The EU framework for implementation of the Nagoya Protocol

European Bio-tech week

Mechelen, 12 October 2015

Environment

Overview of the presentation

- *Background*
- *EU legislation*
  - **EU ABS Regulation** (Council & Parliament):
    - Main provisions
    - Scope of the EU ABS Regulation
  - **Implementing Regulation** (Commission)
- *Tools to facilitate compliance:*
    - Registered collections
    - Best practices
- *Complementary measures*
    - Guidance documents
    - Consultation forum

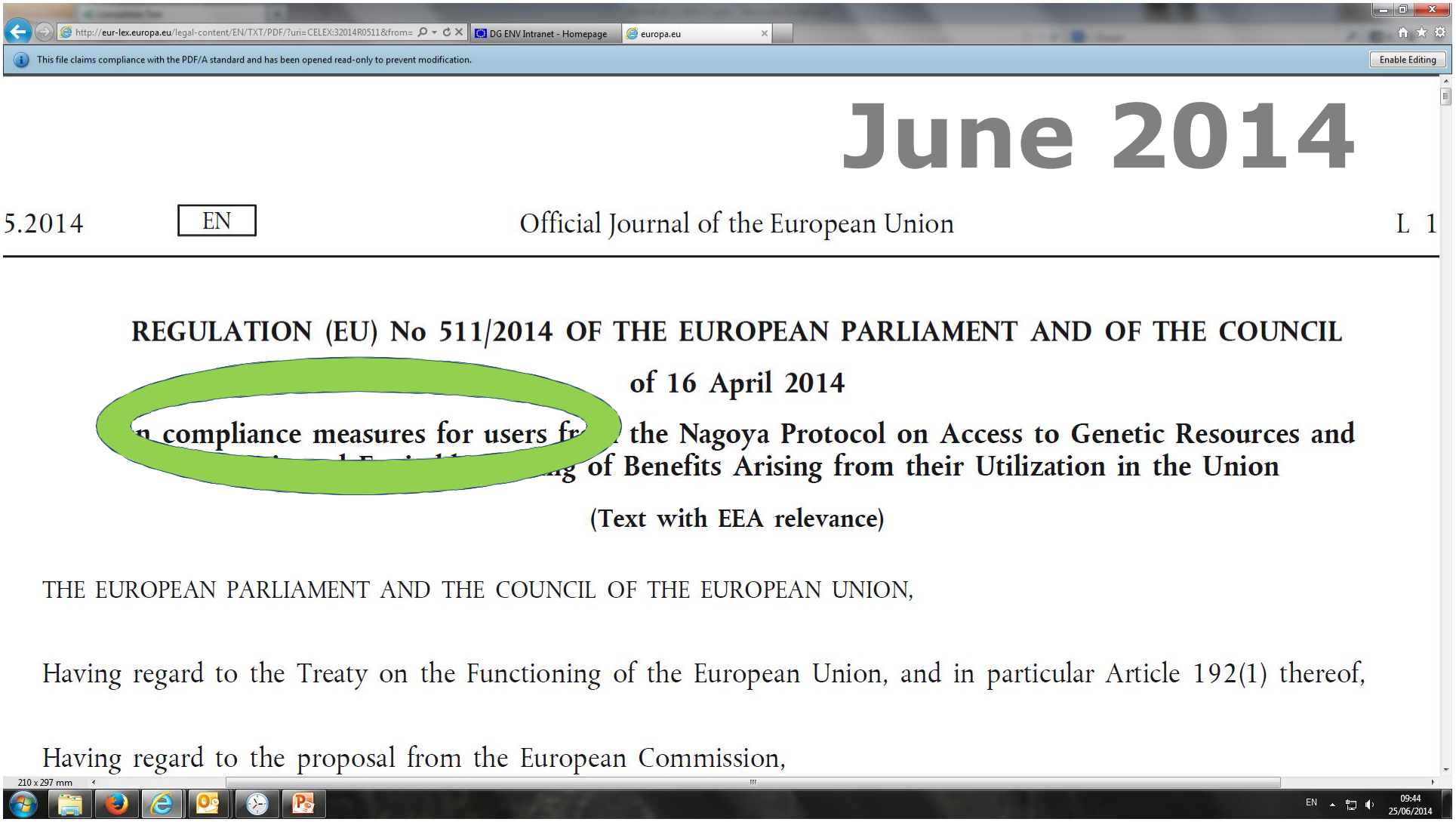
Oct. 2010

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

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

