

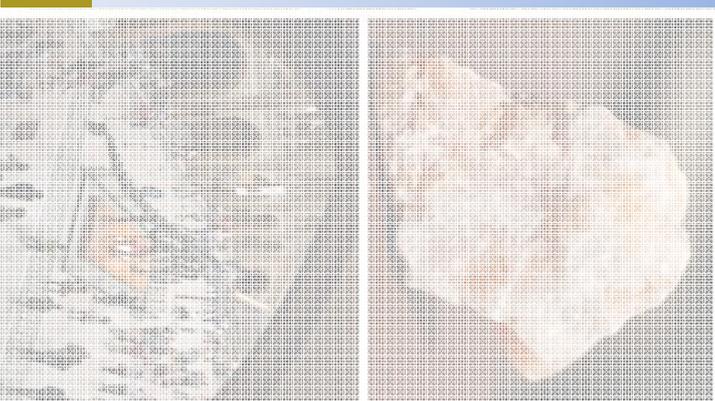
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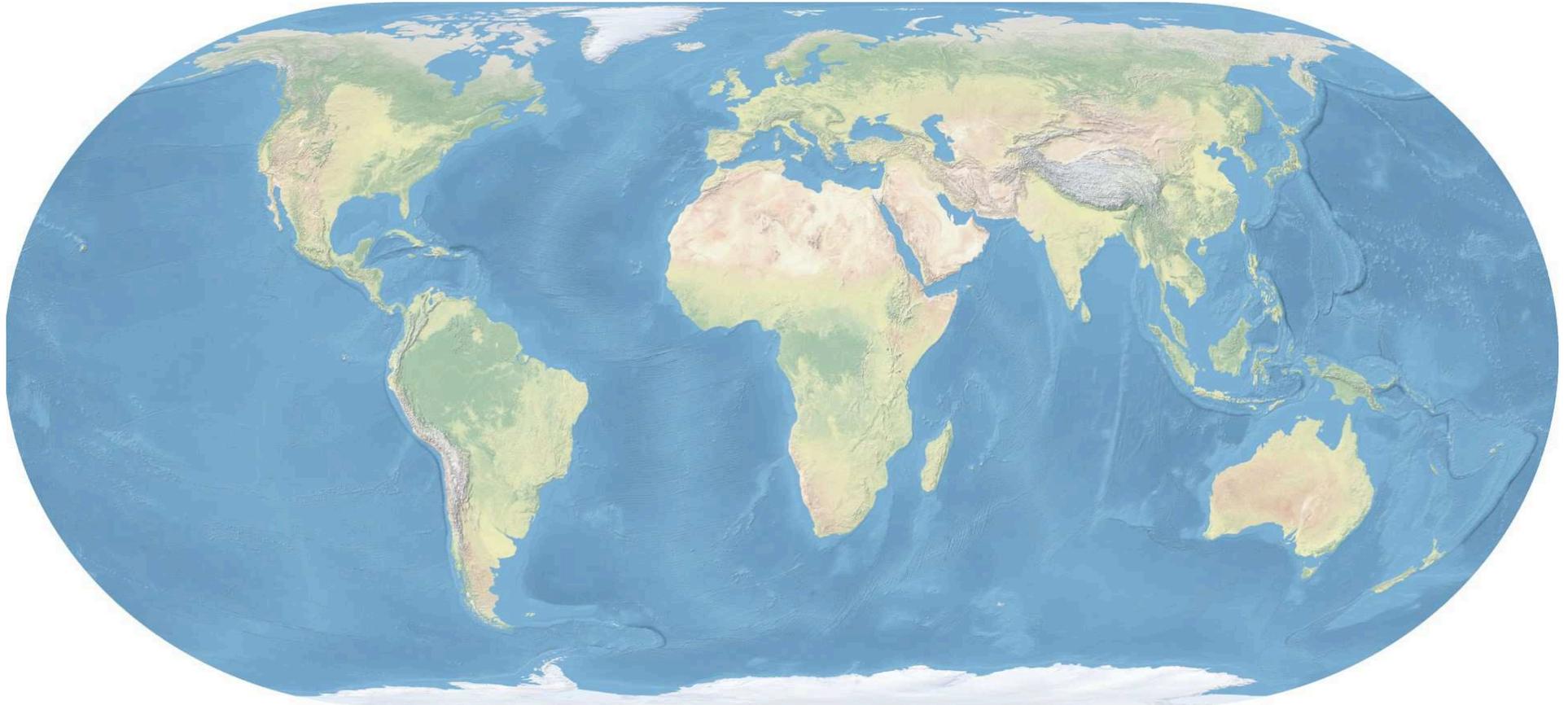
The European ABS Legislation

CETAF Legislation and Regulations Liaison Group

CETAF WORKSHOP ON ABS - Berlin, 25 June 2016



The World of ABS



The World of ABS

Basic Principles of Access & Benefit Sharing

- (1) States have **sovereign rights** over their genetic resources and may regulate access and utilization
- (2) Before accessing a genetic resource a potential user has to obtain a permit (**Prior informed Consent, PIC**) from the providing country's authorities and negotiate Mutually Agreed Terms (MAT), if necessary
- (3) **Benefits** generated out of the utilization of genetic resource have to **be shared** fairly and equitably with the providing country

