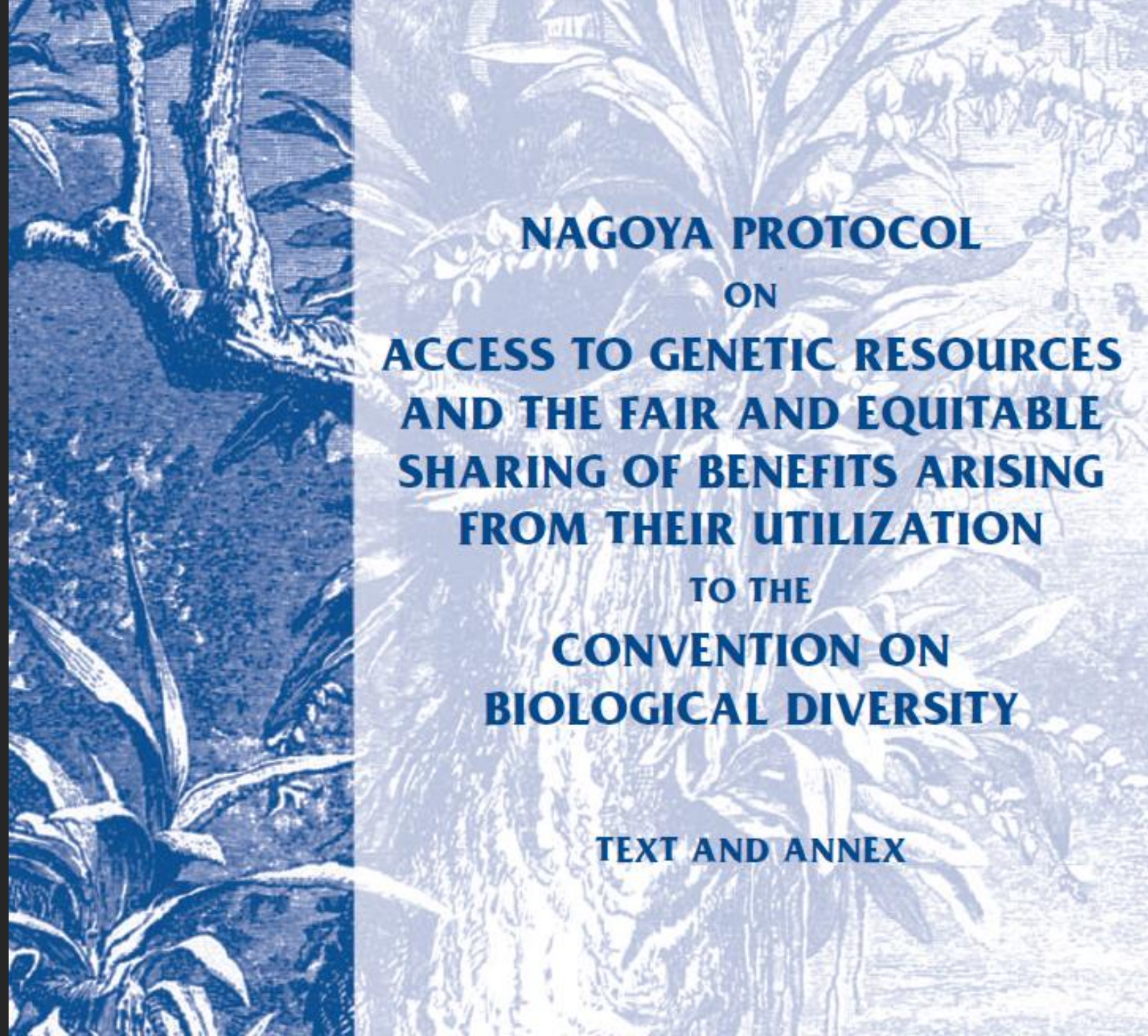
National Institute for Public Health and the Environment
Ministry of Health, Welfare and Sport

