National Institute for Public Health and the Environment
*Ministry of Health, Welfare and Sport*

# The Nagoya Protocol applied to Microbial Genetic Resources

## Challenges and Opportunities for International Networks and Infrastructures

SEQAFRICA – 24 February 2021

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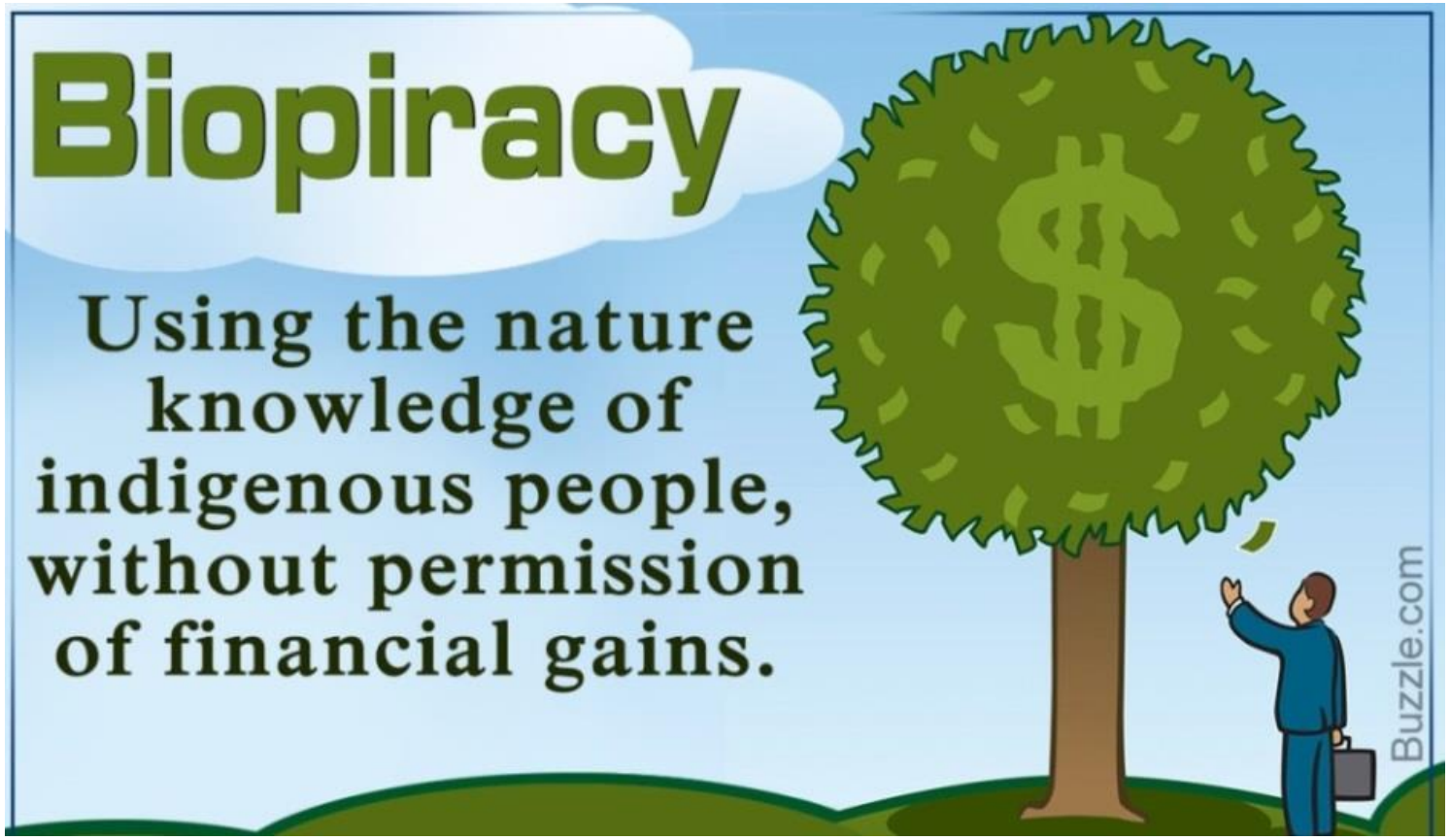
NAGOYA PROTOCOL
ON
ACCESS TO GENETIC RESOURCES
AND THE FAIR AND EQUITABLE
SHARING OF BENEFITS ARISING
FROM THEIR UTILIZATION
TO THE
CONVENTION ON
BIOLOGICAL DIVERSITY

TEXT AND ANNEX

# Overview of the video-lecture

- About the Nagoya Protocol and its context
  - Why it was developed
  - How the adoption process happened
  - How it works in practice
- Checklist for users and providers
  - Definitions
  - Scope
  - Communication process
  - Acquiring documentation
- Challenges and Opportunities for the implementation of the NP
- Take home messages

