

*Rights over genetic resources and  
digital sequence information:  
Current debate*

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*Any opinions in this presentation are my own and not those of  
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# Current situation on Digital Sequence Information (DSI)

- Increasing technological sophistication
  - Possible to take sequence from online digital repository and re-create it
- Concern over ‘digital biopiracy’ / avoiding ABS
- Scientific and philosophical discussions equating genes with information



# Current situation on Digital Sequence Information (DSI)

- Concern brought to CBD COP 13 and MOP 2;
- Launch of fact-finding process:
  - Submission of views
  - Commissioned fact-finding & scoping report
  - Set up AHTEG
- Discussed at SBSTTA 22 and soon at COP14 / MOP3
- Also discussed by ITPGRFA, WHO (PIP), UNCLOS, WIPO

# Key Questions

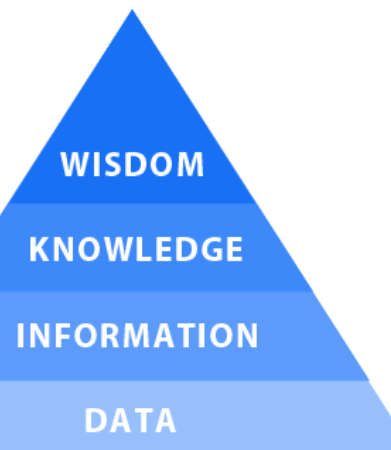
- What is Digital Sequence Information?
  - The term itself
  - What it covers
- Does DSI fall under the sovereign rights of the provider country of the genetic resource?
- Can use of DSI fall under CBD / Nagoya Protocol?
- Can DSI be incorporated into current ABS model?
- If DSI did fall under the NP, how would it be implemented?

# What is Digital Sequence Information on Genetic Resources?

- Term rarely used outside CBD
- Might include:
  - in silico*, genetic sequence data, genetic sequence information, digital sequence data, genetic information, dematerialized genetic resources, intangible genetic resources, *in silico* utilization, information on nucleic acid sequences, nucleic acid information, natural information, sequences, ...
- Which might or might not be fully synonymous

# What is Digital Sequence Information on Genetic Resources?

- ‘Digital’
  - Only digital, or in print as well?
  - Omits developing data storage systems (e.g. on DNA)?
  - Perhaps unnecessary qualification
    - it is not GR but stored and transmitted otherwise.
- ‘Sequence’
  - Applies to proteins as well as nucleic acids?
  - Limits wider interpretations
- ‘Information’
  - Data: *observations lacking meaning*
  - Information: *emerges through cognitive (or other) processing of data*
  - Terminology not fully understood in law



# What is Digital Sequence Information on Genetic Resources?

## Relating to DNA and RNA:

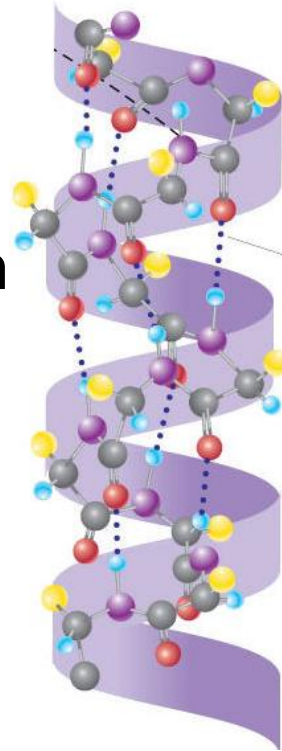
- Nucleic acid sequence data
  - raw sequences as displayed on databases
  - Include DNA, RNA
  - non-coding & coding sequences, regulatory sequences, conserved sequences, genes that encode specific traits, 'junk' DNA, with or without known function
- Structural annotation
  - gene structure; coding regions
- Functional annotation
  - biochemical function; [biological function; involved regulation and interactions; expression] – latter misquoted in Synthesis of views



# What is Digital Sequence Information on Genetic Resources?

## Relating to derivatives:

- amino-acid sequence of proteins produced from gene expression
- molecular structures of gene products and derivatives





# What is Digital Sequence Information on Genetic Resources?

Contextual information (metadata) – may help interpret function

- ecological relationships;
- abiotic factors of the environment;
- function, such as behavioural data;
- structure, including morphology and phenotype;
- taxonomy;
- modalities of use.

