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

Environment

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 contetxt:
CBD (3rd objective)

European Commission

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 -

"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

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

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,

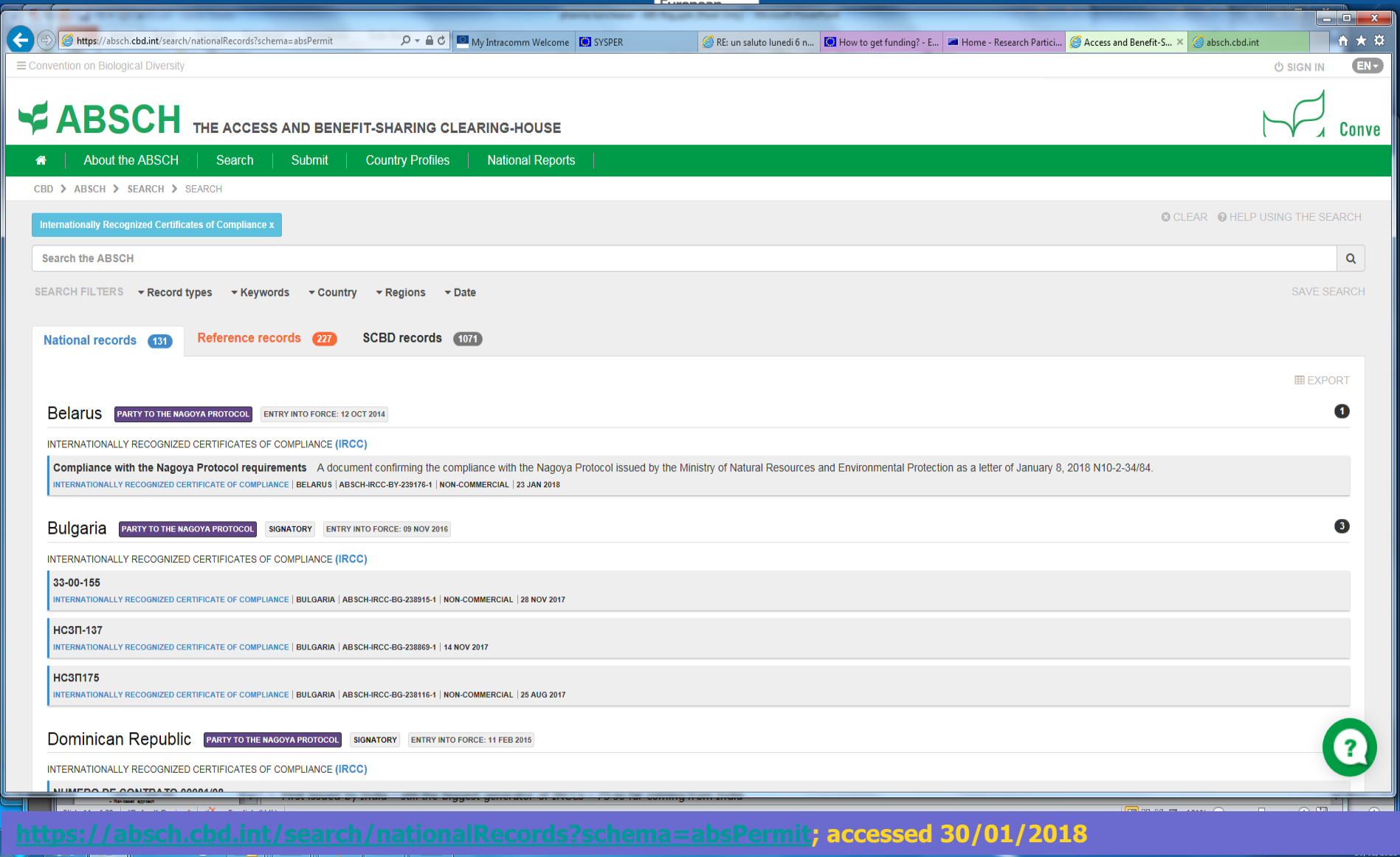
EU ABS Regulation: **User obligations (art.4)**