The Nagoya Protocol applied to Microbial Genetic Resources

Challenges and Opportunities for International Networks and Infrastructures

OHEJP CARE – 7 December 2020

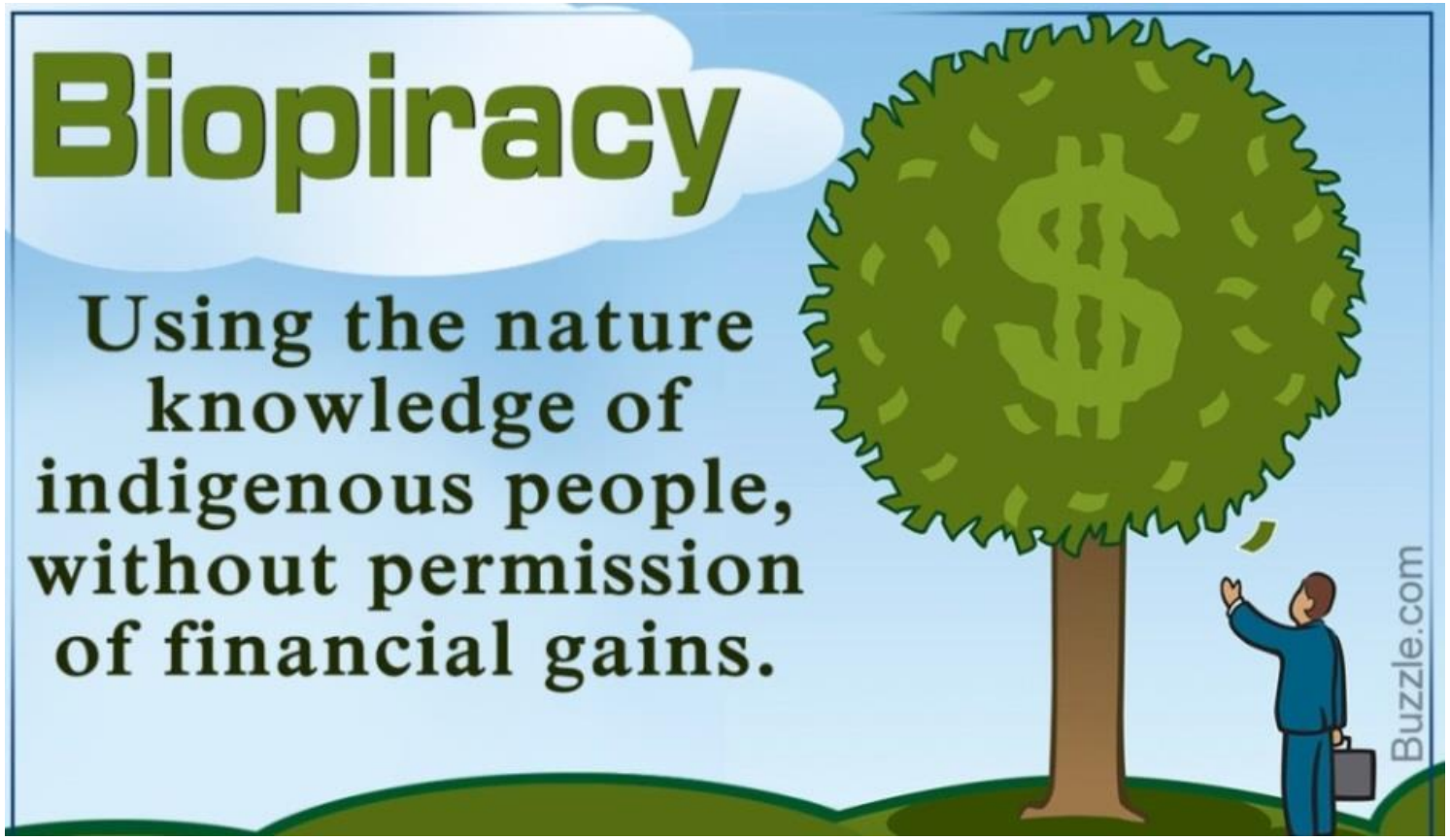
Carolina dos Santos Ribeiro
(*carolina.dos.santos.ribeiro@rivm.nl*)



Overview of the talk

- About the Nagoya Protocol and its context
  - Why it was developed
  - How the adoption process happened
  - How it works in practice
  - How it is regulated in the EU
- Challenges on implementation
  - Definitions
  - Communication
  - Diversity in national jurisdictions
  - Achieving the objectives
- Opportunities for developing a compliance strategy
  - Acquiring the basic information
  - Deciding on the responsibility for due diligence
    - EU Registered Collection
    - Multilateral system for non-commercial use
- Main points and last remarks

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 works?

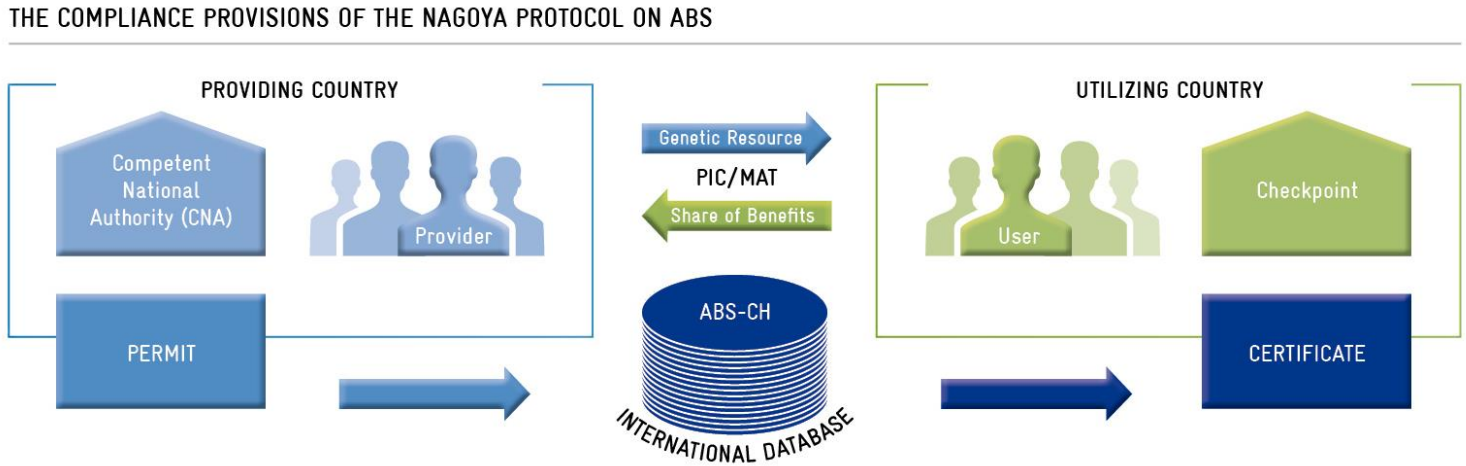
The Convention on Biological Diversity (CBD)

