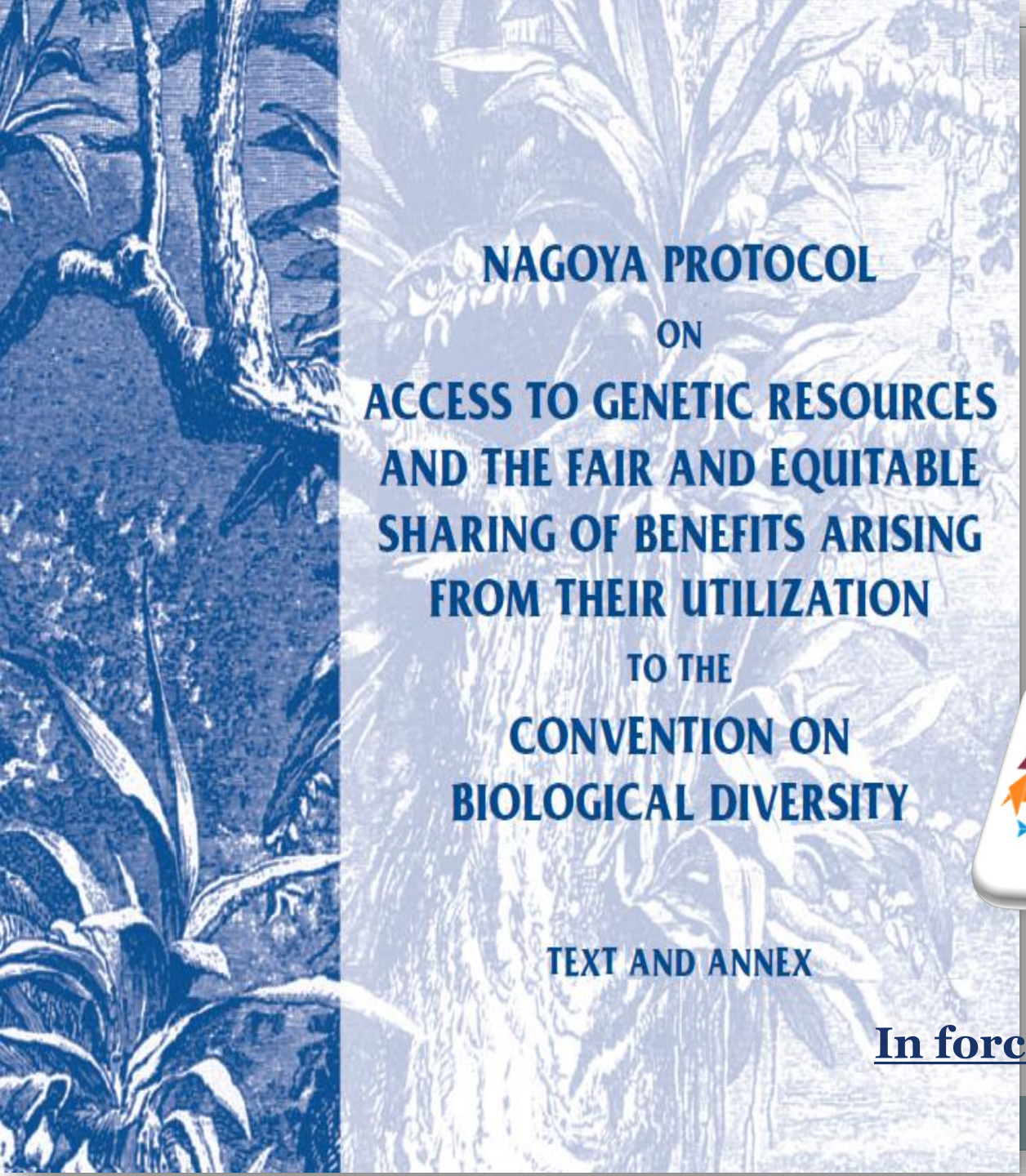


NAGOYA PROTOCOL
ON
ACCESS TO GENETIC RESOURCES AND THE FAIR AND EQUITABLE SHARING OF BENEFITS ARISING FROM THEIR UTILIZATION
TO THE
CONVENTION ON BIOLOGICAL DIVERSITY

