Eine Zukunftsaufgabe in guten Händen

Bundesamt für Naturschutz

The Nagoya Protocol & its implementation in the EU - What does it mean for biodiscovery?

Greifswald, 23/08/2018

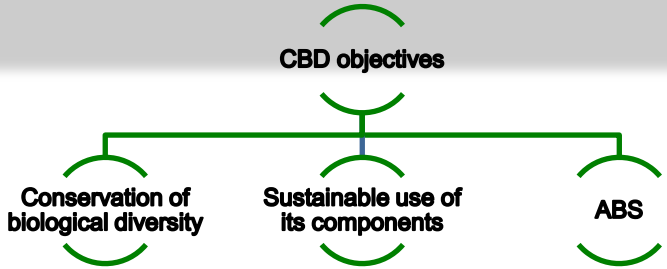


The Origins of ABS

Since entry into force of CBD (1993):

- Access and Benefit-sharing (ABS) as 3rd CBD objective

„… 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.“ (Art. 1 CBD)



- Clarification: states have sovereign rights over their (biological & genetic) resources (Art. 3 CBD)
- ABS as innovative instrument for biodiv conservation

The Origins of ABS: Article 15 CBD

ABS principles according to CBD:

Art. 15(1)	• Sovereign rights of states over their (biological) resources, incl. **right to regulate access to GR**
Art. 15(2)	• Create conditions to **facilitate access** to GR
Art. 15(4)	• Access based on **mutually agreed terms** (MAT)
Art. 15(5)	• Access subject to **prior informed consent** (PIC), unless otherwise determined
Art. 15(7)	• Take measures with the aim of **fair & equitable sharing of benefits** from utilization

From CBD to Nagoya Protocol

1993:
CBD enters into force

1998:
COP 4 establishes ABS Expert Panel (after COP 5 Ad Hoc Open-ended Working Group)

2002:
COP 6 adopts the voluntary Bonn Guidelines

2002:
Rio+10 calls for negotiation of an internat. ABS regime

2004-2010:
Negotiations on the Nagoya Protocol

October 2010:
COP 10 adopts the legally binding Nagoya Protocol

12 October 2014:
Nagoya Protocol enters into force

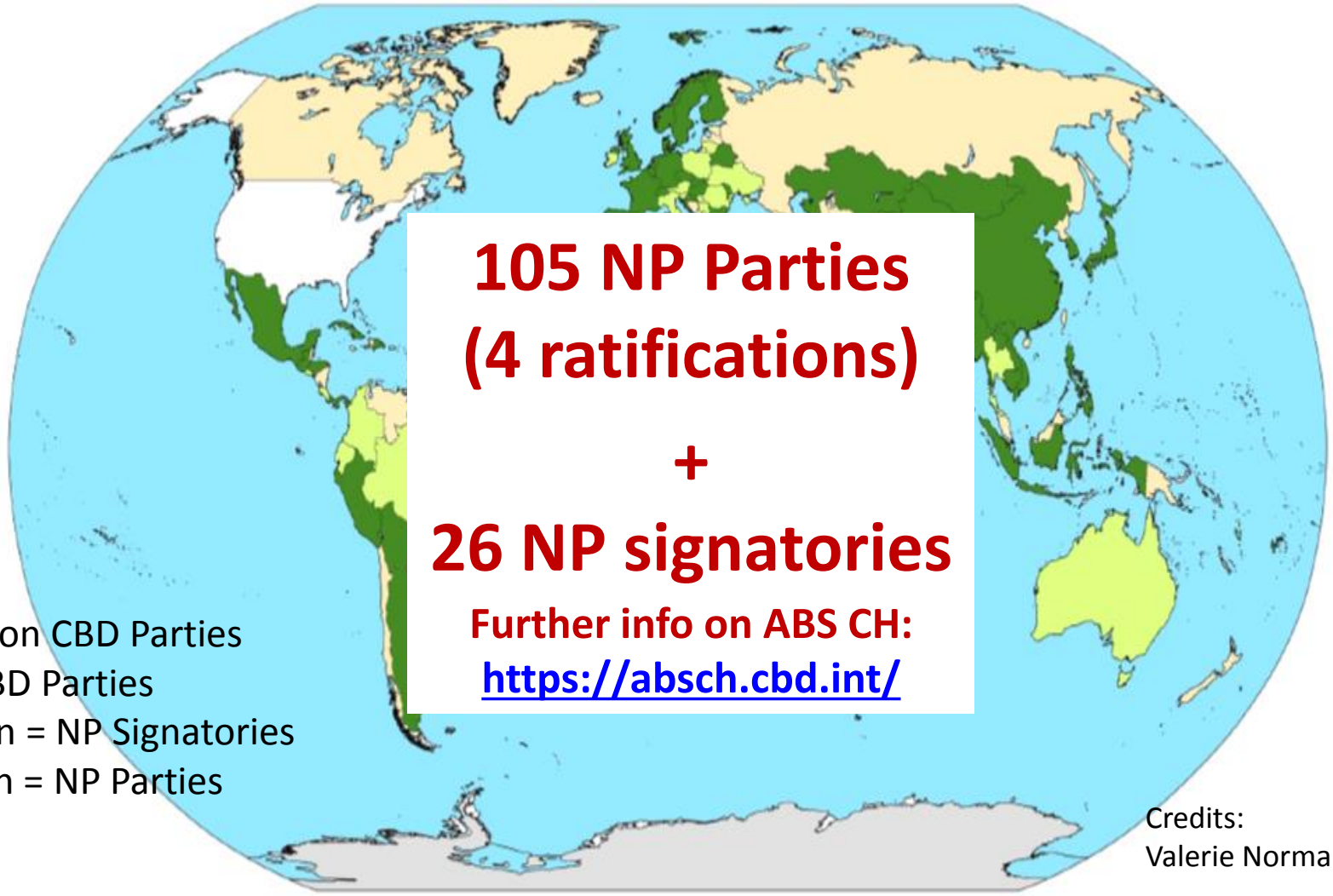
June 2004:
FAO ITPGRFA enters into force

May 2011:
WHO adopts PIP Framework

2018-2020:
UNCLOS negotiations on BBNJ

?