Wider information

- [Biomimicry – one NGO in Synthesis of views document]
- [phyllotaxis, colouring etc – from Synthesis document but not included by submissions]

# What is Digital Sequence Information on Genetic Resources?

- NP only sets minimum obligations
- Countries may refine scope in legislation
- Access legislation typically covers all biological resources
  - All natural resources (NR) are covered under UN GA Resolution 1803 (XVII) of 1962
  - Sovereignty over NR confirmed under CBD Art 15; access to GR is a subset of NR
- Some countries include *ex silico* explicitly

# What is Digital Sequence Information on Genetic Resources?

- Compliance legislation may be far more restricted
  - May take minimum level of obligation under NP
  - *Only presence of PIC and MAT – not detail of MAT contents*
- Scope in provider country does not determine regulatory scope in a user country
  - If provider country includes DSI this does not require user country to bring it within scope of NP regulation

# Does DSI fall under the sovereign rights of the provider country?

- No evidence from wider discussions that information is a natural resource as set out in UN GA resolution 1803 (XVII)
- Is sequence information IPR of provider?
  - Consensus seems not.
  - WIPO: “GRs as encountered in nature are not creations of the human mind and thus they cannot be directly protected as ... IP”

# Does DSI fall under the sovereign rights of the provider country?

- Countries can manage use of DSI in databases within their jurisdiction;
  - Cf. data sovereignty discussions
  - If DSI do fall under the CBD, does CBD Art 15(3) allow any country to claim rights over DSI stored in its territory?
- Countries can set out restrictions in PIC and MAT

# Does DSI come under the CBD?

Vienna Convention Art 31(1)

*“A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.”*

- *“in the case of genetic resources, the genetic information is the resource being used and valued”*  
(Deplazes-Zemp, 2018)
- *“genetic resources as natural information”*  
(Vogel, 1994)
- *“the gene as a form of information”*  
(Dawkins, 2008)

# Does DSI come under the CBD?

But more often genes are referred to as ‘carrying’ or ‘containing’ information.

- “*Genes are not information*”  
(Rossi, 2014)
- “*chromosomes were identified as the carriers of genetic information*”  
(Goldman & Landweber, 2016)
- “*Each genome contains all of the information*”  
(NIH, 2016)
- “*genome as a physical entity encoding the information*”  
(Goldman & Landweber, 2016)

# Does DSI come under the CBD?

Is including DSI correct

“in the light of [the CBD’s] object and purpose”

## **Pro:**

- if not potentially undermines the third objective of the Convention (Synthesis of views).
- “digital sequence information is included in the definitions of “genetic resources” and “genetic material” in the Convention ... these terms ... include both the tangible and intangible components” (Synthesis of views).

## **Con:**

Some maintain that DSI was omitted explicitly from both CBD and NP (Submission of views):

- ‘genetic resources’ – subset of ‘biological resources’ which are biotic components of ecosystems
- ‘derivatives’ - “naturally occurring biochemical compound”



# Does DSI come under the CBD?

*Vienna Convention Article 32: Recourse may be had to supplementary means of interpretation, including the preparatory work of the treaty and the circumstances of its conclusion.*

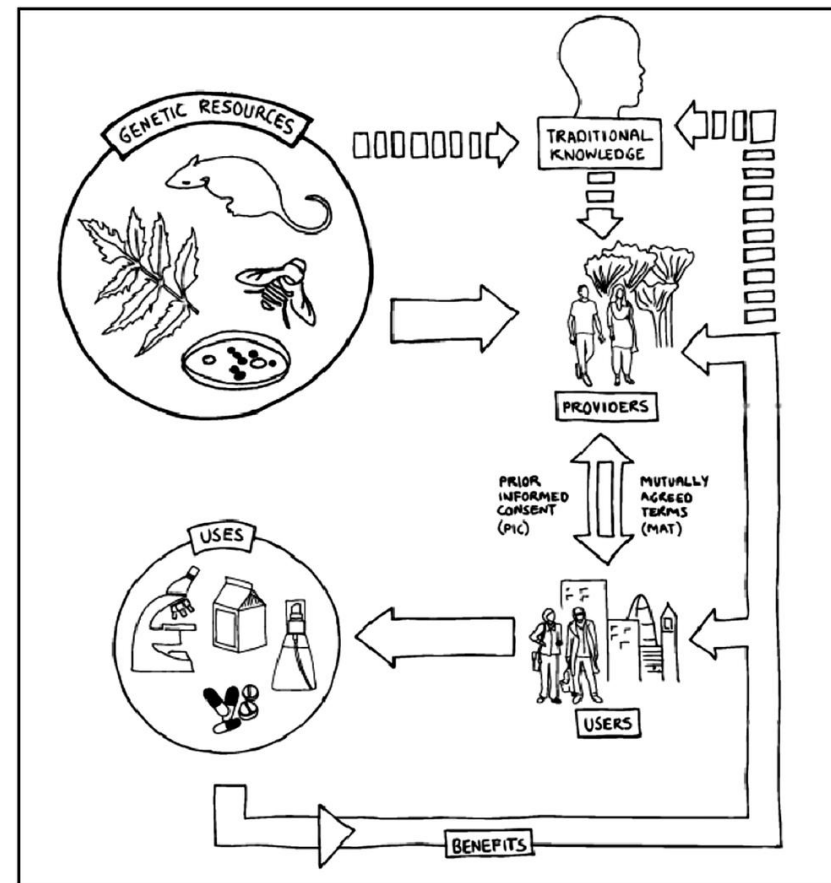
- DSI was discussed in the development of the Bonn Guidelines, the meaning of 'derivatives' and the development of the NP
- But not included in the final text, which limited coverage to physical material