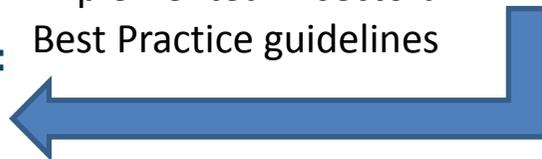
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Implemented in sectoral
Best Practice guidelines

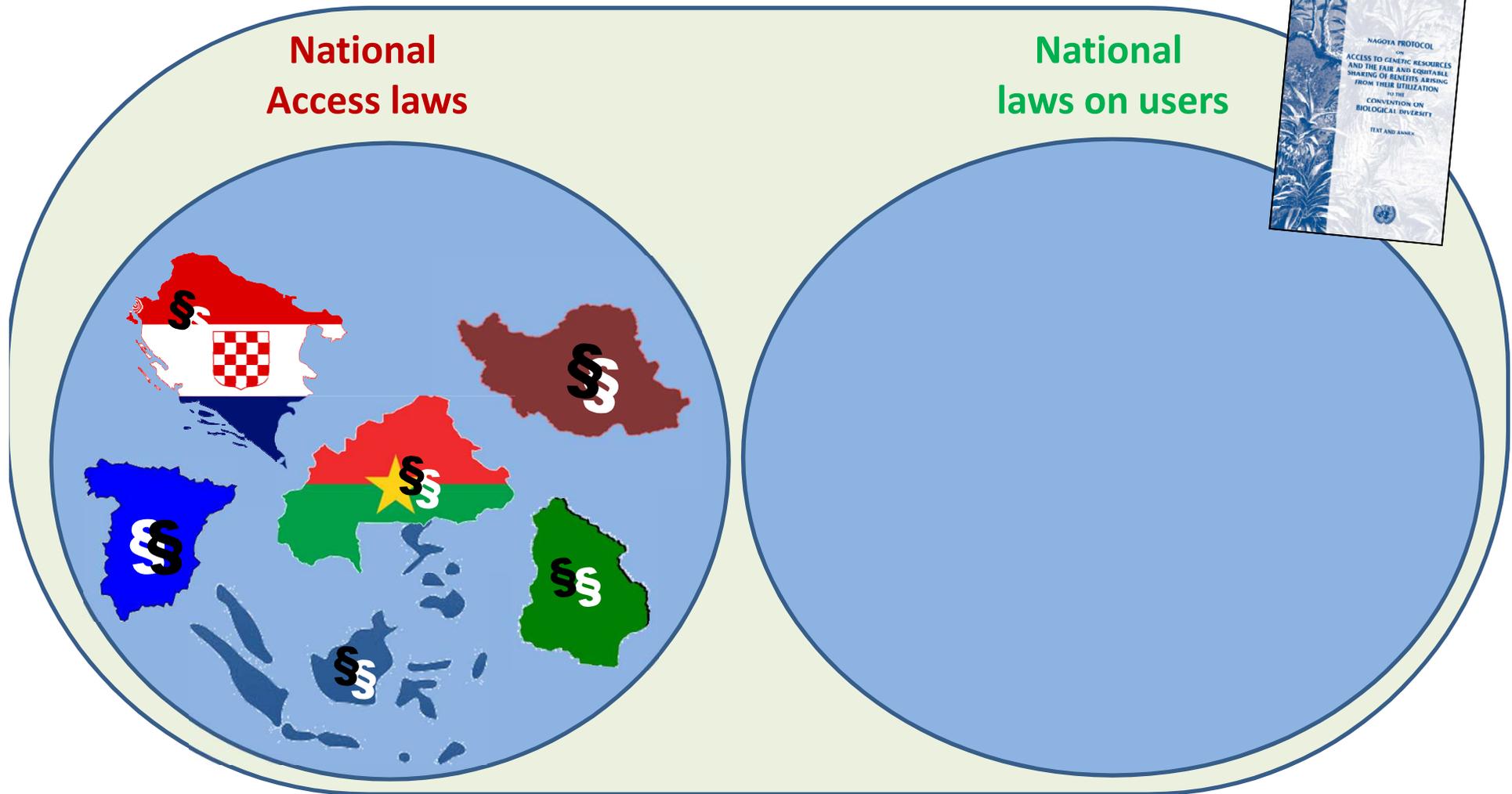


laid down in
(since 1992)

