IFPMA

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Convention on Biological Diversity

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Subject: IFPMA views on the potential implications of the use of Digital Sequence Information (DSI) on the objectives of the Nagoya Protocol (NP)

Introduction

In December 2016, in response to concerns from some developing countries that use of digital sequence information (DSI) could undermine the benefit sharing objective of the Nagoya Protocol (NP), the Conference of the Parties to the CBD adopted a decision to consider the potential implications of DSI use in greater detail. It endorsed the creation of an ad hoc technical expert group to consult on the implications and asked that the Subsidiary Body on Scientific, Technical and Technological Advice make recommendations to the Third Meeting of the Conference of the Parties in November 2018.

This paper represents the **IFPMA's contribution to this DSI debate**.

The Importance of Open Access to DSI

In all research areas, open access to data is fundamental to research; to the free flow of knowledge and sharing of the genetic information on novel species and new research breakthroughs; to publication in reputable journals; and in general to the continued development and growth of global research and development, both within and external to the life sciences sector.

Research advances by sharing information. The use of DSI in research allows for swift compilation, comparison and reanalysis of genetic information from a variety of sources, across multiple databases and gene sequences. The field of bioinformatics research, in addition to other research disciplines, relies heavily on this level of open access in DSI.

Requiring ABS agreements to permit legal access to each sequence and/or database throughout the research process would significantly undermine this open access framework and the public good it serves.

The scale of open access to DSI

There is a well-established international framework for submitting DSI and making it freely available on the internet to all. The data are made available by researchers globally and open access to it represents a crucial tool in scientific research.

It is estimated that publicly available databanks collectively already contain quadrillions (>10^{15}) of nucleotides of DNA sequence data and that this figure will soon move into the quintillions (>10^{18} bases). These have been collected from over 300,000 different species of organisms."[1]

Additionally, public databanks are not the only sources of DSI. It also appears in the pages of journals and in supplementary files linked to published papers. Legal and technical measures aimed at controlling and/or policing access to DSI would need to be take this into account.

IFPMA Position

The IFPMA supports the CBD's access and benefit sharing objective. However, notwithstanding our assumption that *existing* DSI would be explicitly exempt from any change in the scope of the CBD ie any change would be prospective in nature, we feel very strongly that DSI should not be included within the scope of the CBD and Nagoya Protocol (NP). Our reasons for this are set out below:

- **There is no evidence of a problem.** Any decision to amend the scope of the CBD and NP must be based on clear evidence that the current system is failing and that to add DSI would cure this failure. There is no such evidence. If there are shortcomings with the CBD, it is largely due to the lack of provider country laws which facilitate access and thus generate benefits. Once addressed, and a comprehensive legal framework of national ABS laws is put in place, concerns about the lack of benefit sharing related to GR access and use, should disappear.

- **Inclusion of DSI would fundamentally hinder R&D. It would either dramatically restrict the data available in public databanks or else introduce excessive obligations which would deter potential users**.

  Restrict available data: The CBD is clear that countries have sovereignty over genetic resources (GRs) found on their territory and are free to regulate access to those GRs, how they are used and on what terms. Theoretically, therefore, Governments are already able to regulate, either by statute or agreement with those accessing the GRs, whether and on what terms any DSI can subsequently be published. Widespread exercise of this 'right' however is likely to result in a dramatic reduction in information being made available in public databanks in the first place, as access to DSI shifts from an open, multilateral approach to a closed, bilateral one.

  Create excessive burdens on users: Alternatively, DSI could continue to be uploaded to public databanks at the current rate, with ABS obligation only exercised at the point of access. As noted above, in a matter of only a few years, public databanks have become home to a significant number of data sequences. The working assumption must therefore be that, even if the inclusion of DSI were to be *prospective*, relating only to sequence

[1] Pevsner, J. (2015). *Bioinformatics and functional genomics*. Chichester, West Sussex: Wiley Blackwell.

information generated after an agreed date, the amount of data within scope would rapidly become unmanageable. Bringing DSI into the CBD and Protocol would potentially mean that anyone seeking to access and use such information contained in a databank would need to obtain the consent of the provider of the genetic resource and would potentially need to pay for such access and use.

