



Implementation of the Nagoya Protocol in the EU: the EU ABS Regulation

EU-Brazil dialogue, Brasilia

10 December 2019

Environment



Content

- **Nagoya Protocol and the international context**
- **Scope of the EU ABS Regulation**
- **Main provisions of the EU ABS Regulation**
 - Due diligence
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 - Checks
- **Challenges of the implementation**

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

"**A**ccess"

"**B**enefit
sharing"

"**C**ompliance"



**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



Implementation of the Protocol in the EU

- **Access:**

- Left to individual Member States; no EU legislation
- Some countries have decided to develop access legislation
 - » Spain - France – Croatia – Malta – Bulgaria

- **Benefit-sharing**

- Contractual arrangement between user and provider

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Implementation of the Protocol in the EU

- **Compliance**

- EU ABS Regulation: Regulation (EU) no. 511/2014
- Commission Implementing Regulation: 2015/1866

- Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014: Commission Notice (2016/C 313/01)



When does the EU ABS Reg. apply? To whom and what does it mean?

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EU ABS Regulation – Geographic scope

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

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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)

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EU ABS Regulation – Material scope

- **Genetic resources**
 - Definition as in CBD (actual and potential value)
 - Genetic resources governed by specialised ABS international instruments not covered
- **Utilisation - research and development**
 - No legal definition of R&D or lists of activities
 - Broad interpretation prevailing
 - Main outline provided in guidance document
 - ongoing work on more precise boundaries of the concept

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5.2014 EN Official Journal of the European Union L 1

June 2014

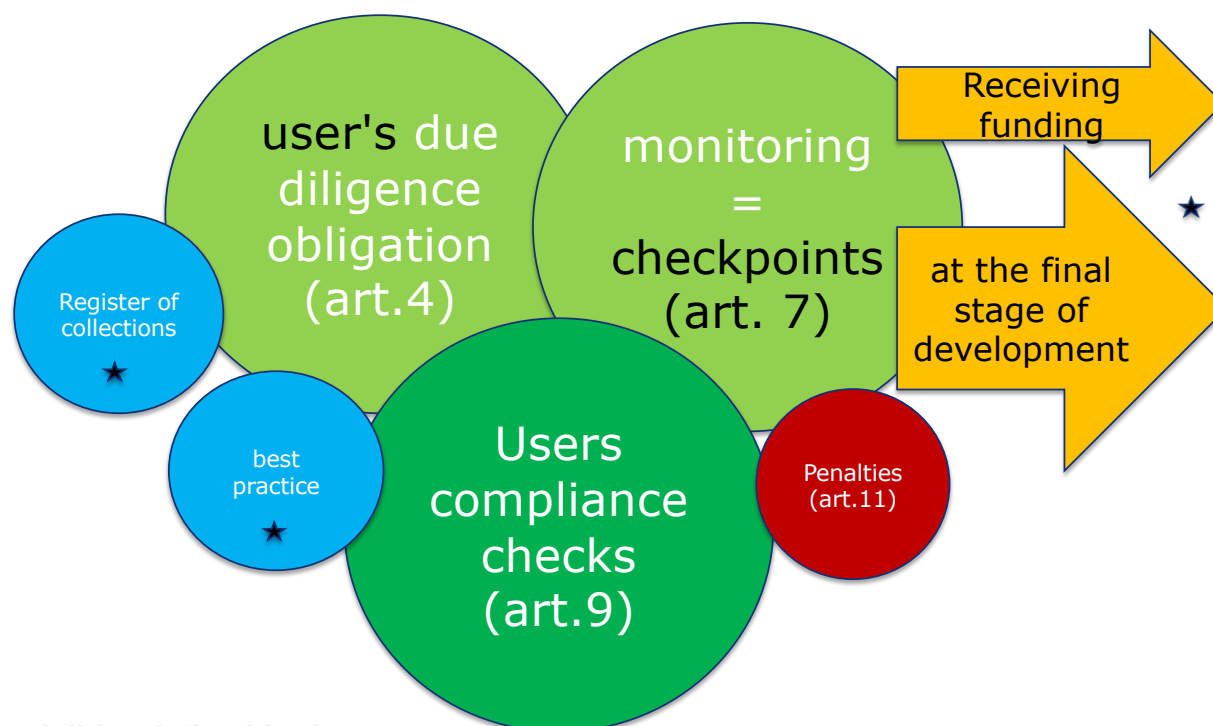
REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 16 April 2014
on compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and
the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union
(Text with EEA relevance)

