



ARCHE NOAH

# ACCESS and USE of Plant Genetic Resources under the Nagoya Protocol

## A SEED SAVER'S DIGEST



***Workshop on Nagoya Compliance for Seed Savers  
Wolkersdorf, 25-26.02.17***



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# *SEED SAVERS' DIGEST*

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- I. USER OBLIGATIONS UNDER NAGOYA
- II. ASSESSING THE EXISTENCE OF ACCESS RULES
- III. ESTABLISHING MAT
- IV. MEMBER STATES PRACTICES
- V. INFLUENCE FUTURE POLICY





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# *I. USER OBLIGATIONS*

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- LEGALITY OF ACCESS TO GR
- INFORMATION ON GR
- RESPECT MAT
- MAKE DD DECLARATIONS
- BE PREPARED FOR DD CHECKS





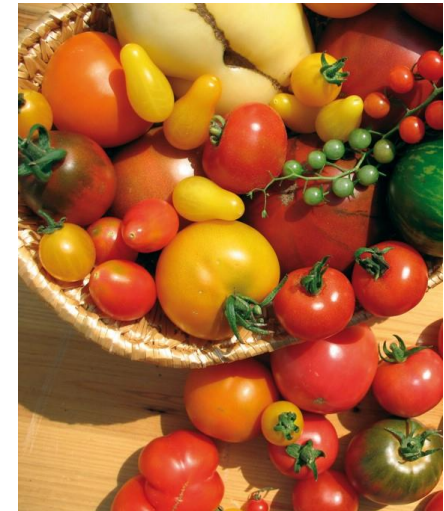
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# I. USER OBLIGATIONS

- LEGALITY OF ACCESS TO GR
  - Access « Genetic Resources »

*ART.2 CBD & ART 3 EU Reg* « Genetic material (any material of plant, animal, microbial or other origin containing functional units of heredity) of actual or potential value »

- **What if GR is a traded commodity?**
  - I purchase a tomato to use seeds or genetic material !
  - General Guidance document on core obligations EU Regulation 511/2014 : mere trade & exchange outside of scope BUT if genetic resources are used for research and development ::: NAGOYA APPLIES



# I. USER OBLIGATIONS

- LEGALITY OF ACCESS TO GR
  - **Access « Genetic Resources »**

*ART.2 CBD & ART 3 EU Reg « Genetic material (any material of plant, animal, microbial or other origin containing functional units of heredity) of actual or potential value »*

- **What if the GR is privately held?**
- **Or if it is a commercial variety?**
- *Depends on the access laws of the country of origin !*



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# I. USER OBLIGATIONS

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- LEGALITY OF ACCESS TO GR

- **Access « for utilisation »**

ART.2(c) NAGOYA « Utilisation of genetic resources means to conduct research and development on the genetic and/or biochemical composition of genetic resources ».

- Mere planting or harvesting? OUTSIDE SCOPE (General Guidance doc)
- Research and/or development : not limited to product development.  
Upstream research activities covered, but not all

- OUTSIDE SCOPE

- » Maintenance of collection for conservation purposes
- » Description of material. Use for testing or comparison

WITHIN SCOPE

- » Description combined with research on the resource
- » Participatory plant breeding
- » Selection of any spontaneous mutations in fields





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# I. USER OBLIGATIONS

- LEGALITY OF ACCESS TO GR
  - DUE DILIGENCE OBLIGATION TO ENSURE ACCESS FOR UTILISATION IS LEGAL

*ART. 4 §1 EU REG. « Users shall exercise due diligence to ascertain that genetic resources and TK associated with genetic resources which they utilise, have been accessed in accordance with applicable ABS legislation or requirements, and that benefits are fairly and equitably shared upon mutually agreed terms ».*

- Not a prohibition to use illegally acquired material !
- BUT obligation to discontinue use :

*ART. 4 §5 EU REG. « When the information in their possession is insufficient or uncertainties about the legality of access and utilisation persists, users shall obtain an access permit or its equivalent and establish mutually agreed terms, or discontinue utilisation».*



