



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

**Webinar on the implementation of the Nagoya Protocol
in H2020 projects**

27th September 2019

Content

- *Introduction to ABS and policy context*
- *Content of the Nagoya Protocol and how is implemented in the EU*
- *The EU ABS Regulation and links to the H2020 Programme*
 - Focus on 1st checkpoint: funding research

ABS

the concept beyond the acronym



It is a concept:
A= access
BS= benefits sharing

Origin: back to the 80s-90s

International legal context:
CBD (3rd objective)



Convention on Biological Diversity



CBD

1993

Article 1. Objectives

The objectives of this Convention, to be pursued in accordance with its relevant provisions, are the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources, including by appropriate access to genetic resources and by appropriate transfer of relevant technologies, taking into account all rights over those resources and to technologies, and by appropriate funding.



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 -

"**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

Implementation of the Protocol in the EU

- **Compliance**

- EU ABS Regulation (Regulation n.511/2014)
- Commission Implementing Regulation (2015/1866)

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



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

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**
 - **Further work needed on exact boundaries of the concept**

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
on 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,



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**

IRCCs: (14 Parties: 670)



Convention on Biological Diversity

ABSCH THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE

Home | About the ABSCH | Search | Submit | Country Profiles | National Reports

CBD > ABSCH > SEARCH > SEARCH

INTERNATIONALLY RECOGNIZED CERTIFICATES OF COMPLIANCE x

SEARCH FILTERS | Record types | Keywords | Country | Regions | Date

National records 431 | Reference records 227 | SCBD records 1071

EXPORT

Belarus PARTY TO THE NAGOYA PROTOCOL | ENTRY INTO FORCE: 12 OCT 2014

INTERNATIONALLY RECOGNIZED CERTIFICATES OF COMPLIANCE (IRCC)

Compliance with the Nagoya Protocol requirements A document confirming the compliance with the Nagoya Protocol issued by the Ministry of Natural Resources and Environmental Protection as a letter of January 8, 2018 N10-2-34/84.

INTERNATIONALLY RECOGNIZED CERTIFICATE OF COMPLIANCE | BELARUS | ABSCH-IRCC-BY-239176-1 | NON-COMMERCIAL | 23 JAN 2018

Bulgaria PARTY TO THE NAGOYA PROTOCOL | SIGNATORY | ENTRY INTO FORCE: 09 NOV 2016

INTERNATIONALLY RECOGNIZED CERTIFICATES OF COMPLIANCE (IRCC)