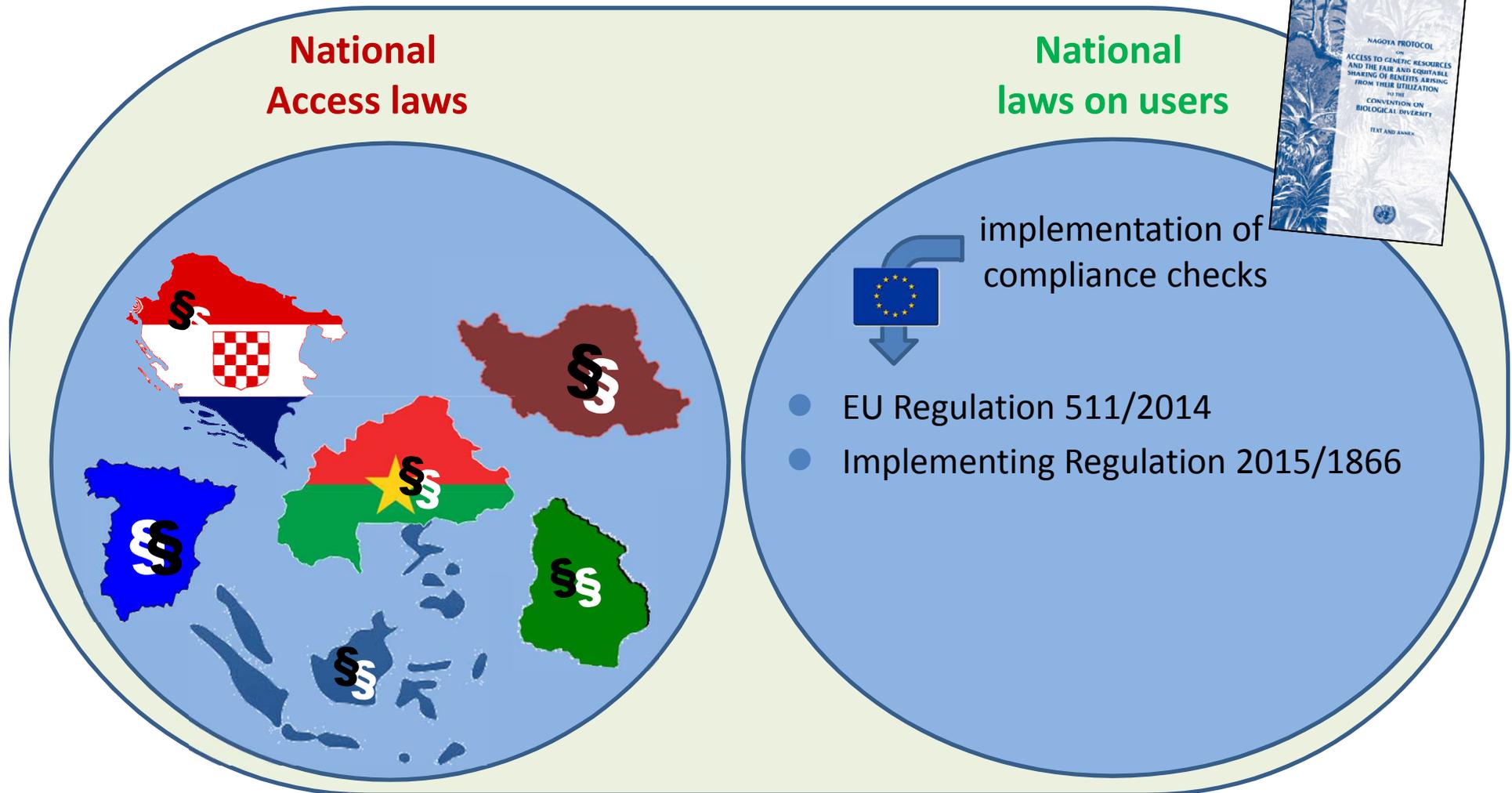


Convention on
Biological Diversity

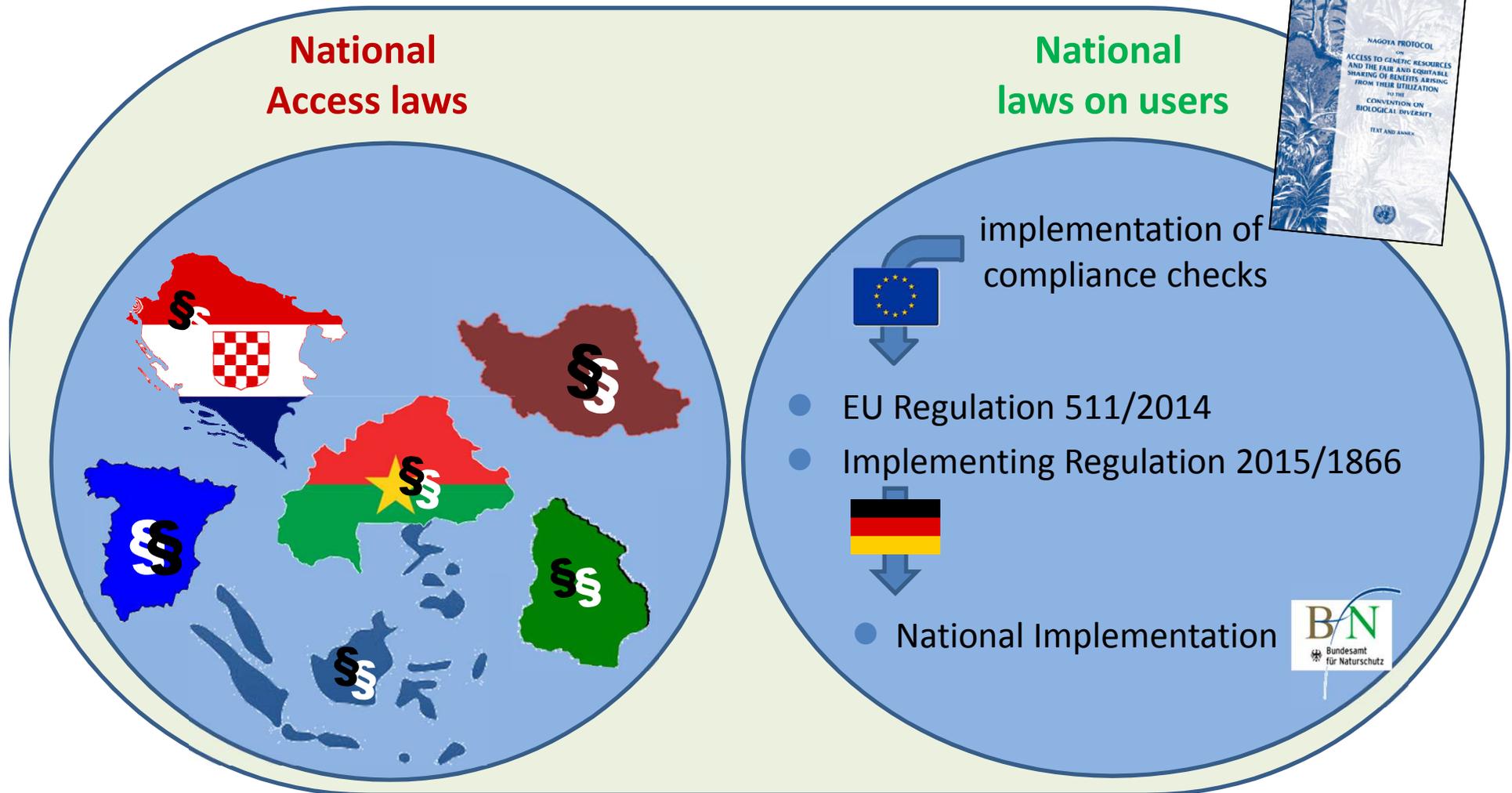
Basic Principles of the legal framework



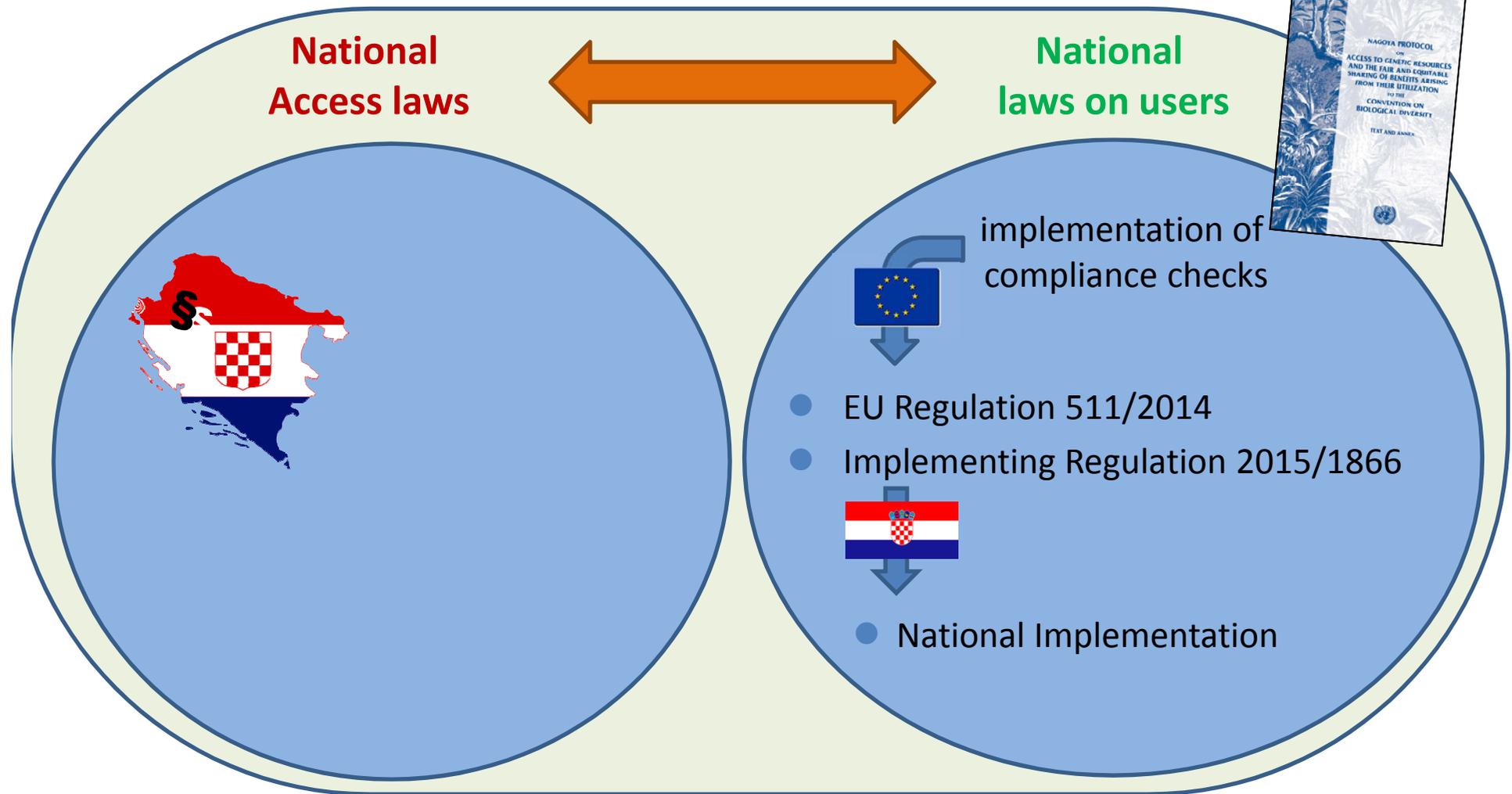
Basic Principles of the legal framework



Basic Principles of the legal framework



Basic Principles of the legal framework



NP countries acts as **Provider** and **User** and have to establish different sets of laws