Nagoya Protocol – Status Quo



105 NP Parties
(4 ratifications)

+

26 NP signatories

Further info on ABS CH:
https://absch.cbd.int/

White = Non CBD Parties
Beige = CBD Parties
Lime green = NP Signatories
Dark green = NP Parties

Credits:
Valerie Normand - SCBD

Nagoya Protocol – Main Content

The ABC of ABS

- **A** ccess: internat. „standards“ / criteria for domestic access measures (Art. 6(3), 8 NP)
- **B** enefit-sharing: based on MAT (incl. IPLCs) (Art. 5 NP)
- **C** ompliance measures (Art. 15-17 & 18-20 NP)

Institutional provisions:

- ABS National Focal Point (Art. 13(1) NP):
  - Information on ABS rules & procedures in provider state
- Competent National Authority(ies) (Art. 13(2) NP):
  - Responsible for implementation of ABS rules & procedures
- ABS Clearing-House (Art. 14 NP): https://absch.cbd.int/

Nagoya Protocol

Article
36
AUTHENTIC TEXTS

The original of this Protocol, of which the Arabic, Chinese, English, French, Russian and Spanish texts are equally authentic, shall be deposited with the Secretary-General of the United Nations.

IN WITNESS WHEREOF the undersigned, being duly authorized to that effect, have signed this Protocol on the dates indicated.

DONE at Nagoya on this twenty-ninth day of October, two thousand and ten.

Annex
MONETARY AND NON-MONETARY BENEFITS

1. Monetary benefits may include, but not be limited to:
   (a) Access fees/fee per sample collected or otherwise acquired;
   (b) Up-front payments;
   (c) Milestone payments;
   (d) Payment of royalties;
   (e) Licence fees in case of commercialization;
   (f) Special fees to be paid to trust funds supporting conservation and sustainable use of biodiversity;
   (g) Salaries and preferential terms where mutually agreed;
   (h) Research funding;
   (i) Joint ventures;
   (j) Joint ownership of relevant intellectual property rights.
2. Non-monetary benefits may include, but not be limited to:
   (a) Sharing of research and development results;
   (b) Collaboration, cooperation and contribution in scientific research and development programmes, particularly biotechnological research activities, where possible in the Party providing genetic resources;

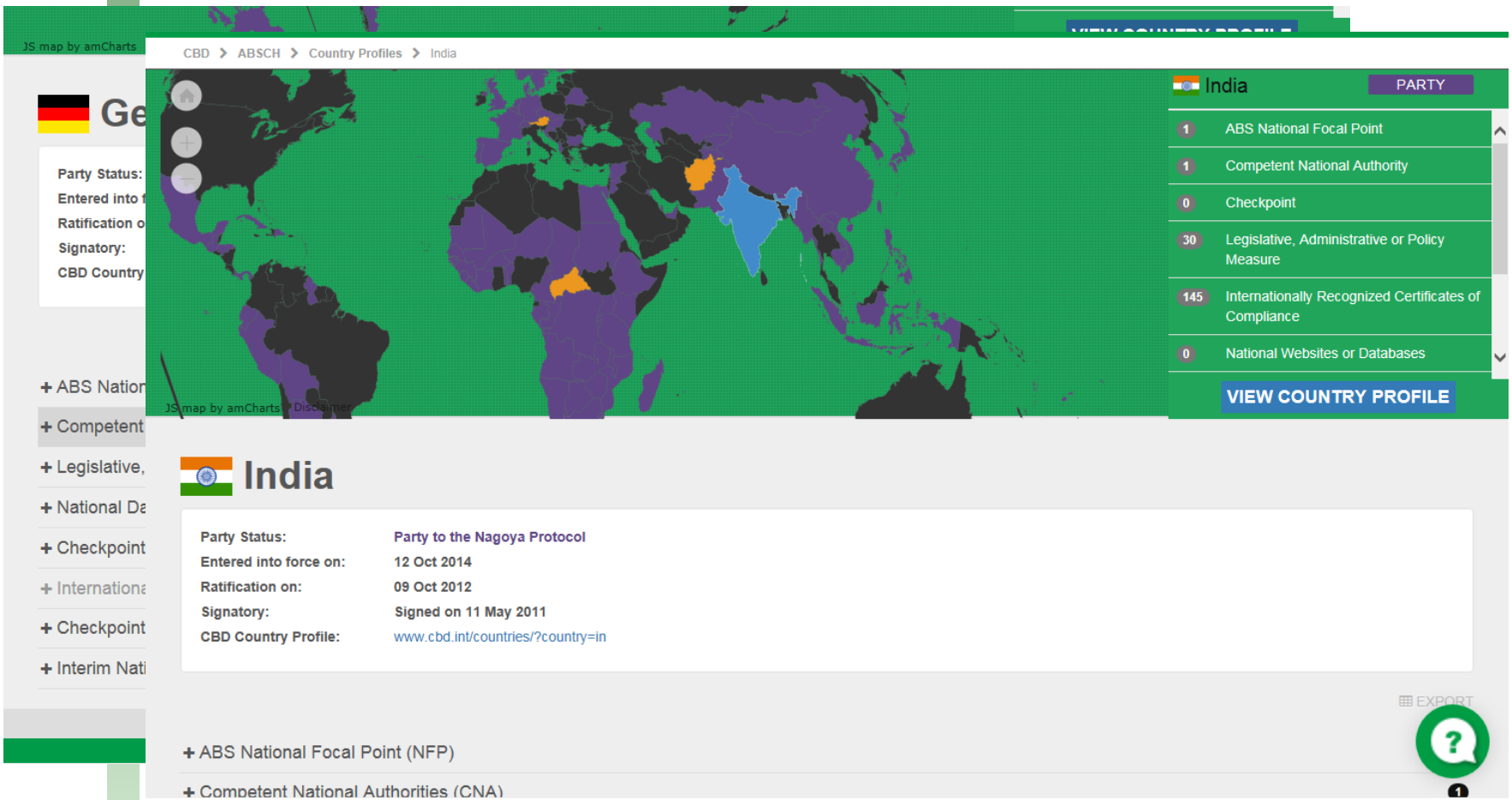
   (c) Participation in product development;
   (d) Collaboration, cooperation and contribution in education and training;
   (e) Admittance to *ex situ* facilities of genetic resources and to databases;
   (f) Transfer to the provider of the genetic resources of knowledge and technology under fair and most favourable terms, including on concessional and preferential terms where agreed, in particular, knowledge and technology that make use of genetic resources, including biotechnology, or that are relevant to the conservation and sustainable utilization of biological diversity;
   (g) Strengthening capacities for technology transfer;
   (h) Institutional capacity-building;
   (i) Human and material resources to strengthen the capacities for the administration and enforcement of access regulations;
   (j) Training related to genetic resources with the full participation of countries providing genetic resources, and where possible, in such countries;
   (k) Access to scientific information relevant to conservation and sustainable use of biological diversity, including biological inventories and taxonomic studies;
   (l) Contributions to the local economy;
   (m) Research directed towards priority needs, such as health and food security, taking into account domestic uses of genetic resources in the Party providing genetic resources;
   (n) Institutional and professional relationships that can arise from an access and benefit-sharing agreement and subsequent collaborative activities;
   (o) Food and livelihood security benefits;
   (p) Social recognition;
   (q) Joint ownership of relevant intellectual property rights.