TEXT AND ANNEX

CBD

COP10/MOP5
AICHI-NAGOYA
JAPAN 2010

In force since 12 October 2014

The Nagoya Protocol: key elements

- Implements **art. 15 of CBD** – third pillar of the Convention (ABS)

- Establishes an **International framework of common rules** on access to genetic resources and/or traditional Knowledge associated to GRs

- Aims at ensuring the **fair** and **equitable sharing of benefits** arising from utilization of GRs (monetary and/or non monetary)

- Contributes to the **conservation of Biological diversity** and the **sustainable use of its components**

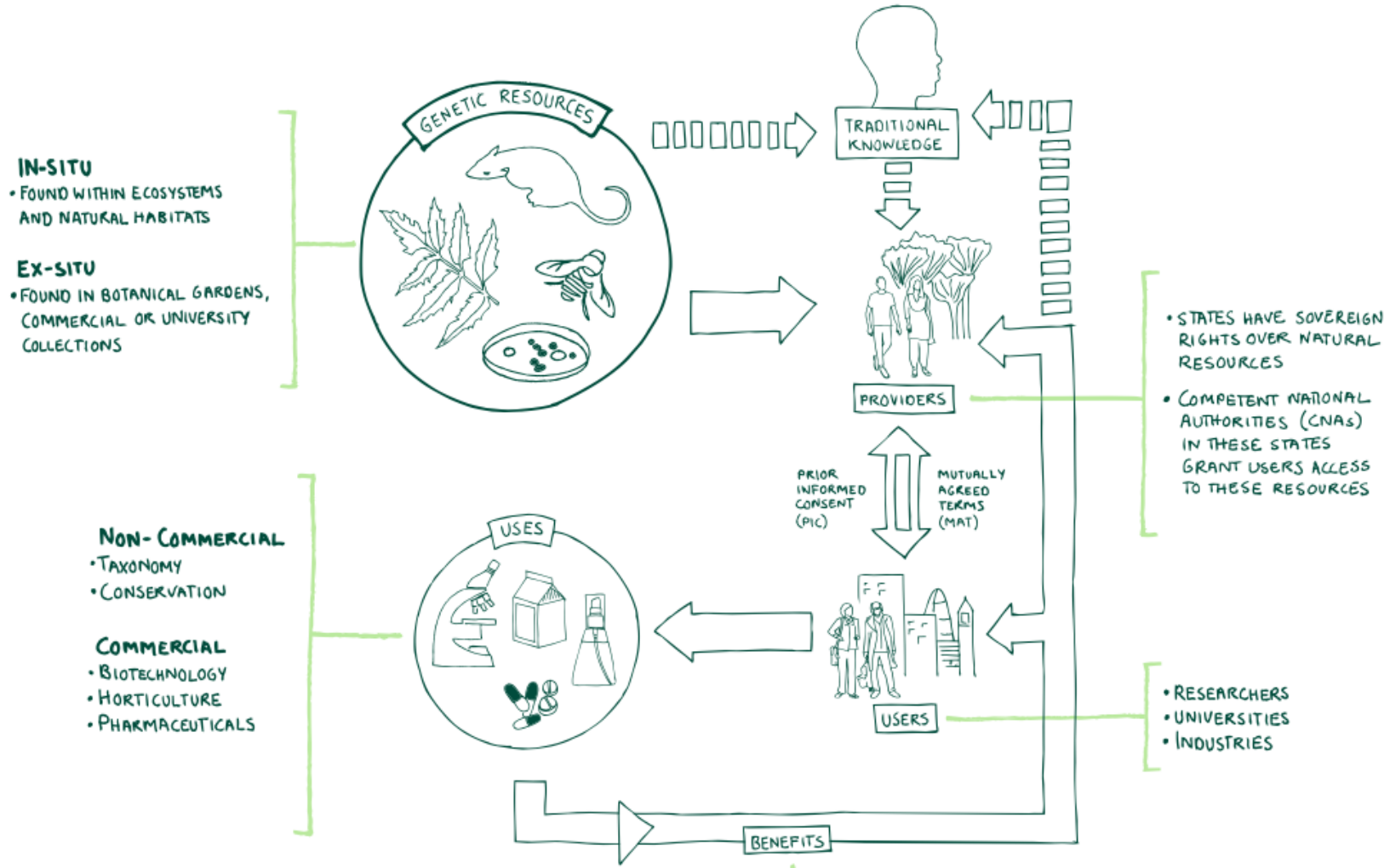
The Pillars of the Protocol

- ✓ Access Pillar : access to GRs according to specific measures (PIC and MAT)
- ✓ Compliance Pillar : utilization of GRs has to be legal = monitoring mechanism through checkpoints

Aim:

- ✓ Legal certainty
- ✓ Legal clearty
- ✓ Legal transparency

Key themes

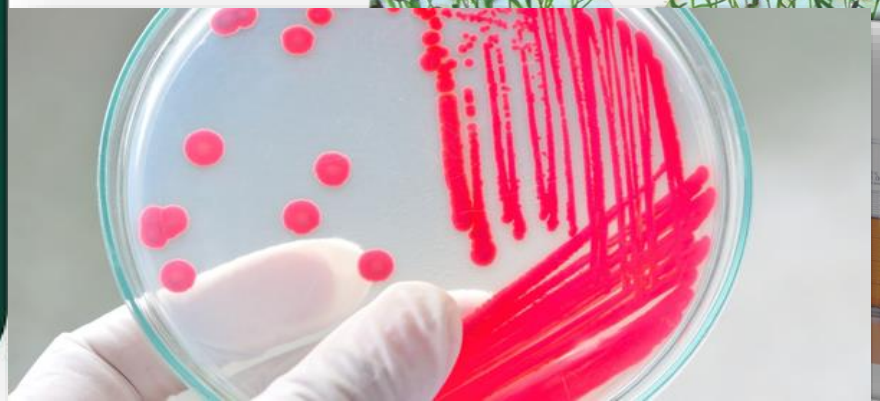


There are five key themes that underpin access and benefit-sharing of genetic resources. These are covered in a series of factsheets, which tackle each theme individually.

Utilization

Utilization = "to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology" (art. 2 (c) of NP – art. 3 (5) of EU Regulation)

- ✓ No close list of activities = not to pre-empt changes in the evolving technology.
- ✓ Utilization = both basic and applied research.