The European ABS Legislation on utilisation

Relevant legal acts

- **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

http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2014.150.01.0059.01.ENG

- **Commission Implementing Regulation (EU) 2015/1866** of 13 October 2015, laying down details on Articles 5, 7 and 8 of Regulation 511/2014

<http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32015R1866>

(EU) No. 511/2014 regulating use inside the EU

- published in the Official Journal of the European Union: 20 May 2014; available in various languages
http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2014.150.01.0059.01.ENG
- entered into force on 9 Jun 2014; applicable since 12 Oct 2014 (entry-into-force of the NP)
- directly applicable and binding in all EU Member States (no matter whether they are parties to the Nagoya Protocol or not)
- Further details on Articles 5, 7 and 8 are laid down in the **Implementing Regulation (EU) 2015/1866** (including standard forms for declarations and applications)

EU Regulation No. 511/2014 in detail

Art. 1: Subject matter

Art. 2: Scope of the Regulation

Art. 3: Definition of Terms

Art. 4: Due diligence obligation: user must ensure to use only legally acquired GR

Art. 5: Register of Collections: EU system to obtain GR from ex-situ sources

Art. 6: Competent authorities and focal point

Art. 7: Monitoring user compliance: two check points, 1) reception of research funding, 2) final stage of product development

Art. 8: Best Practise: procedures, tools and mechanisms acknowledged as Best Practice to minimise checks by national authorities

Art. 9: Checks on User Compliance

Art. 10: Records of Checks

Art. 11: Penalties

Art. 12-14: Final Provisions

EU Regulation No. 511/2014 in detail

SUBJECT MATTER

The EU Regulation establishes rules governing **compliance** of users of genetic resources **with the Nagoya Protocol**

EU Regulation No. 511/2014 in detail

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The EU Regulation establishes rules governing **compliance** of users of genetic resources **with the Nagoya Protocol**

- It does not regulate access to genetic resources in EU member states (each member state may set up its own national access legislation)

EU Regulation No. 511/2014 in detail

SUBJECT MATTER

The EU Regulation establishes rules governing **compliance** of users of genetic resources **with the Nagoya Protocol**

- It does not regulate access to genetic resources in EU member states (each member state may set up its own national access legislation)
- It does not regulate benefit-sharing (this has to be negotiated individually between provider and user → mutually agreed terms, MAT)

Side Note 1: National Access Legislation in EU countries

- *The EU Regulation 511/2014 does not regulate access to GR or TKaGR in European countries. Instead, each member state may set up it's own national access legislation.*

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***Current status of national access legislation in the EU
(according to an unofficial survey from spring 2015):***

In place or planned	Not intended	Maybe
<ul style="list-style-type: none">• Bulgaria• Croatia• France• Hungary• Malta• Netherlands (only overseas territories)• Spain	<ul style="list-style-type: none">• Austria• Germany• Poland• Slovakia• Sweden• UK	<ul style="list-style-type: none">• Cyprus• Denmark• Estonia• Ireland• Portugal

EU Regulation No. 511/2014 in detail

SCOPE, part 1

The Regulation refers to genetic resources (GR) and to traditional knowledge associated with genetic resources (TKaGR).

Except:

- human genetic material
- GR/TKaGR falling under specialized international instruments, such as the “International Treaty on Plant Genetic Resources for Food and Agriculture” (ITPGRFA) or the “Pandemic Influenza Preparedness (PIP) Framework”

EU Regulation No. 511/2014 in detail

SCOPE, part 1

The Regulation refers to genetic resources (GR) and to traditional knowledge associated with genetic resources (TKaGR).

Except:

- human genetic material (excluding human microbiota, viruses, etc.)
- GR/TKaGR falling under specialized international instruments, such as the “International Treaty on Plant Genetic Resources for Food and Agriculture” (ITPGRFA) or the “Pandemic Influenza Preparedness (PIP) Framework”
 - but covered if utilised for research & development outside such frameworks

EU Regulation No. 511/2014 in detail

SCOPE, part 2

The Regulation is only applicable if **all** of the following conditions are met:

1. GR / TKaGR come from a country that is Party to the Nagoya Protocol (NP) and that has national access legislation in force
 - GR from areas beyond national jurisdiction are not covered
 - GR/TKaGR from countries that aren't parties to the NP are not covered
 - GR/TKaGR from countries that do not regulate access are not covered

EU Regulation No. 511/2014 in detail

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2. GR/TKaGR were accessed from that country after the entry-into-force of the NP
 - GR/TKaGR that were accessed before 12 October 2014 are not covered

EU Regulation No. 511/2014 in detail

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3. GR / TKaGR are utilized according to Art. 3(5) of the EU Regulation
 - collecting, storing, trading, commercializing (without utilization) is not covered

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 - GR/TKaGR that were accessed before 12 October 2014 are not covered
3. GR / TKaGR are utilized according to Art. 3(5) of the EU Regulation
 - collecting, storing, trading, commercializing (without utilization) is not covered
4. Utilization of GR / TKaGR takes place within the EU

Side Note 2: Where to get information on ABS legislation?