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# I. USER OBLIGATIONS

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- LEGALITY OF ACCESS TO GR
- **INFORMATION ON GR**
- RESPECT MAT
- MAKE DD DECLARATIONS
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# I. USER OBLIGATIONS

- LEGALITY OF ACCESS TO GR
- INFORMATION ON GR
  - **Obligation to seek, keep & transfer information to subsequent users**

*ART. 4 §3 EU REG. Users shall seek, keep and transfer to subsequent users, [...] information and relevant documents on:*

- (i) the date and place of access of genetic resources or of TK;*
- (ii) the description of the genetic resources or of TK utilized;*
- (iii) the source from which the genetic resources or TK were directly obtained, as well as subsequent users of genetic resources or TK;*
- (iv) the presence or absence of rights and obligations relating to access and benefit-sharing including rights and obligations regarding subsequent applications and commercialisation;*
- (v) access permits, where applicable;*
- (vi) mutually agreed terms, including benefit-sharing arrangements, where applicable.*



# I. USER OBLIGATIONS

- LEGALITY OF ACCESS TO GR
- INFORMATION ON GR
  - **Obligation to seek, keep & transfer information to subsequent users**
  - **Long term obligation**

*ART. 4 §6 EU REG. « Users shall keep the information relevant to access and benefit sharing for 20 years after the end of the period of utilisation».*



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# I. USER OBLIGATIONS

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- LEGALITY OF ACCESS TO GR
- INFORMATION ON GR
- ESTABLISH & RESPECT MAT
  - **Principle** : Bilateral negotiations with competent national authority (STATE)
  - **National rules on MAT ?**
    - Minimum content?
    - Model contract?
    - Use of sMTA for all agri crops used for food/feed?
    - Users' own contract?



# I. USER OBLIGATIONS

- LEGALITY OF ACCESS TO GR
- INFORMATION ON GR
- ESTABLISH & RESPECT MAT
  - **Principle : enter into MAT and respect terms**



*ART. 4 §2 EU REG. « Genetic resources and TK shall only be transferred and utilised in accordance with mutually agreed terms if they are required by applicable legislation or regulatory requirements.».*

- **Practice : Operate system for transfer information & obligations downstream**





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# I. USER OBLIGATIONS

- LEGALITY OF ACCESS TO GR
- INFORMATION ON GR
- ESTABLISH & RESPECT MAT
- **MAKE DD DECLARATIONS**
- BE PREPARED FOR DD CHECKS



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# I. USER OBLIGATIONS

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- **MAKE DD DECLARATIONS**

- **DD Declaration at the stage of research funding (ART.5 & Annex II COM Implementing Regulation)**
  - For « any financial contribution by means of a grant to carry out research, whether from commercial or non-commercial sources ».
  - After reception of the first instalment of funding
- **DD Declaration at the stage of final development of a product (ART.6 & Annex III COM Implementing Regulation)**
  - « Market approval or authorisation, notification ... » (or if transferred/sold to third person to do this)
  - « products or parts of products to be incorporated into a final product



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# I. USER OBLIGATIONS

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- LEGALITY OF ACCESS TO GR
- INFORMATION ON GR
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- MAKE DD DECLARATIONS
- **BE PREPARED FOR DD CHECKS**





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# I. USER OBLIGATIONS

- **BE PREPARED FOR DD CHECKS**

*ART. 9 EU REG. « 1. The competent authorities shall carry out checks to verify whether users comply with their obligations under Articles 4 and 7.*

*2. Member States shall ensure that the checks carried out pursuant to paragraph 1 are effective, proportionate, dissuasive and detect cases of user non-compliance with this Regulation.*

*3. The checks referred to in paragraph 1 shall be conducted:*

- (a) in accordance with a periodically reviewed plan developed using a risk-based approach;*
- (b) when a competent authority is in possession of relevant information, including on the basis of substantiated concerns provided by third parties, regarding a user's non-compliance with this Regulation. Special consideration shall be given to such concerns raised by provider countries.*

