



4th Image Dialogue
Forum
August 25th 2019

ABS rules in the EU – EU ABS legal framework

Content

- **ABS legal framework:**
 - Nagoya Protocol
 - EU ABS Regulation
 - Implementing Regulation
 - DECLARE
- **Complementary measures**
- **EU ABS legal framework and animal breeding**



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**

Each State/Party to decide if they
establish access rules, incl. EU Member
States

**Subject to
contractual
agreement**

**See EU ABS
Regulation**

Directly applicable in all Member
States, regardless of ratification
status



Implementation of the Protocol in the EU

- **Access:**
 - Left to individual Member States; no EU legislation
 - Countries with access legislation: Spain, France, Croatia, Malta, Bulgaria;
 - IRCC issued by FR (153), ES (43), BG (3), MT (1)
- **Compliance**
 - Harmonized implementation across EU
 - » → EU ABS Regulation (511/2014)
 - » → EU Implementing Regulation (2015/1866)

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
the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union

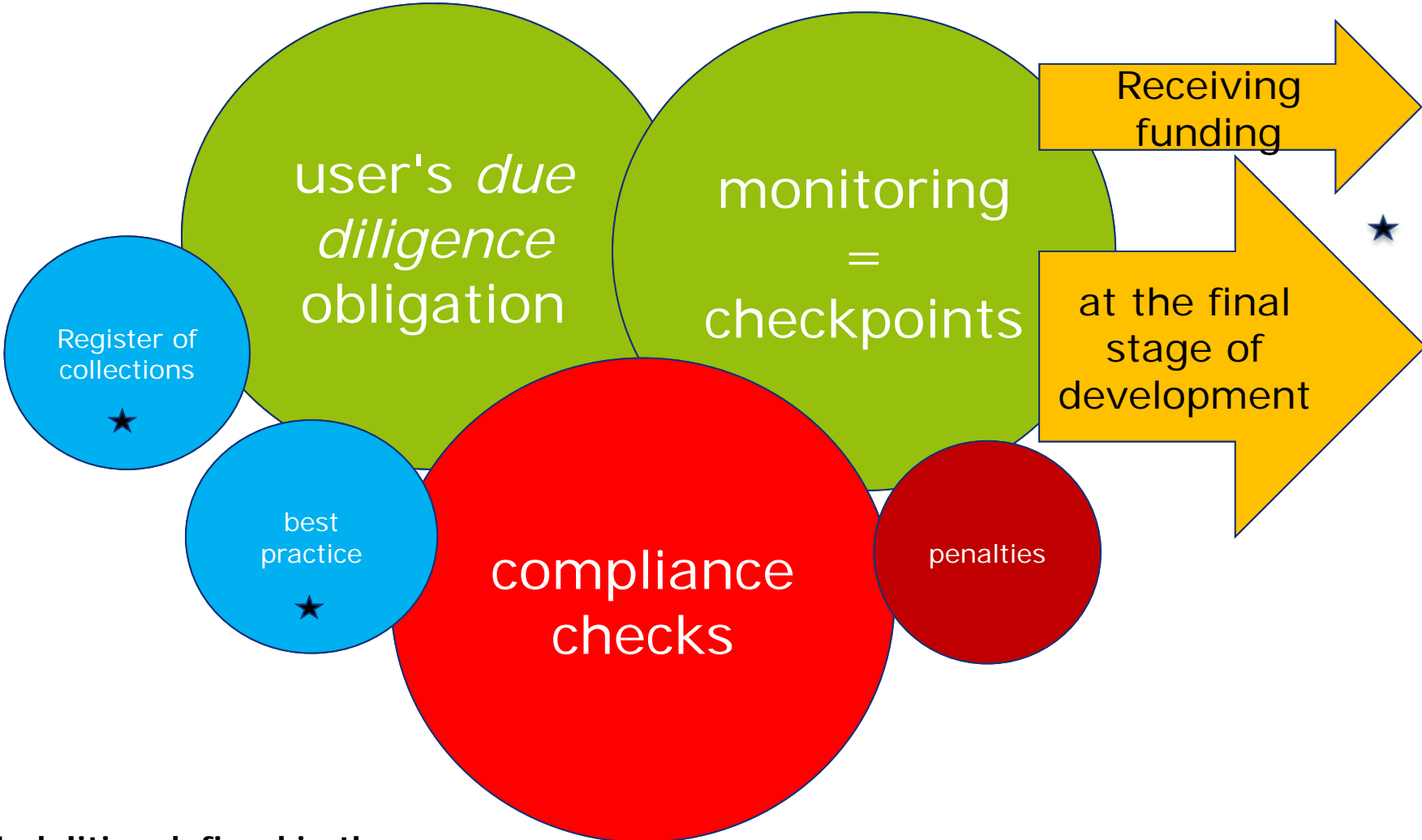
(Text with EEA relevance)

