



**BiodivERsA COFUND
kick off meeting
Brussels,
04 April 2017**

The EU legal and policy framework for implementation of the Nagoya Protocol



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

Content

- *Nagoya Protocol*
- *EU ABS Regulation*
- *Commission Implementing Regulation*
 - **"Research" checkpoint**
 - **Final stage of development of a product**
- *Scope of measures*
- *Complementary measures*

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,

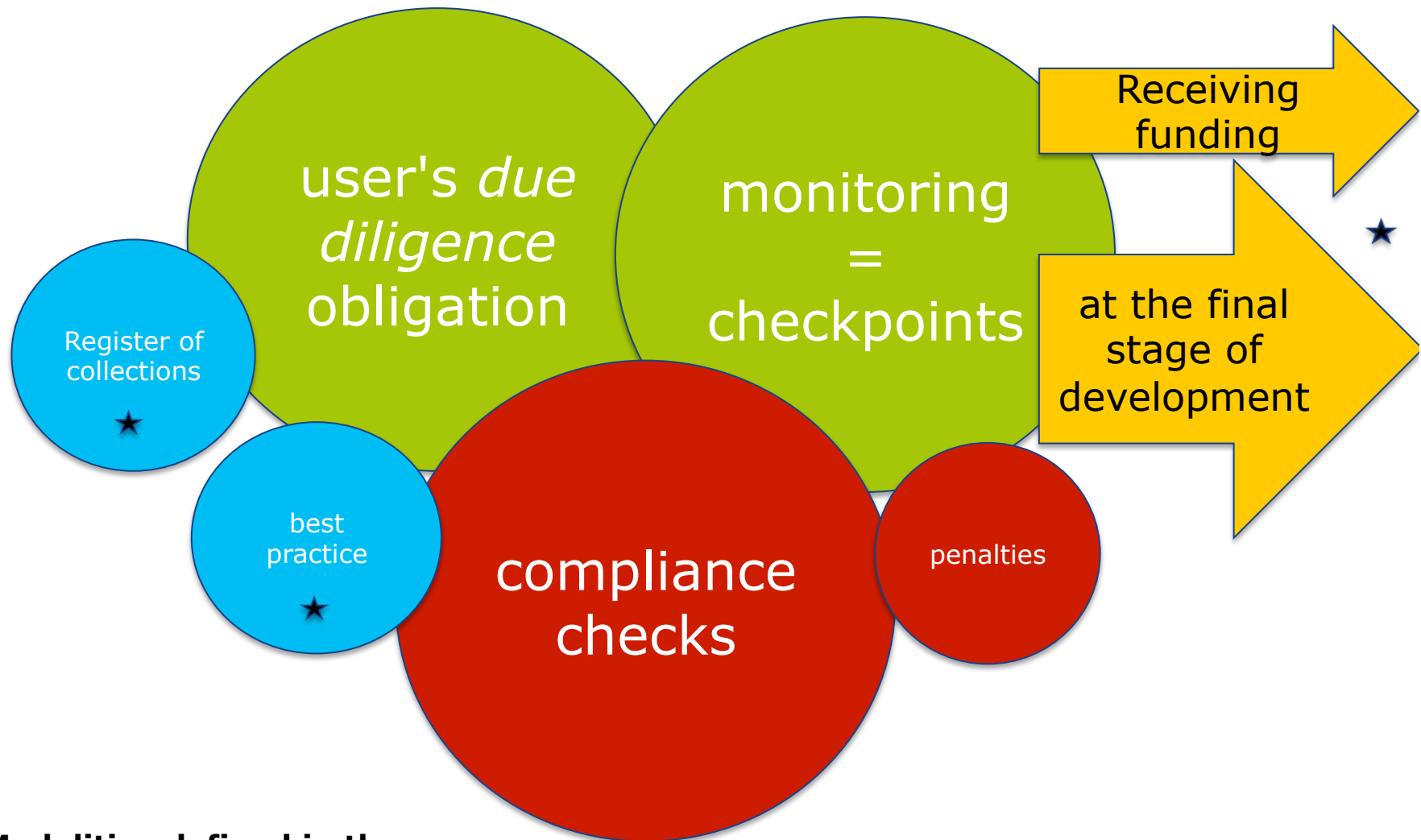
Having regard to the Treaty on the Functioning of the European Union, and in particular Article 192(1) thereof,