*4. The checks referred to may include an examination of:*

- (a) the measures taken by a user to exercise due diligence in accordance with Article 4;*
- (b) documentation and records that demonstrate the exercise of due diligence in accordance with Article 4 in relation to specific use activities;*
- (c) instances where a user was obliged to make declarations under Article 7.*

*On-the-spot checks may also be carried out, as appropriate».*





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# *SEED SAVERS' DIGEST*

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I. USER OBLIGATIONS UNDER NAGOYA

II. ASSESSING THE EXISTENCE OF ACCESS RULES

- *Applicable law & Decision tree*

III. MEMBER STATES PRACTICES

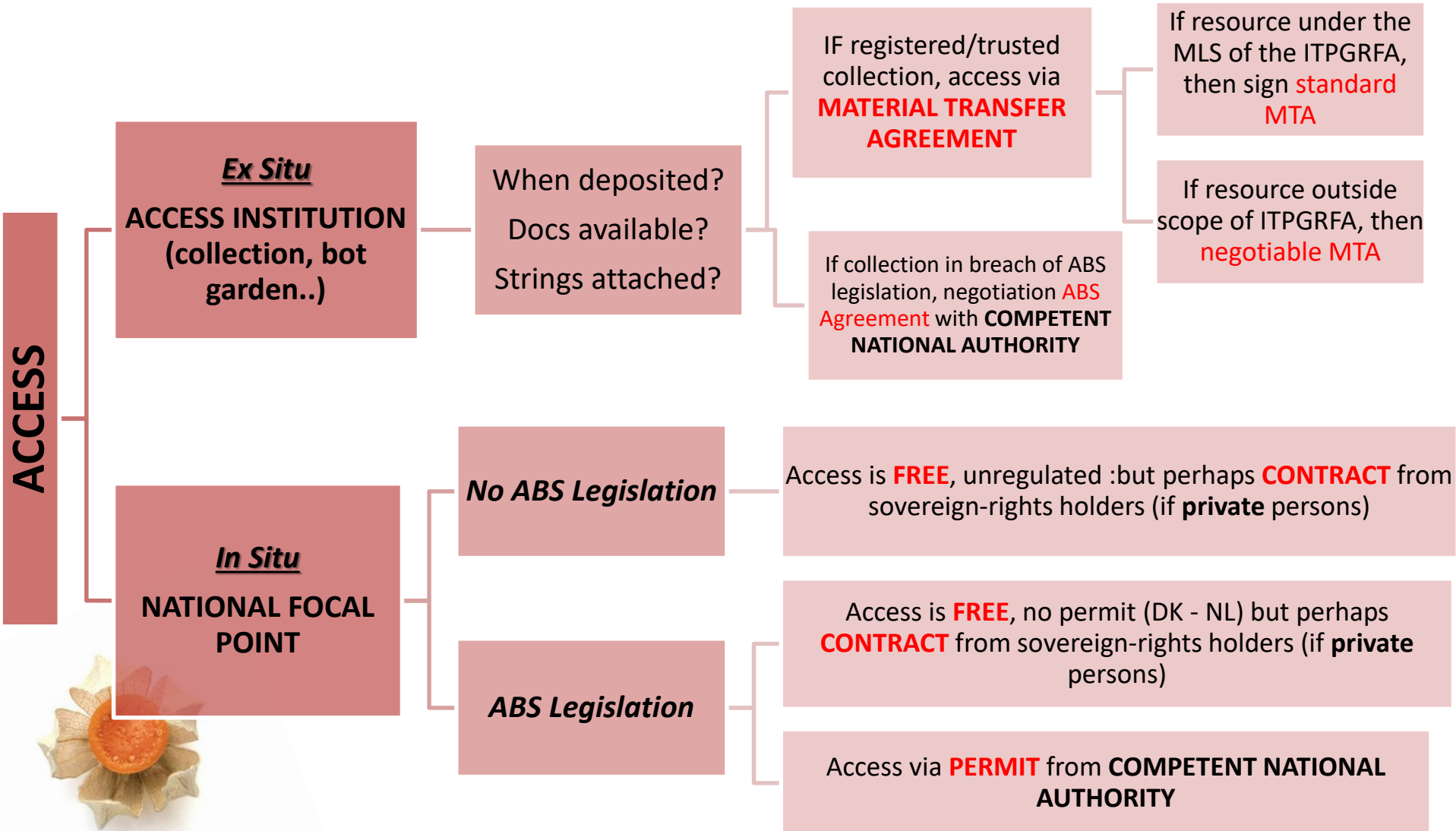
IV. INFLUENCE FUTURE POLICY



## II. EXISTENCE OF ACCESS RULES



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## *II. EXISTENCE OF ACCESS RULES*

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### *ASSESSMENT OF APPLICABLE LAW*

- *Legal Status of GR?*
  - Current regulation of GR & ownership
  - Exercise of sovereignty
  - Traditional knowledge
  
- *Access rules?*
  - ABS competences?
  - General rules?
  - Specific conditions?



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## *II. EXISTENCE OF ACCESS RULES*

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### **LEGAL STATUS OF GR**

- **Current regulation of GR & ownership**
  - Property law, administrative law, nature protection
  - Ownership of biophysical entity & informational component
- **Exercise of sovereignty**
  - Assert separate State ownership OR rely only on private property rules?
  - Require PIC or not?