- As a 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

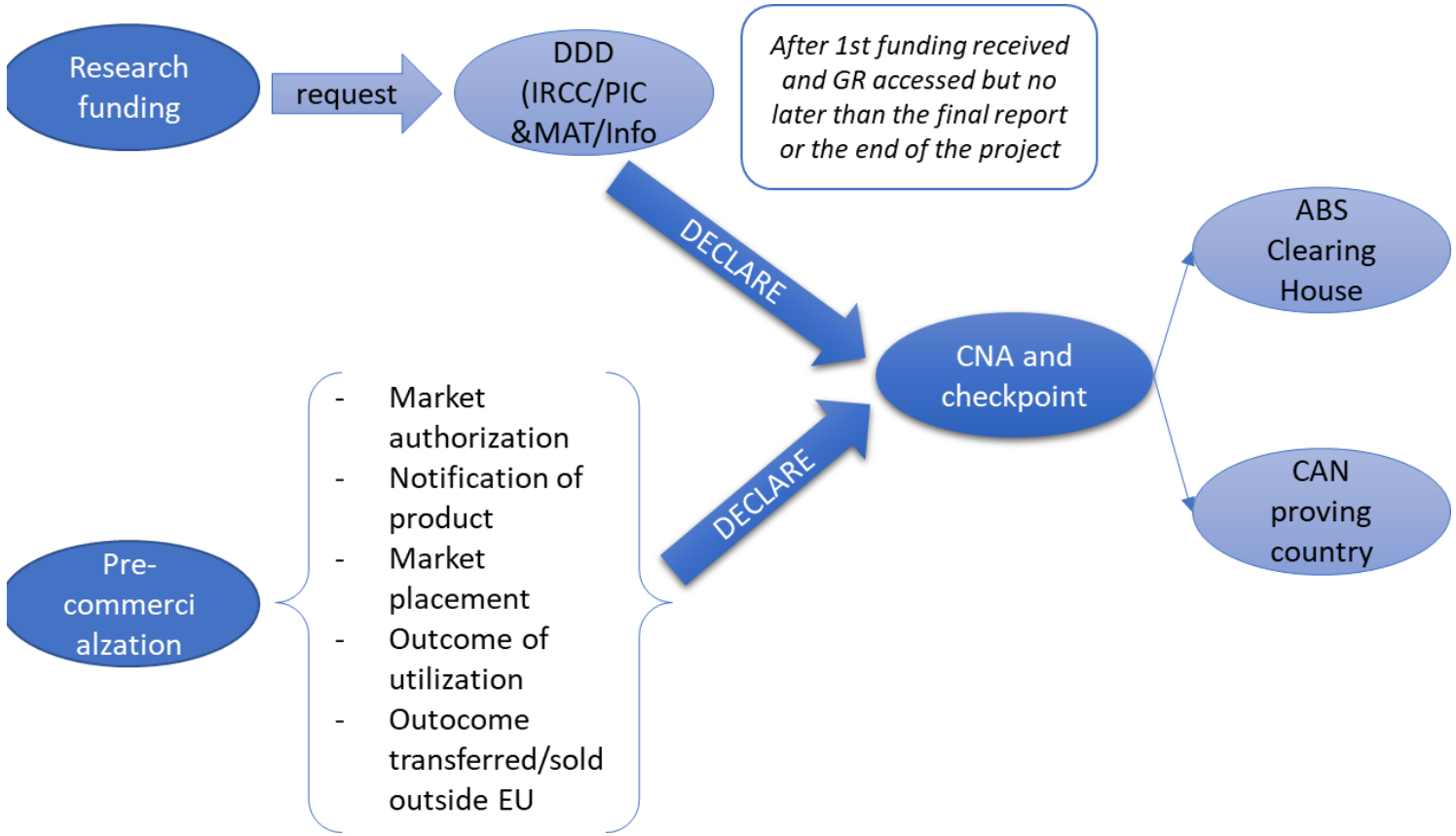
Convention on Biological Diversity

→ **NAGOYA PROTOCOL**

- Functioning since
  - **12 October 2014**
  - 128 Parties
- Establishes a binding legal frame-work for access and benefit sharing
- Implementation
  - https://vimeo.com/263320356/513f748f8a



Guidance for EU users of Genetic Resources



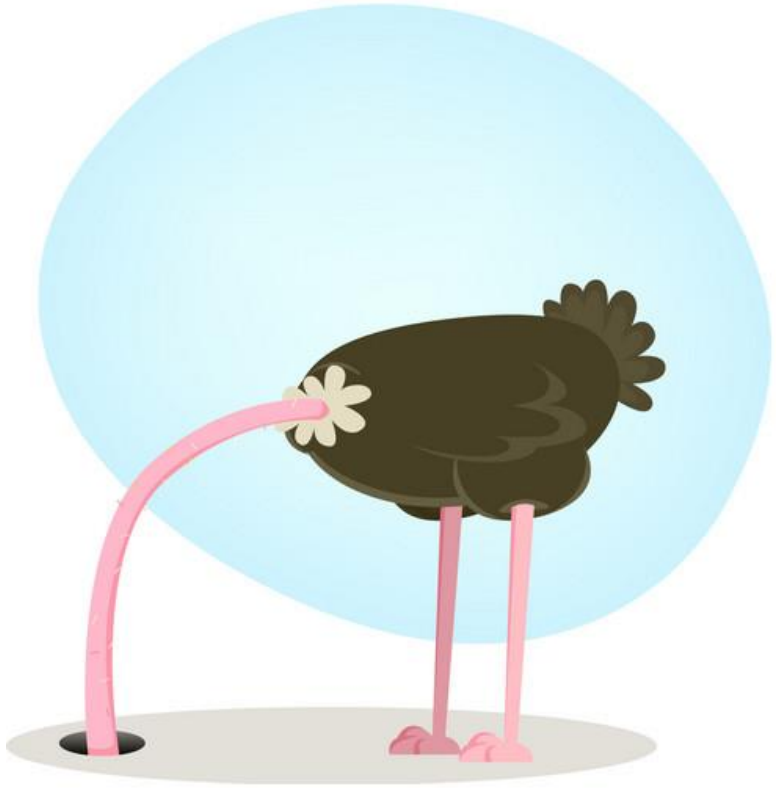
https://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/Question%20and%20answer%20users.pdf