# Why the Nagoya Protocol was developed?




- The environmental problem
  - Unsustainable global economy: natural resources depletion; environmental degradation; extinction of species; climate change; water shortage
  - More frequent natural disasters and global health threats
  - Perception that conservation areas equal economic losses
- The social problem
  - Besides the social impact of environmental degradation: poverty, immigration, disease
  - Threats and exploitation of indigenous people as custodians of biodiversity
- The global political problem
  - Heritage from colonization process
  - Appropriation of biodiversity through patents
  - Inequalities in benefiting from biotech research and development

# How the Nagoya Protocol was adopted?

- Polarization between developed and developing countries
  - The Indonesian case on the sharing of influenza strains at the WHO's GIS

  ***No benefit sharing, no access!***
- Results: the NP, the ITPGRFA, and the PIP Framework

# How does the Nagoya Protocol work?

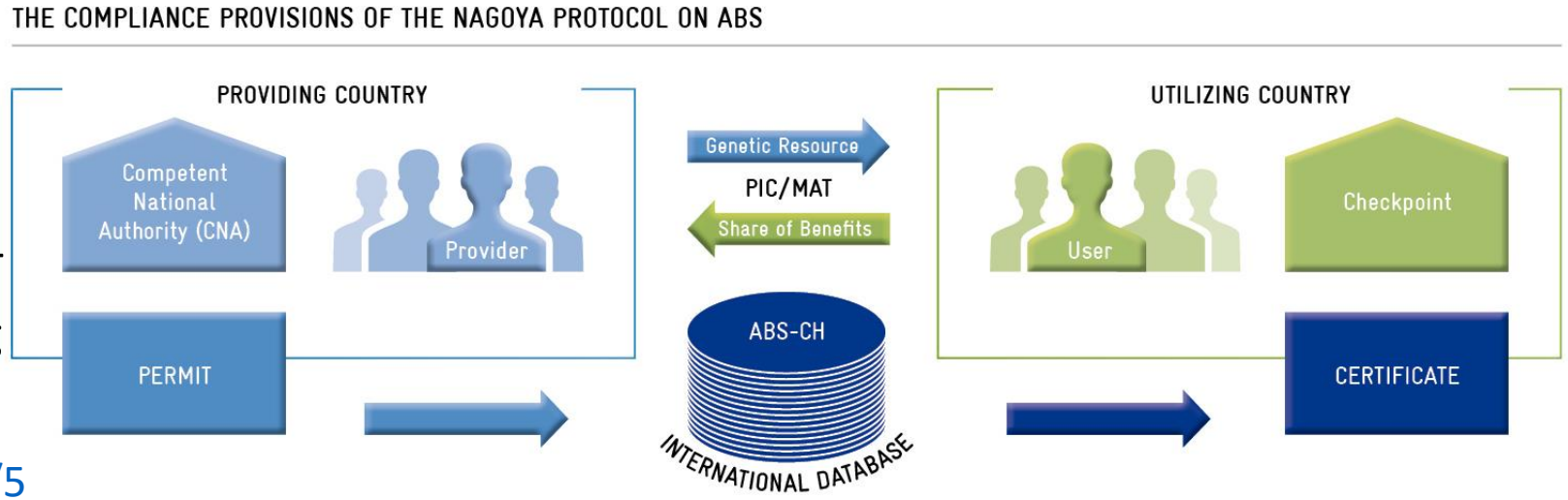
**The Convention on Biological Diversity (CBD)**

- The recognition of biological diversity as an asset to present and future generations
- Functioning since **29 of December 1993** (196 Parties)
- 3 objectives:
  - The conservation of biological diversity
  - The sustainable use of its components
  - The fair and equitable sharing of benefits arising of the utilization of genetic resources