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

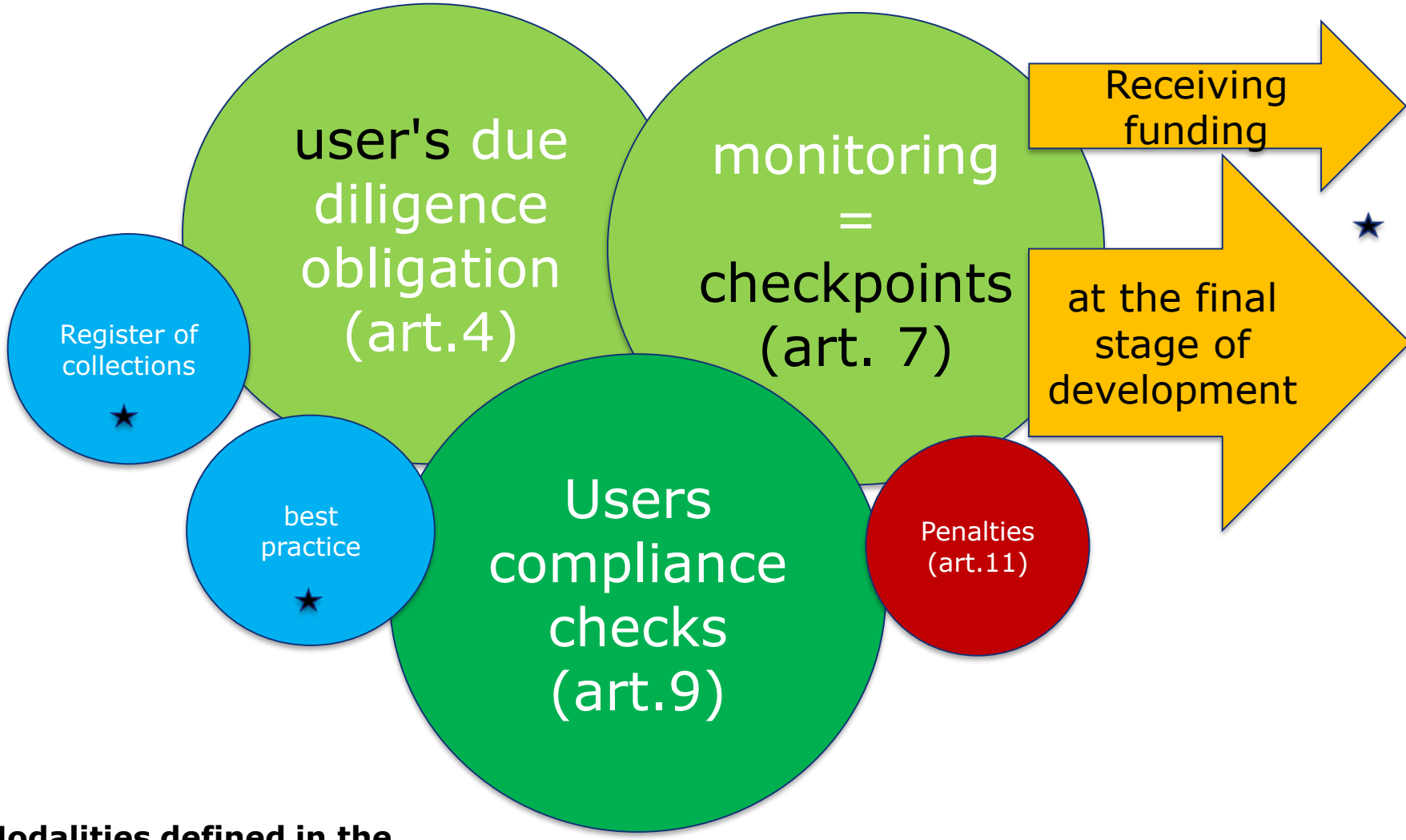
    GR/TKaGR, date/place of access, source, any rights & obligations, PIC & MAT
- **Insufficient info – discontinue utilisation**