ABS Clearing-House

Which countries are Parties to the NP?

ABS Clearing-House

Country profiles:



Legal Framework in Germany

A(ccess)

- **Regulated by EU MS themselves**
- **In Germany, generally free (no PIC)**

B(enefit Sharing)

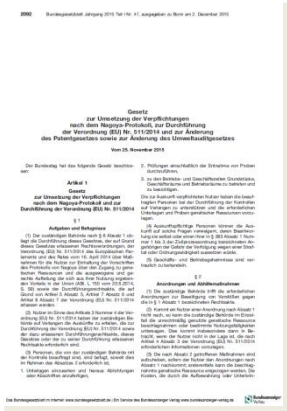
- **Regulated by EU MS themselves**
- **In Germany, not required (no MAT)**

C(ompliance)

- **Based on EU legislation**

- Regulation (EU) No 511/2014: Entry into force on 12.10.2014
- Impl. Regulation (EU) 2015/1866: Entry into force on 9.11.2015
- EU Guidance Document (EC) 2016/C 313/01: Published on 27.08.2016

- Implementing Act adopted on 25.11.2015
- Entry into force on 1.7.2016
- Party to Nagoya Protocol since 21.7.2016



Scope of Regulation (EU) No 511/2014

All prerequisites must be fulfilled

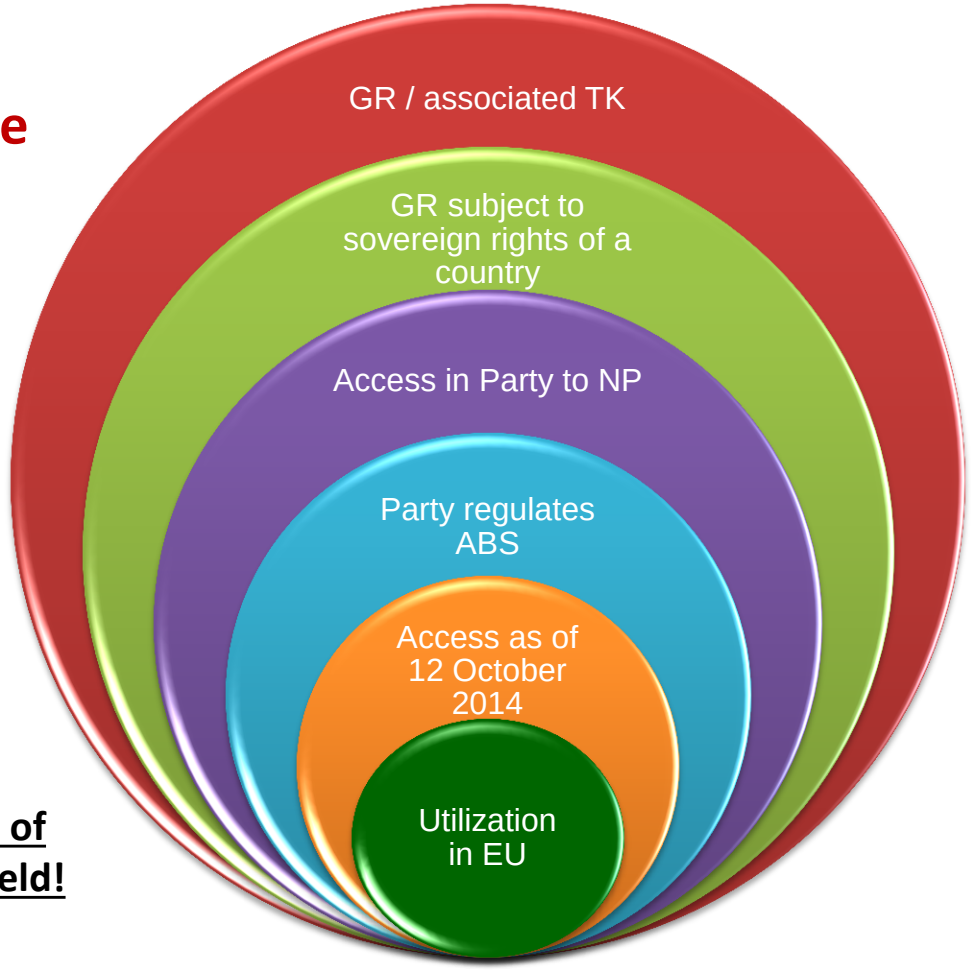
If one is not fulfilled

↓

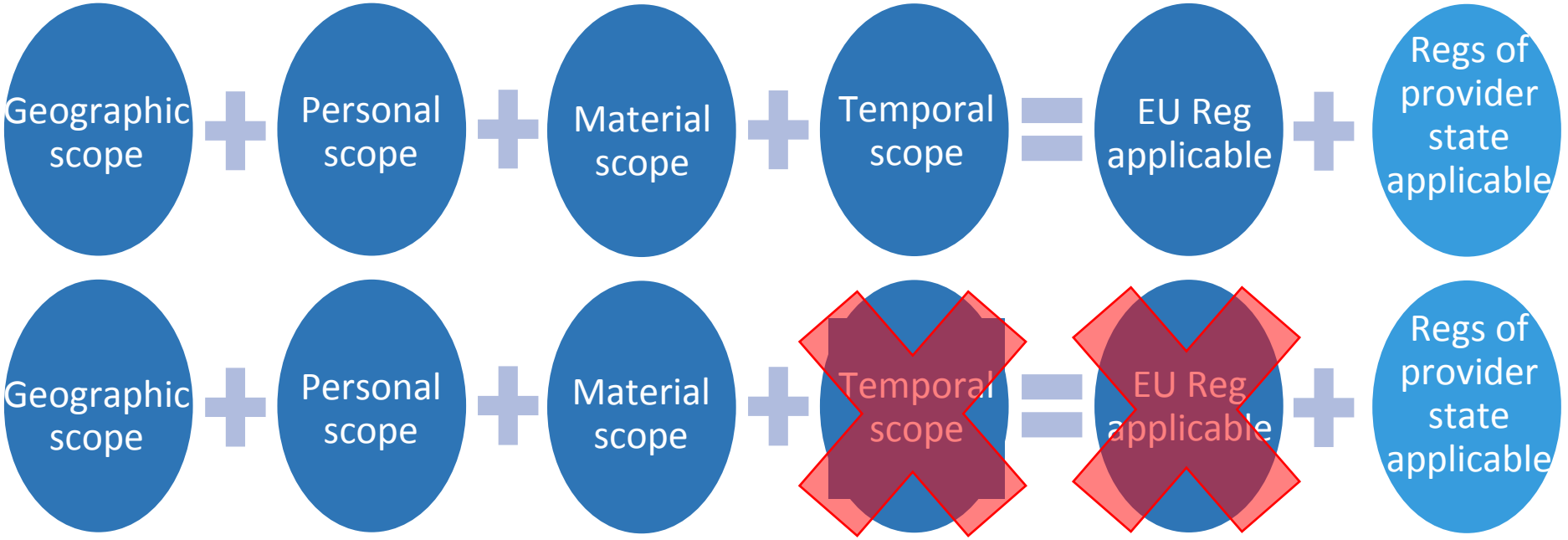
EU Reg. & Impl. Act not applicable

↓

<u>However, existing ABS legislation of provider country must still be upheld!</u>



Scope of Regulation (EU) No 511/2014



Due Diligence System

Art. 4 EU Reg.: General DD obligation

- User to ascertain that
  - GR/TK accessed in accordance with applicable ABS legislation
  - Benefits fairly & equitably shared upon MAT