33-00-155

INTERNATIONALLY RECOGNIZED CERTIFICATE OF COMPLIANCE | BULGARIA | ABSCH-IRCC-BG-238915-1 | NON-COMMERCIAL | 28 NOV 2017

HC3П-137

INTERNATIONALLY RECOGNIZED CERTIFICATE OF COMPLIANCE | BULGARIA | ABSCH-IRCC-BG-238869-1 | 14 NOV 2017

HC3П175

INTERNATIONALLY RECOGNIZED CERTIFICATE OF COMPLIANCE | BULGARIA | ABSCH-IRCC-BG-238116-1 | NON-COMMERCIAL | 25 AUG 2017

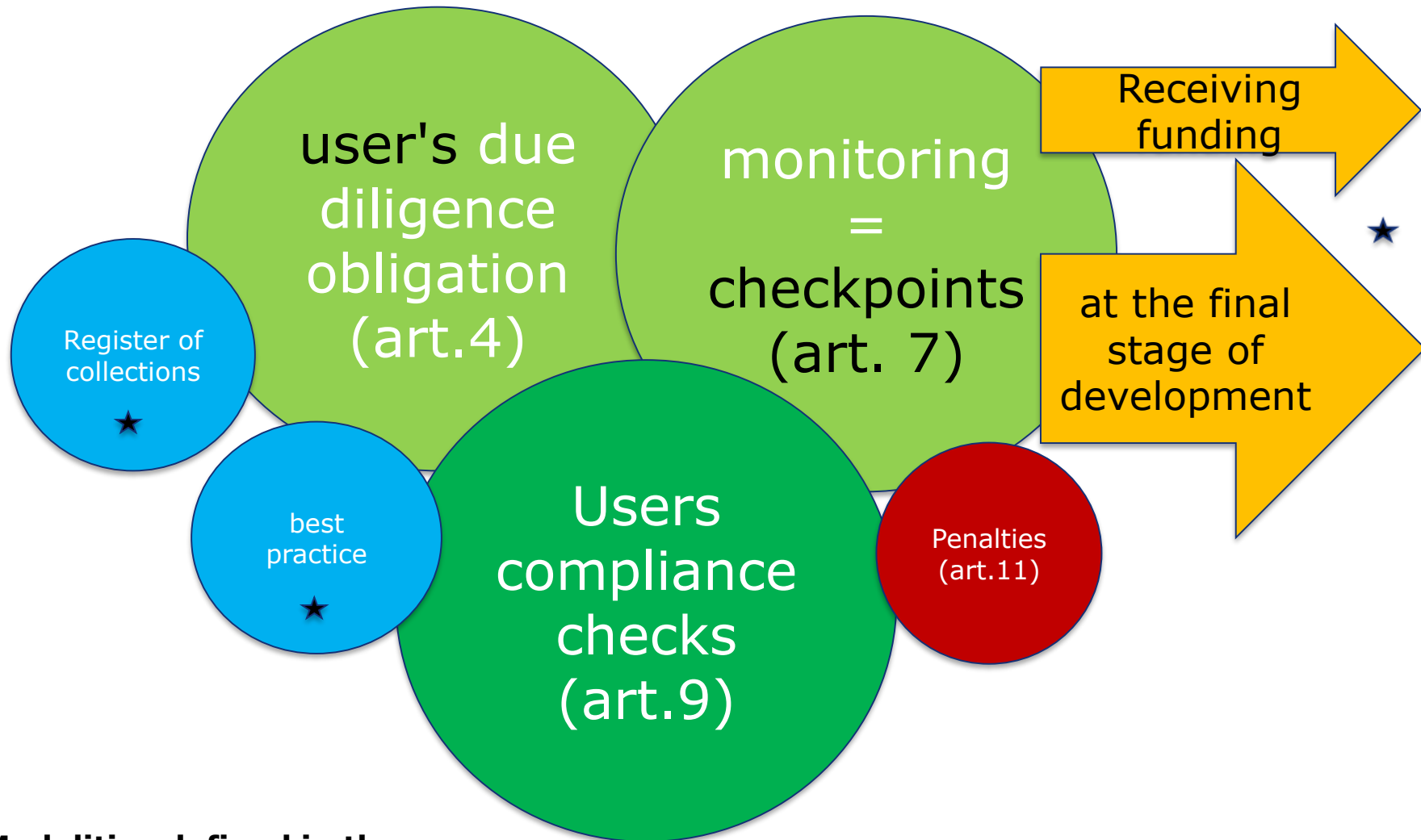
Dominican Republic PARTY TO THE NAGOYA PROTOCOL | SIGNATORY | ENTRY INTO FORCE: 11 FEB 2015

INTERNATIONALLY RECOGNIZED CERTIFICATES OF COMPLIANCE (IRCC)