- ✓ Access regulations in provider countries are not unanumous = different conditions for different types of utiliz



The Nagoya Protocol state of play up to December 2018

ABSCH THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE

Convention on Biological Diversity

About the ABSCH | Search | Submit | Country Profiles | National Reports

The Access and Benefit-Sharing Clearing-House (ABSCH) is a platform for exchanging information on ABSCH and a key tool for facilitating the implementation of the Nagoya Protocol.

National Records

172	ABS National Focal Point
102	Competent National Authority
224	Legislative, Administrative or Policy Measure
0	ABS Procedure
0	National Model Contractual Clause
301	Internationally Recognized Certificates of Compliance
44	National Websites or Databases
52	Checkpoint

110 Parties to the Nagoya Protocol

4 Ratified, not yet Party

88 Non-Parties

REGULATION (EU) NO 511/2014

on compliance measures for users from the Nagoya Protocol in the Union

9 June 2014: ABS Regulation in force

12 October 2014: ABS Regulation is applicable

Scope of the EU Regulation (when the Regulation applies?)

- ✓ ***Geographic Scope*** (provider country)
- ✓ ***Temporal scope*** (time of access and utilization)
- ✓ ***Material scope*** (type of GRs)
- ✓ ***Personal scope*** (all users in the EU territory)

The Regulation is applicable

Scope of the EU Regulation (when the Regulation applies?)