Documentation obligation	• Seek • Keep (20 years after utilization) • Transfer • Relevant documentation (Art. 4.3 a) or b))
Risk assessment obligation	• If insufficient information or uncertainties about legality of access & utilization • PIC & MAT or equivalent to be obtained or • Utilization to be discontinued (Art. 4.5)
Options for mitigating risks	• Acquisition of GR from registered collection (Art. 5) • Recognized best practice (Art 8.2 EU Reg. or Art 20.2 NP)

Art. 7 EU Reg.: Obligations to file DD declarations

DD Declaration I

At stage of research funding (Art. 7.1)

Content: Annex II of Implementing Reg.

Submission by r

jects funded by commercial or non-
al sources
not internal budgetary resources

Submission after 1st instalment of funding & GR/TK obtained

But no later than time of final report or project end

In Germany, DDD under Art. 7.1 mandatory since 10.05.2018

DD Declaration II

At stage of final product development (Art. 7.2)

Content: Annex II of Implementing Reg.

Only made once

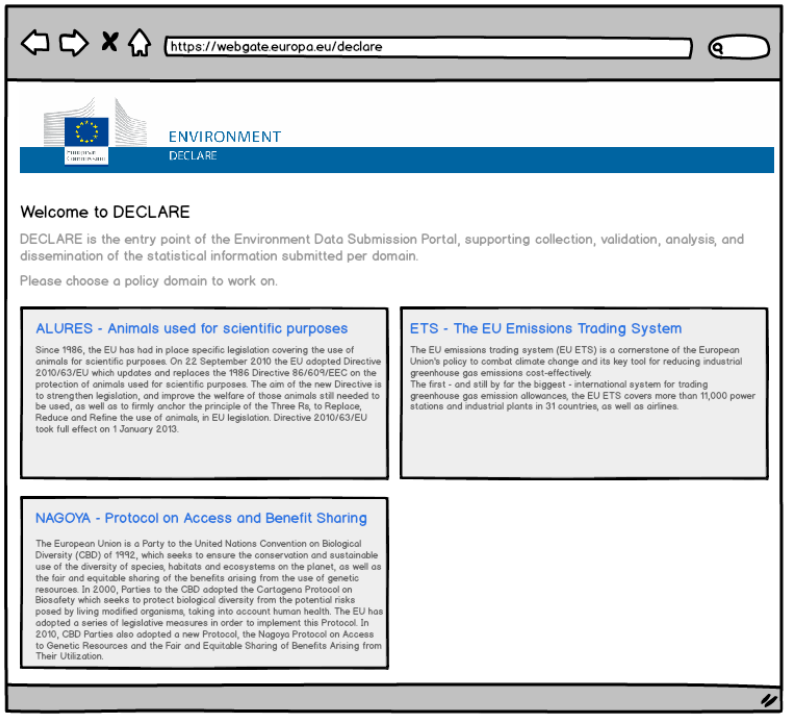
Prior to first of following events

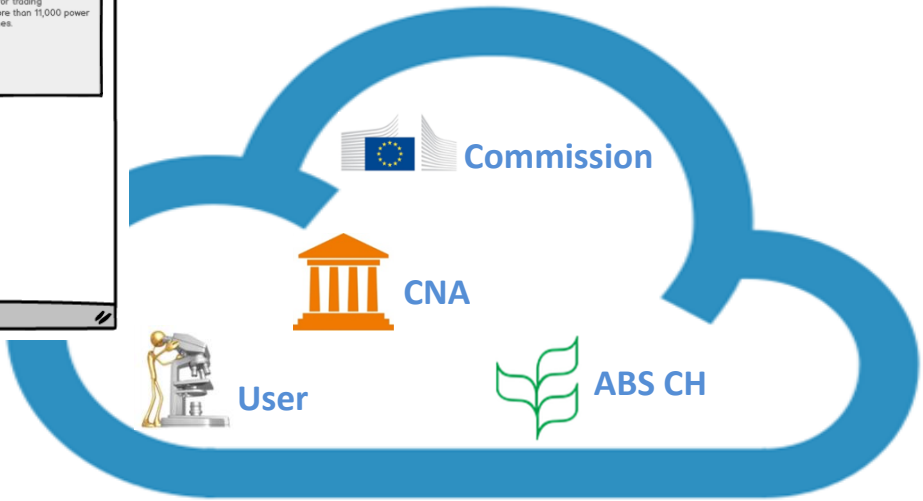
Market approval; notification prior to placing on Union market for first time; placing on Union market for first time; sale or transfer of result of utilization within Union; end of utilization in Union & sale or transfer of outcomes outside Union