NUMERO DE CONTRATO 0000400



Key provisions of the EU ABS regulation



★ Modalities defined in the implementing regulation

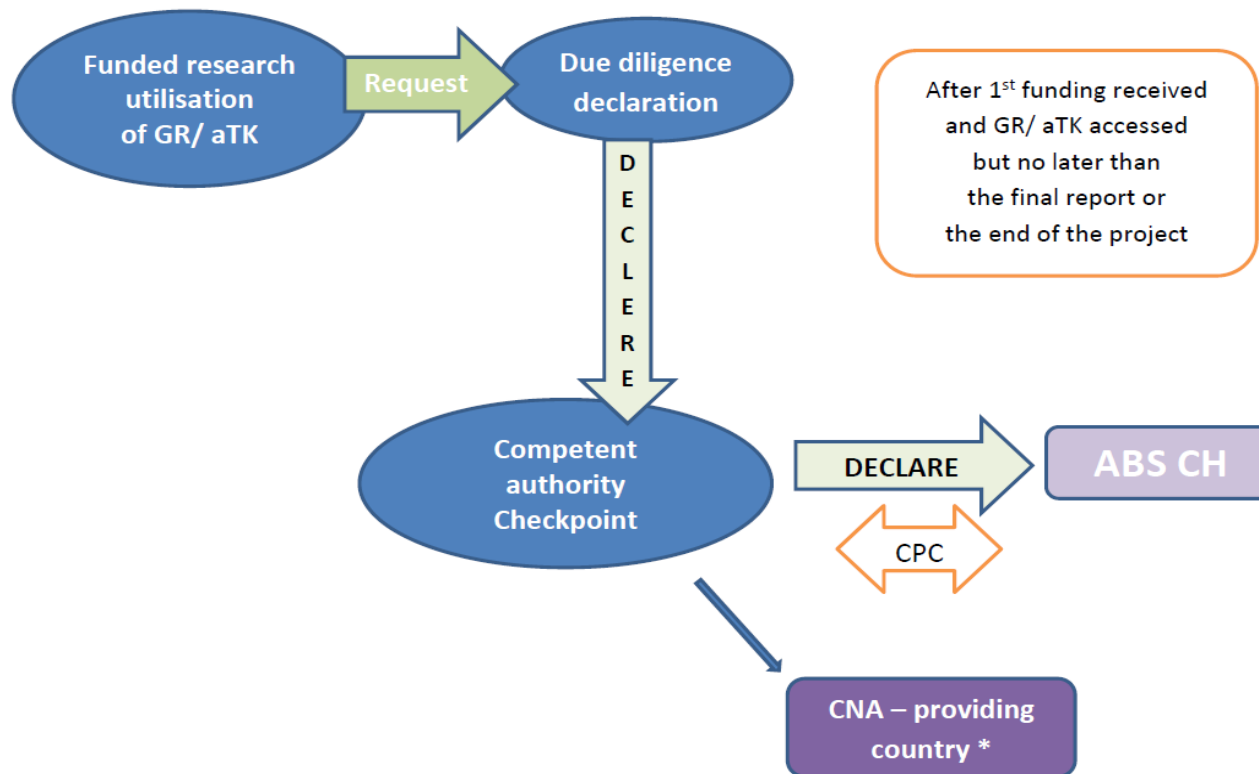
Enforcement measures: MS level

- **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
 - » 5 MS adopted plans
 - » other MS: carrying out risk analyses to identify risk factors and potential users for checks
- **Rules on penalties**
 - 21 MS adopted; other MS – work ongoing

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

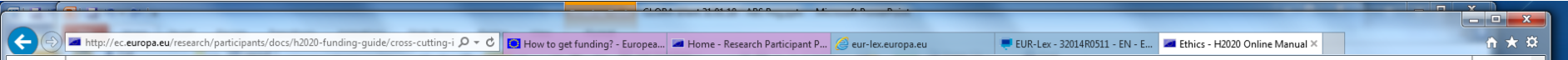
- **Due diligence declaration at the stage of research funding where research involves utilisation of GR and TKaGR**
 - MS and EC are to request the declaration from all recipients of funding (public or private)
 - If mixed sources or multiple recipients of funding, declaration required only once (→ 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)