EU ABS legislative framework

- Access regulations is defined by individual Member States
- Compliance standardized across the EU
  - EU ABS Regulation (511/2014)
  - EU Implementing Regulation (2015/1866)
  - Guidance document on the scope of application and core obligations (2016/C 313/01)
- Users shall take reasonable measures to seek, keep and transfer information
  - IRCC, PIC/MAT and/or related information
  - Insufficient info -> discontinue utilization
- Checkpoints on user compliance
  - National inspectorates (CNA) adopted by all but 1 MS
  - Penalties
  - EU monitoring: DECLARE

Challenges for the NP Implementation

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



➢ 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

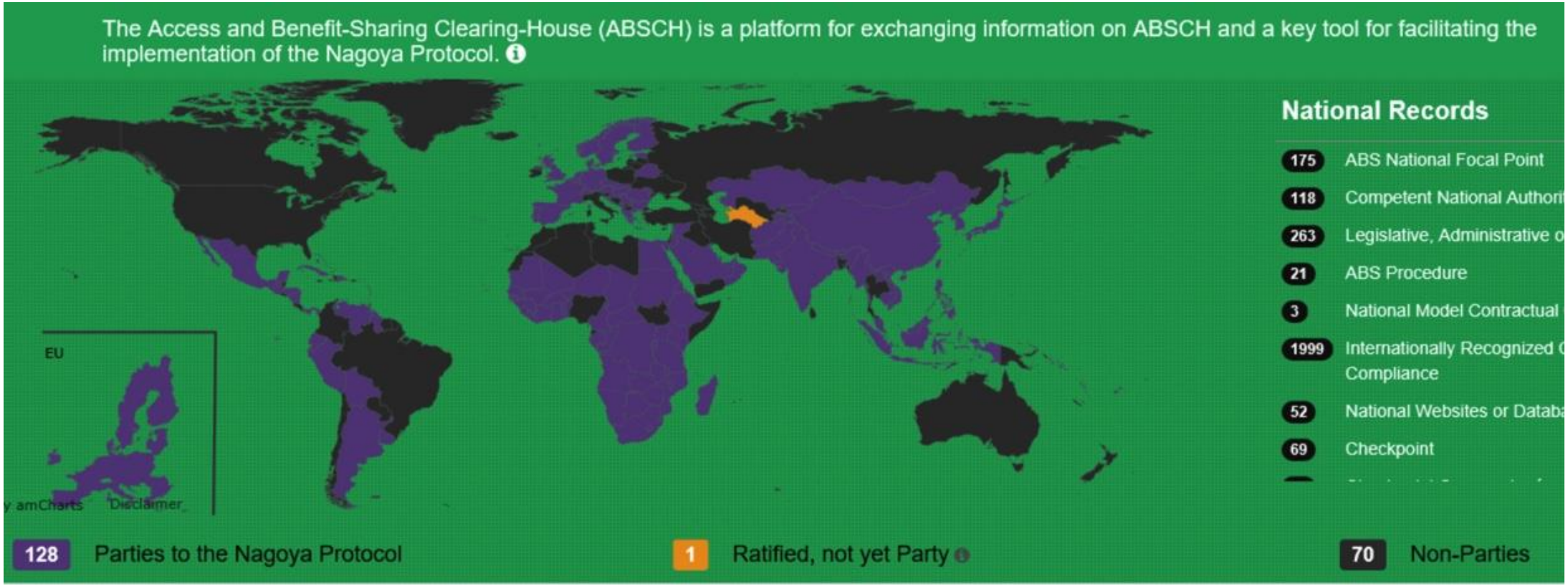
Biological materials /samples with DNA/RNA

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*”

➢ 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**
- Outside the scope for the EU Regulation:
  - the maintenance and management of a collection for conservation purposes, including storage of resources, quality/phytopathology checks/control, verification of material upon acceptance;
  - taxonomic identification of biological or genetic material, by morphological or molecular analysis, including through use of DNA sequencing;
  - GRs as testing/reference tools such as reference material (strains), reagents and samples of proficiency tests, diagnostics;
  - rearing and culturing without intentional selection; large-scale screening; **public health emergencies.**