The official ABS Clearing House website <https://absch.cbd.int/>

- Provides basic information for each country (whether NP member or not, contact details of National Focal Points and Competent National Authorities)*
- Provides information on national access legislation*

Side Note 2: Where to get information on ABS legislation?

The official ABS Clearing House website <https://absch.cbd.int/>

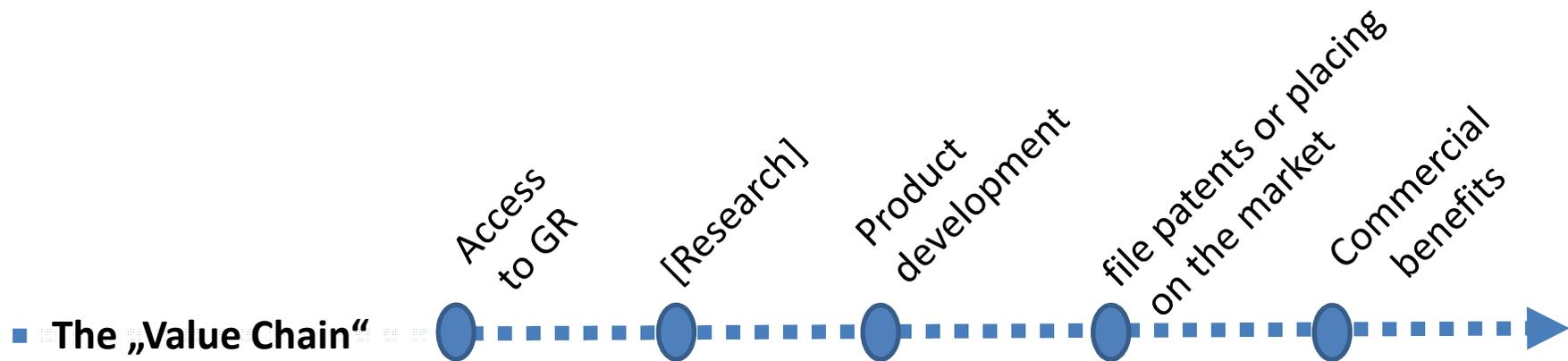
- *Provides basic information for each country (whether NP member or not, contact details of National Focal Points and Competent National Authorities)*
- *Provides information on national access legislation*

ATTENTION: The information provided at the Clearing House might not be up-to-date. Countries are obliged to upload relevant information, but the process is slow.

- *It is recommended to directly contact the Focal Point and ask for confirmation or guidance or to double-check with other sources of information (e.g. local scientists).*
- *Further recommended reading: Cabrera Medaglia, Perron-Welch & Philipps (2014): Overview of National and Regional Measures on Access and Benefit-Sharing – Challenges and Opportunities in Implementing the Nagoya Protocol. Third Edition. CISDL Biodiversity & Biosafety Law Research Programme. 125 pages [available [online](#)]*

Side Note 3:

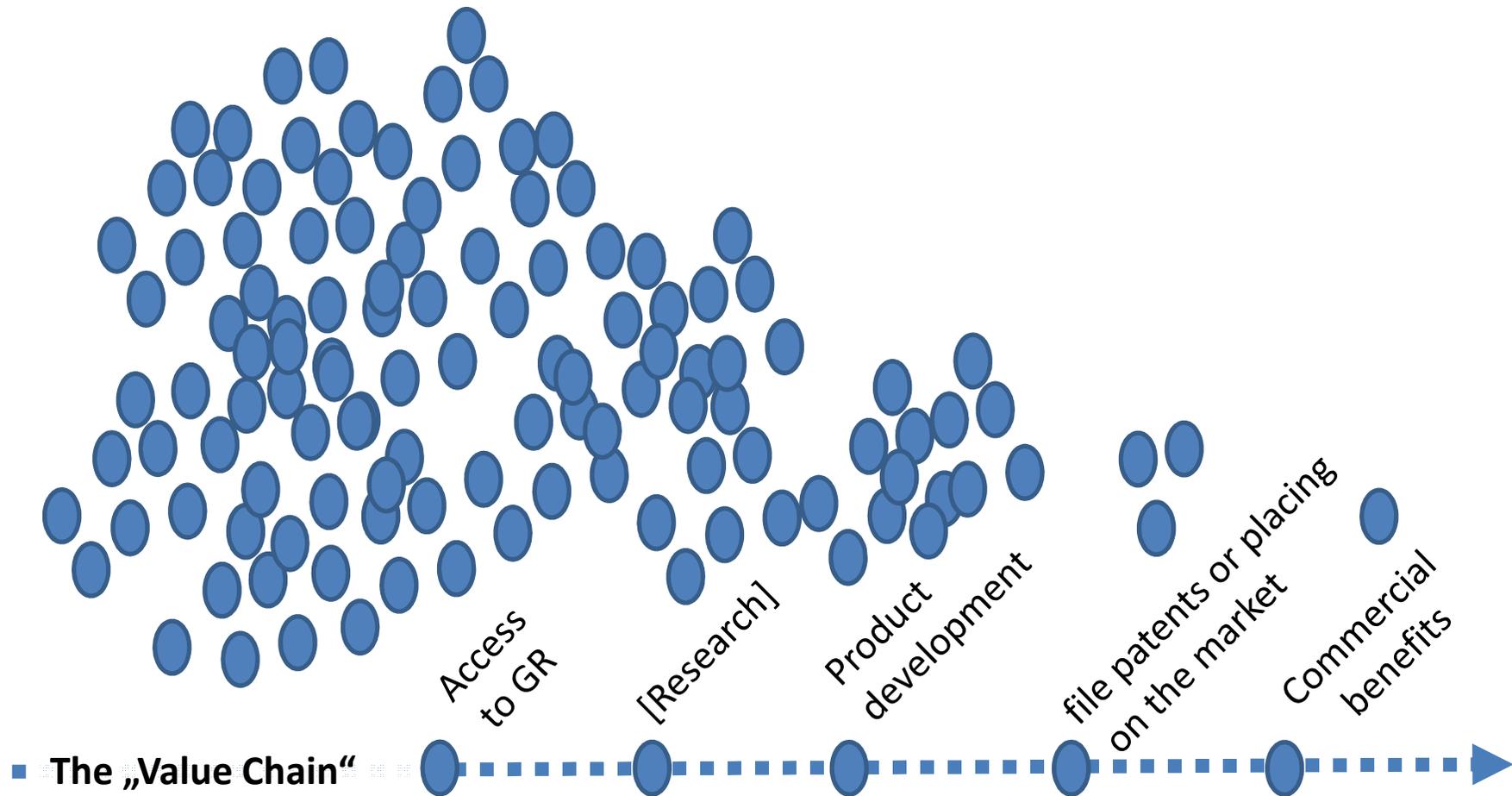
The “EU baseline” of the European Commission



The majority of activities regarding access to GR/TKaGR and utilization take place at the beginning of the value chain and do only rarely lead to commercial benefits.

Side Note 3:

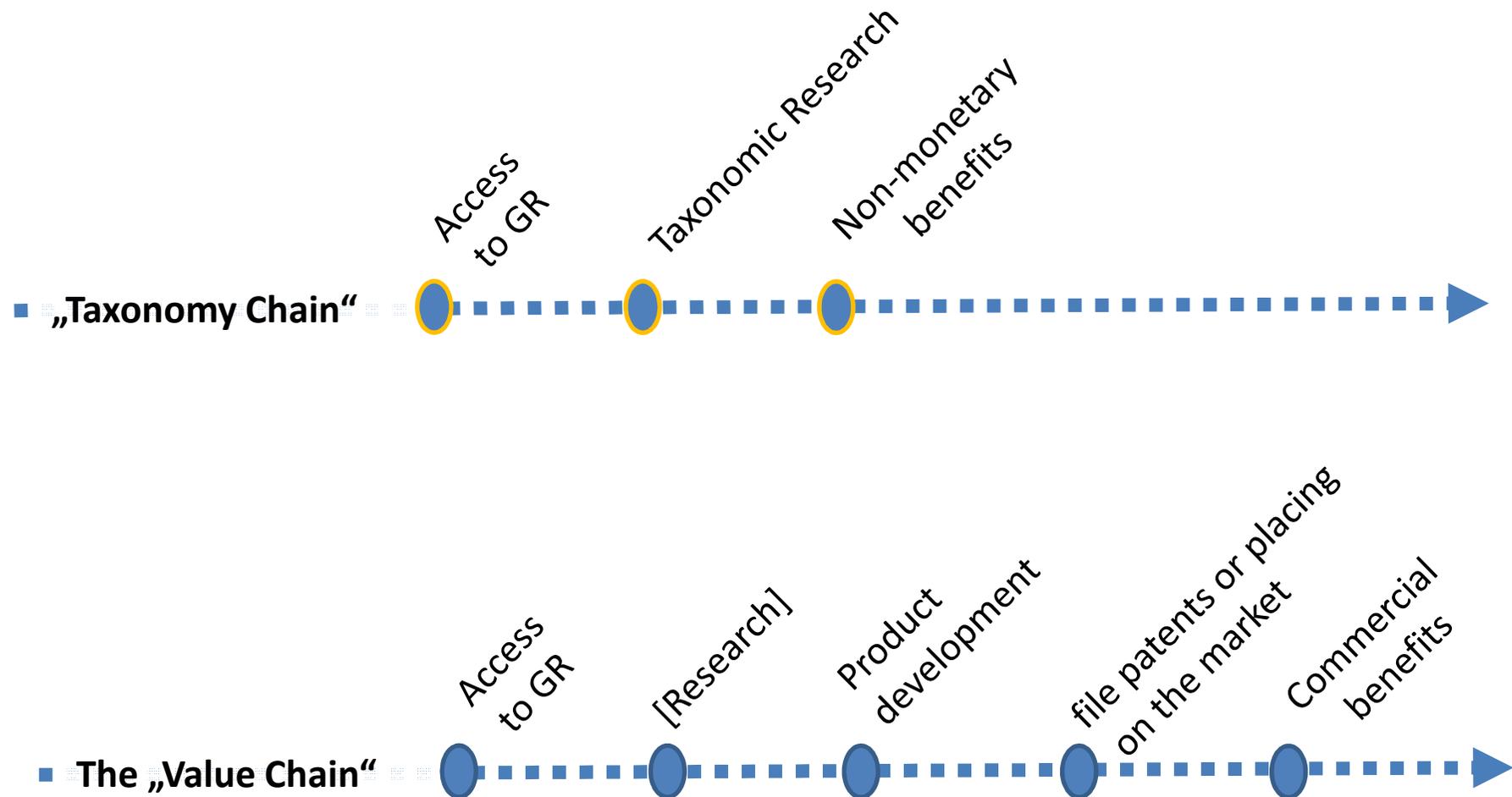
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EU Regulation No. 511/2014 in detail