4 weeks before end of utilization

Submission of DDD

DECLARE:





IT Tool

Submission of DDD

How to use DECLARE:

- Registration of user institution through ECAS
  https://webgate.ec.europa.eu/cas

- Login with ECAS-ID in DECLARE
  https://webgate.ec.europa.eu/declare/

- Automated notification of BfN as CNA & activation of user institution

- Automated notification of user institution after activation

Submission of DDD

- User institution may navigate in DECLARE system
  - Adding further users of same or partnering institution
  - Drafting & submitting DDDs

- Automated notification of BfN after submission of DDD

- Reply to user or DDD forwarded to ABS CH

- Automated conversion into checkpoint communiqué published on ABS CH & notification of provider state

For further info see DECLARE User Guide:
http://ec.europa.eu/environment/nature/biodiversity/international/abs/pdf/Question%20and%20answer%20users.pdf

Register of Collections

Art. 5 EU Reg.:

- Register established & maintained by Commission
- Application to & recognition by Member States
- Criteria to register collection or part of it:
  - Standardized procedures for exchanging samples of GR
  - Supply of GR only with appropriate documentation
  - Keep records of all samples of GR suppiled to 3rd persons
  - Establish or use unique identifiers where possible
  - Use appropriate tracking & monitoring tools
- Content of application: Annex I of Implementing Reg.

First (and so far only) registered collection in EU

Best Practices

Art. 8 EU Reg.:

- Recognized by Commission
- Who can apply?
  - Association of users &
  - Other interested parties
- Criteria defined in EU Reg.
  - Combination of procedures, tools & mechanisms
  - Enabling user to comply with obligations under Art. 4 & 7
- Content of application: Annex IV of Implementing Reg.

Compliance Checks

Art. 9 EU Reg. & Art. 5.4 EU Reg.:

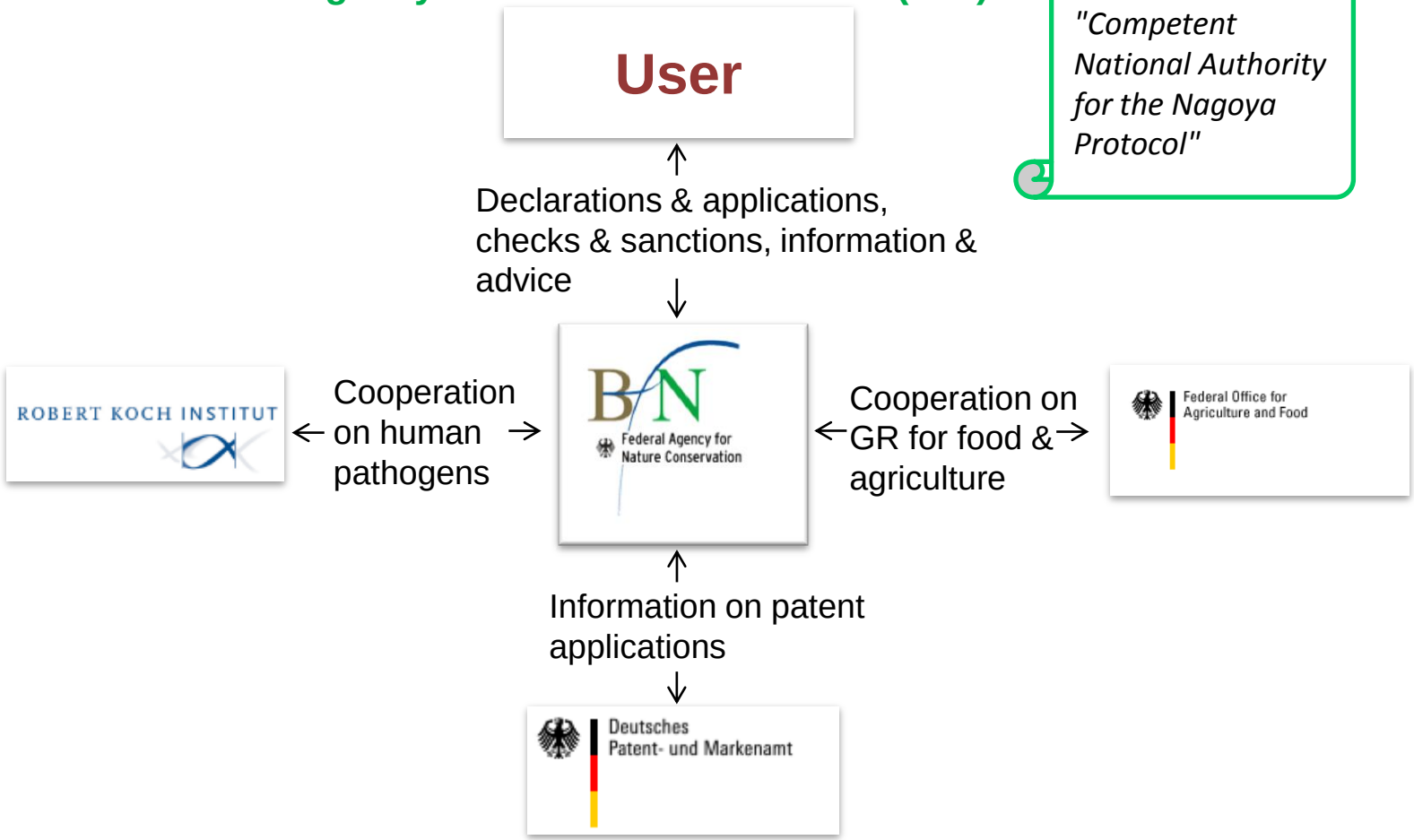
- Compliance checks carried out by competent national authorities
- On the basis of
  - Periodically reviewed control plans using risk-based approach
  - Substantiated concerns
- Subject matter:
  - Due diligence obligation
  - DDDs
  - Criteria of registration

Competencies in Germany

NFP: **Federal Ministry for the Environment, Nature Conservation and Nuclear Safety (BMU)**

CNA: **Federal Agency for Nature Conservation (BfN)**

Division I 1.3 "Competent National Authority for the Nagoya Protocol"