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**

- 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**



Enforcement measures: MS level

- **Designation of competent authorities**
- **Check on user compliance**
 - Carried out by Member States
 - Risk-based approach
 - » Surveys on users of GR/ TKaGR
 - » Awareness-raising as part of the plans
 - Taking into account application of best practice
- **Rules on penalties**



Measures encouraging compliance

- **Voluntary instruments**
- **Register of collections**
 - User **obtaining** GR from registered collection considered to have exercised due diligence re. seeking of information
 - » Member States in charge (grant recognition & perform risk-based checks on the collections)
 - » European Commission – keeps register
- **Best practices:**
 - MS authorities to take into consideration implementation of best practices while performing compliance checks
 - » European Commission in charge (grants the recognition)
 - » Member States – submission of views

http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015R1866&from=EN

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Web Slice Gallery

This file claims compliance with the PDF/A standard and has been opened read-only to prevent modification. Enable Editing

Nov. 2015

L 275/4 EN Official Journal of the European Union 20.10.2015

COMMISSION IMPLEMENTING REGULATION (EU) 2015/1866

laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user access and best practices

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to 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 ⁽¹⁾, and in particular Article 5(5), Article 7(6) and Article 8(7) thereof,

FR 16:48 24/08/2016



Monitoring measures: **Checkpoints**

- **Two checkpoints:**
 - at the stage of **research funding** where research involves utilisation of GR and TKaGR
 - at the stage of **pre-commercialisation** (final stage of development of the product)
- **IT tool developed to facilitate the process of exchange of information (DECLARE)**