    - Facilitated access? Fast-track? Single procedure?
- **Traditional knowledge**
  - Mention? Definition?



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## *II. EXISTENCE OF ACCESS RULES*

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### **ACCESS RULES**

- **Distribution of ABS Competences**

- Vertical division

- Territorial decentralisation (co-governance by national, sub-national & local)
- Private & public actors

- Horizontal division

- Environmental affairs, agriculture, economy/industry, ...
- Division according to the type of resources accessed? Subject of research conducted?

- **Nagoya: « Access for utilisation »**

- National laws: usually collecting, capturing, exchanging, selling etc...





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## II. EXISTENCE OF ACCESS RULES

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### ACCESS RULES

- **General rules : Wide range of legislation**

- Nature protection, Agriculture, Research & Development, Real & intellectual property, private international law, ...
- How?
  - Unrestrained?
  - Restrictive? Permits / Notification
  - Undefined? Unclear conditions / completely *ad hoc*
- Distinction between purposes? Commercial or not, export, emergency

- **Specific rules**

- Protected species / areas
- ITPGRFA:
  - « Under management & control »
    - » Formal or informal request/order to use sMTA to collections under direct/indirect control of focal point/State
  - « Public domain »: identify?



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# ***SEED SAVERS' DIGEST***

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# III. MEMBER STATE PRACTICE