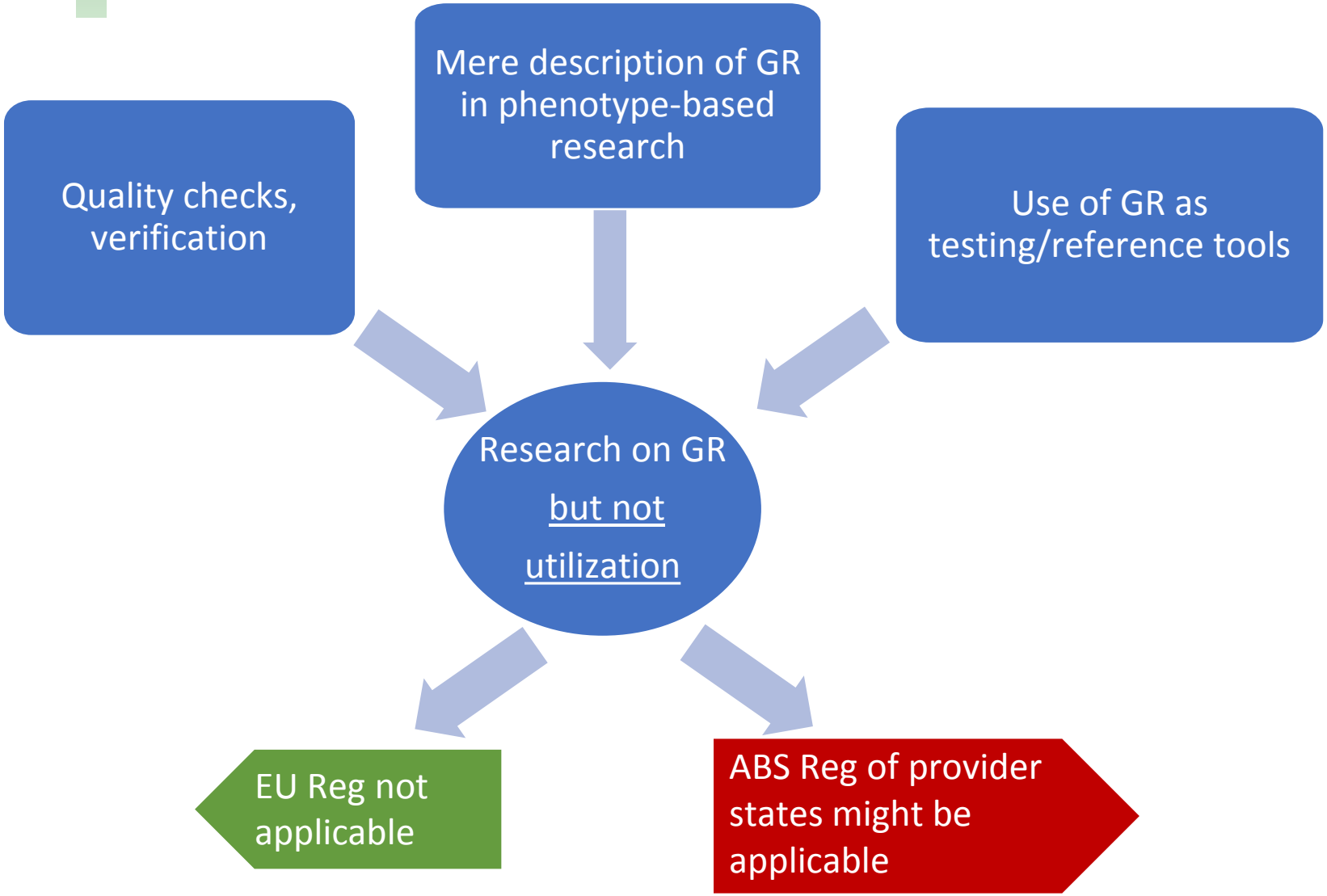


Utilization under Regulation (EU) No 511/2014

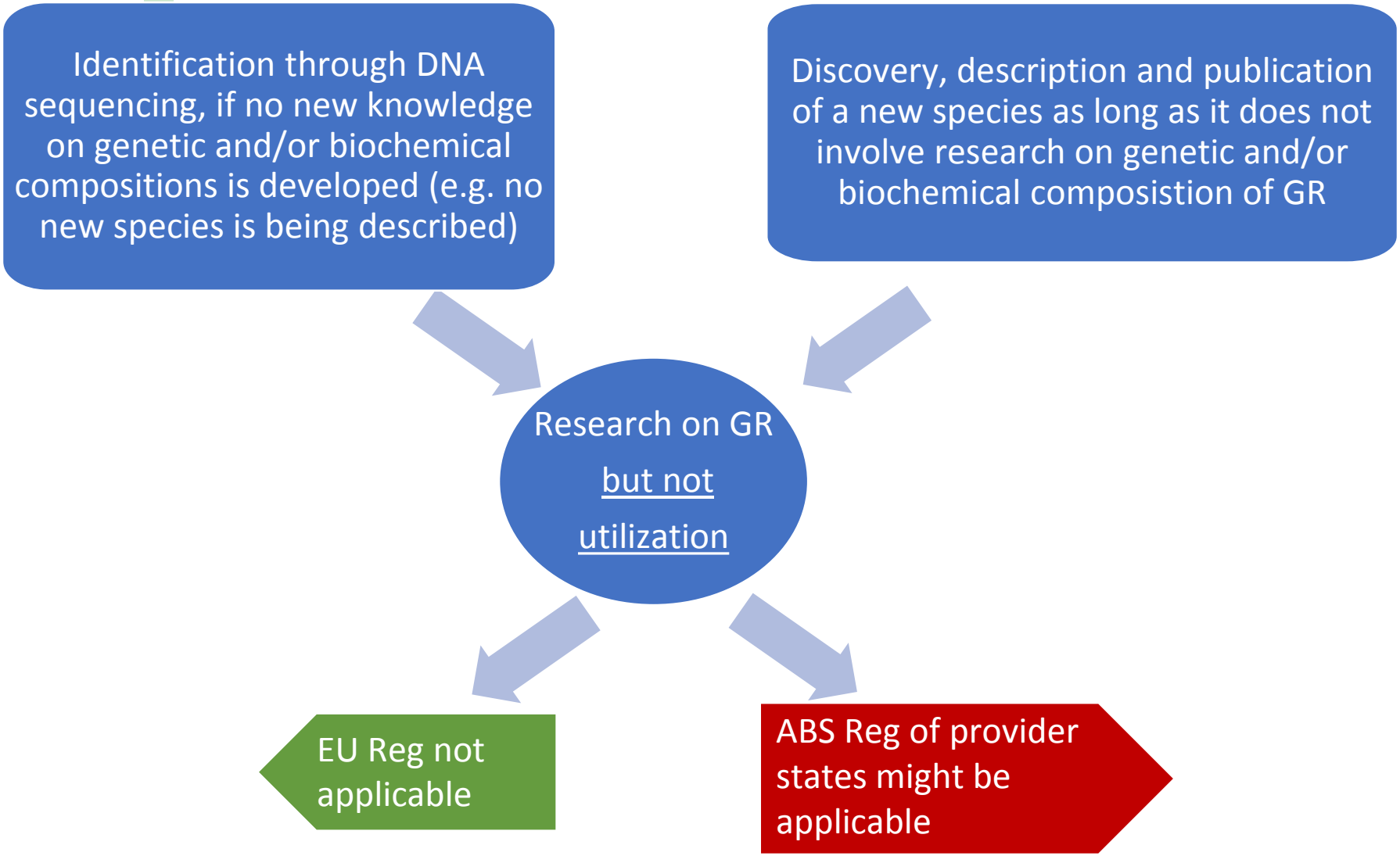
- … Depending on the specific activity undertaken, both basic and applied research may be considered as "utilization" in the sense of the NP and EU Regulation. (EU Guicance Doc (EC) 2016/C 313/01; 2.3.3.)