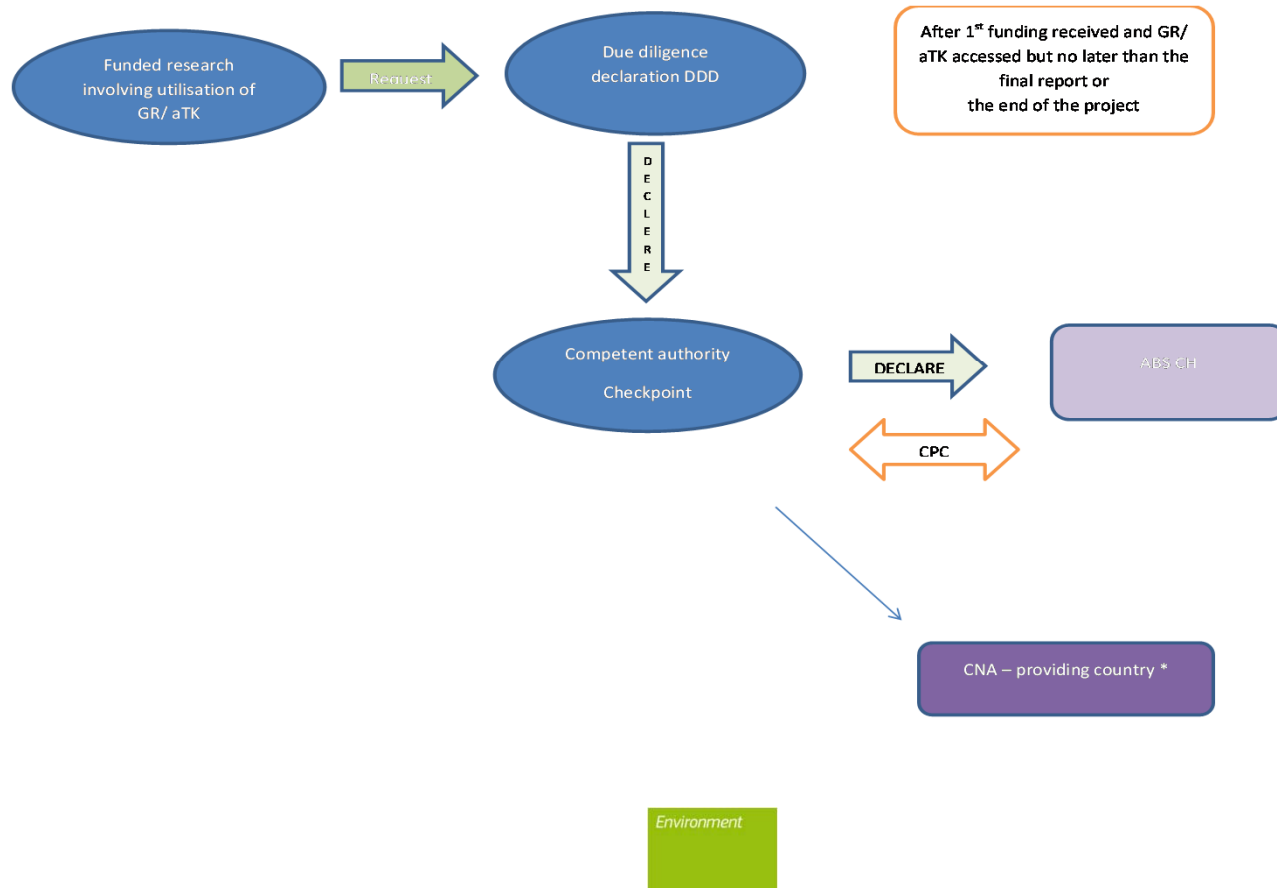


Implementing Regulation – 1st checkpoint for monitoring compliance

- **Due diligence declaration at the stage of research funding**
 - MS, EC 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 established)
 - Time of submitting due diligence defined (at the stage of submitting final report at the latest)



