



Implementation of the Nagoya Protocol in the EU

ECPGR Steering
Committee Meeting,
1 June 2016



Overview of the presentation

- *Background- Nagoya Protocol*
- *EU legislation*
 - **EU ABS Regulation** (Council & Parliament):
 - Scope of the EU ABS Regulation
 - Main provisions
 - Tools facilitating compliance
 - **Implementing Regulation** (Commission)
 - **Complementary measures**
 - Consultation forum
 - Guidance documents



Oct. 2010

**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



Ratification by Member States

- EU and 3 Member States ratified the Protocol in 2014: EU + DK, ES, HU
- 2015: HR and SK
- 2016: UK, DE and CZ
- More to follow

Pillars of the Nagoya Protocol - the **ABC** of ABS -

"**A**ccess"

"**B**enefit
sharing"

"**C**ompliance"



**Not implemented
at EU level**

Each State/Party to decide if they
establish access rules, incl. EU Member
States

**Subject to
contractual
agreement**

**See EU ABS
Regulation**

Key: Due diligence obligation for all
users

June 2014

5.2014

EN

Official Journal of the European Union

L 1

REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 16 April 2014

on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and
of Benefits Arising from their Utilization in the Union

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 192(1) thereof,

Having regard to the proposal from the European Commission,



EU ABS Regulation – scope

- **Geographic**
- **Temporal**
- **Material**



EU ABS Regulation – Geographic scope

- *GR/TKaGR from Parties to the Protocol*
 - **Currently 75 Parties, incl. 8 EU MS** (more to follow)
 - **Non-Party access legislation to be respected** (but not covered by EU Regulation)
- *With access legislation in place – info from:*
 - **ABS Clearing-House** <https://absch.cbd.int/>
- *Applicable to GR within national jurisdictions:*
 - **Areas beyond national jurisdiction (in particular high seas) out of scope**
 - **Areas covered by Antarctic Treaty System also out of scope**



EU ABS Regulation – Temporal scope

- *GR/TK accessed after NP entry into force*
 - **No retro-active effect of EU legislation**
 - **Time of access (not utilisation) determines applicability**
 - **Provider-country legislation may diverge**
(but does not affect temporal scope of EU Regulation)



EU ABS Regulation – Material scope

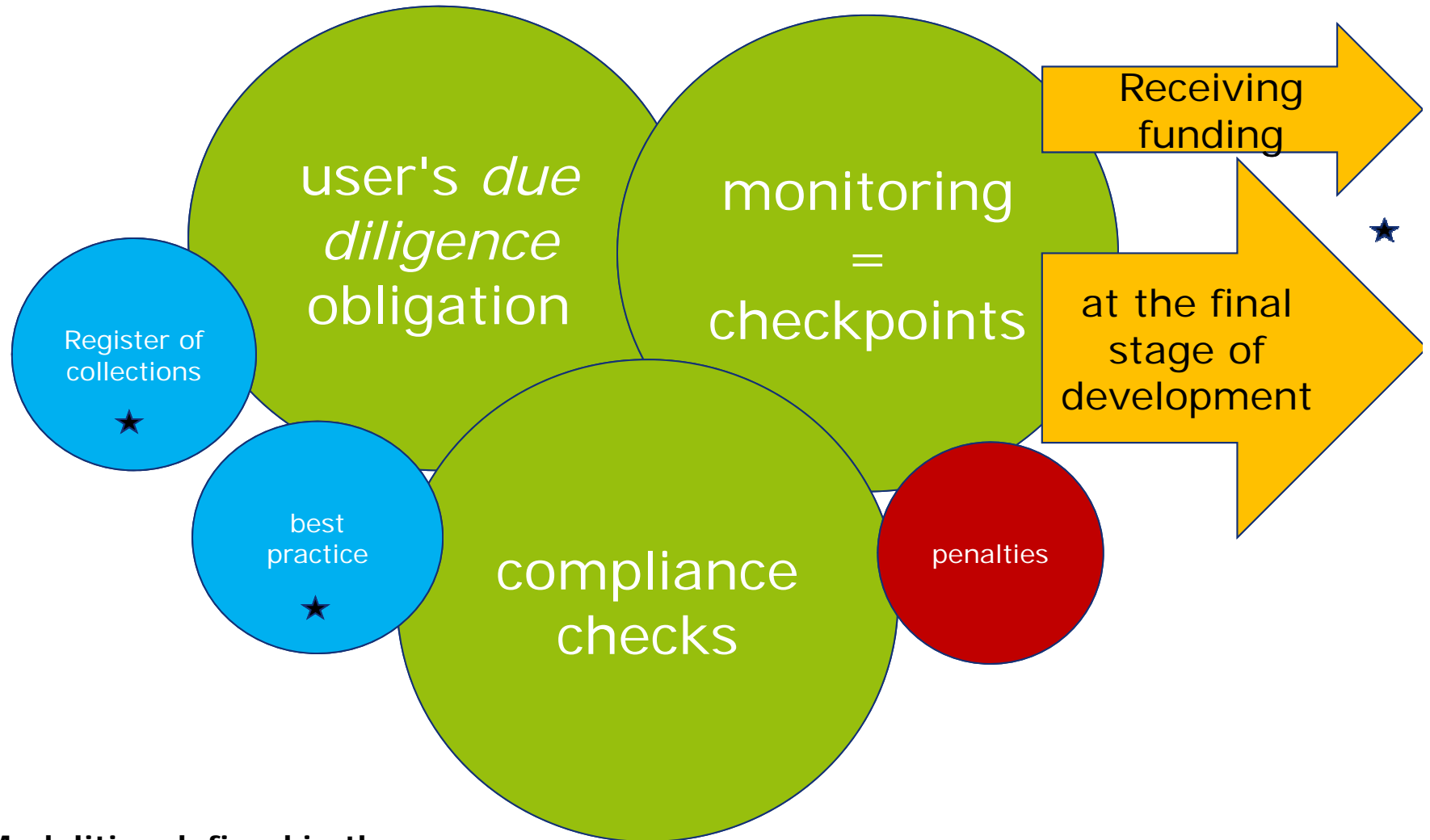
- *Utilisation = research and development*
 - No legal definition of R&D or lists of activities
 - Users best placed to assess applicability of the activities undertaken while guidance provided
- *Genetic resources*
 - Excluding GR governed by specialised international instruments on ABS (ITPGRFA, WHO PIP)
- *Traditional knowledge associated with GR*
 - Must be covered by relevant MAT