- Litmus test: Users should ask themselves whether what they are doing with the GR creates new insight into **characteristics of the GR** which is of (potential) benefit to the further process of product development. If this is the case, the activity goes beyond mere description, should be considered research and therefore falls under the term "utilization". (EU Guidance Doc (EC) 2016/C 313/01; 2.3.3.)

Utilization under Regulation (EU) No 511/2014



Utilization under Regulation (EU) No 511/2014



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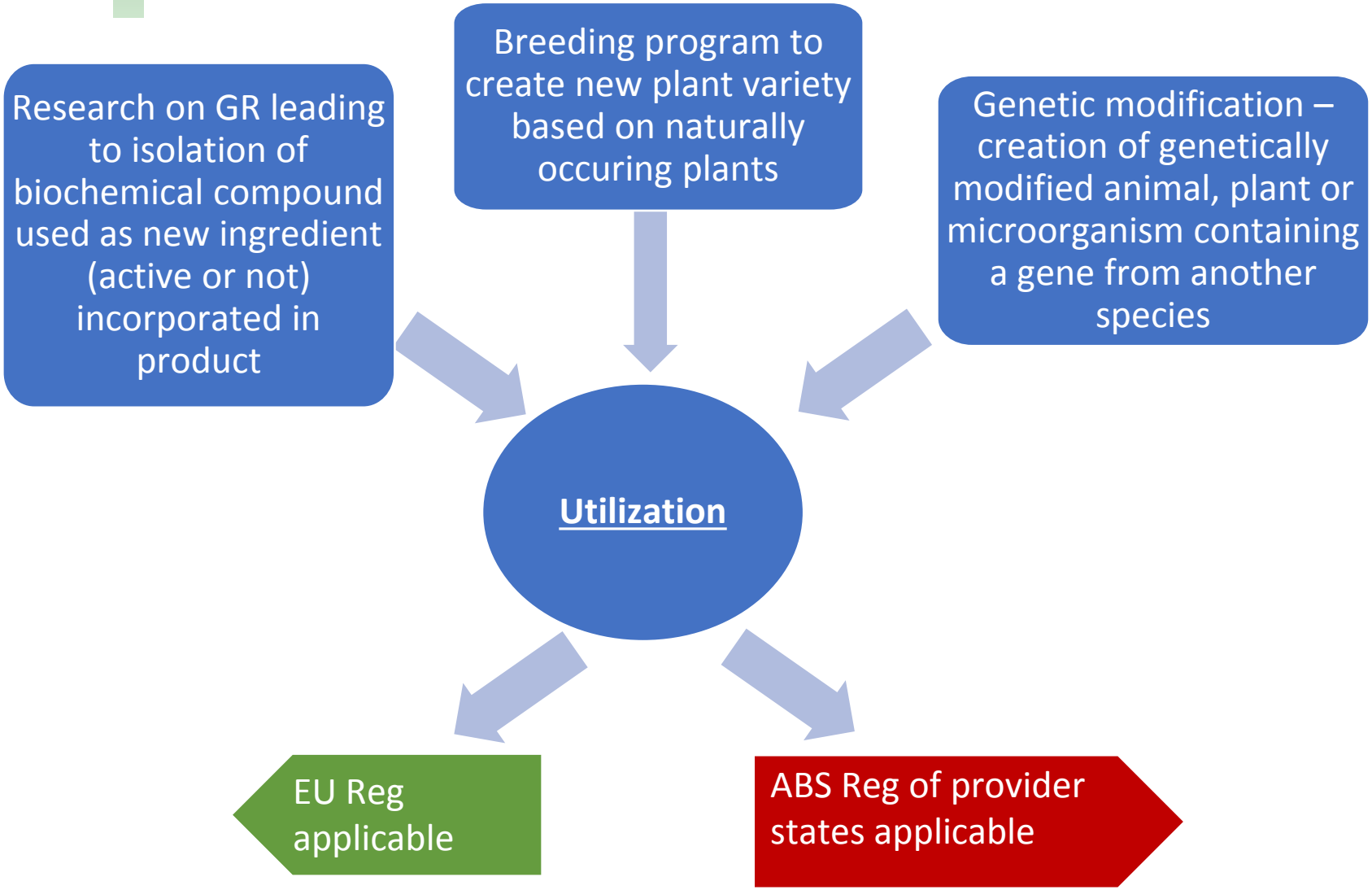
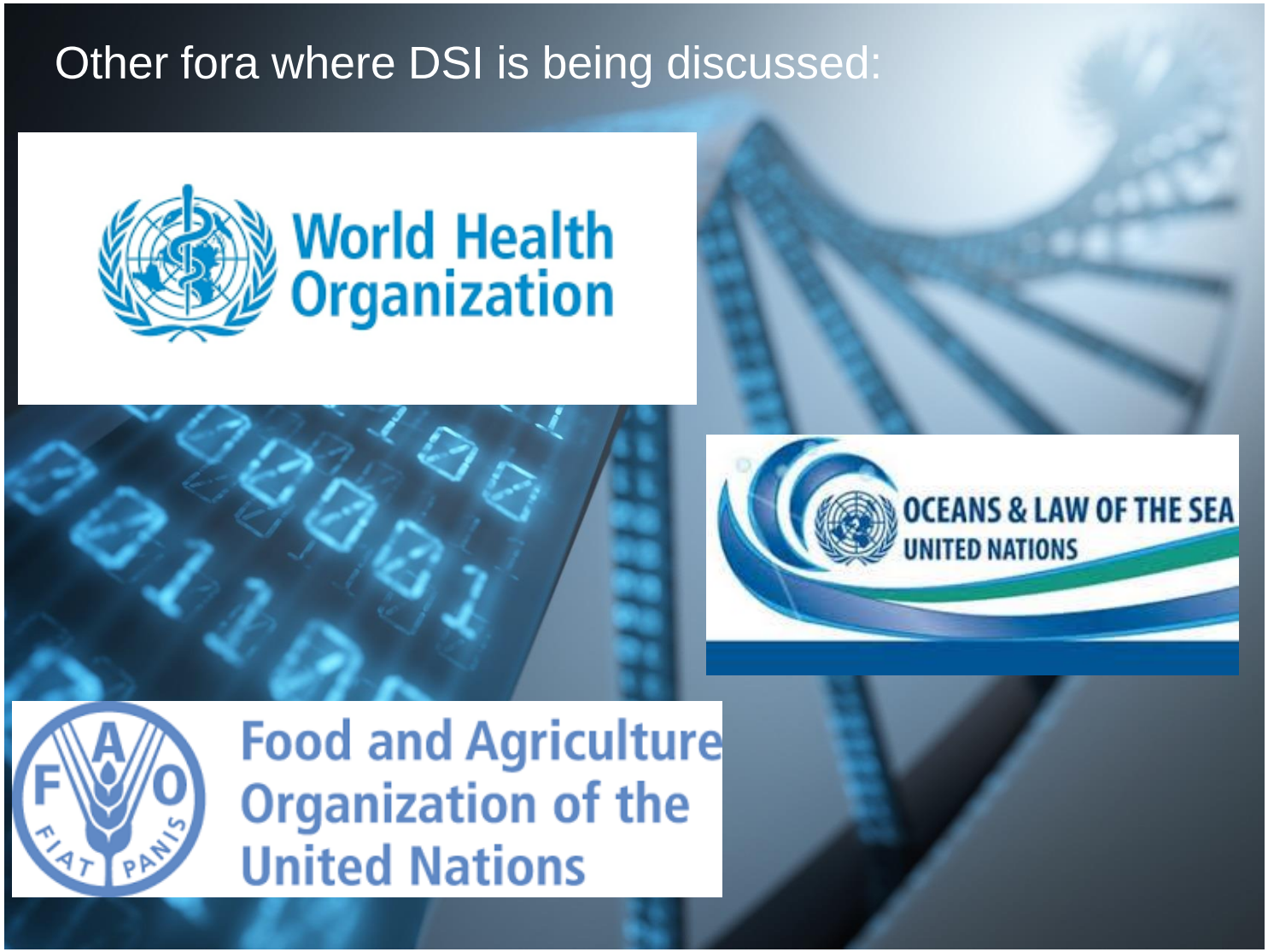