IRCCs: (14 Parties: 670)



https://absch.cbd.int/search/nationalRecords?schema=absPermit; accessed 30/01/2018

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)**

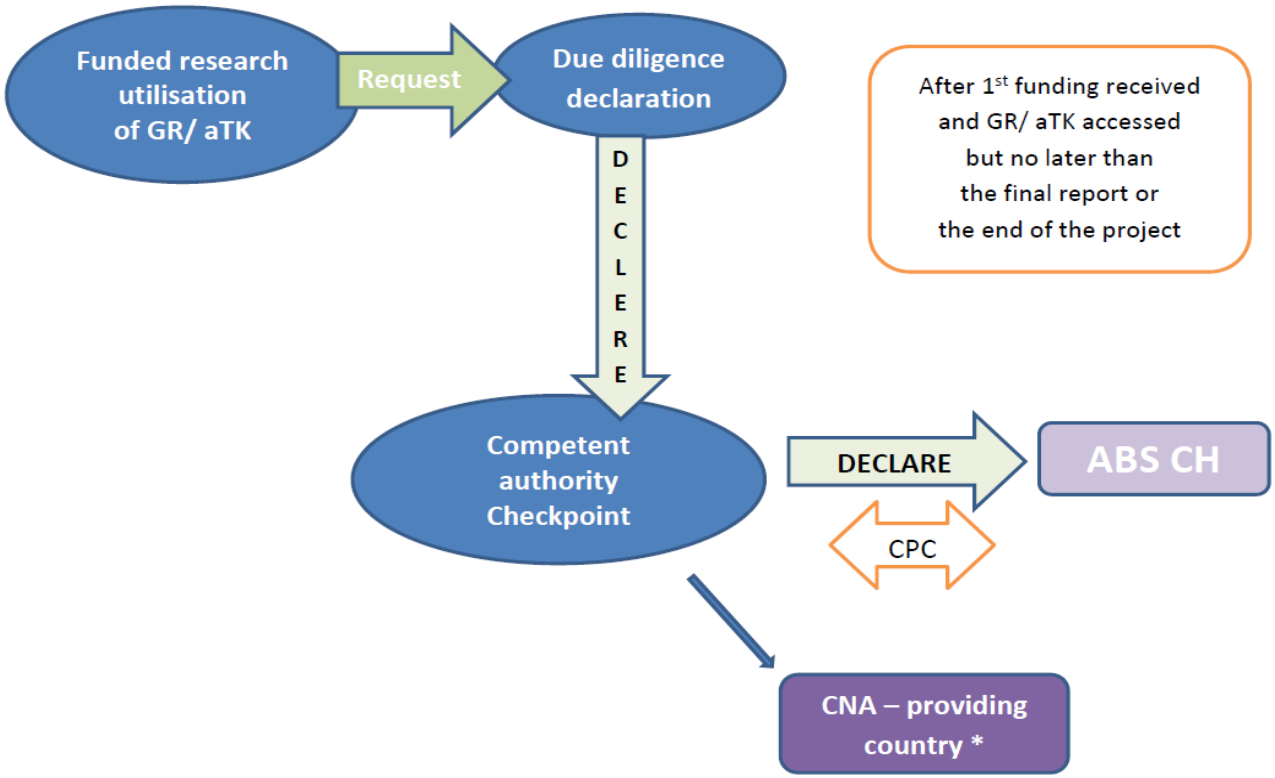
- **Check on user compliance**
  - Carried out by Member States
  - Periodically reviewed plan developed using risk-based approach
    - » 5 MS adopted plans
    - » other MS: carrying out risk analyses to identify risk factors and potential users for checks
- **Rules on penalties**
  - 21 MS adopted; other MS – work ongoing

