worldwide membership based in universities, industry, hospitals, research institutes and schools.

The Society publishes key academic journals, organises international scientific conferences and provides an international forum for communication among microbiologists and supports their professional development. The Society promotes the understanding of microbiology and microbes to a diverse range of stakeholders, including policy-makers, students, teachers, journalists and the wider public, through a comprehensive framework of communication activities and resources.

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