

THE ABS  
CAPACITY  
DEVELOPMENT  
INITIATIVE



L'INITIATIVE DE  
RENFORCEMENT  
DES CAPACITES  
POUR L'APA

# Compliance under the Nagoya Protocol & the Compliance Regulation of the EU

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ABS Capacity Development Initiative

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funded by



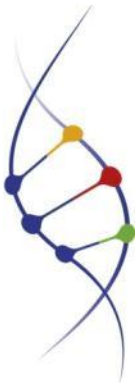
DANISH MINISTRY  
OF THE ENVIRONMENT



implemented by



# Compliance within the NP



- Article 15. Compliance with **Domestic Legislation or Regulatory Requirements** on Access and Benefit-sharing
- Article 16. Compliance with Domestic Legislation or Regulatory Requirements on Access and Benefit-sharing **for Traditional Knowledge Associated** with Genetic Resources
- Article 17. **Monitoring the Utilization** of Genetic Resources
- Article 18. Compliance with **Mutually Agreed Terms**
- *Article 30. Procedures and Mechanisms to Promote Compliance with this Protocol*



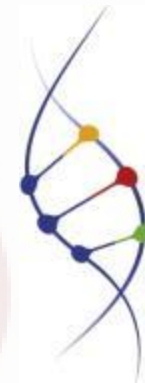


## **Compliance with national ABS legislation**

### **Obligation to take measures:**

- **To provide that genetic resources utilized within a Party's jurisdiction have been accessed in accordance with PIC and MAT**
- **To address situations of non-compliance**

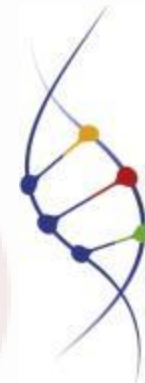
**Obligation to cooperate** in cases of alleged violation of domestic ABS legislation or regulatory requirements



## Compliance with MAT

### - obligation to:

- Encourage users and providers to include **provisions in MATs** to cover dispute resolution (including the jurisdiction; the applicable law; and/or options for alternative dispute resolution)
- Ensure that **opportunity to seek recourse** is available under each Party's legal systems
- To take effective measures regarding **access to justice**; and the utilization of mechanisms regarding **mutual recognition and enforcement of foreign judgments and arbitral awards**