Geographic Scope

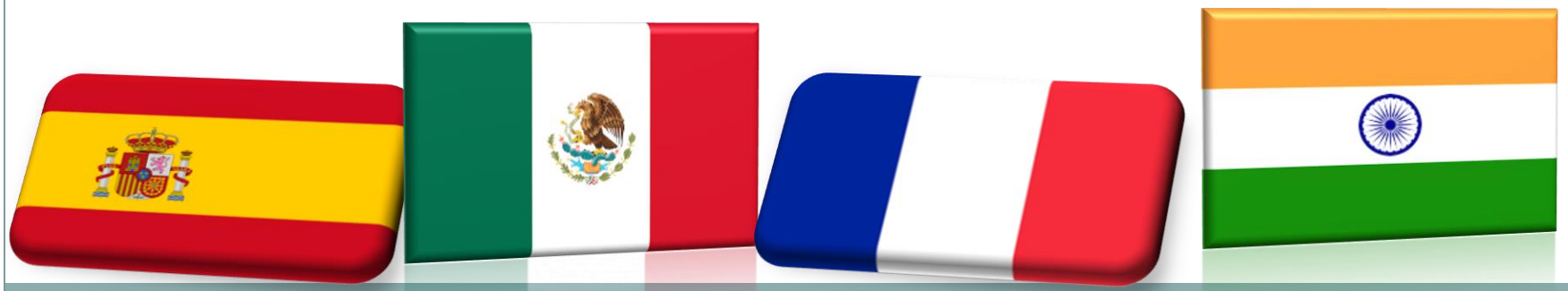
The Provider Country:

***a. exercises** its sovreign rights over GRs (art. 15 CBD, art. 6 NP)*

- No GRs from high seas
- No GRs from areas covered by Antarctic Treaty System
- No Grs from States that do not exercise their sovreign rights

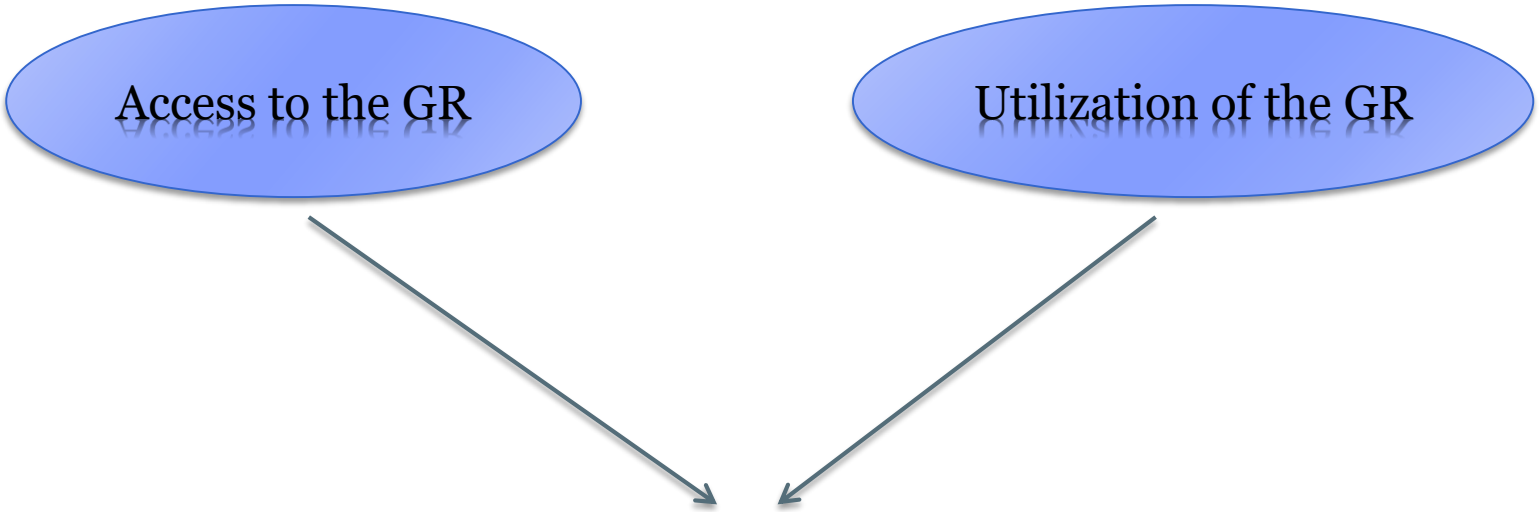
*a. has **ratified** the Nagoya Protocol*

*a. has **access regulation***



Scope of the EU Regulation (when the Regulation applies?)