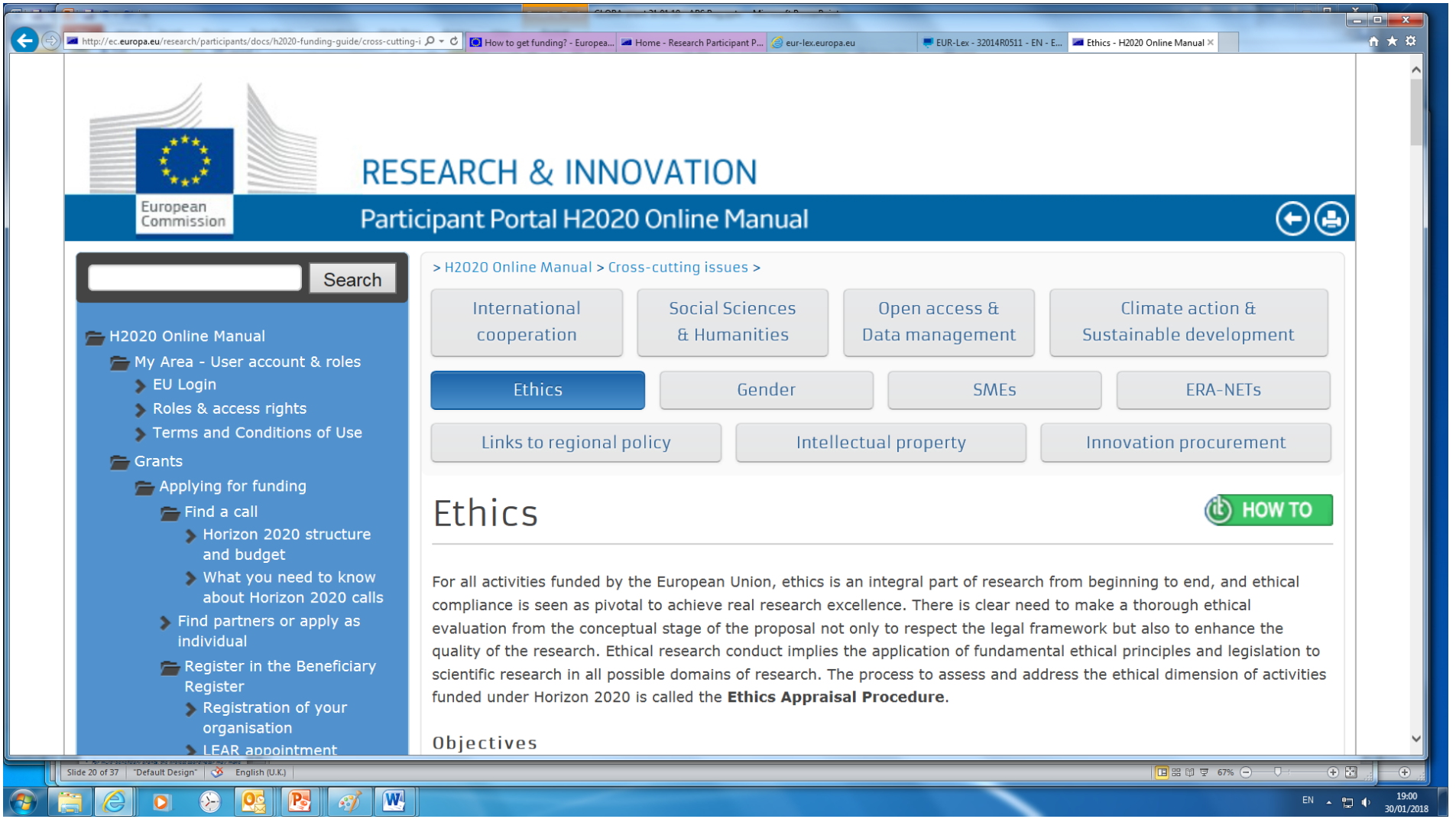
Implementing Regulation – 1st check-point for monitoring compliance (art. 5 Implementing Reg.)