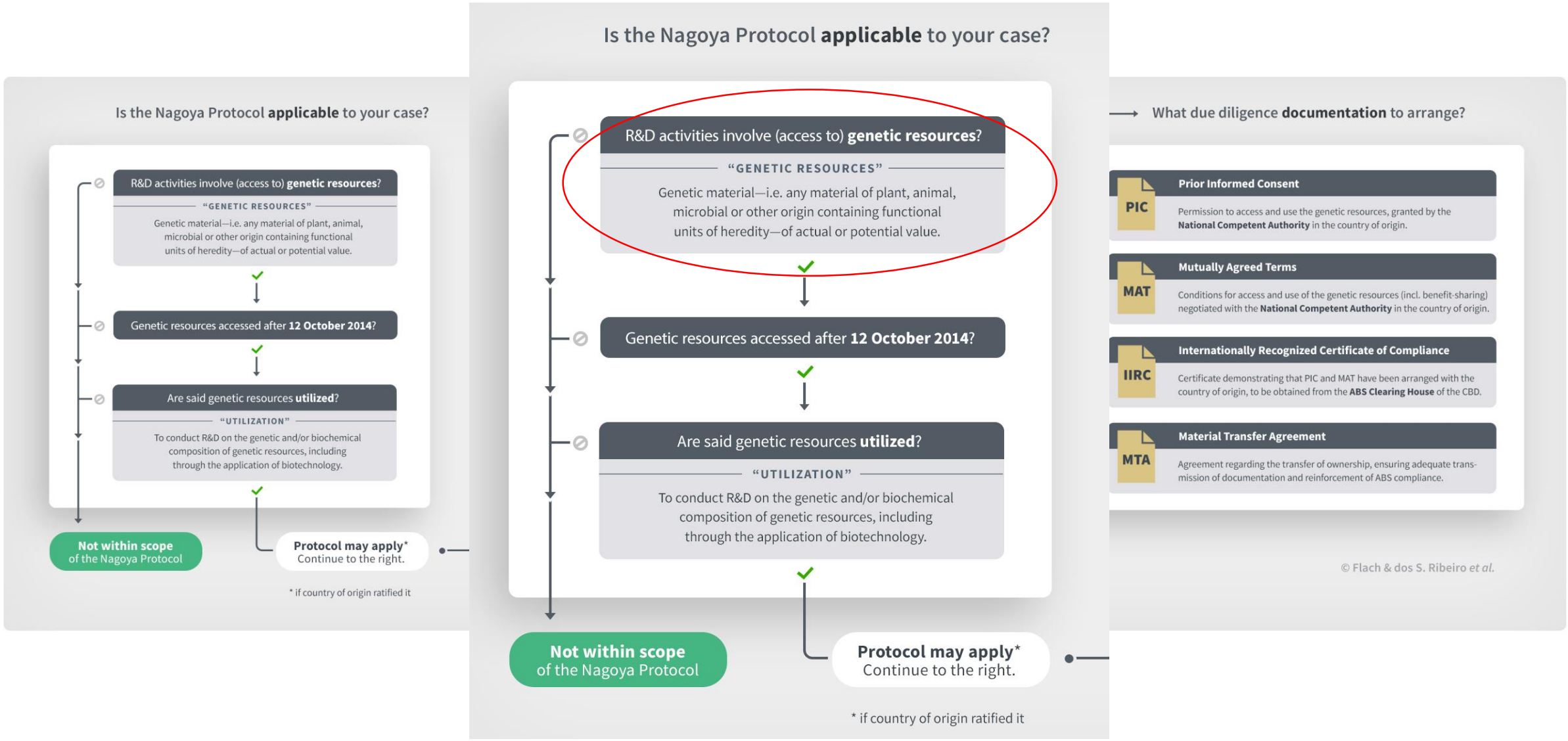
Convention on Biological Diversity

**NAGOYA PROTOCOL**

- Functioning since
  - **12 October 2014**
  - 128 Parties
- Establishes a binding legal frame-work for access and benefit sharing
- For more details check:
  - https://vimeo.com/263320356/5



# Checklist for users and providers of Genetic Resources



# ➢ Defining genetic resources

- What is a ‘genetic resource’ according to the CBD, NP and EU Regulation
  - “genetic material of actual or potential value“
  - genetic material: “any material of plant, animal, microbial or other (non-human) origin containing functional units of heredity i.e. genes“
  - derivatives: “naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity”
    - proteins, metabolites, lipids, enzymes, RNA and organic compounds
    - does not cover synthetic gene segments
- Non-human organisms containing DNA + derivatives