Temporal Scope



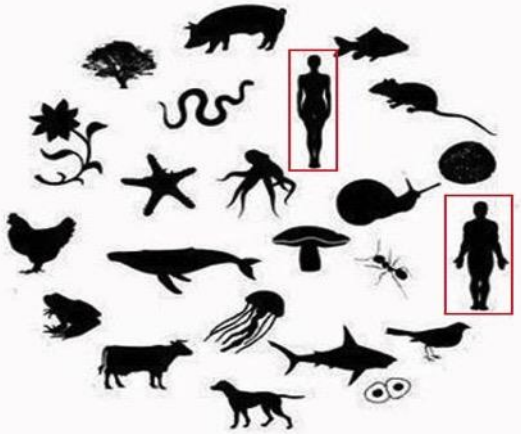
12 October 2014

=

entry into force of Nagoya Protocol in EU

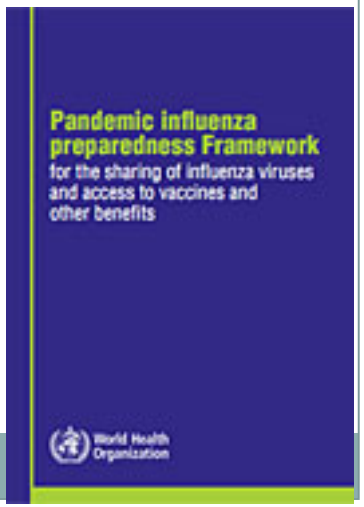
Scope of the EU Regulation (when the Regulation applies?)
Material Scope

No human genetic resources



No plant GRs for Food and Agriculture in Annex I of ITPGRFA /FAO

No GR covered by the WHO's Pandemic Influenza Preparedness Framework (PIP)



Scope of the EU Regulation (when the Regulation applies?)
Material Scope

*NO Genetic Resources as **traded commodities***
(agricultural, fishery, fotestry products)

BUT

Scope of the EU Regulation (when the Regulation applies?)

Personal Scope

All users utilizing the GR in the EU territory

INDIVIDUALS

RESEARCHERS

UNIVERSITIES

RESEARCH ORGANIZATIONS

SMEs

MULTINATIONAL COMPANIES

Regulation (EU) no 511/2014: basic rules

*a) Does **NOT** regulate access*

*b) Regulates the **compliance pillar** of the NP*

*c) Introduces the due diligence obligation - "**due diligence**"*

d) Attention to: a) plant GRs for Food and Agriculture (PGRFA) not in Annex 1 of FAO Treaty (ITPGRFA); b) GRs likely to be the causing pathogen of public health

*e) Sets a **Register of Collections** in the Union*

*f) Establishes a mechanism for the recognition of **best practice***

*g) Establishes a mechanism for the **monitoring of user compliance** in the Union **(checkpoints)***

*h) foresees a system of **checks***

Does not regulate access to GRs

Access = **exclusive competence of MSs**

States exercise sovereign rights over GRs:

- ✓ Art. 15 CBD
- ✓ Art. 6 NP
- ✓ Art. 2 REG.

User compliance = **concurrent competence EU and MSs**

- ✓ Environment (art. 2, lett e – TFUE)
- ✓ Internal market = need for harmonization (art. 2, a) – TFUE)

Due diligence obligation (art. 4 Reg. EU 511/2014)

User of GRs in EU
Seeks, keeps and transfers to subsequent users

Internationally recognised certificate of compliance (IRCC)

If IRCC is not available

Inf. on:

- ✓ Date and place of access;
- ✓ Description of GR;
- ✓ source;
- ✓ Presence or absence of rights and obligations on ABS;
- ✓ Access permit;
- ✓ MAT

Due diligence (art. 4 Reg. 511/2014)

If information is not sufficient or the legality of access is uncertain, the user has:

- Obtain the access permit and MAT

or

- Discontinue use

Monitoring of user compliance (art. 7 Reg. 511/2014)