# Does DSI come under the CBD? (and if not, should it be?)

- If DSI is not covered by the CBD it cannot be covered by the subsidiary NP
- Legal opinions support both alternatives
- Inclusion may not damage Protocol
  - but administrative complexities of managing implementation could cause problems.
- Ultimately it must be a policy decision

# Can DSI be incorporated into the current ABS model?

- ABS conceived as simple linear process
- Few actors
- Direct relationship between providers and users
- Bilateral contracts appropriate



# Can DSI be incorporated into the current ABS model?

- Increasingly multiple actors in supply and value chains
  - Users may not have direct agreement with provider
  - EU regulation requires ‘transfer’ between users of IRCC / documents , MAT etc.
  - Not always clear to providers who has GR
  - Rights and obligations not always clear to users

# Can DSI be incorporated into the current ABS model?

## **ABS contracts** - general properties:

- Put conditions of 3<sup>rd</sup> party transfer in PIC and MAT
- 3<sup>rd</sup> party transfer uses contract signed by both parties
  - commits 3<sup>rd</sup> party to rights and obligations set out in the original PIC and MAT
  - excludes 2nd party from liability for 3<sup>rd</sup> party actions
- Viral clause requiring same conditions for further transfer.
- Include list of previous contractors to facilitate tracing.

# Can DSI be incorporated into the current ABS model?

- GR may be multiple taxa or genes being used
  - no 1:1 relationship between IRCC and utilisation
- GR may be used by different entities in different projects
- All soluble, but add complexity and risk of error.
- Addition of DSI from public databases magnifies all of these issues

# Can DSI be incorporated into the current ABS model?

## **Public databases**

- No contract with data provider regarding rights & obligations under PIC and MAT
- No contract with provider country
- Often required by funders / host country policy to provide contents with no restrictions
- Gene sequences are not unique to particular organisms / sources / countries
  - Potential for 'jurisdiction shopping'
  - Challenge to identify / track where a sequence came from

# Can DSI be incorporated into the current ABS model?

- Data queries and downloads at very high volumes
- “Chain of adequate causality” might operate to transfer rights and obligations
  - currently no clear mechanism to do this
- All challenge potential to operate bilateral contracts
  - Consequently the compliance mechanism set out in the NP is inappropriate.
  - Art 11 probably insufficient
  - Art 10 may need to be implemented



# If DSI did fall under the NP, how would it be implemented?

- Number and complexity of transactions render core model of NP inadequate
- Needs clarity on meaning of ‘utilisation’
  - Many high-volume uses of DSI do not include R&D, but may be considered indexing and location (e.g. BLAST)
  - Issue for user countries in regulation, but also for providers in MAT
- Would need greater transparency on use of DSI at relevant checkpoints
  - Tech solutions possible?

# Status of DSI

- DSI probably limited to nucleotide sequence data and its structural and functional annotation;
  - May also include the same for derivatives;
- National law may explicitly state rights (e.g. Brazil)
  - Can be exercised in country but outside country is unclear
- Rights over DSI under international law are debatable
- No unequivocal inclusion in CBD and hence NP
  - Will require policy decision
- If included in NP will require movement from bilateral model



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