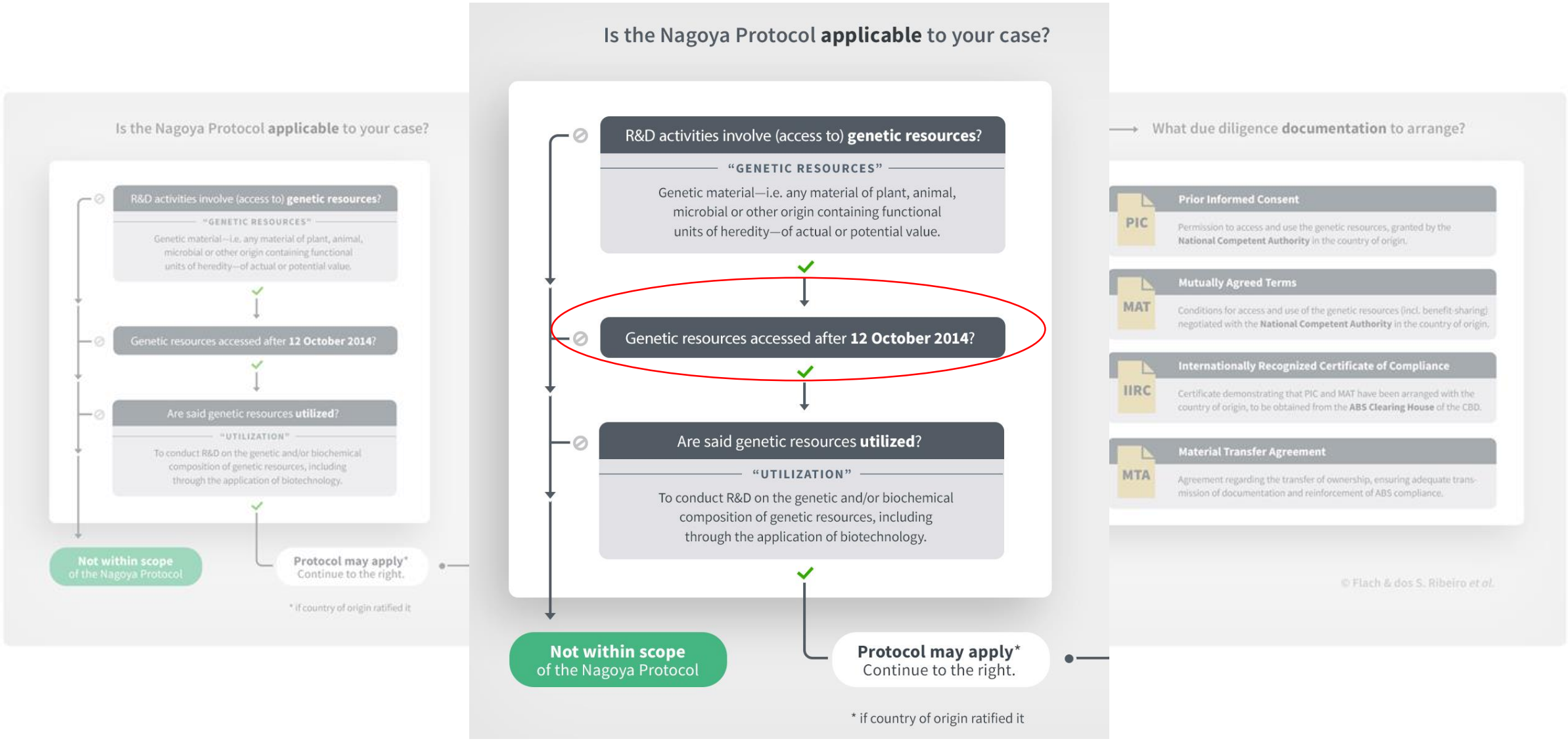
Plants, animals, fungi, microbes, viruses

Biological materials /samples with DNA/RNA

Biochemial compounds (proteins and metabolites)