1st checkpoint





European Commission



RESEARCH & INNOVATION

Participant Portal H2020 Online Manual

 Search

- H2020 Online Manual
- My Area - User account & roles
 - EU Login
 - Roles & access rights
 - Terms and Conditions of Use
- Grants
 - Applying for funding
 - Find a call
 - Horizon 2020 structure and budget
 - What you need to know about Horizon 2020 calls
 - Find partners or apply as individual
 - Register in the Beneficiary Register
 - Registration of your organisation
 - LEAR appointment

> H2020 Online Manual > Cross-cutting issues >

International cooperation Social Sciences & Humanities Open access & Data management Climate action & Sustainable development

Ethics Gender SMEs ERA-NETs

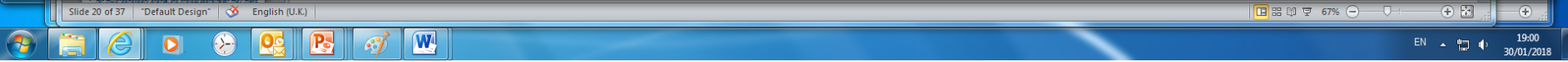
Links to regional policy Intellectual property Innovation procurement

Ethics

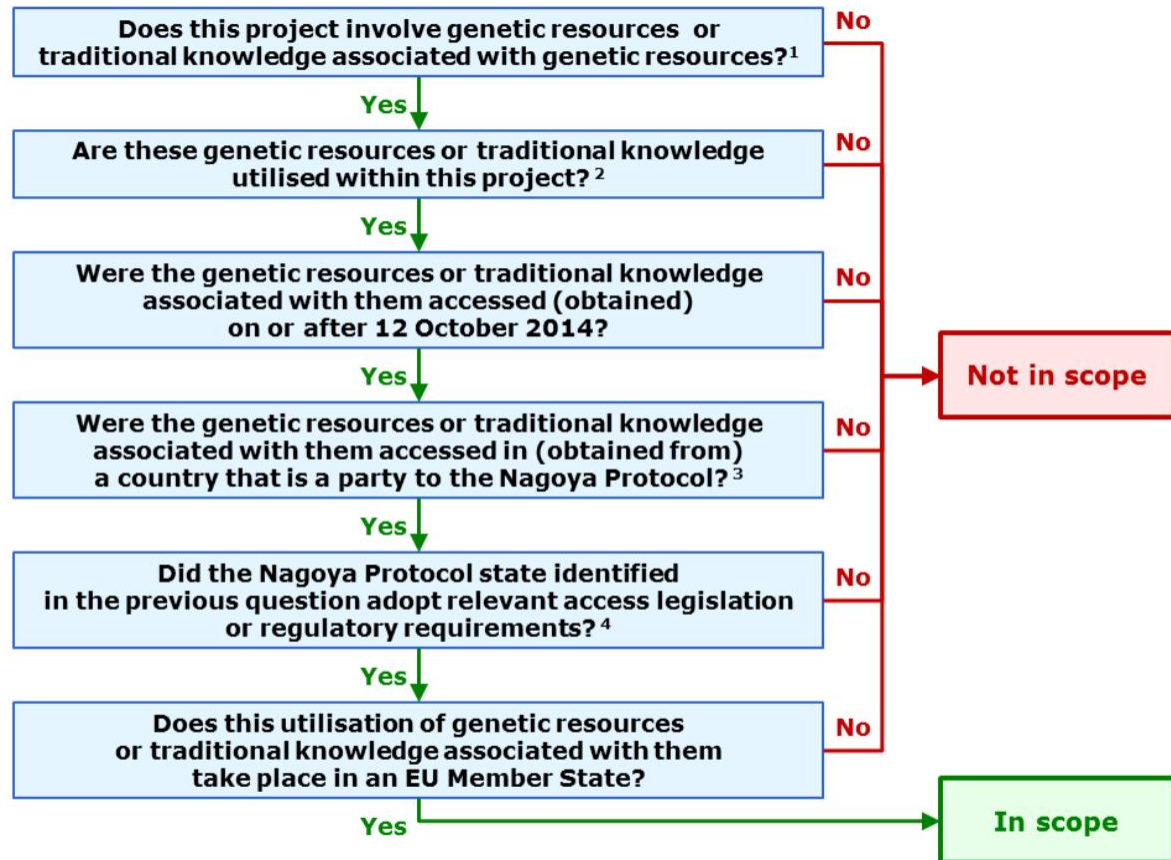


For all activities funded by the European Union, ethics is an integral part of research from beginning to end, and ethical compliance is seen as pivotal to achieve real research excellence. There is clear need to make a thorough ethical evaluation from the conceptual stage of the proposal not only to respect the legal framework but also to enhance the quality of the research. Ethical research conduct implies the application of fundamental ethical principles and legislation to scientific research in all possible domains of research. The process to assess and address the ethical dimension of activities funded under Horizon 2020 is called the **Ethics Appraisal Procedure**.