- **Due diligence declaration at the stage of research funding where research involves utilisation of GR and TKaGR**

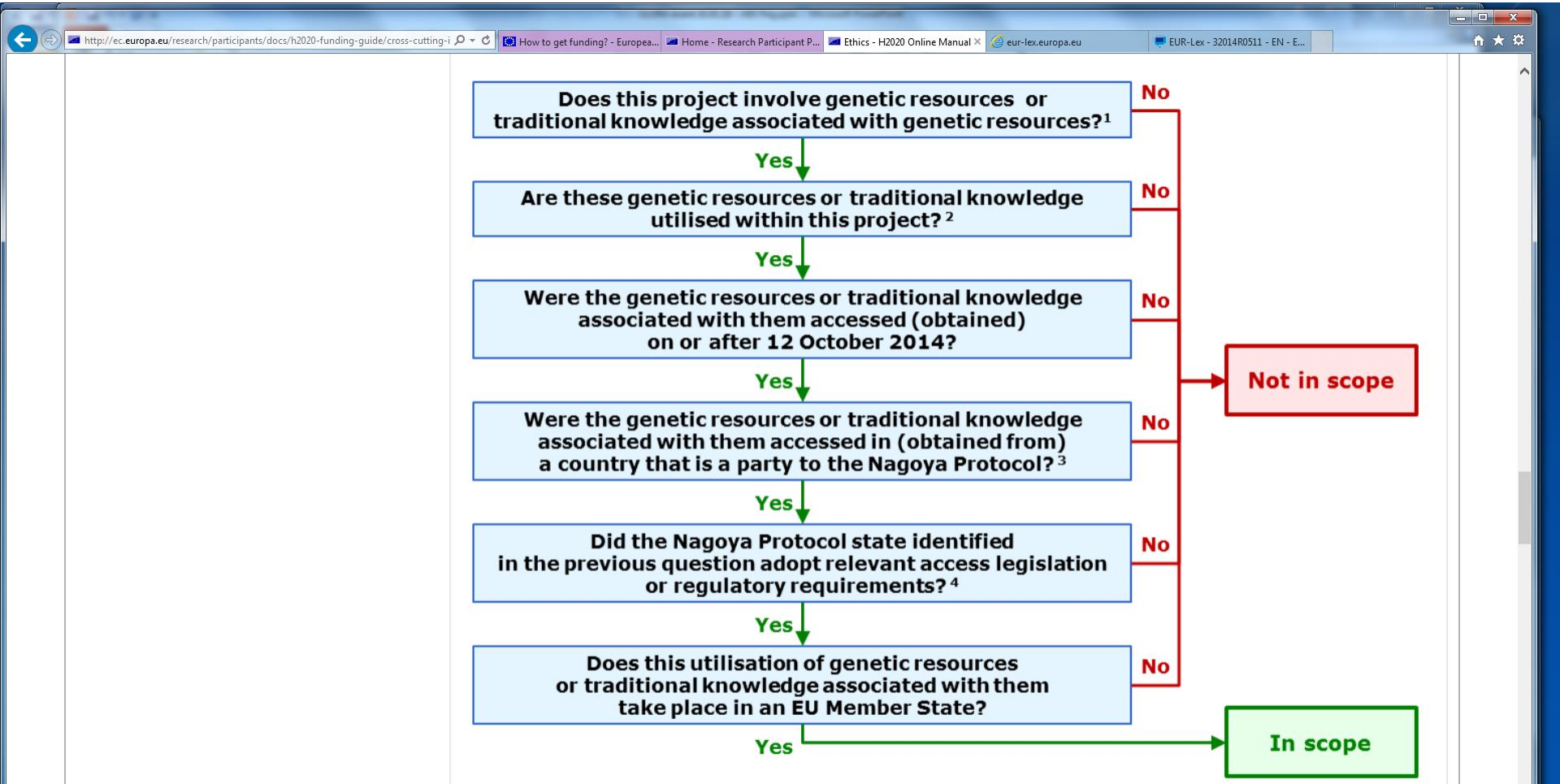
  - MS and EC are to request the declaration from all recipients of funding (public or private)
  - If mixed sources or multiple recipients of funding, declaration required only once (→ coordinator)
  - Declaration to be submitted to MS competent authorities (where user/coordinator established)
  - Time of submitting due diligence defined (at the stage of submitting final report at the latest)