1st checkpoint

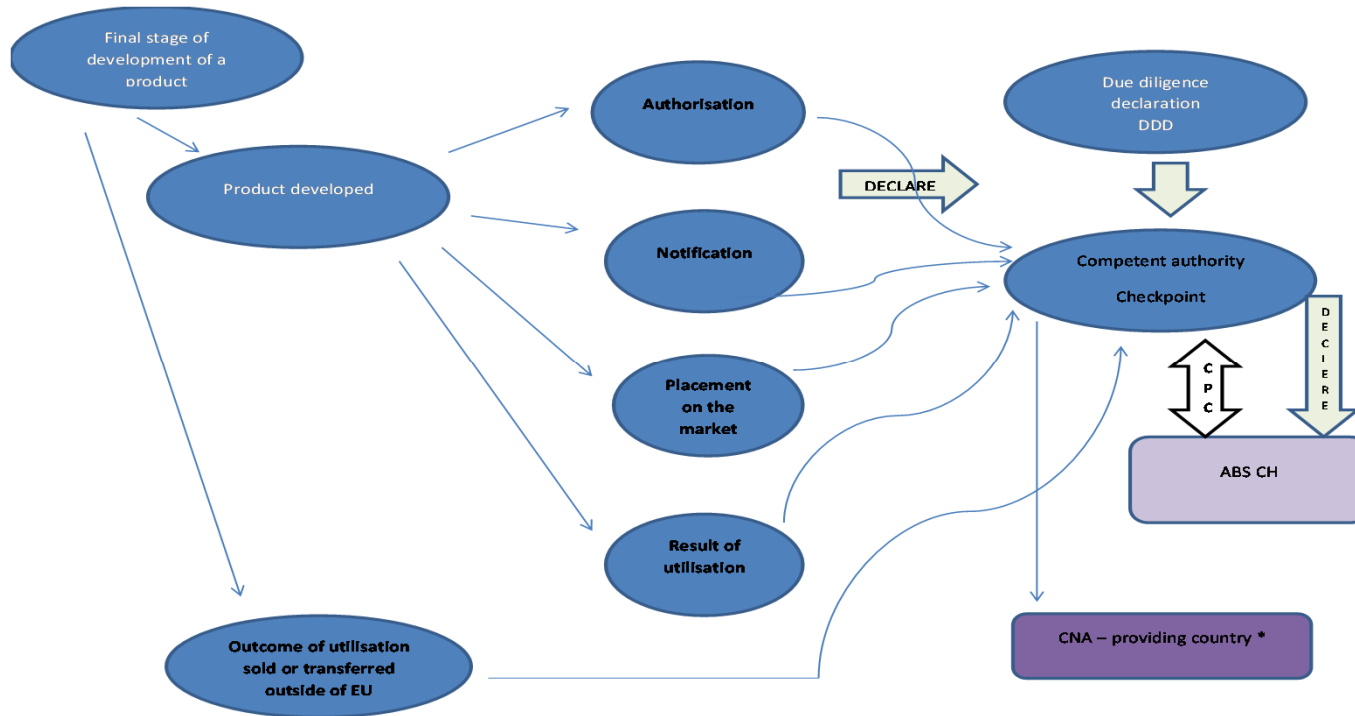




Implementing Regulation – 2nd check-point for monitoring compliance

- **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

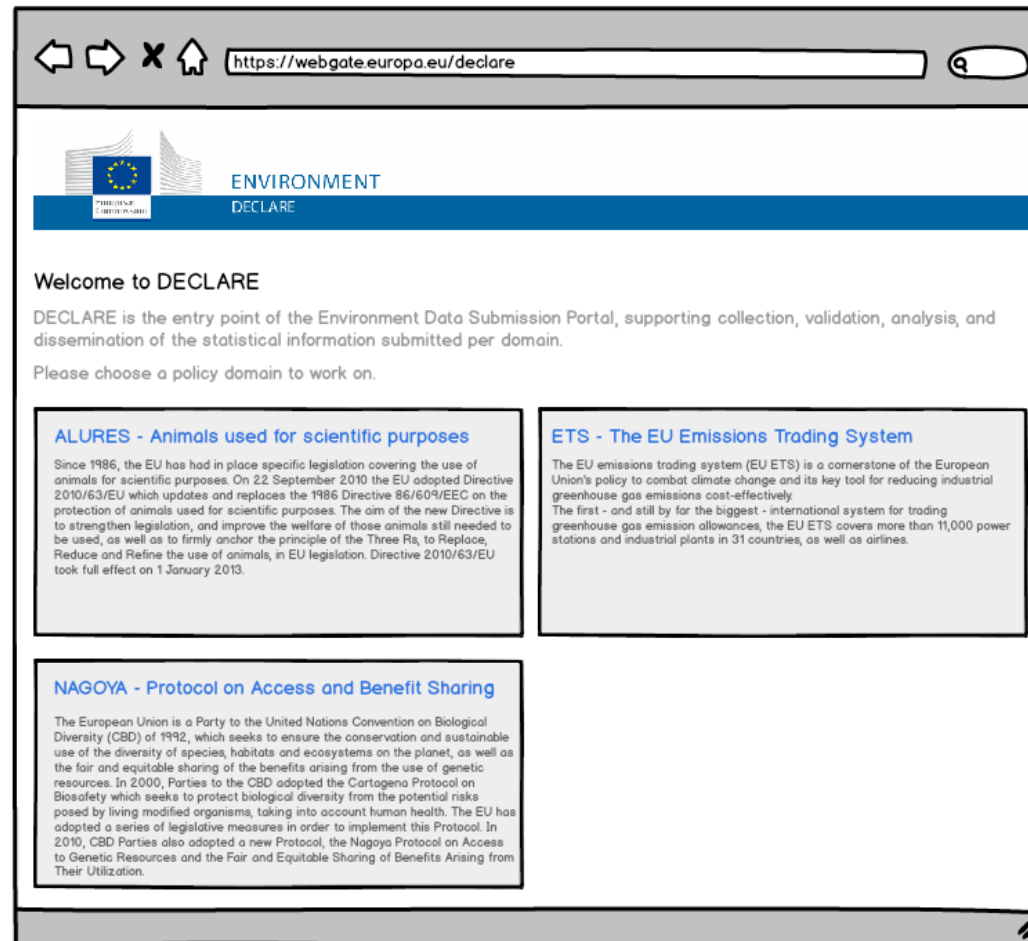




DECLARE

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

DECLARE



The screenshot shows a web browser window with the URL <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 a brief description of the portal's purpose: "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." Below