Objectives



Check if your project is in scope of the ABS regulation



Due diligence declaration: remember that...

- The due diligence declaration must be submitted to the competent authority of the member state where the coordinator or beneficiary is established. The contact details of these competent authorities are available on the Europa website.
- For multi-beneficiary grants, the project coordinator may make a single declaration. Alternatively, each beneficiary whose activities fall within the scope the EU ABS Regulation must make an individual declaration.
- The declaration must be made at the latest by the end of the project (final report).



Obligations for projects in scope of the ABS regulation

If your project falls within the scope of the ABS regulation you must

- report that your project is in scope before you receive the first payment (the pre-financing is not considered a payment for this purpose) - through Horizon 2020 Portal
- comply with the ABS Regulation, in particular
 - **exercise due diligence**
 - **submit a due diligence declaration** (at the latest before submission of the final report)

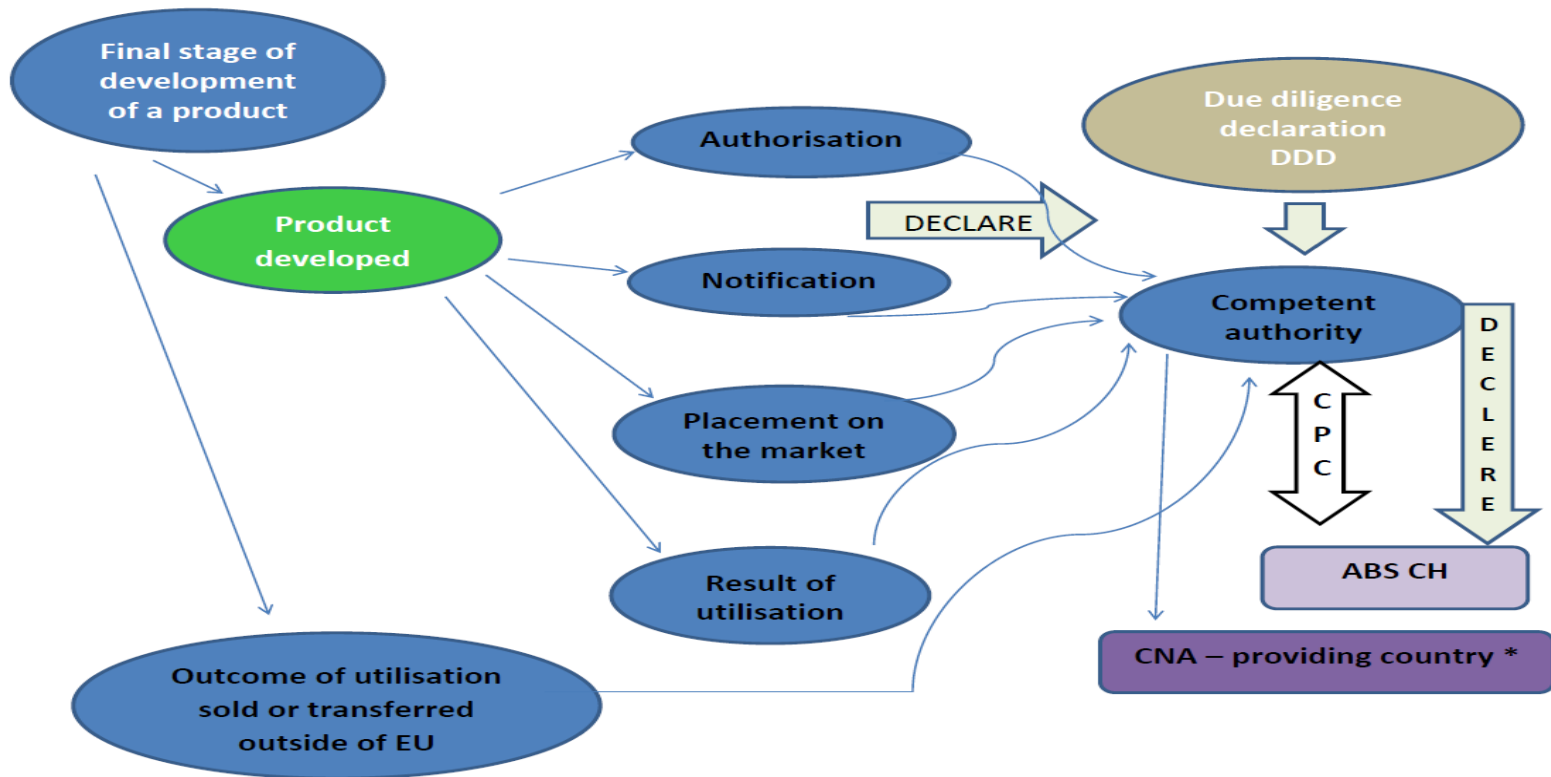
Due diligence declaration submission: be aware that...