1st checkpoint




http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-i
How to get funding? - Europea...
Home - Research Participant P...
eur-lex.europa.eu
EUR-Lex - 32014R0511 - EN - E...
Ethics - H2020 Online Manual
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
HOW TO
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
Slide 20 of 37
"Default Design"
English (U.K.)
67%
EN
19:00
30/01/2018

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…

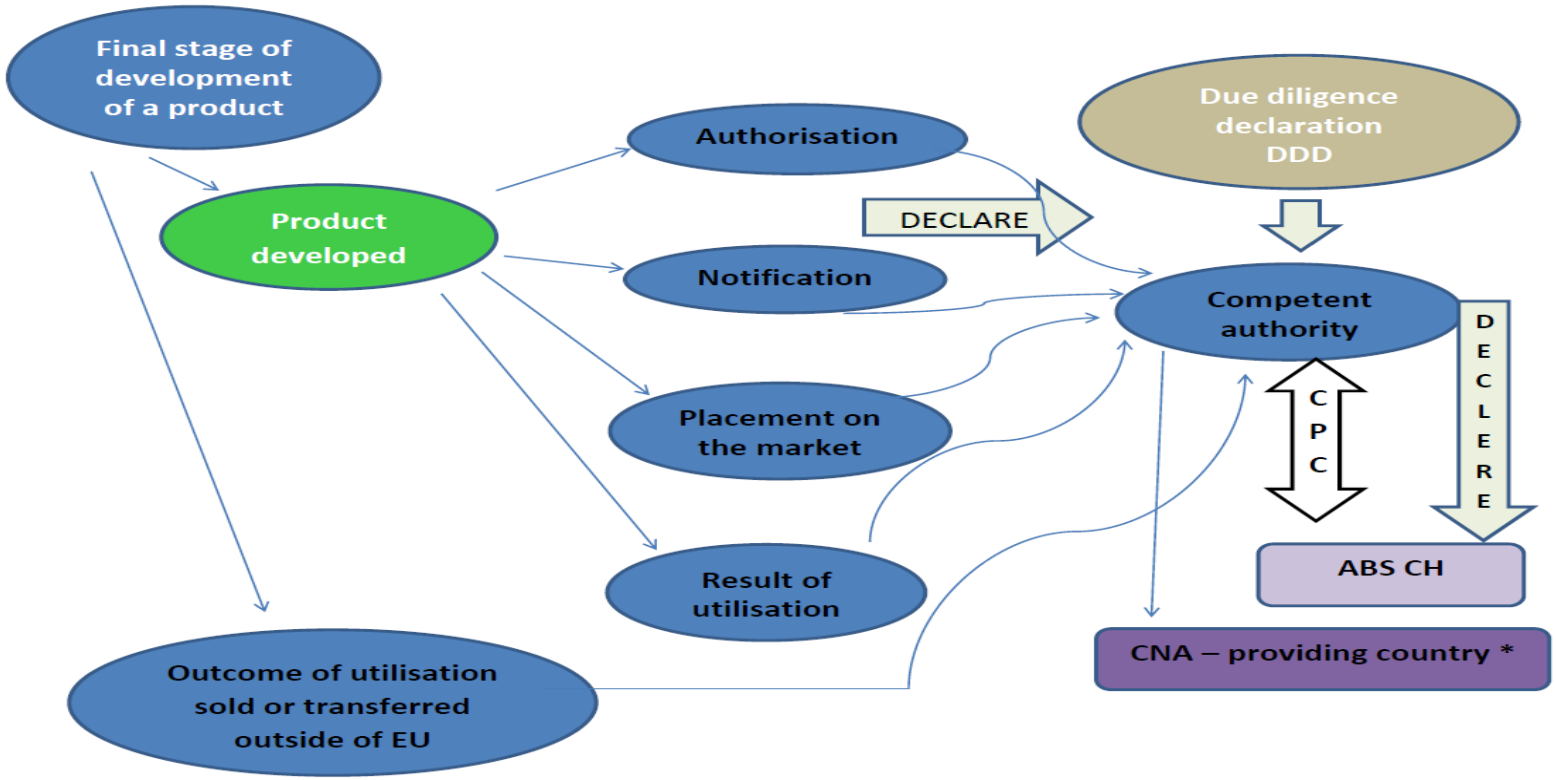
- *If the coordinator or beneficiary is established outside the EU and the relevant research activity takes place inside the EU, the declaration must be submitted to the competent authority of the Member State where the research is carried out.*