this, there are three main sections, each with a title and a descriptive paragraph:

- 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

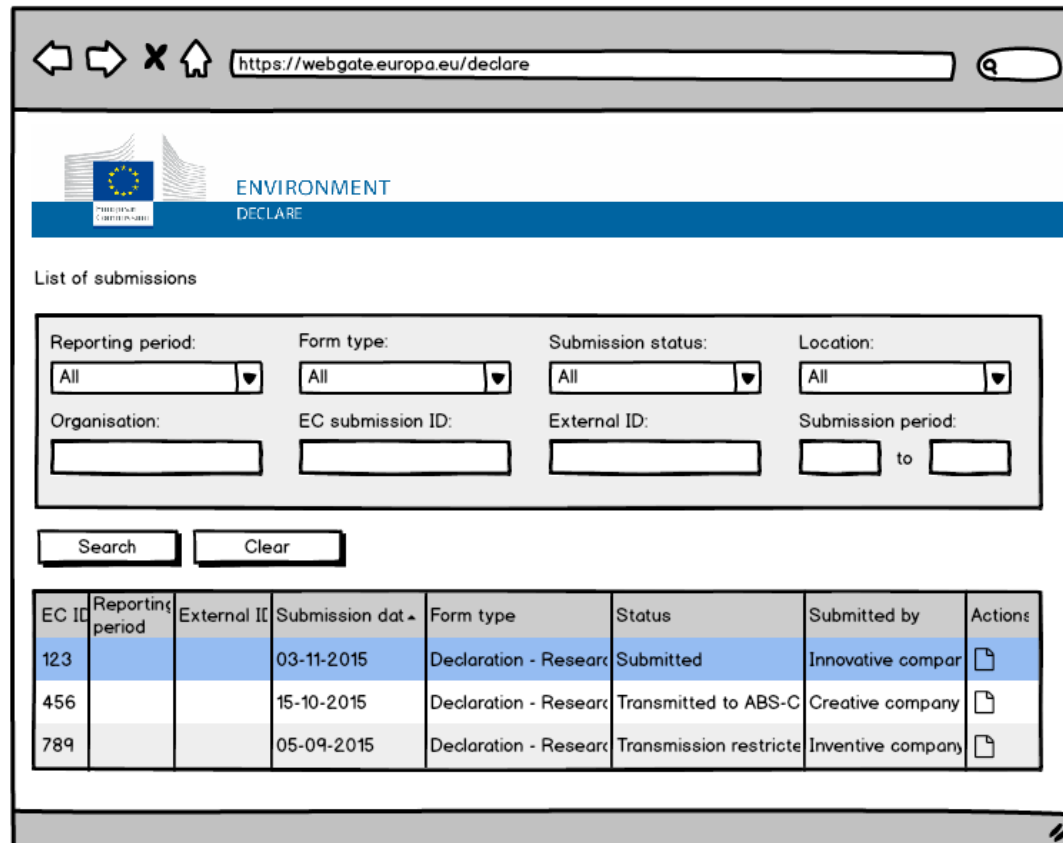
(iii) Identifier of access permit or its equivalent¹, where available:

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 compar	
456			15-10-2015	Declaration - Research	Transmitted to ABS-C	Creative company	
789			05-09-2015	Declaration - Research	Transmission restricte	Inventive company	