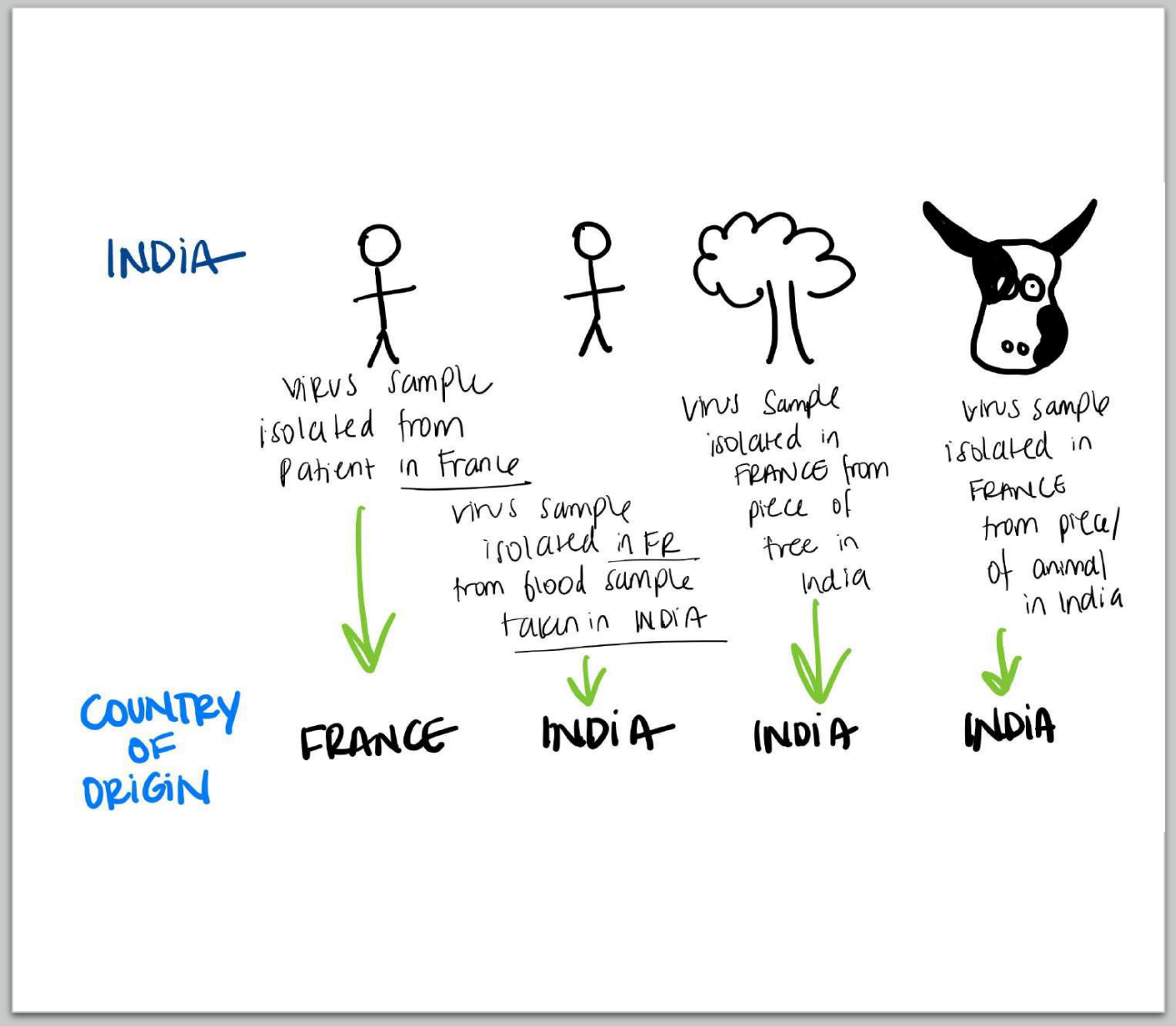
- **What about genetic sequence data?**
  - The DSI discussion
  - The EU position on DSI: “*the use of digital data obtained from gene sequencing, which is frequently stored in publicly available databases, could be considered to be out of scope*”

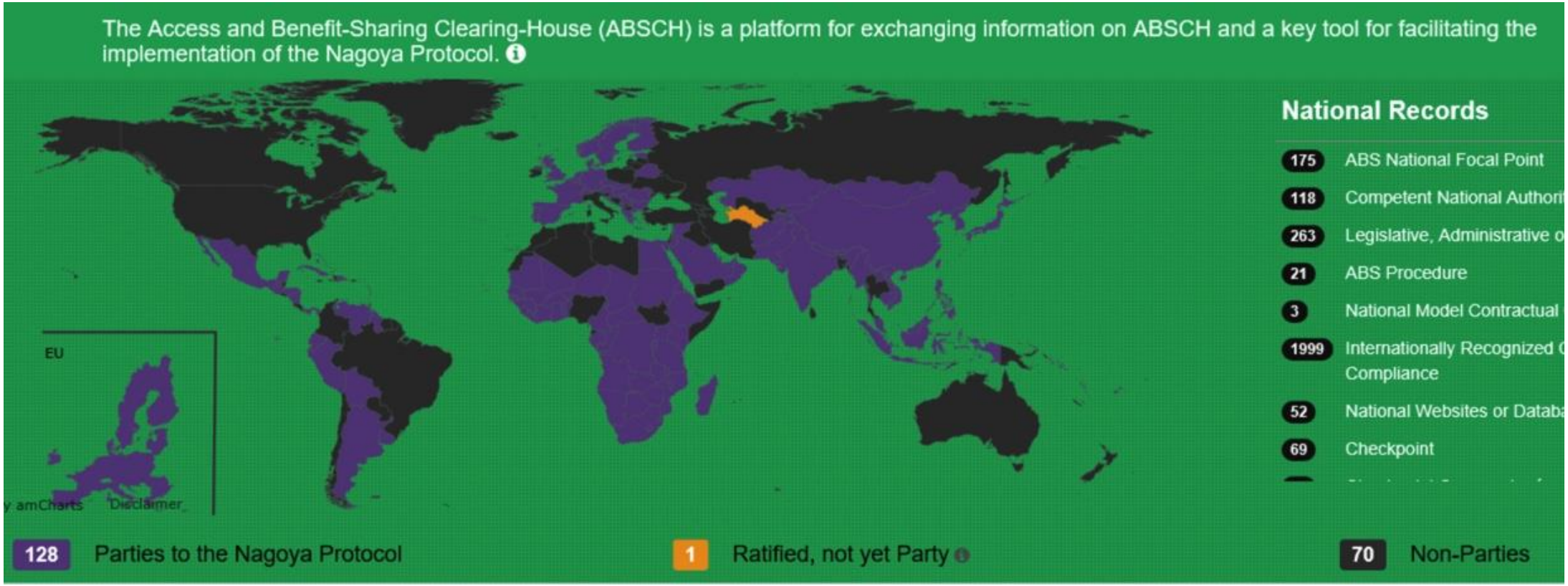
# Checklist for users and providers of Genetic Resources