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 EU ABS regulation



★ Modalities defined in the implementing regulation



EU ABS Regulation: **User obligations (art.4)**

Users shall:

- **Exercise due diligence regarding legality of access (and sharing of benefits)**
- **Seek, keep and transfer to subsequent users:**
 - Internationally recognised certificate of compliance, where available
 - If IRCC not available, information on GR/TKaGR, date/place of access, source, any rights & obligations, PIC & MAT
- **Insufficient info – discontinue utilisation**



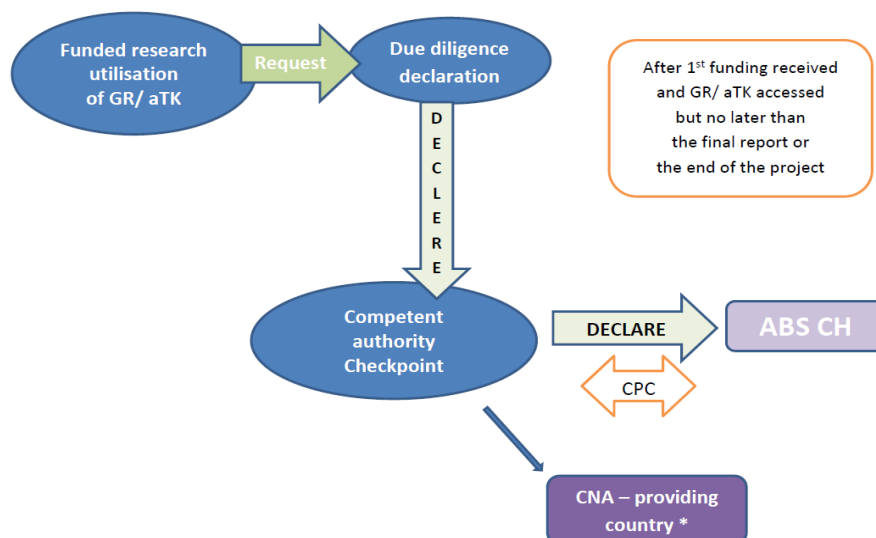
Implementing Regulation – 1st check-point for monitoring compliance (Art. 5)

- **Due diligence declaration at the stage of research funding where research involves utilisation of GR and TKaGR**
 - MS and EC are 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/coordinator established)
 - Time of submitting due diligence defined (at the stage of submitting final report at the latest)

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1st checkpoint



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DECLARE

https://webgate.europa.eu/declare

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Welcome to DECLARE

DECLARE is the entry point of the Environment Data Submission Portal, supporting collection, validation, analysis, and dissemination of the statistical information submitted per domain.

Please choose a policy domain to work on.

ALURES - Animals used for scientific purposes

Since 1986, the EU has had in place specific legislation covering the use of animals for scientific purposes. On 22 September 2010 the EU adopted Directive 2010/63/EU which updates and replaces the 1986 Directive 86/609/EEC on the protection of animals used for scientific purposes. The aim of the new Directive is to strengthen legislation, and improve the welfare of those animals still needed to be used, as well as to firmly anchor the principle of the Three Rs, to Replace, Reduce and Refine the use of animals, in EU legislation. Directive 2010/63/EU took full effect on 1 January 2013.

ETS - The EU Emissions Trading System

The EU emissions trading system (EU ETS) is a cornerstone of the European Union's policy to combat climate change and its key tool for reducing industrial greenhouse gas emissions cost-effectively. The first - and still by far the biggest - international system for trading greenhouse gas emission allowances, the EU ETS covers more than 11,000 power stations and industrial plants in 31 countries, as well as airlines.

NAGOYA - Protocol on Access and Benefit Sharing

The European Union is a Party to the United Nations Convention on Biological Diversity (CBD) of 1992, which seeks to ensure the conservation and sustainable use of the diversity of species, habitats and ecosystems on the planet, as well as the fair and equitable sharing of the benefits arising from the use of genetic resources. In 2000, Parties to the CBD adopted the Cartagena Protocol on Biosafety which seeks to protect biological diversity from the potential risks posed by living modified organisms, taking into account human health. The EU has adopted a series of legislative measures in order to implement this Protocol. In 2010, CBD Parties also adopted a new Protocol, the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization.



Submitting due diligence declaration

2. Information on exercise of due diligence:

- (a) An internationally recognised certificate of compliance (i) was issued for my (entity's) access or (ii) covers the terms of this access to the genetic resource(s) and traditional knowledge associated with genetic resources.