The user has to DECLARE the due diligence
(and provide further info upon request of the NCA)

Research stage
When the research project on GRs receives an external funding (public or private)

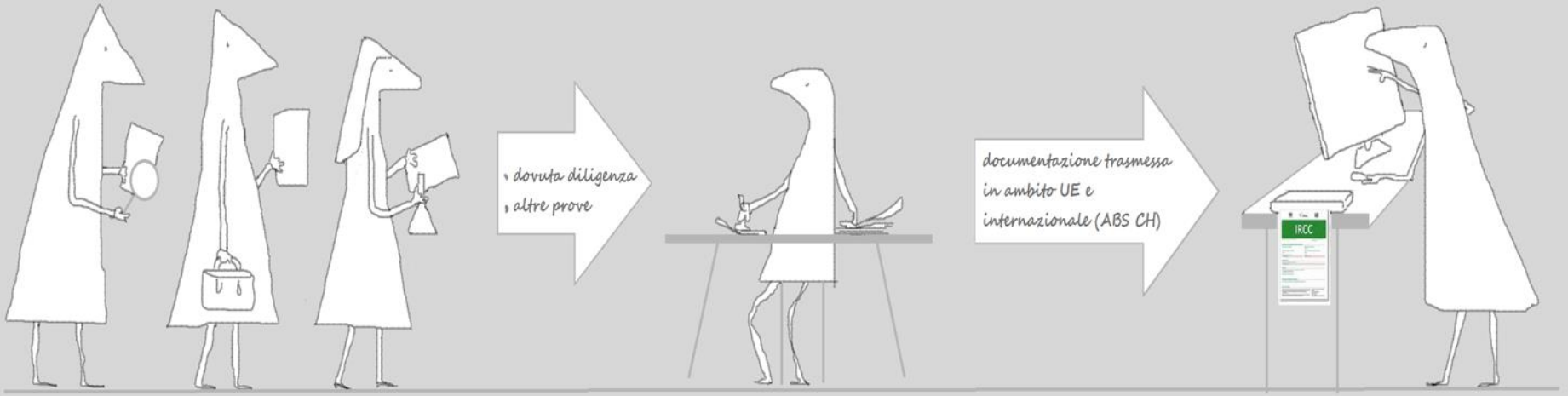
Final development of a product
When a product has been developed via the utilization of GRs

monitoraggio della conformità dell'utilizzatore (art.7 del regolamento UE 511/2014)

L'utilizzatore UE deve dichiarare la dovuta diligenza
(e fornire altre prove su richiesta del ANC)

nel momento in cui riceve un finanziamento alla ricerca che implica utilizzo di RG e/o TK

nella fase di sviluppo finale del prodotto realizzato mediante utilizzo di RG e/o TK



Research funding

- ✓ Research projects involving utilization of GRs
- ✓ Public and private funding (both in the scope of Reg)

- ✓ When is the declaration due?

- after the first instalment of funding is received
- all genetic resources have been utilized
- no later at time of final report or end of the project

Final development of a product

a) Market approval or authorization is requested for a product

a) Notification required prior to placing for the first time a product on Union market

a) Placing for the first time the product on EU market (no authorization or notification is requierd)

a) The result of utilization is sold or transfered to natural or legal person in the EU (for a), b) and c) purposes)

a) The result of utilization is sold or transfered to natural or legal person outside EU

Particular cases

- Utilization of **PGRFA not in annex I** of the ITPGRFA (FAO Treaty) = no due diligence required if the provider country of PGRFA has decided to use the Standard Material Transfer Agreement (SMTA) for their exchange.

- Utilization of genetic resources determined to be (or likely to be) the **causing pathogen** of present or imminent public health emergency of international concern = extended deadline for due diligence obligation.