EU ABS Regulation – User obligations

- Exercise due diligence regarding legality of access (and sharing of benefits)
 - Recognition of users' ability to "do the right thing"
- „Seek, keep and transfer to subsequent users“:
 - Information on
GR/TKaGR, date/place of access, source, any rights & obligations, PIC & MAT
 - Internationally recognised certificate of compliance, where available
- **Obligation of conduct? Obligation of result?**
→ **Without sufficient info: discontinue utilisation**

Key provisions of the EU ABS regulation



★ Modalities defined in the implementing regulation



Due diligence – PGRFA covered by sMTAs (ITPGRFA)

PGRFA coming from NP Party which determined that non-Annex I material under its management and control, and in public domain is to be subject to sMTAs for the purposes of ITPGRFA

- **Users acquiring such PGRFA considered to have exercised the due diligence**
- **No need for due diligence declarations**



EU ABS Regulation – tools facilitating compliance

- *Voluntary instruments*
 - **Register of collections *)**
 - User obtaining GR from registered collection considered to have exercised due diligence re. seeking of information
 - MS: granting recognition; performing risk-based checks
 - EC: establishing and maintaining the register

***) elaborated in Implementing Regulation**



EU ABS Regulation – tools facilitating compliance

- *Voluntary instruments*
 - **Recognition of best practices *)**
 - MS authorities to take into consideration implementation of best practices while performing compliance checks
 - EC: granting (and withdrawing) the recognition
 - MS: views on the application

***) elaborated in Implementing Regulation**



Implementing Regulation – 1st check-point

- *Due diligence declaration at the stage of research funding*
 - MS, EC to request the declaration from all recipients of funding (public or private)
 - If mixed sources or multiple recipients of funding, declaration required only once
 - Declaration to be submitted to MS competent authorities (where user established)
 - Research funding defined as grant
 - Role of project co-ordinator



Implementing Regulation – 2nd check-point

- *Due diligence declaration at the stage of final development of a product – i.e.:*
 - a) When market approval sought**
 - b) When notification required**
 - c) When placing product on a market (developed via utilisation of GR)**
 - d) When result of utilisation sold or transferred for the purpose of (a), (b) or (c)**
 - e) When utilisation has ended in EU and its outcome sold or transferred outside of EU**



Complementary measures

– Consultation forum

- **Art. 15 ABS Regulation**
 - Balanced representation of MS and other interested parties (stakeholder representatives, NGOs) to discuss implementation issues
- **First meeting January 2016**
- **Next meeting – either autumn 2016 or early 2017**



Complementary measures

– Guidance documents

- Horizontal guidance on scope of the EU ABS Regulation
 - **Commission with MS expert support**
 - **Feedback from consultation forum considered**
 - **Final stage of preparation**
- Sector-specific (incl. plant breeding) guidance on utilisation
 - **External consultants under EC supervision and with stakeholder input & MS expert support**



MS level

- Designation of competent authorities
- Rules on penalties
- Risk-based plans on checks



Further information

- *CBD Nagoya website* <https://www.cbd.int/abs/default.shtml>
- *EC ABS website* http://ec.europa.eu/environment/nature/biodiversity/international/abs/index_en.htm
- *EC Policy Officers*
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 - matthias-leonhard.maier@ec.europa.eu