# Assessing temporal and geographic info

- **Temporal information:** (*in situ*) sampling date
  - 12 of October 2014
  - 29.12.93-12.10.2014 “moral” period
  - Date that a country became Party/ratified
- In case do not know: Proxy
  - When it first came into your institution/lab (PI arrival)
  - First publication with the material
  - Before XX.XX.XXXX (indicating it is a proxy date)
- **Geographic information:** where the GR was collected (*in situ*)
  - Nagoya Party and Non-Nagoya Party
  - Cannot identify: out of scope
  - If new information arrive, than it needs to be addressed





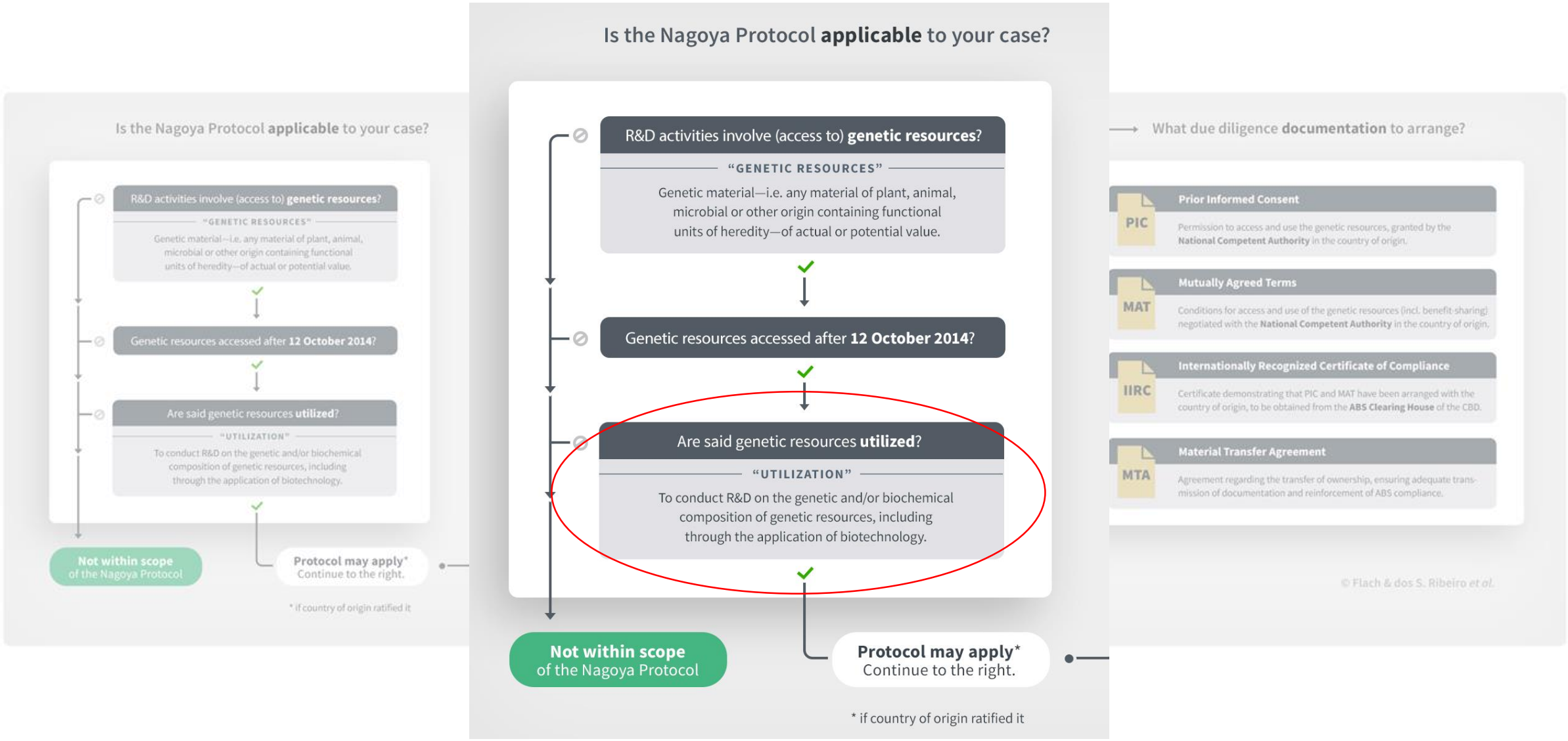