EU Register of Collections (art. 5 of EU Reg)

- ✓ **Applies standard procedures for the exchange of GR samples in line with CBD;**
- ✓ **Transfers to third parties only documented GR samples**
- ✓ **Holds a register of the GR samples exchanged**
- ✓ **Uses unique indicators**
- ✓ **Uses traceability and monitoring tools for the exchange of GR samples.**

Benefits:

- Users of GRs from the registered collection do not have to **seek** information on GRs

- The holder of the collection has to provide GRs together with related information (the duty is on him not on the user)

- Simplified access procedures

Establishes a mechanism for the recognition of best practice

Association of users or interested parties

Submit an application to the EU Commission

Application verified by NCAs of all MSs (two months)

Positive evaluation= recognition of best practice

System of checks (MSs)

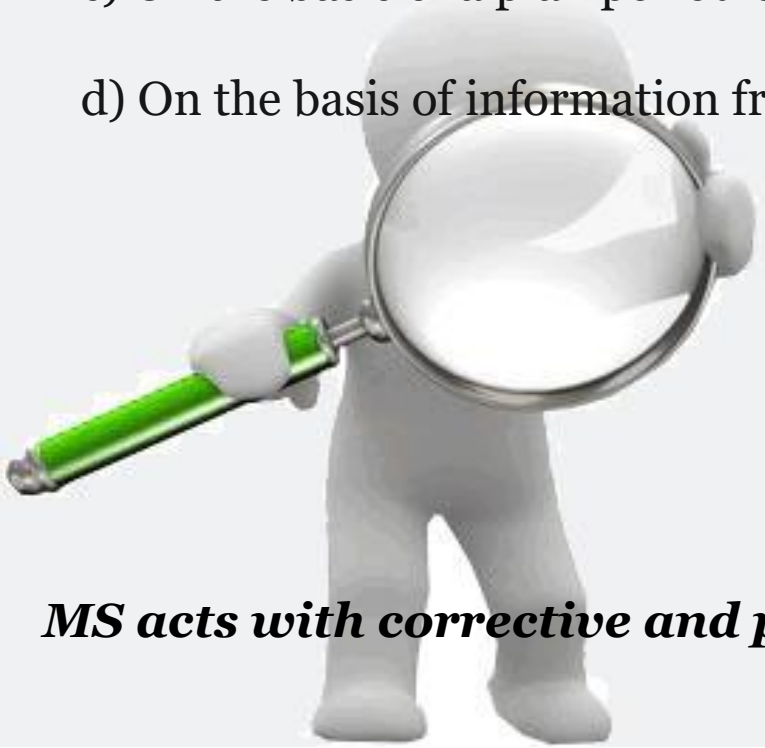
Checks are undertaken:

a) By the NCA of the MS on users

b) To assess the compliance to obligations under art. 4 and 7 ofReg;

c) On the basis of a plan periodically reviewed/risk based approach

d) On the basis of information from provider Countries or third parties



MS acts with corrective and provisional immediate measures

Penalties

Penalties must be:

a) Effective, dissuasive and proportionate

b) To be applied when art. 4 and 7 of Reg are breached

a) To be determined by MSs (upon MS competence)