Unique identifier of the internationally recognised certificate of compliance *:

- (b) Please fill in the following information:

(i) Place of access: *

Confidential

(ii) Description of the genetic resources or traditional knowledge associated with genetic resources utilised, or unique identifier(s), where available: *

Confidential

(iii) Identifier of access permit or its equivalent ¹, where available:

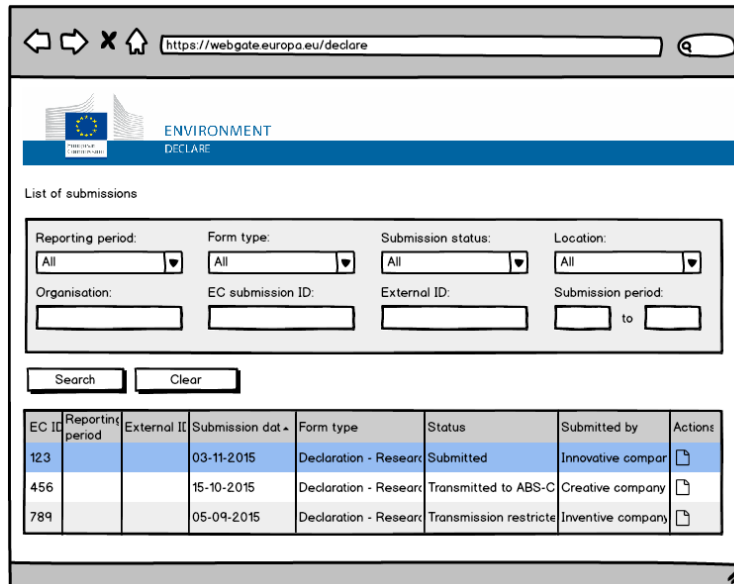
Confidential



¹ Evidence of the decision to grant prior informed consent or approval for access to genetic resources and traditional knowledge associated with genetic resources.



Overview of submitted declarations



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List of submissions

Reporting period: All | Form type: All | Submission status: All | Location: All

Organisation: | EC submission ID: | External ID: | Submission period: | to |

Search Clear

EC ID	Reporting period	External ID	Submission date	Form type	Status	Submitted by	Actions
123			03-11-2015	Declaration - Research	Submitted	Innovative company	
456			15-10-2015	Declaration - Research	Transmitted to ABS-C	Creative company	
789			05-09-2015	Declaration - Research	Transmission restricted	Inventive company	



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Enforcement measures: MS level

- **Designation of competent authorities**
(http://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation_en.htm)
- **Check on user compliance**
 - Carried out by Member States
 - Periodically reviewed plan developed using risk-based approach
- **Rules on penalties**
 - 27 MS adopted; other MS – work ongoing

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Measures encouraging compliance: **register of collections**

- **Voluntary instrument**
- **Principle:**
 - User **obtaining** GR from registered collection considered to have exercised due diligence re. seeking of information
- **Member States:**
 - Receive applications
 - Grant recognition
 - Perform risk-based checks on the collections
- **European Commission**
 - Establishment and maintaining of the register

*



Measures encouraging compliance: **recognition of best practice(s)**

- **Voluntary instrument**
- **Principle:**
 - MS authorities to take into consideration implementation of best practices while performing compliance checks
- **European Commission**
 - Receives the applications
 - Grants (and withdraws) the recognition
- **Member States:**
 - Submit views on the application





Complementary measures – Sectorial Guidance document

- Sector-specific guidance on utilisation for 7 sectors:
 - **Animal breeding, plant breeding, biocontrol, biotechnology, food & feed, cosmetics, pharmaceutical sector**
- Additional guidance dedicated to **researchers** and **collections** (upstream users)
- Both sets followed similar process
 - Drafts prepared by external consultants under EC supervision and with stakeholder input & MS experts' support;
 - Drafting groups
 - Sectorial workshops
 - Consultation with MS experts and Consultation Forum representatives
 - Discussion with Member States on the more controversial issues
 - Final drafts consulted with MS and stakeholders

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Challenges of implementation

- Continuous need for awareness raising on ABS and its legal framework (incl. EU ABS Regulation)
- Users find the legal framework challenging – variety of legislations out there
- Ongoing work on defining the boundaries of scope of application (notion of utilisation)
- Technological developments discussed at international level: 'digital sequence information' (DSI)

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Thanks for your attention

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