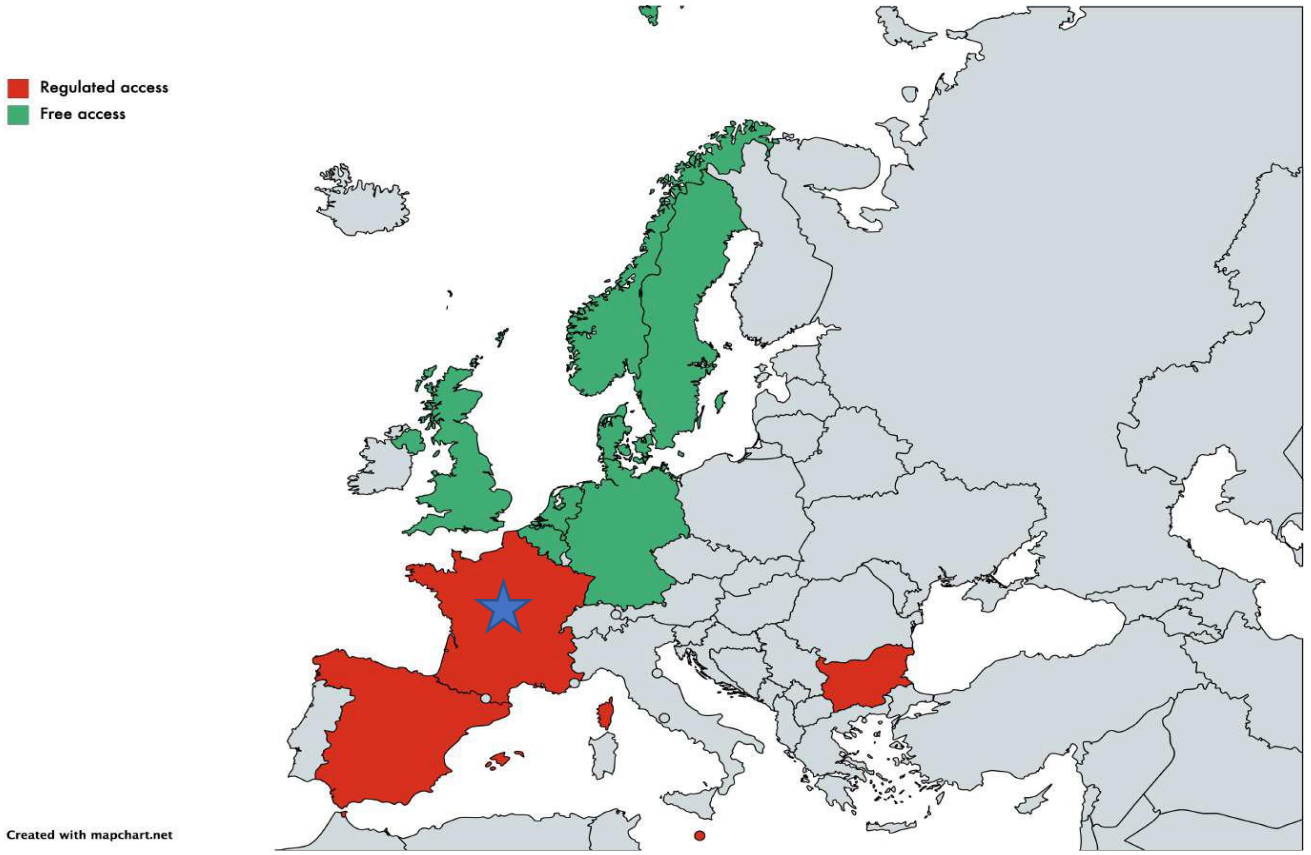
➢ Communication

*https://absch.cbd.int/

- Identifying Parties
  - There are non-Nagoya Parties that have ABS regulations
- Discovering ABS regulations (ABSCH and NFP)
  - There are Nagoya Parties that have not yet ratified
- Understanding ABS regulations and acquiring permits (NFP)

➢ Diverse National Jurisdiction

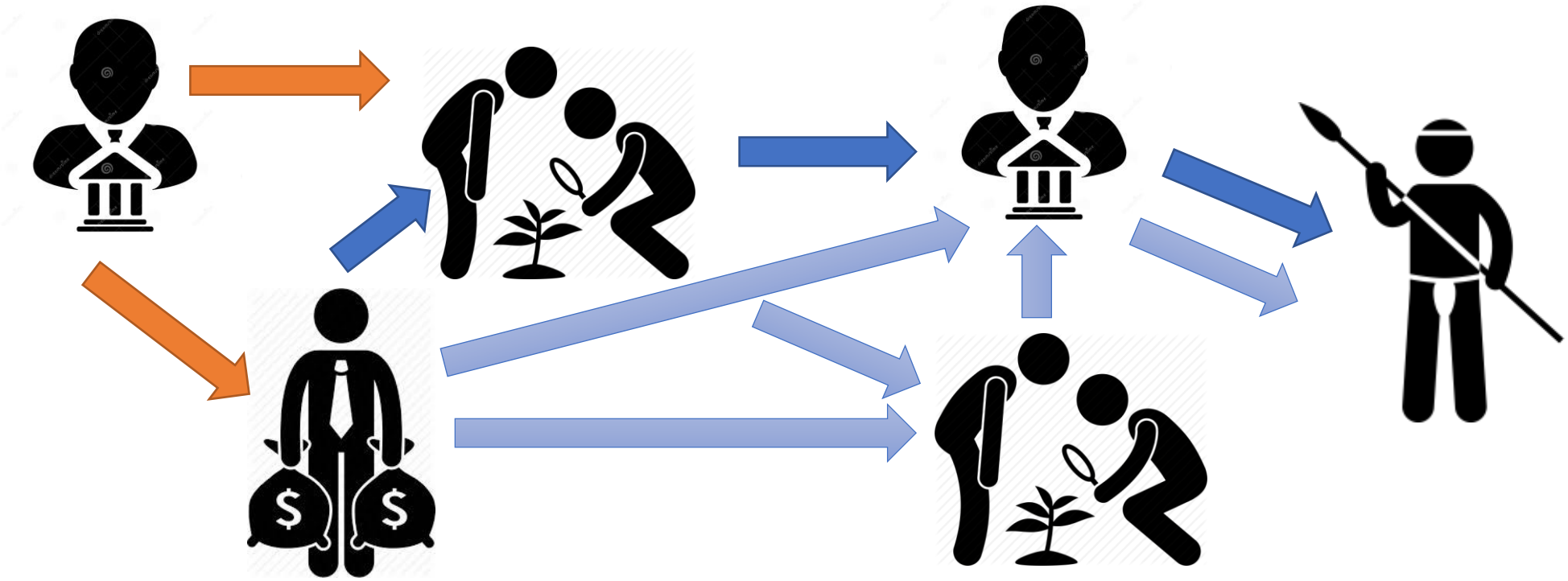
- **Sovereign rights:** each country can decide IF and HOW they regulate their resources
  - EU countries that regulate ABS to GRs: Spain, France, Croatia, Malta and Bulgaria
- Negotiating permits and contracts bilaterally (NFP)