## ➢ How to identify NP-Parties?

- Identifying Parties
  - https://absch.cbd.int/
  - There are non-Nagoya Parties that have ABS regulations
- Discovering ABS regulations (ABSCH and NFP)
  - There are Nagoya Parties that have not yet ratified

# Diverse National Jurisdiction

- **Sovereign rights:** each country can decide IF and HOW they regulate their resources
  - Nigeria: not a Party (signatory but not ratified)
  - Ghana: Party
  - Tanzania: Party
  - South Africa: Party with implemented ABS measures

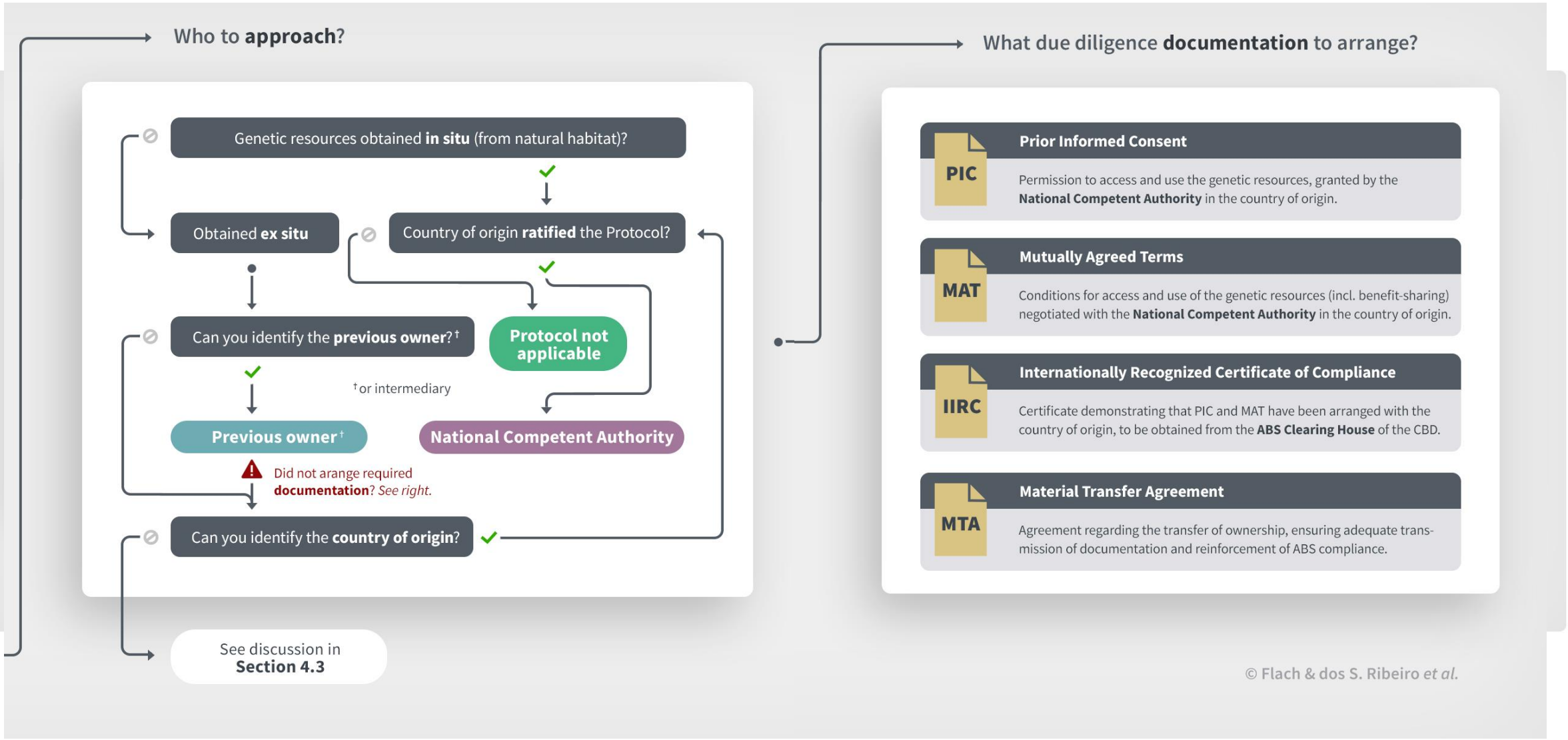
# Checklist for users and providers of Genetic Resources