Digital Sequence Information

UN BIODIVERSITY CONFERENCE
COP13 -COPMOP8-COPMOP2
CANCUN, MEXICO 2016
MAINSTREAMING BIODIVERSITY FOR WELL-BEING

- Call by developing countries to include DSI within scope of NP
- CBD COP Decision XIII/16 & NP MOP Decision 2/14:
  - Consider (by COP XIV / MOP 3) any potential implications of use of DSI on GR for the 3 objectives of CBD & objective of NP
- Open process comprising following steps:
  - 04-12/2017 Scoping study on terminology & concepts
  - 09/2017 Submission of views & information
  - 02/2018 Meeting of AHTEG
  - 07/2018 SBSTTA to make recommendations
  - 11/2018 Negotiations at COP XIV / MOP 3

Digital Sequence Information



Thank You Very Much!

Federal Agency for Nature Conservation
(Bundesamt für Naturschutz - BfN)
Division I 1.3
Konstantinstr. 110, D-53179 Bonn

Email: Nagoya-CNA@bfn.de
Tel: +49-228/8491-1311
Fax: +49-228/8491-1319
Web: http://abs.bfn.de

Credits

Slide 2	“Logo Convention on Biological Diversity”, https://www.cbd.int/
Slide 4	”Text of the Convention on Biological Diversity”, www.cbd.int/programmes/outreach/awareness/publications.shtml, “Bonn Guidelines“, www.cbd.int/abs/bonn/, ”World Summit on Sustainable Development”, www.un.org/events/wssd/, ”Logo COP 9”, www.cbd.int/cop9/default.shtml , “Logo COP 10”, https://labexkorea.files.wordpress.com/2010/11/cop-10-nagoya.jpg , ”Logo COP 12”, http://cbdcop12.kr/eng/index.php, “Text of the Treaty“, http://planttreaty.org/content/texts-treaty-official-versions, “Pandemic influenza preparedness Framework“, www.who.int/influenza/resources/pip_framework/en , “Logo UNDOALOS“, http://www.un.org/Depts/los/convention_agreements/convention_overview_convention.htm
Slide 7	“Annex of the Nagoya Protocol“, www.cbd.int/abs
Slides 8-9	“ABS Clearing-House“, https://absch.cbd.int
Slide 10	“EUR-Lex Access to European Union law”, http://eur-lex.europa.eu/legal-content/de/TXT/?uri=OJ:L:2014:150:TOC
Slide 16	Graphics by the European Commission
Slide 19	“Logo of DSMZ”, https://www.dsmz.de/
Slide 22	Logo of Robert Koch Institut, http://www.rki.de/DE/Home/homepage_node.html , Logo of Bundesanstalt für Landwirtschaft und Ernährung, http://www.ble.de/DE/00_Home/homepage_node.html , Logo of deutsches Patent- und Markenamt“, http://www.dpma.de/
Slide 27	“Logo CBD COP XIII“, https://www.cbd.int/conferences/2016
Slide 28	ktsimage_istockphoto.com, “Logo WHO“, http://www.who.int/ , “Logo FAO“, http://www.fao.org/ ,“Logo UNDOALOS“
Slide 29	Сергей_Хакимуллин_istockphoto.com