Potential users, ranging from large corporations, to SMEs, academia and single researchers - would be expected to identify the 'country of origin' of the information, when the reality is that 'new' DSI may well be created from long standing, readily available data for which no country of origin information exists. And how would DSI accidentally created on computers (a common occurrence in laboratories around the world) be handled? What due diligence requirements would then be required for this data? More fundamentally, who would police the due diligence requirement. And how would they police it?

Furthermore, unlike many biological samples, DSI can be reused indefinitely. If DSI were to be incorporated within Nagoya, this could result in an increasingly complex picture involving multiple agreements on benefit sharing for any given genetic sequence, which would be attached to the sequence forever, with each further transfer requiring additional permission and documentation resulting in long term and increasing litigation burden, financial and time delays to research and innovation.

Standard Access Fee: Some have suggested that one way of avoiding the complexity of a DSI due diligence system would be for public databanks to introduce a standard, if very small, financial charge for accessing any sequence. The generated funds would then be shared on a multilateral basis with all DSI providers. However, given the huge number of sequences being accessed, this would add a significant financial burden on users of DSI, when the isolated value of the information accessed may be limited.

- **Inclusion of DSI would further aggravate the public health concerns associated with implementation of the CBD/NP:** We are increasingly concerned that the way the NP is being implemented in provider and user countries will in fact have adverse effects on public health-related R&D, adding to the cost of and time taken to bring pharmaceutical products and vaccines to market and potentially diverting research away from areas of public health need.

  The EU Regulation 511/2014 (a user country law) is a good example of a law that will have adverse effects. Though-well intentioned, it is extremely unclear and creates significant risks for those engaged in R&D involving natural products (including pathogens) in the EU. Of note, it includes a specific provision relating to the use of pathogens causing a '*present or imminent public health emergency of international concern or a serious cross border threat to public health'.* In these cases, the Regulation mandates that highly impractical (if not impossible) due diligence obligations will need to be fulfilled within three months of starting research based on the pathogen or else the research must stop**.** The suggestion

that DSI be included within the scope of the CBD would further aggravate these challenges.

Regulation of DSI amongst CBD countries would create incentives to move R&D to non-CBD countries. This would simply serve to benefit non-CBD signatory countries and undermine the CBD's benefit sharing objective.

The CBD is an illogical framework for regulating public information: Use of DSI was common when the NP was negotiated in 2011. However, Parties to the Treaty decided that it should only apply to tangible/'material' GRs, not information about them. The resulting scope of the Nagoya (and CBD) does not lend itself to non-tangible data. It would be entirely inappropriate now to try and shoehorn sequence data into its scope.

By seeking to regulate and restrict access to commonly and openly available DSI, an amendment would be inconsistent with the requirements of the CBD that include: promoting and encouraging research that contributes to the conservation and sustainable use of biological diversity (Article 12); public awareness and education (Article 13); exchanging information, including scientific research (Article 17); technical and scientific cooperation (Article 18); and promoting and advancing the benefits of biotechnology (Article 19). Open exchange of scientific information, including DSI, contributes to all these activities and thereby supports the objectives of the CBD. The activities are also consistent with established principles of ethical and responsible scientific research.

Arguably the rationale used for seeking to bring DSI into the scope of the NP could apply equally to other information concerning a GR eg to chemical structures of compounds found within a GR such as a plant. If extended beyond DSI, it could mean that anyone accessing a journal article containing information about a GR or its components would be obliged to obtain consent to use – or perhaps even reference - that information. The public domain would be subject to regulation.

Such a fundamental change to open access policy merits full scale debate by all relevant stakeholders, including public health experts and the scientific community. It would be totally inappropriate to carve out and regulate only one element of publicly available information without considering the precedent and broader implications associated with it. It certainly should not be subject to a simple COP decision.

Thank you for your consideration.

Yours sincerely,

Thomas B. Cueni

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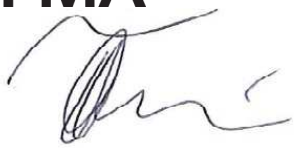

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