- *If the coordinator or beneficiary is established outside the EU and the relevant research activity takes place inside the EU, the **declaration must be submitted to the competent authority of the Member State where the research is carried out.***
- *Beneficiaries established outside the EU and carrying out research outside the EU are not concerned by the EU ABS regulation. They may have to comply with their own national ABS legislation (if any).*

Implementing Regulation – 2nd checkpoint for monitoring compliance

- **Due diligence declaration at the stage of final development of a product**
- **Final stage of development of a product defined:**
 - When market approval sought
 - When notification required
 - When placing product on a market
 - 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

2nd checkpoint



DECLARE

- **EU wide IT tool for submission of due diligence declarations:**
 - Users to checkpoints (competent authorities)
 - Authorities to ABS Clearing House (relevant parts, after verification)
- **Operational (1st checkpoint since Sept. 2017)**
- **Confidentiality aspect**




European
Commission

DECLARE

The screenshot shows a web browser window with the address bar containing <https://webgate.europa.eu/declare>. The page header includes the European Commission logo and the text "ENVIRONMENT DECLARE". The main content area is titled "Welcome to DECLARE" and provides an overview of the portal's purpose. Below this, there are three distinct boxes, each representing a different policy domain: ALURES (Animals used for scientific purposes), ETS (The EU Emissions Trading System), and NAGOYA (Protocol on Access and Benefit Sharing). Each box contains a brief description of the domain and its legislative context.

[←](#) [→](#) [✕](#) [🏠](#)