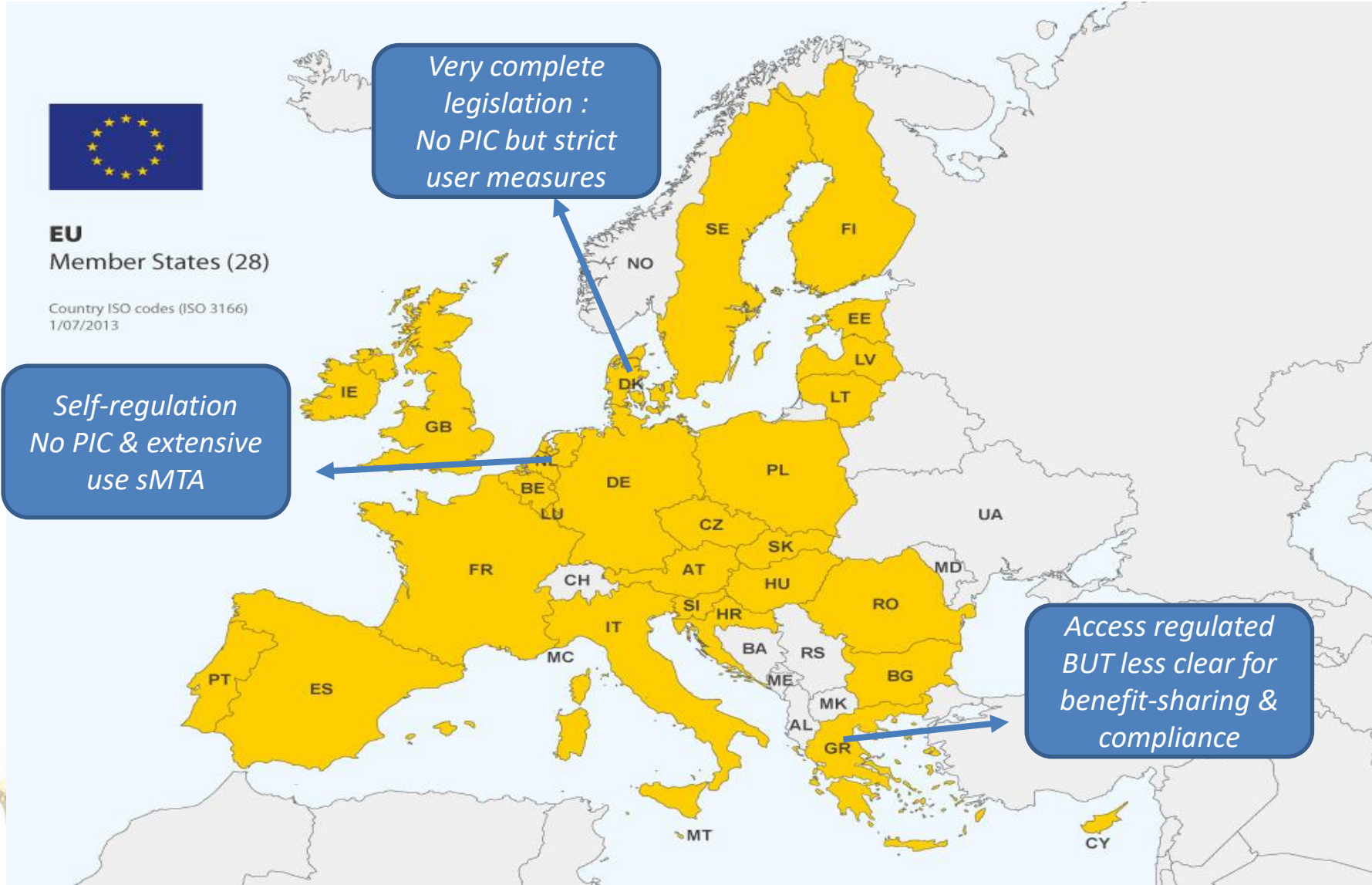
**EU**  
Member States (28)

Country ISO codes (ISO 3166)  
1/07/2013

*Very complete  
legislation :  
No PIC but strict  
user measures*

*Self-regulation  
No PIC & extensive  
use SMTA*

*Access regulated  
BUT less clear for  
benefit-sharing &  
compliance*



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## *III. MEMBER STATES PRACTICE*

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### **DENMARK**

- **Legal Status of GR**
  - *Physical access to GR : ownership organism as a whole includes ownership informational components, except IPR*
- **Access to GR**
  - *Restrictions for protected areas & species*
  - *NO PIC requirements for Danish GR (indirectly from DK ABS Act – explicit in Explanatory Notes)*
- **Distribution of ABS Competences**
  - *Ministry of Environment (decretal power for reporting) & Nature Agency (monitors compliance with ABS Act)*



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## *III. MEMBER STATES PRACTICE*