➢ Achieving the CBD 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

What about the microbial / public health sector?

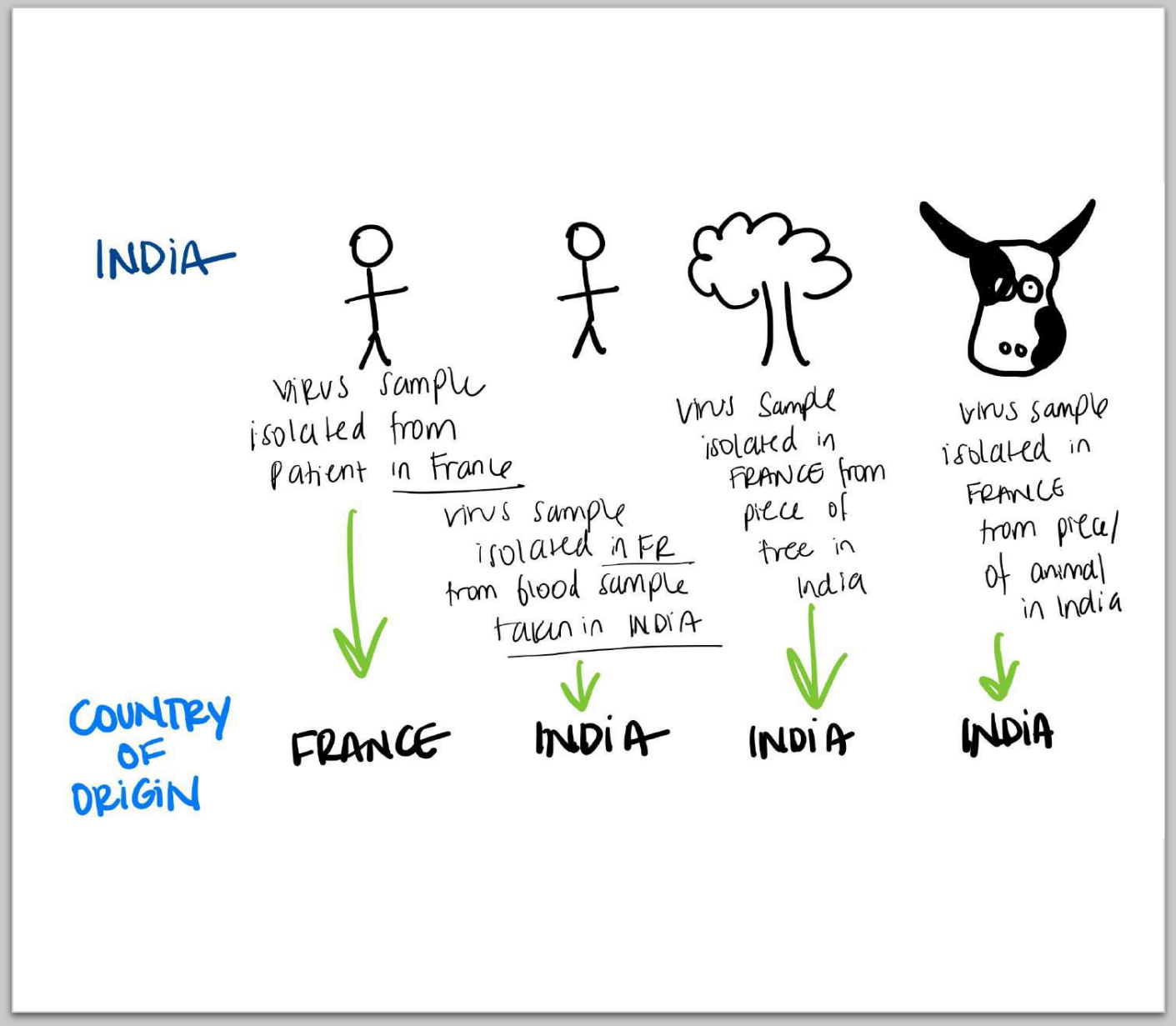


Opportunities for developing a NP compliance strategy

- Stepwise approach
  1. Acquiring the necessary information for compliance assessment
     a) Date of collection
     b) Country of origin
  2. Deciding on the responsibilities and curation startegies for due diligence
     a) End users complete responsibility
     b) Provide a governance system but end user with final responsibility
     c) EU Registered Collection taking the responsibility
  3. Main points and last remarks