 ENVIRONMENT
DECLARE

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

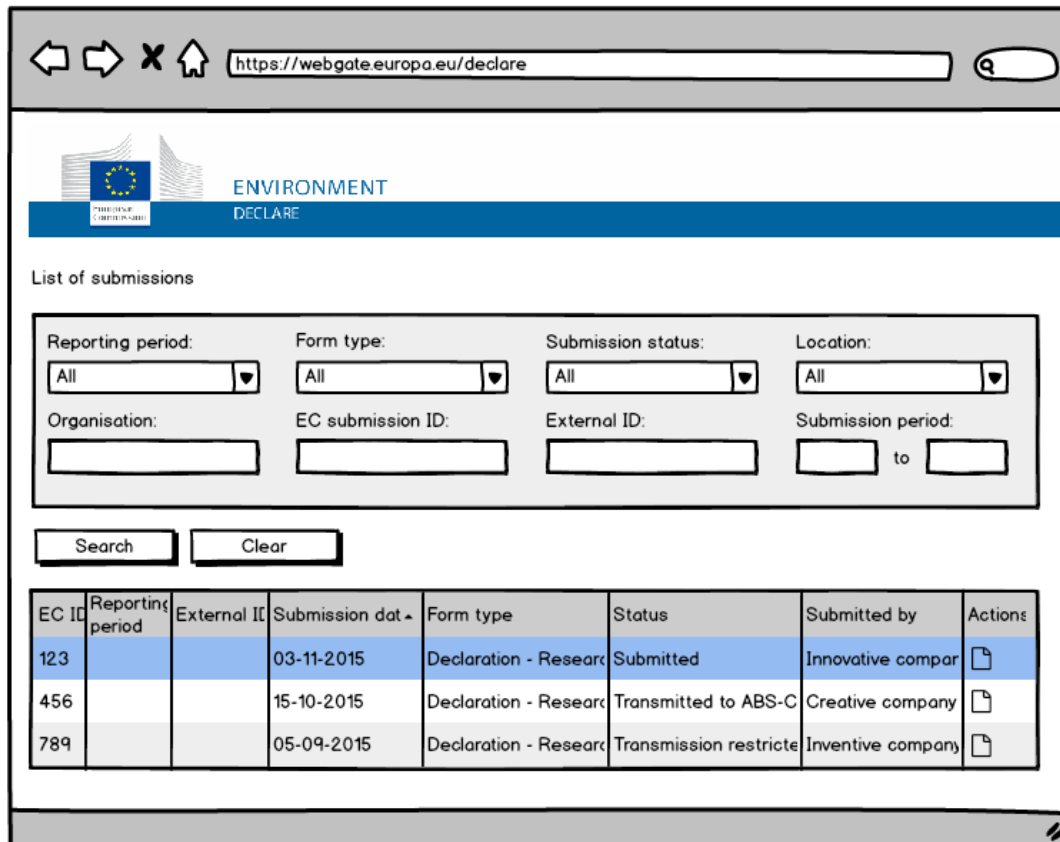
(iii) Identifier of access permit or its equivalent ¹, where available:

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



ENVIRONMENT
DECLARE

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	



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

– Guidance documents

- Horizontal guidance on the scope of application and core obligations of the EU ABS Regulation
 - Commission with MS experts' support & feedback from Consultation Forum
 - Adopted as Commission Notice 22/08/2016;
 - Published in OJ 27/08/2016;
 - Available on the ABS Clearing House
- Clarifies the geographical, temporal, personal and material scope of EU ABS Regulation
- Clarifies main obligations under the Regulation
 - what does it mean to be due diligent;
 - when to file due diligence declaration etc.

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

Complementary measures

– Sectorial Guidance documents

- Consultants on 7 drafts finalised:
 - **March 2017 – for the 7 sectorial drafts**
 - **December 2017 – for upstream users**
- Number of unresolved issues identified
 - **Discussed with Member States experts over 2017/2018/2019**
- Current status: first draft (a compiled document) now being object of discussion with MS – consultation
- Way forward: consultation with stakeholders – further redrafting upon discussion

Challenges of implementation

- Continuous need for awareness raising on ABS legal framework (incl. EU ABS Regulation)
- Research community: need to integrate ABS into training or communication strategy policies for funding recipients
- Ongoing work on defining the boundaries of scope of application
- International developments (CBD/NP): ongoing discussion on *digital sequence information* (DSI)



Thanks for your attention

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