NHM ABS Training: 2. The EU Regulation on Access and Benefit-Sharing

Chris Lyal

NATURAL HISTORY MUSEUM

EU and UK legislation on ABS

- EU Regulations
  - ABS Regulation (No. 511/2014) (12 Oct 2014)
  - Commission Implementing regulation (No. 2015/1866) (9 Nov 2015)
    - Covers Articles 5, 7 and 8 (register of collections, monitoring user compliance and best practices) which did not apply before then
  - applicable to all Member States:
- UK:
  - The Nagoya Protocol (Compliance) Regulations 2015 Statutory Instrument 2015 No. 821 (Mar 2015).

Pillars of the Nagoya Protocol
- the ABC of ABS -

"Access"	"Benefit sharing"	"Compliance"
Not implemented at EU level	Subject to contractual agreement	EU ABS Regulation
Each State/Party to decide if they establish access rules, incl. EU Member States		Key: Due diligence obligation for all users

EU Regulation 511/2014

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

of 16 April 2014

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

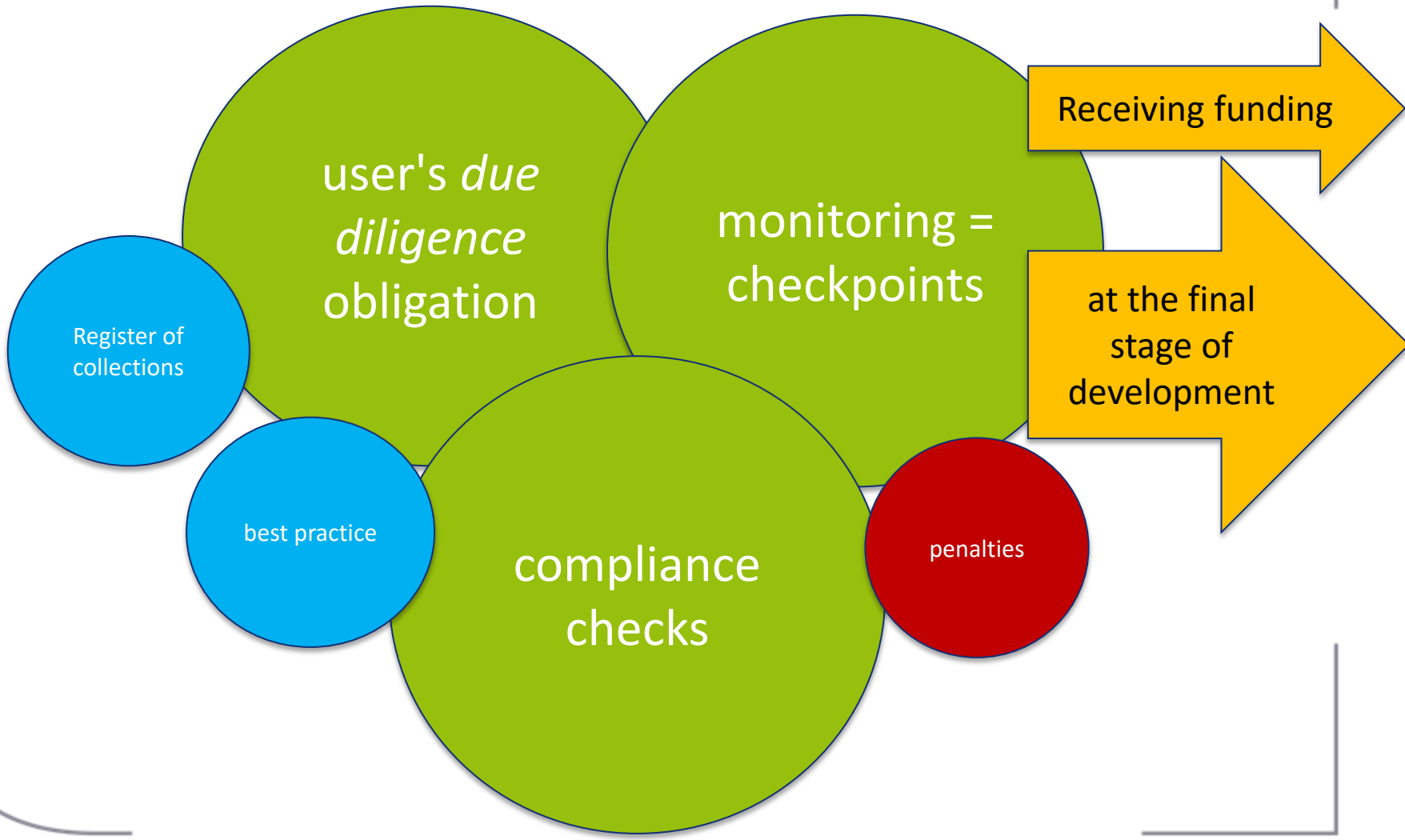
(Text with EEA relevance)

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,

Key provisions of the Regulation



Material Scope

The EU ABS Regulation:

- concerns 'utilisation' of genetic resources
  - not commodity trade

- applies to genetic resources (GR) (and associated traditional knowledge) (aTK)
  - Human genetic resources out of scope
  - does not cover GR / aTK that are governed by specialised international instruments
    - e.g. ITPGRFA, WHO PIP Framework

Temporal Scope

The EU ABS Regulation:

- applies to GR / aTK accessed after entry into force of the Nagoya Protocol for the European Union (12 Oct. 2014)
- Has no retro-active effect
- Time of access (not utilisation) determines applicability

Provider-country legislation may diverge

  - (but does not affect temporal scope of EU Regulation)

Geographical Scope

The EU ABS Regulation applies to:

- GR/aTKa from Parties to the Protocol
  - With access legislation in place
- Non-Party access legislation to be followed (but not covered by EU Regulation)

Does not apply to

- Genetic resources obtained from areas beyond national jurisdiction (ABNJ)
  - e.g. high seas (see UNCLOS) or areas covered by the Antarctic Treaty

The core of the EU ABS regulation: Due Diligence

The EU ABS Regulation requires users:

- to exercise and demonstrate *Due Diligence* regarding legality of access (and sharing of benefits)
  - Recognition of users' ability to “do the right thing”
  - Decision made based on reasonable analysis and assessment of facts

Due Diligence

EU ABS Regulation – establishing applicability

- Applying due diligence:
  - Seek access legislation: Parties are obliged to put this on the ABS Clearing House
  - Contact with National Focal Point
  - Local co-operation? Official journal?
- For users to assess:
  - If due diligence applied in the process – necessary steps undertaken to establish applicability
  - If GR/ aTK turns out to be in scope – Article 4(5) applies – cease utilization and seek PIC

Due Diligence

Users must:

- “Seek, keep and transfer to subsequent users”
  - Internationally Recognised Certificate of Compliance, where available
  - Information listed in Article 4(3) of the Regulation:
    - Information on GR/aTK,
    - date/place of access,
    - source,
    - PIC & MAT,
    - any rights & obligations

Due Diligence

Plant Genetic Resources for Agriculture (PGRFA) covered by Standard sMTAs

- Users acquiring 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;
  - are considered to have exercised the due diligence
  - are not required to declare due diligence under Article 7 of the EU Regulation

Monitoring: Declarations of Due Diligence

Users are obliged to provide information on:

- When? Where? What?
- From whom and to whom?
- Access permit (PIC)?
- Mutually agreed terms?
  - incl. benefit-sharing
- Presence or absence of rights and obligations?

Monitoring

Two points in value chain requiring due diligence declarations (“Checkpoints”)

- Funding (public and private) of research
- Final stage of product development

- Exchange of information through ABS Clearing House (Check-point Communiqué)

Monitoring

Due diligence declaration at the stage of research funding

- MS, EC to *request* the declaration from all recipients of funding (public or private)
- Research funding defined as grant

- *Multiple recipients of funding*
  - Declaration may be done only once
  - Project co-ordinator reports on all utilisation of project, even if taking place in more than one MS

Monitoring

Due diligence declaration at the stage of research funding

- Declarations to be made to the competent authorities of MS
- Declarations to be made when 1st payment received and genetic resources obtained, but not later than the final report
- MS may define further timeline

Monitoring

Due diligence declaration at the point of commercialisation

- Events triggering the obligation to declare

  a) When market approval is sought

  b) When notification is 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 ended in EU and its outcome sold or transferred outside of EU

Monitoring

Due diligence declaration at the point of commercialisation

- Declarations to be made to the competent authorities of MS
- Declarations to be made before, i.e. prior to the events listed
- Submission of due diligence declaration is not directly linked with authorisation procedure of products

Tools to facilitate compliance

Best practices

- "Combination of procedures, tools and mechanisms" enabling users to comply with due diligence obligations"
- Basic Regulation: standards to be met
- Implementing Regulation specifies procedures:
  - Application process
  - Recognition of best practices by EC
  - Dealing with deficiencies, withdrawing recognition
- Implementation of recognised best practice to be taken into account in MS checks on users

Tools to facilitate compliance

Registered Collections

- User obtaining GR from registered collection considered to have exercised due diligence re seeking of information
- Process:
  - EU Regulation gives standards to be met by collections
  - Implementing Regulation gives information to be provided by applicants, verification by MS authorities
  - MS can grant / withdraw recognition, perform risk-based checks
  - EC establishes and maintains register

Complementary Measures

Guidance documents

- Horizontal guidance on scope of the EU Regulation
  - Commission with MS expert support
  - Work in progress
- Sector-specific guidance on utilisation
  - External consultants under EC guidance and with stakeholder input & MS expert support
  - Most of the work to be done in 2016

Web Resources

- For Regulation texts see:
  http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0511&from=EN
  http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:JOL_2015_275_R_0003&from=FR

  as well as
  https://absch.cbd.int/ - the ABS Clearing-House

Resources

- Links to documents and sites we refer to are being posted on a scratchpad

  http://nagoyaprotocol.myspecies.info/

- Legislation of all countries and EU online at ABS Clearing-House

  https://absch.cbd.int/

Acknowledgements

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