1. Acquiring the basic information for compliance

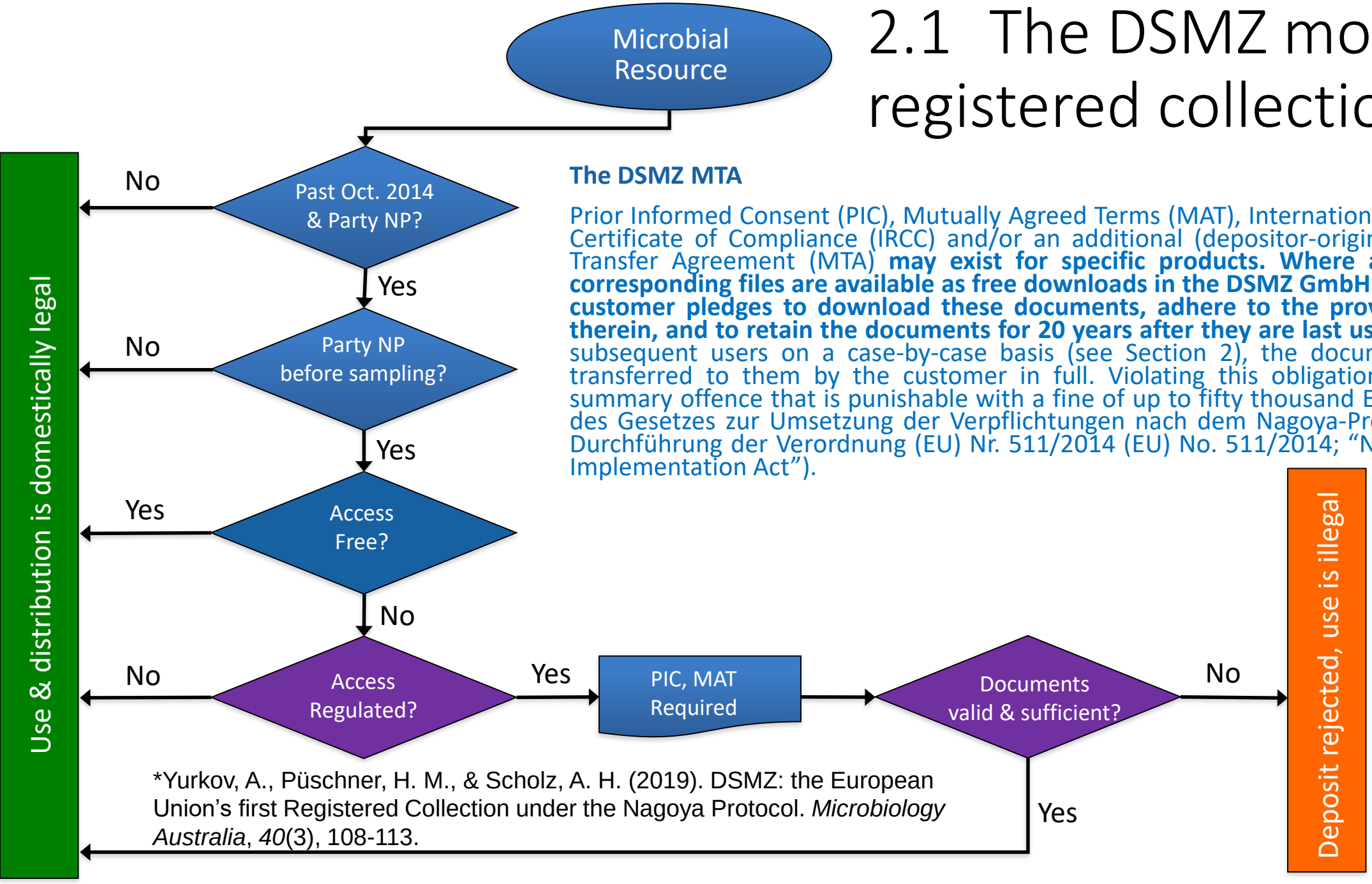
- **Temporal information:** (*in situ*) sampling date
  - 12 of October 2014
  - 29.12.93-12.10.2014 “moral” period
  - Date that a country became Party/ratified
- In case do not know: Proxy
  - When it first came into your institution/lab (PI arrival)
  - First publication with the material
  - Before 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 unintentional introduction, country of origin = where the pathogen is isolated



2. Defining a strategy for due-diligence

- The NP and EU Regulation defines the ultimate responsibility of due diligence to end users
  - Handling, storing and transferring GRs are not considered utilization
- Governance systems and curation strategies can facilitate users due diligence
  - EU trusted intermediary model
  - The Asian ACM-NIEMA multilateral system for non-commercial use
- EU registered collections
  - User obtaining GR from registered collection is considered to have exercised due diligence (seeking of information)
  - Currently 3 registered collections

