



BACKGROUND PAPER

Brazilian ABS Rules

Procedural Clarifications & the Specific Case of
in silico Genetic Heritage

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Brasil – EU Dialogue, Brasilia Workshop, 10th December 2019



General Clarifications on
Brazilian ABS Rules



In Silico Genetic Heritage



Open Questions





General Clarifications

1. Scope

2. Access & Benefit-sharing





General Clarifications

1. Scope

2. Access & Benefit-sharing

➤ MATERIAL SCOPE

- GH as “genetic information on “plants, animals, and microbial species, or any other species, including substances originating from the metabolism of these living organisms”
- Does it include all types of information?
- When does information stop being genetic (is there a limit to GH information)?

➤ GEOGRAPHIC SCOPE

- Does GH include information & physical resource held in collections outside Brazilian national territory when Brazilian origin established?

➤ TEMPORAL SCOPE

- Determined through date of access (not acquisition) & limited to 30th June 2000?



General Clarifications

1. Scope

2. Access & Benefit-sharing

➤ ACCESS

- Access as research and development
- Registration not always at beginning of research, rather trigger points : sending or shipment of GH, publication results, claim IPR, intermediate product
- MTA (shipment): Minimum CGen Res.12 ; Institutional practice & Third party transfers?

➤ BENEFIT-SHARING

- ONLY at notification of finished product
- How to distinguish intermediate & finished product in cumulative incremental chains?
- GH needs to be “one of the main elements adding value” to product : How to determine?



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Open Questions





In Silico Genetic Heritage

1. Brazil Rules

2. Sectoral Practice





In Silico Genetic Heritage

1. Brazil Rules 2. Sectoral Practice

➤ DEFINITION

- GH held *in silico* sources : generated by computer modelling or simulation; or stored in a computer
- Information on all genes, genetic sequences, protein expressions, metabolites? Phenotypic & associated information?

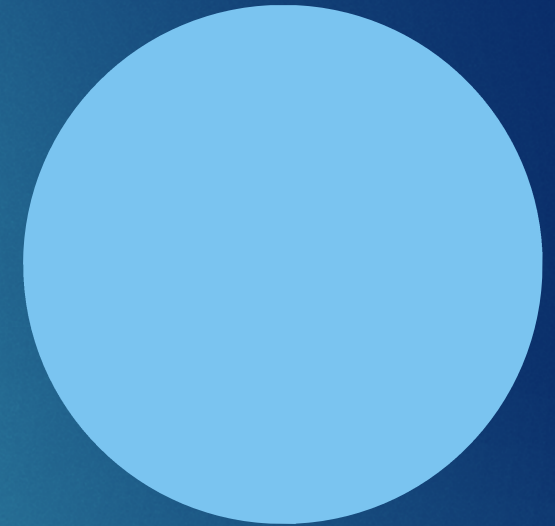


In Silico Genetic Heritage

1. Brazil Rules 2. Sectoral Practice

➤ ACCESS RULES & PROCEDURES

- No prior requirement for research on *in silico* GH
- Registration triggers
 - Consultation (online or email) of *in silico* sources?
 - Publication? Download?
 - Transfer via email or other digital means?
- Procedural aspects
 - Accessing Brazilian GH in a privately held database?
 - Multiple genetic information sources for one product?
 - Multiple geographic sources for one particular sequence (which is considered Brazilian GH)?





In Silico Genetic Heritage

1. Brazil Rules 2. Sectoral Practice

➤ COMPLIANCE & MONITORING

- Contractual terms: Addressing third party transfers ? Additional aspects?
- Declaration of origin (product authorization)
 - Mandatory before which institutions?
 - What if origin unknown?
- Access outside Brazil
 - Mechanisms to facilitate monitoring?

In Silico Genetic Heritage

1. Brazil Rules 2. Sectoral Practice

➤ SOURCES OF *in silico* GH

• Where is information found?

- International public sequence databases (DNA, RNA, protein..)
- Digital interfaces of physical collections
- Subsidiary information : associated data sources

• Challenges?

- What if no link between *in silico* information and Brazil?
- Should origin data be mandatory? Could it be?
- Should databases, collection interfaces & other data sources play a role? To which extent?
- When would associated data be considered Brazilian GH?



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1. *Brazil Rules* 2. *Sectoral Practice*

➤ GOOD PRACTICES

- Difficult to establish : how to provide support?
- How to reinforce ABS functionality in different databases & GH sources?

➤ USES OF *in silico* GH

- Would there be any difference of treatment between different uses of *in silico* GH?
- Which systems or tools could be developed to increase linkage between different uses & ABS information?



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In Silico Genetic Heritage



Open Questions





Open Questions (1-2-4 technique)



- NOTION OF GENETIC HERITAGE
- ACCESS & TRIGGERS
- *In Silico* ABS INFORMATION
- COMPLIANCE





Open Questions

Notion of GH

- All types of information & their physical counterparts?
- In silico: all genetic sequences, protein expressions, metabolites, phenotypic & associated data?
- Where would be the limit to “genetic” information?
- Development of distinctive characteristics in Brazil? Proof in publications & analysis?
- Clear temporal trigger? Date of access (not acquisition) after 30th June 2000?
- GH in finished product as the “value-adding element”?



Open Questions

Access & Triggers for GH sourced in silico

- Consultation of GH on the web or via email?
- Publication and/or download of GH?
- Transfer of GH via email or other digital means?
- Access from privately held database?
- Adaptation rules for products with multiple sequences from different origin?
- Same sequence existing from multiple origins, incl. Brazil?
- Distinction intermediate & finished product?





Open Questions

ABS Information in silico GH

- Mechanisms to make users aware of ABS obligations linked to accessed GH?
- Should and could ABS functionality of in silico sources of GH be reinforced? How?
- Role of international sequence databases? Digital interfaces of physical collections? Any other site where GH associated information is published?
- Communication & development of best practices?
- Could systems or tools be developed to reinforce linkage between ABS related information & GH information?
- Legal & practical implications of publication, download & transfer of incomplete data considered as GH? Status of research based on such data?



Open Questions

Compliance - Monitoring

- Contractual terms : addressing third-party transfers & other obligations for better compliance?
- Would it be possible to monitor use of GH sourced *in silico*? How and by whom?
- Do sanctions also apply when no link can be established between information accessed & its geographical ABS origin?
- Extent and expected impact of declaration of origin before Brazilian product authorization institutions?
- Outside Brazil : Use compliance mechanisms set out in countries signatories to NP? Private international law?
- Could system be envisaged to facilitate monitoring use and compliance with Brazilian ABS Rules?



THANK YOU!

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