DECLARE – statistics

- **Information on users of DECLARE:**
 - Users of GR registered in DECLARE – 143 (most from DE (46), FR (23), UK (28), NL (21));
 - Public authorities registered in DECLARE – 14 Member States
- **Information on declarations:**
 - » 37 forms (most in draft form)
 - » 10 forms completed
 - » 4 due diligence declarations submitted to ABSCH
 - » 3 from DE CAs (for SA and FR GRs)
 - » 1 from MT CAs (for MT GR)



DECLARE – ABSCH

A screenshot of a web browser displaying the search results for the ABSCH database. The browser's address bar shows "absch.cbd.int/search". The page has search filters for "Record types", "Keywords", "Country", "Regions", and "Date". The results are categorized into "National records" (5), "Reference records" (1), and "SCBD records" (1). The first section is for "Germany" (NON-PARTY), which includes three "CHECKPOINT COMMUNIQUÉ (CPC)" entries. The first entry is titled "Research - Genetic resources: Isolation of Pristionchus nematodes from insects, i.e. scarab beetles. This work has institutional funding through the Max-Planck Society until 2031." The second entry is titled "Research - Genetic resources: Evolution, genetic basis, and behavioural consequences of cuticular hydrocarbon profiles in parabiotic ants". The third entry is titled "Research - Genetic resources: Various grants on sociobiology and evolution of ants DFG He1623/31, He1623/33, He1623/34, He1623/39, He1623/40, He1623/42". The second section is for "Malta" (NON-PARTY), which includes one "CHECKPOINT COMMUNIQUÉ (CPC)" entry titled "Research - Genetic resources: EN". The Windows taskbar at the bottom shows the date as 04-12-2018 and the time as 17:59.



Challenges of implementation

- Continuous need for awareness raising on ABS legal framework (incl. EU ABS Regulation)
 - **Workshops for researchers carried out in various European cities in 2015 and 2016;**
 - **Consultation Forum;**
 - **Involvement with various sectors**
- Insufficient clarity and legal certainty regarding the concepts used (utilisation – genetic resources)



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**



Scope

Geographic – temporal - material

- **GR/aTK 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
- **GR/TK accessed as of NP entry into force**
- **GRs utilised in the EU**



Complementary measures

– further guidance

- Request for sector-specific guidance on utilisation for 7 sectors:
 - **Animal breeding, plant breeding, biocontrol, biotechnology, food & feed, cosmetics, pharmaceutical sector**
- Dedicated documents for researchers and other upstream users (collections)
 - **External consultants under EC supervision and with stakeholder input & MS experts' support**
 - **Inclusive process: drafting groups, sectorial workshops**
- MS discussions on unresolved issues;

Animal breeding and ABS

- Animal breeding
 - **one of 7 sectors „tackled“ by the sectorial guidance**
 - **ABS relevant to animal breeding**
 - less than other sectors due to phyto-sanitary measures in the EU;
 - Import of animal material to the EU limited
 - EU MS (access) – no legislation on animal breeding;
- Specificity of animal breeding
 - **Similarly to plant breeding: outcome of the process → genetic resource**
 - **Similarly to plant breeding → need for a cut-off point**



Animal breeding and ABS

- Differences with plant breeding:
 - **Continuous process of improvement**
 - **New distinct breeds or lines – rarely created**
- Different scenarios possible when introducing NP material:
 - Registration in herd book (Reg. 2016/1020) (bovine, porcine, ovine, caprine...)
 - „in house” breeding programmes by companies (poultry/ fish)
 - Individuals (dealing with livestock or pet animals) – not a member of recognised breeding organisation



Animal breeding and ABS

- New product -- > in scope of EU ABS Regulation:
 - **Requires due diligence/ due diligent declaration**
 - **Further use of the material – considered out of scope**
 - **Contractual obligations to be fulfilled**



Further information

- DG ENV, ABS website
http://ec.europa.eu/environment/nature/biodiversity/international/abs/legislation_en.htm
- DG ENV Policy Officer(s) (Unit F3 – 'Multilateral Environmental Cooperation')
alicja.kozlowska@ec.europa.eu
- CBD Nagoya Protocol and ABSCH websites
<https://www.cbd.int/abs/default.shtml>
- <https://absch.cbd.int/>