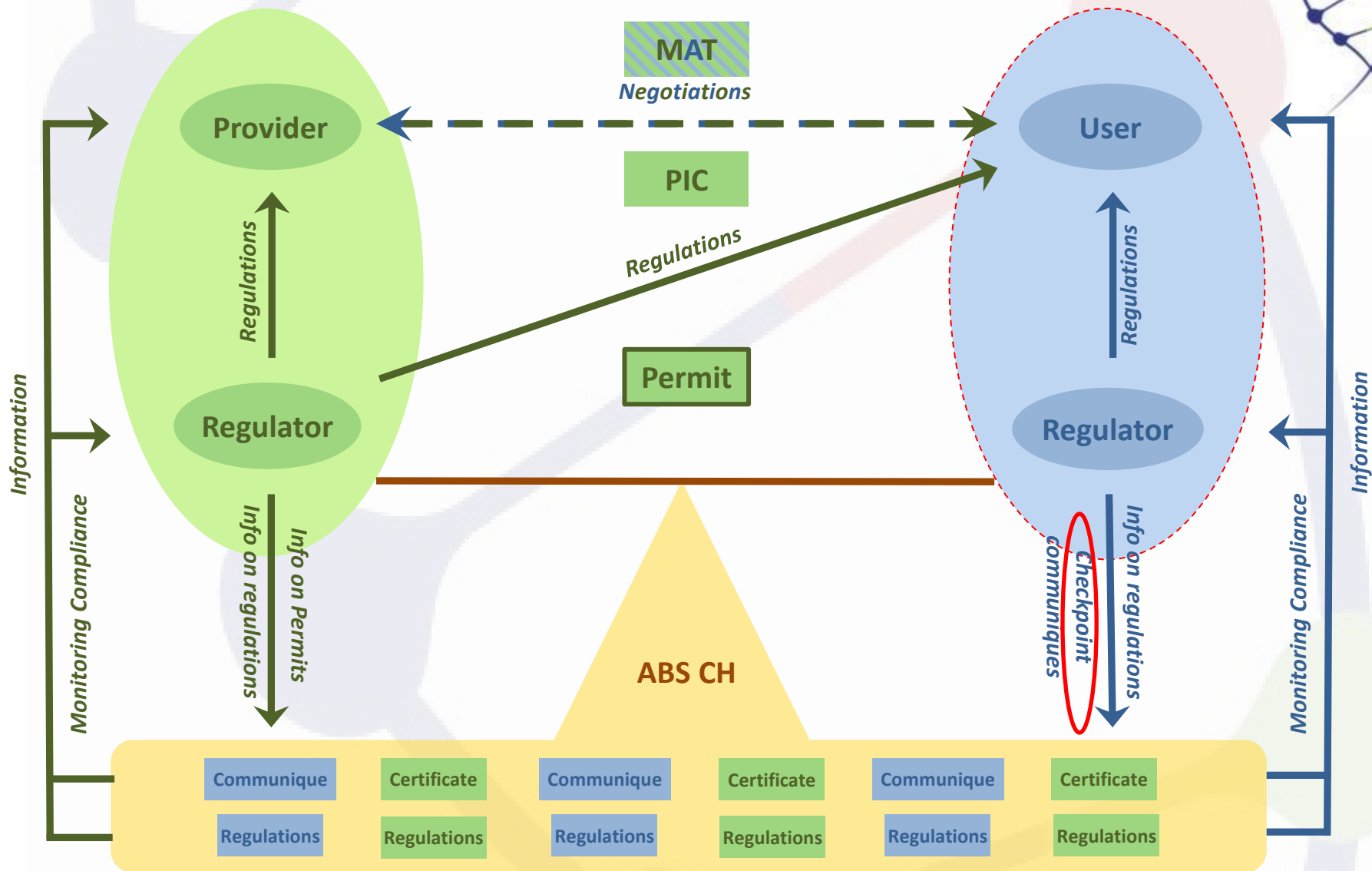


## Monitoring of genetic resources

Obligation to take **measures to monitor** the utilization of genetic resources:

- Designation of effective check points for collection of information at any stage of research, development, innovation, pre-commercialization or commercialization
  - Encouraging reporting requirements in MAT
  - Encouraging cost-effective communication tools
- **Internationally recognized certificate of compliance** as evidence that PIC was obtained and MAT established

# Provider-User Interplay



User  
country

To monitor  
utilization of GRs

**Checkpoints:**

- Research publishing houses*
- Research institutions subject to public funding*
- Patent examination offices*
- Authorities providing regulatory or marketing approval of products*

**Permit / IRCC**

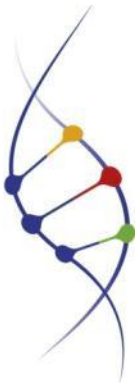
**provide information :**

date, UID, providing  
entity, PIC, MAT, source of  
GRs, (non-) comm. use





# Political statements on ABS / NP



## **Commission Proposal COM(2012) 576 final (04.10.2012)**

- "The Protocol rests on two main pillars: measures on access, and measures on user compliance."

## **EU Council Note on Art. 7 during EU Trialogue (Nov. 2013)**

- Restricting checkpoints to the phase of utilisation "Using the principle of: 'nothing more, nothing less, than the Nagoya Protocol.' "

# Art. 2 – Scope & Art. 3 - Definitions



## EU ABS compliance rules only apply when these six conditions are met:

### 1. Access to genetic resource or associated traditional knowledge

"Genetic resources" means genetic material of actual or potential value.

"Genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity.

Access to e.g. oils, isolated biochemicals, heat-treated material is not under the scope of the EU ABS regulation – but maybe under the scope of the provider country's ABS regulation

# Art. 2 – Scope & Art. 3 - Definitions



**EU ABS compliance rules only apply when these six conditions are met:**

2. Genetic resources accessed is under sovereignty of a State  
Access to GR outside of the jurisdiction of States e.g. in the Antarctica or the High Sea - no compliance obligations in the EU
2. Aquisition occurs in a Party to the Nagoya Protocol  
Access to GR and aTK in non-Parties - no compliance obligations in the EU  
Exclusion of any access before the entry into force of the NP for a specific country

# Art. 2 – Scope & Art. 3 - Definitions



**EU ABS compliance rules only apply when these six conditions are met:**

4. ABS regulative framework exists in this Party

No ABS framework / no ABS contract – no compliance obligations in the EU

Exclusion of access to any GR, including commodities, in EU countries without access regulation, e.g. DE

4. Access after 12 Oct. 2014

Exclusion of all GR and aTK which were accessed before

Exclusion of any future utilisation of such GR and aTK

# Art. 2 – Scope & Art. 3 - Definitions



**EU ABS compliance rules only apply when these six conditions are met:**

## 6. Utilisation in the EU

“Utilization of genetic resources” means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention;

**Exclusion of any activity that is not R&D on the GR, e.g. several ecological and taxonomical methodologies, trade for use in production process**

# Compliance during utilisation