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

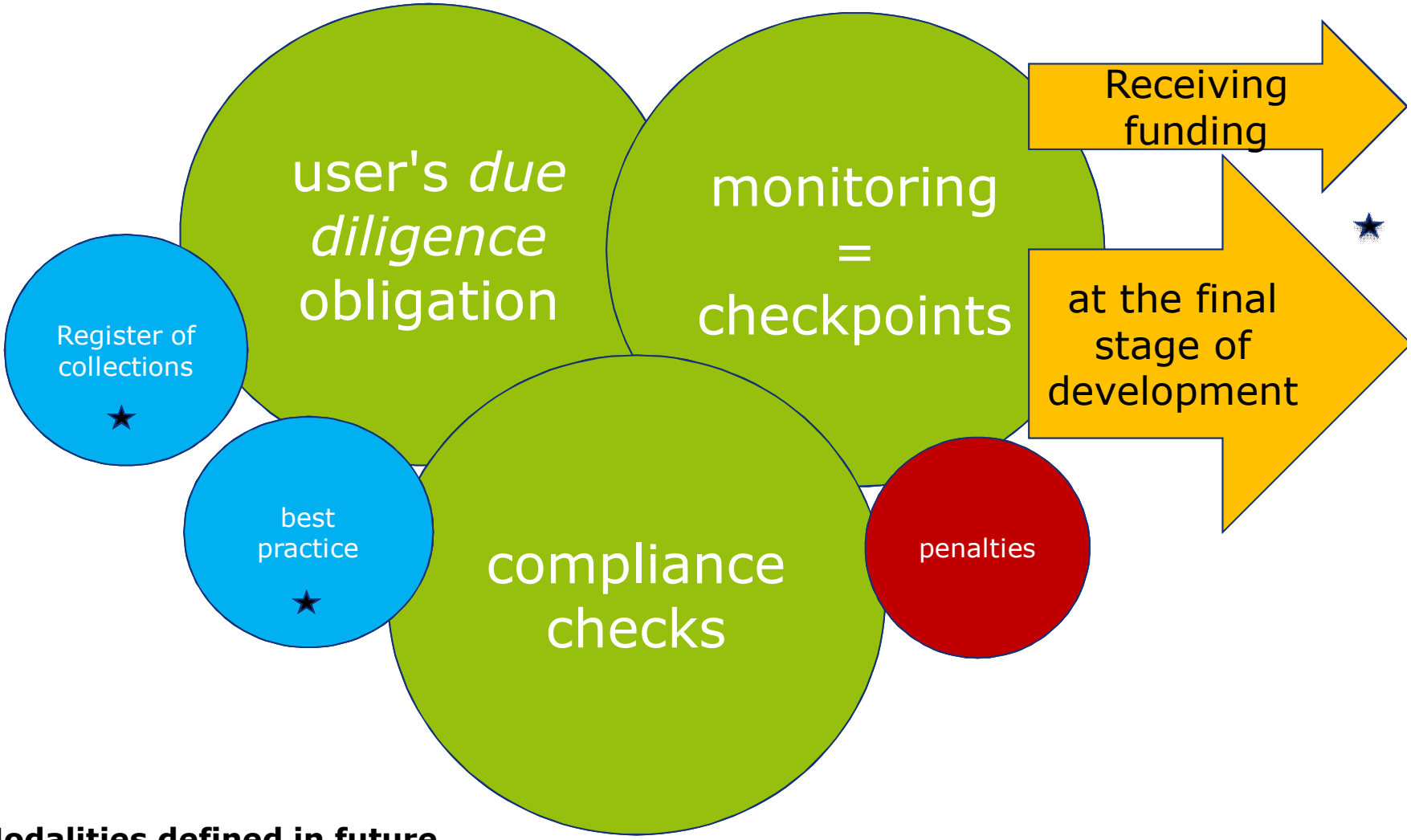

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32014R0511&from=
DG ENV Intranet - Homepage
europa.eu
This file claims compliance with the PDF/A standard and has been opened read-only to prevent modification.
Enable Editing
June 2014
5.2014 EN Official Journal of the European Union L 1
REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 16 April 2014
n compliance measures for users fr the Nagoya Protocol on Access to Genetic Resources and
g 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,
210 x 297 mm
EN
09:44
25/06/2014