- *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 check-point 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



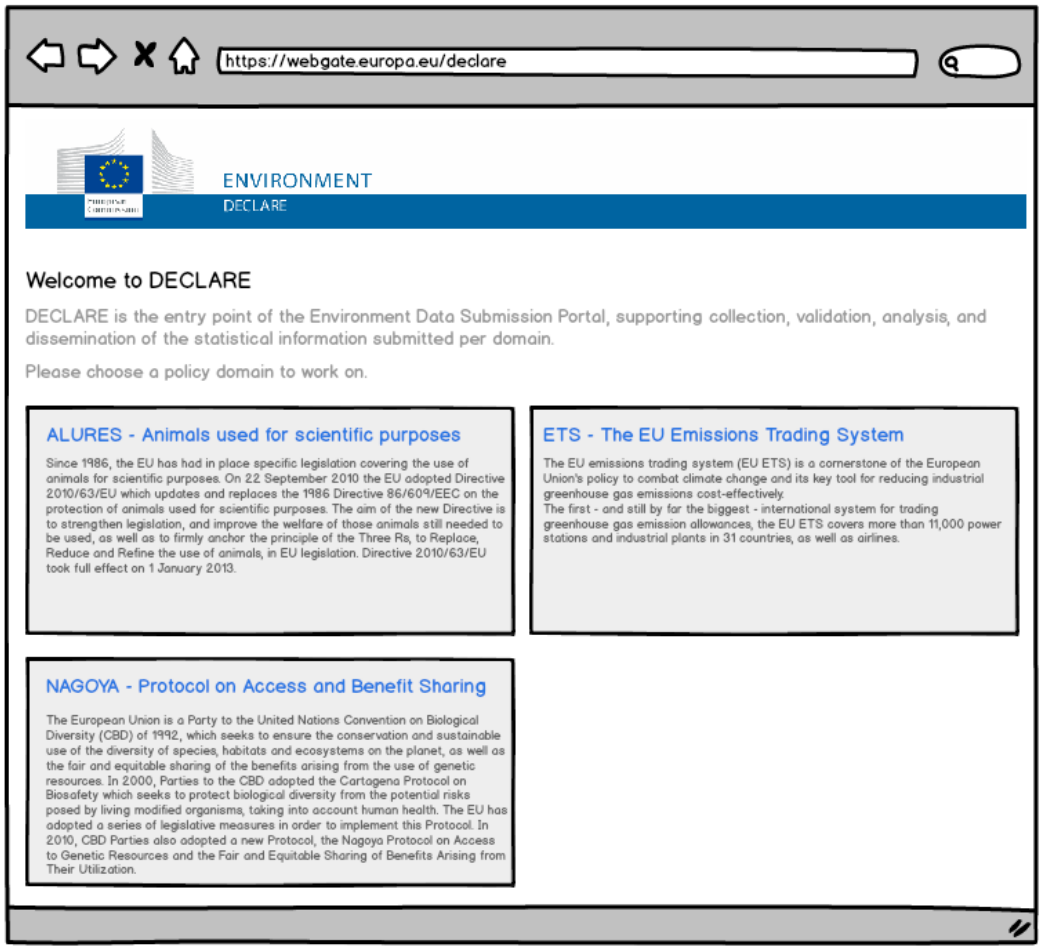
DECLARE

- **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



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: *

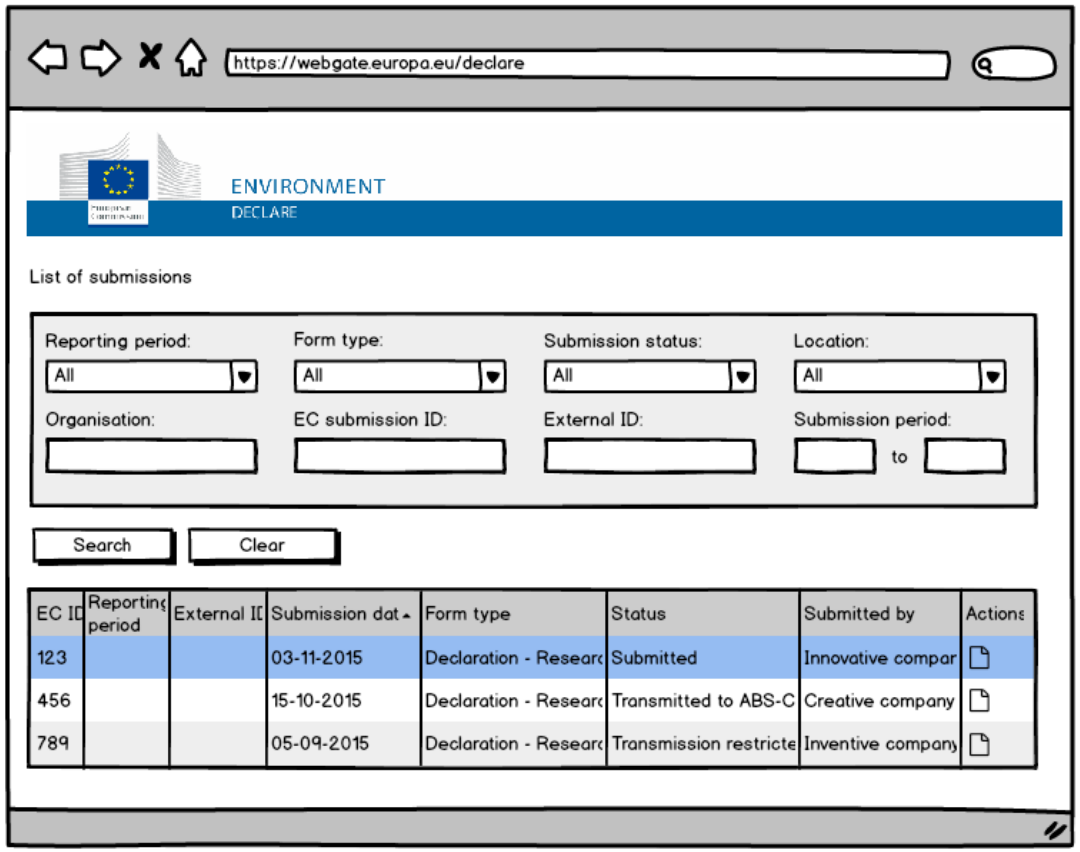
☐ Confidential

(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



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 preforming 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 meant 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

Mery Ciacci
Policy Officer
DG ENV-F.3 Multilateral Environmental Cooperation
Mery.ciacci@ec.europa.eu