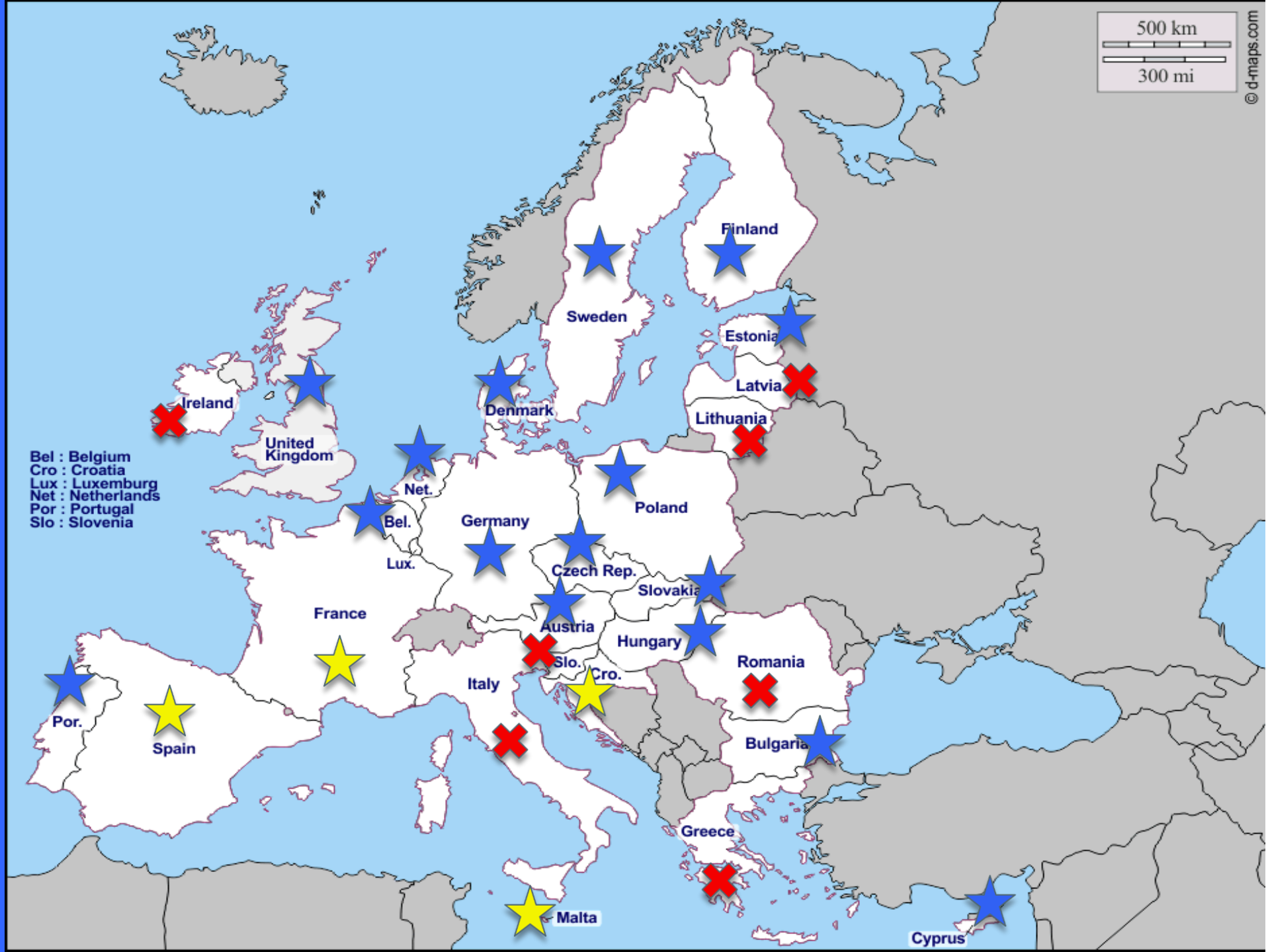
FURTHER DOCUMENTATION EU

Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015

art. 5 = EU register of collections
art. 7 = monitoring
art. 8 = best practice

Guidance document on the scope of application and core obligations of Regulation (EU) 511/2014

Sectoral horizontal Guidance


500 km
300 mi
© d-maps.com
Bel : Belgium
Cro : Croatia
Lux : Luxemburg
Net : Netherlands
Por : Portugal
Slo : Slovenia
Finland
Sweden
Estonia
Latvia
Lithuania
Ireland
United Kingdom
Denmark
Net.
Bel.
Lux.
Germany
Poland
Czech Rep.
Slovakia
France
Austria
Hungary
Slo.
Cro.
Romania
Italy
Por.
Spain
Bulgaria
Greece
Malta
Cyprus

Implementation of the EU Regulation no. 511/2014 state of play

- The majority of the EU Member States have ratified the Protocol: no access regulations but only **"Implementing Acts"** transposing nationally the EU Regulation.
- The implementation of the EU Regulation is still at early stage
- Only 3DDD submitted (in DE) and no DDD submitted to the ABS CH
- 16 MSs have set administrative penalties (up to 2.000.000 euros) and 9 MSs also criminal penalties (imprisonment). But no penalties imposed yet.
- Only one collection succesfully registered (in DE).
- Ongoing work on issues related to the EU Reg. scope (what in and what out)
- Lack of human and financial resources to set up a proper structure (few ABS staff or existing personnel employed on ABS in addition to their ordinary tasks)


Thank you for the attention
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