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### **DENMARK**

- ***Benefit Sharing mechanisms***
  - *Autonomy of contracts : civil legal proceedings*
  - *BUT absence of MAT when provider country's legislation imposes : infringement ABS Act*
- ***Compliance mechanisms***
  - *General prohibition to use on Danish territory GR acquired in violation of laws of country of origin*
  - *Reporting requirements & designation checkpoints not yet operational*
    - *Disclosure of origin patent applications*



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## *III. MEMBER STATES PRACTICE*

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### **THE NETHERLANDS**

- **Legal Status of GR**
  - NL Civil Code: Ownership land & physical resources extends to informational component
- **Access to GR**
  - No PIC required : complete self-regulation approach
  - Exceptions to self-regulation
    - In situ material : consent of land owner
    - Restrictions protected areas & species (Flora & Fauna Act, Nature Conservation Act)
    - Declaration ITPGRFA GB of material in MLS : Use of sMTA for all PGRFA (not just Annex 1)



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## *III. MEMBER STATES PRACTICE*

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### **THE NETHERLANDS**

- **Distribution of ABS Competences**
  - Coordinating entity: Ministry of Economic Affairs (staff is CNA ABS & NFP together with CGN Director)
- **Benefit Sharing mechanisms**
  - Autonomy of contracts
- **Compliance mechanisms**
  - New measures & institutions to monitor compliance : The NL Food & Consumer Product Safety Authority
  - Enforcement: criminal sanctions & administrative fines



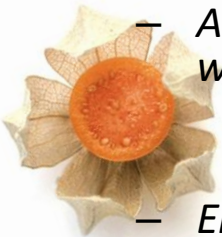


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## III. MEMBER STATES PRACTICE

### GREECE

- **Legal Status of GR**
  - State sovereignty solemnly declared (CBD ratification law) : GR are « protected national capital »
  - Civil law : rights in rem extend to information
- **Access to GR**
  - Horizontal rule on access to GR for research (2011 Law on Biodiversity conservation)
    - Principle : State licenses, controls & encourages research
    - Implementation: different entities % subject research
      - Species & habitats (Environment Ministry)
      - Rural species in ITPGRFA (AGri)
  - Protected areas & forests:
    - Complete prohibition collect
    - OK research on « wild fauna & native flora » (announcement) BUT Permit (Ministry of Agriculture) IF research aims at collection material destined for export or if specific species
  - Access to plant genetic material (specific decree 1990), whether in situ or ex situ, including wild species
    - Principle: PERMIT for all (Ministry of Agriculture) & additional conditions for foreign researchers
  - Endemic species: Prohibition access, but PERMIT for research can be granted by Min. Env



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## *III. MEMBER STATES PRACTICE*

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### **GREECE**

- ***Benefit Sharing mechanisms***
  - *No provisions on use of GR*
  - *Access to endemic species conditional on waiver of rights for benefit of State & sharing of research results*
- ***Compliance mechanisms***
  - *Heavy administrative penalties environmental degradation (includes illicit acquisition, pollution or degradation of GR)*



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II. ASSESSING THE EXISTENCE OF ACCESS RULES

- *Applicable law & Decision tree*

III. ESTABLISHING MAT

- *Minimum Content & Control*

IV. MEMBER STATES PRACTICES

V. **INFLUENCE FUTURE POLICY**





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## V. SEED SAVERS & NAGOYA POLICY

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- **ESTABLISH CONTACT**
  - **Contact National Focal Point & perhaps Competent National Authority**
  - **Awareness Of Existence, Goals, Issues/Challenges Faced**
- **FACILITATED ACCESS FOR NON COMMERCIAL RESEARCH**
  - **Advocate efficient measures to implement Art 8a Nagoya**
  - **Show existing fast track procedures (FR, ESP...)**
- **FARMERS KNOWLEDGE AS TK?**
  - **Advocate for the recognition of farmers' knowledge as TK & regulation of access to it ?**
- **MODEL FORMULARS & BEST PRACTICES**
  - **Assess whether useful to elaborate best practices (less chance of DD checks in theory)**





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***THANK YOU FOR YOUR ATTENTION !***

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