2.1 The DSMZ model for registered collections



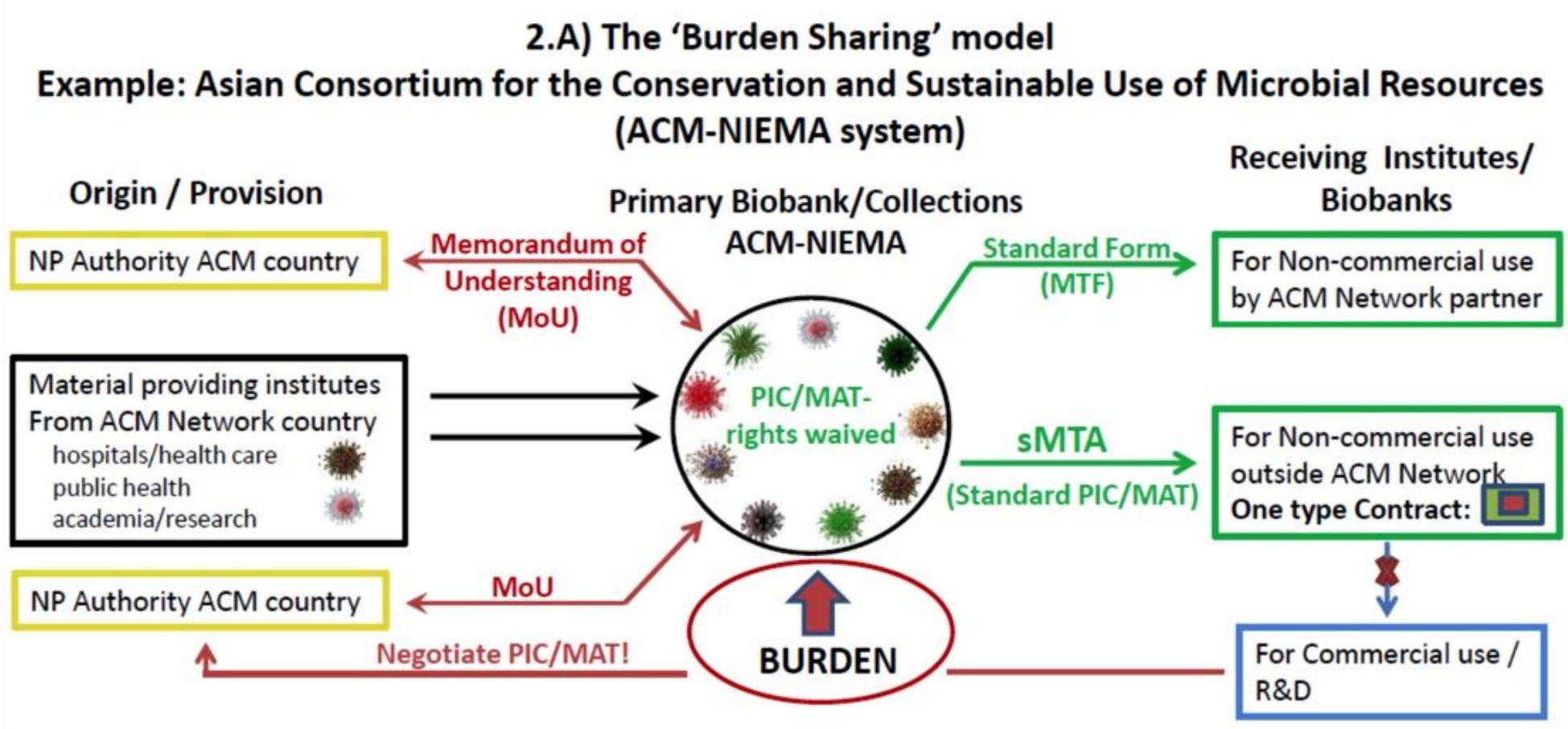
The DSMZ MTA

Prior Informed Consent (PIC), Mutually Agreed Terms (MAT), Internationally Recognised Certificate of Compliance (IRCC) and/or an additional (depositor-originated) Material Transfer Agreement (MTA) **may exist for specific products. Where applicable, the corresponding files are available as free downloads in the DSMZ GmbH catalogue. The customer pledges to download these documents, adhere to the provisions defined therein, and to retain the documents for 20 years after they are last used.** If there are subsequent users on a case-by-case basis (see Section 2), the documents must be transferred to them by the customer in full. Violating this obligation constitutes a summary offence that is punishable with a fine of up to fifty thousand Euros (Section 4 des Gesetzes zur Umsetzung der Verpflichtungen nach dem Nagoya-Protokoll und zur Durchführung der Verordnung (EU) Nr. 511/2014 (EU) No. 511/2014; “Nagoya Protocol Implementation Act”).

*Yurkov, A., Püschner, H. M., & Scholz, A. H. (2019). DSMZ: the European Union’s first Registered Collection under the Nagoya Protocol. *Microbiology Australia*, *40*(3), 108-113.

The ACM-NIEMA multilateral system for non-commercial use

- **Multilateral model;**
- rapid and standardized access for non-commercial use;
- does not cover commercial use;
- receiving repositories cannot redistribute the materials.



*Ribeiro, C. D. S., Koopmans, M. P., & Haringhuizen, G. B. (2018). Threats to timely sharing of pathogen sequence data. *Science*, *362*(6413), 404-406.

3. Main points and last remarks

- ABS requirements exist that go beyond the scope of the EU ABS Regulation
  - Assess temporal and geographic information;
  - Assess Parties regulations regarding access;
  - Assess Parties and EU regulations regarding utilization.
- ABS requirements exist in countries, which are not (or not yet) Parties to the NP
  - Always stay up-to-date with ABS Clearing House;
  - Always check for countries regulatory measures.
- GRs covered by specialized instruments (ITPGRFA and PIP Framework) are out of scope
  - Multilateral systems with specific standard conditions
- Keep in mind some exceptions under the EU ABS Regulation
  - Unintentional introduction;
  - Pathogens related to public health emergencies (3 months exemption);
  - (Diagnostic) tools; identification; description; holding; transferring and monitoring activities.
- Define responsibilities among data providers, users and intermediaries and curation strategies
  - Final responsibility: users
  - Providers and repositories can facilitate by acquiring and transferring the critical information/documentation

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