# ➢ Defining utilization

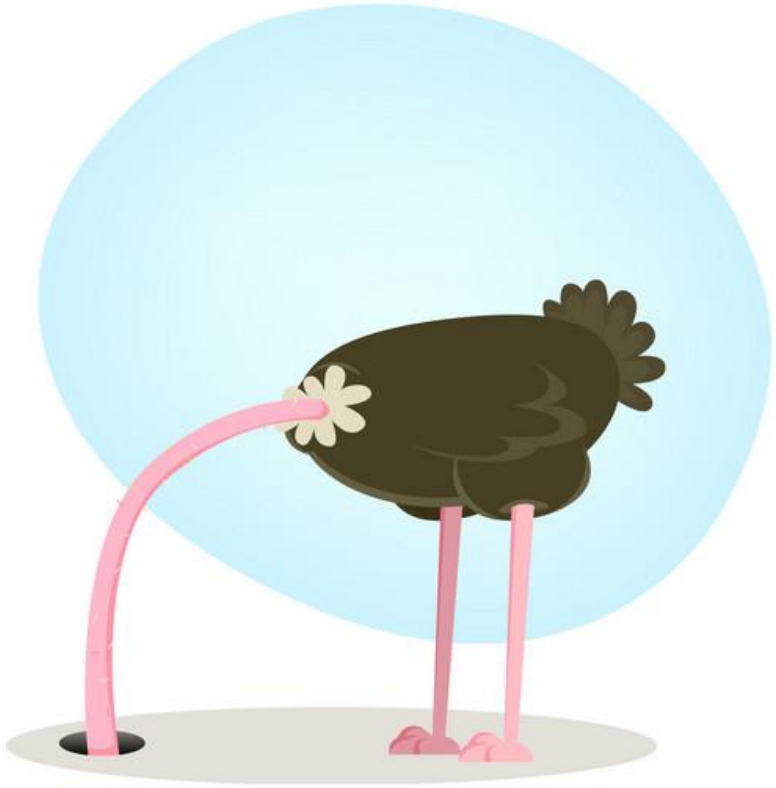
- What exactly is ‘utilization’ of genetic resources according to the CBD, NP and EU Regulation
  - ...“to conduct research and development on the genetic and/or biochemical composition of the genetic resource, including through the application of biotechnology.“
  - R&D: “creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of this stock of knowledge to devise new applications.”
  - **Basic and applied research for commercial and non-commercial purposes**
- GRs covered by specialized instruments (ITPGRFA and PIP Framework) are out of scope
  - Multilateral systems with specific standard conditions
- Examples
  - EU: repositories; taxonomy; diagnostic; some instances of sequencing are not considered utilization.
  - South Africa: Exportation of GR, independent of utilization (bioprospecting), requires a permit

# Checklist for users and providers of Genetic Resources



# Challenges for the NP Implementation

- Defining scope and application
  - ✓ Defining genetic resources
  - ✓ Defining utilization
- Communication
- Diverse national jurisdictions and the bilateral approach
- Achieving the CBD and NP objectives



# Opportunities for developing a NP compliance strategy

- Developing Standard Operational Practices
    1. Developing a system for acquiring and recording the necessary information for compliance assessment
    2. Deciding on the responsibilities and curation strategies for due diligence: agree on the terms and conditions for accessing and using GR per project and not individually

**Discussions on the agenda for the COP-15 2021**

- The DSI discussion:  Genomic Sequence Data = Genetic Resources?
    - GSD is always within the scope of NP otherwise the future of NP would be void
    - No this is practically impossible given the millions of sequences produces & shared each year
    - Policy options for addressing DSI
- Multilateral ABS systems for pathogens and/or DSI
    - Bilateral negotiations on PIC&MAT hampers scientific collaboration and fast public health response on epidemics
    - Harmonized conditions and standard MTAs
    - Examples: FAO-ITPGRFA and WHO-PIP Framework

# Take home messages

- The NP defines the ultimate responsibility of due diligence to end users
  - The governing legal measures for compliance are the one from the provider country and not users
  - The governing legal measures for inspections (checkpoints) are the ones stablished within the country (EU Regulation)
- In international collaborations is always a good facilitator that scientists are aware of the Nagoya-status of their own country
  - Is it a Party? Does it has ABS measures in place?
  - Are certificates and permits only needed for commercial use or also for basic research and PH support?
  - Does it addresses pathogens? And DSI (genomic sequence data)?
- The potential of multilateral systems for facilitating international collaborations

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