EU ABS Regulation
(No. 511/2014 – „Basic Regulation“)

Å *Applicability*

- **Directly applicable in all Member States**
- **With NP entry into force** (12 October 2014)
- **Art. 4, 7, 9 with 1 year‘s delay**
  (→ Implementing Regulation)

Key provisions of the EU ABS regulation



★ **Modalities defined in future implementing regulation**

EU ABS Regulation – User obligations

Å *Exercise due diligence regarding legality of access (and sharing of benefits)*

- **Recognition of users' ability to "do the right thing"**
- **Obligation of conduct? Obligation of result?**
  →Without sufficient info: discontinue utilisation

Å *„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**

Scope of EU ABS Regulation

Does the activity fall under the scope of the ABS regulation?

- On substance, incl. specialised instruments?
- Temporally?
- Geographically?

IF YES

European Commission

EU ABS Regulation – Geographic scope

Å *GR/TKaGR from Parties to the Protocol*

- **Currently 66 Parties, incl. 4 EU MS** (more to follow)
- **Non-Party access legislation to be respected** (but not covered by EU Regulation)

Å *With access legislation in place – info from:*

- **ABS Clearing-House** https://absch.cbd.int/
- **Provider country's National Focal Point**
- **Users' partners in third countries**

Å *Areas beyond national jurisdiction out of scope*

EU ABS Regulation – Temporal scope

Å *GR/TK accessed <u>after NP</u> 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 to assess applicability of the activities undertaken**
- *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**

Commission Implementing Regulation – Process for adoption

- *Implementing powers from Basic Regulation (Art. 5.5, 7.6, 8.7)*
- *Commission proposal, discussed with MS experts in ABS Committee meetings (Feb.–July 2015)*
- *Committee opinion on final draft (September)*
  - **Draft published on Comitology Register**
- *Positive vote obtained: Commission adoption (≥ 12 October)*
  - **Official Journal**

Implementing Regulation – 1st check-point for monitoring compliance

Å *Due diligence declaration at the stage of research funding*

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

Implementing Regulation – 2nd check-point for monitoring compliance

Å *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 ended in EU and its outcome sold or transferred outside of EU**

Tools to facilitate compliance – Registered collections

- *User obtaining GR from registered collection considered to have exercised due diligence re. seeking of information*
- *Basic Regulation:*
  - **standards to be met by collections**
- *Implementing Regulation:*
  - **info to be provided by applicants, verification by MS authorities**
- *MS: granting/withdrawing recognition, performing risk-based checks*
- *EC: establishing, maintaining register*

Tools to facilitate compliance

– Best practices

Å *"Combination of procedures, tools and mechanisms" enabling users to comply with due diligence obligations"*

Å *Basic Reg.: standards to be met*

Å *Implementing Regulation specifies procedures:*

- **Application process**
- **Recognition of best practices by EC**
- **Dealing with deficiencies, withdrawing recognition**

Å *Implementation of recognised best practice to be taken into account in MS checks on users*

Complementary measures – Guidance documents

Å *Horizontal guidance on scope of the EU Regulation*

- **Commission with MS expert support**
- **Work in progress**

Å *Sector-specific (incl. biotechnology) guidance on utilisation*

- **External consultants under EC guidance and with stakeholder input & MS expert support**
- **Most of the work to be done in 2016**

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 November (or December) 2015, after Basic Regulation has become fully applicable*

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*
  - alicja.kozlowska@ec.europa.eu
  - matthias-leonhard.maier@ec.europa.eu