Having regard to the proposal from the European Commission,

EU ABS Regulation – User obligations

- *Exercise due diligence regarding legality of access (and re. sharing of benefits)*
 - **Recognition of users' ability to determine right course of action**
- *„Seek, keep and transfer to subsequent users“:*
 - **Internationally recognised certificate of compliance (IRCC), where available**
 - **Information on GR/TK, date/place of access, source, any rights & obligations, PIC & MAT**
 - **Without sufficient info, discontinue utilisation**

Key provisions of the EU ABS regulation



★ Modalities defined in the implementing regulation

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R1866&from=EN

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Nov. 2015

L 275/4 EN Official Journal of the European Union 20.10.2015

COMMISSION IMPLEMENTING REGULATION (EU) 2015/1866

laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union ⁽¹⁾, and in particular Article 5(5), Article 7(6) and Article 8(7) thereof,

FR 16:48 24/08/2016



Implementing Regulation – 1st checkpoint for monitoring compliance

- *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 (→ coordinator)**
 - **Declaration to be submitted to MS competent authorities (where user established)**



Implementing Regulation – 2nd checkpoint for monitoring compliance

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



Facilitating implementation and compliance – EU-wide IT tool

- *For submission of due diligence declarations*
 - **Users to checkpoints (competent authorities)**
 - **Authorities to ABS Clearing House (relevant parts, after verification)**
- *Pilot testing phase started last autumn*
- *Confidentiality*



EU ABS Regulation

– Member State obligations

- **Designation of competent authorities**
- **Checks on user compliance**
 - Carried out by Member State authorities
 - Risk-based approach
 - Taking into account application of best practice
- **Penalties for infringements**
 - Member State rules (will) apply
- **Relevant measures adopted in many MS, and still pending in others**
 - Commission following up



EU ABS Regulation – Geographic scope

- *GR/TK from Parties to the Protocol*
 - **Non-Party access legislation also to be respected**
(but not covered by EU Regulation)
- *With (relevant) access legislation in place – info:*
 - **ABS Clearing-House** <https://absch.cbd.int/>
 - **Provider-country's national focal point**
- *Areas beyond national jurisdiction not covered*



EU ABS Regulation – Temporal scope

- *GR/TK accessed as of 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

- *Genetic resources*
 - **Definition as in CBD**
 - **GR governed by specialised international instruments on ABS excluded from scope**
- *Utilisation = research and development*
 - **No legal definition of R&D or lists of activities**
 - **Broad interpretation prevailing (no "salami slicing")**
 - **Further work needed on exact boundaries of the concept**



Complementary measures

– Guidance documents

- *Horizontal guidance on scope of the Basic Regulation (27 Aug. 2016 – [Official Journal](#))*
 - **Commission with MS expert support, stakeholder feedback**
- *Sector-specific guidance on utilisation*
 - **External consultants under EC supervision**
 - **With stakeholder input & MS expert support (drafting groups, sectorial workshops)**
 - **Dedicated group on research and other "upstream" utilisation (to be launched)**



Further information

- *Directorate-General for Environment, ABS website* http://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation_en.htm
- *DG ENV Policy Officers (Unit F3 – 'Multilateral Environmental Cooperation')*
 - alicja.kozlowska@ec.europa.eu
 - matthias-leonhard.maier@ec.europa.eu
- *CBD Nagoya Protocol website* <https://www.cbd.int/abs/default.shtml>