OBLIGATIONS OF USERS (Article 4)

1. Users shall exercise **due diligence** to ascertain that GR and TKaGR which they utilise have been accessed in accordance with applicable ABS legislation or regulatory requirements, and that benefits are fairly and equitably shared [...]

EU Regulation No. 511/2014 in detail

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2. GR and TKaGR shall only be **transferred and utilised in accordance with MAT** (mutually agreed terms) [...]
3. Users shall **seek, keep and transfer** to subsequent users the following information:
 - date and place of access
 - description of the GR or TKaGR
 - Source of the GR/TKaGR and subsequent users
 - Presence or absence of ABS rights and obligations
 - Access permits and MAT, where applicable

EU Regulation No. 511/2014 in detail

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*A minor challenge:
those countries that
grant free access do
not necessarily issue a
positive proof for it*

EU Regulation No. 511/2014 in detail

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 - Access permits and MAT, where applicable

→ Or the **Internationally Recognized Certificate of Compliance (IRCC)** which contains the underlined information

EU Regulation No. 511/2014 in detail

OBLIGATIONS OF USERS (Article 4, continued)

5. **Discontinue utilisation**, or obtain PIC and establish MAT, if information is insufficient or uncertainties about legality persist.
6. Keep relevant information **for 20 years after end** of period of utilisation.

→ Certain exemptions for plant genetic resources (PGR) covered by the *International Treaty on PGR for Food and Agriculture* and for human pathogens.

EU Regulation No. 511/2014 in detail

MONITORING OF USERS (Article 7)

“At identified points in the chain of activities that constitute utilisation, **users should declare and provide evidence**, when requested, that they have exercised due diligence.”

EU Regulation No. 511/2014 in detail

MONITORING OF USERS (Article 7)

“At identified points in the chain of activities that constitute utilisation, **users should declare and provide evidence**, when requested, that they have exercised due diligence.”

→ Article 7(1): upon receipt of research funding for projects involving the utilisation of GR or TKaGR

→ Article 7(2): at the stage of final development of a product

EU Regulation No. 511/2014 in detail

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Details on 7(1) are provided in Implementing Regulation 2015/1866:

EU Regulation No. 511/2014 in detail

MONITORING OF USERS (Article 7)

“At identified points in the chain of activities that constitute utilisation, **users should declare and provide evidence**, when requested, that they have exercised due diligence.”

→ Article 7(1): upon receipt of research funding for projects involving the utilisation of GR or TKaGR

→ Article 7(2): at the stage of final development of a product

Details on 7(1) are provided in Implementing Regulation 2015/1866:

- 1 declaration per grant-funded research project (no matter whether grants come from private or public sources)
- declarations are to be made to the competent authority of the grant recipient's country

EU Regulation No. 511/2014 in detail

MONITORING OF USERS (Article 7, continued)

Declarations upon receipt of research funding have to include information on

L 275/14 EN Official Journal of the European Union 20.10.2015

ANNEX II
Template for a due diligence declaration to be submitted at the stage of research funding pursuant to Article 3(2)

PART A
Information to be transmitted to the ABS Clearing House pursuant to Article 7(3) of Regulation (EU) No 511/2014

If the information provided is confidential within the meaning of Article 7(5) of Regulation (EU) No 511/2014, please provide it nonetheless, tick the respective box and provide the justification for confidentiality at the end of this Annex.

If you marked as confidential essential information (such as about the genetic resources or traditional knowledge associated with genetic resources, access place, form of utilisation), without which the return would not be published on the website of the ABS Clearing House, this information will not be shared with the ABS Clearing House, but it may be passed on directly to the competent authorities of the provider country.

At least one declaration is required per grant received, i.e. different recipients under one grant may choose to submit either individual declarations or a joint declaration, through the project coordinator.

I am making this declaration for the utilisation of:

Please tick the appropriate box or boxes:

Genetic resources
 Traditional knowledge associated with genetic resources

1. Subject matter of the research or identification code of the grant:
 Confidential

2. Recipient or recipients of funding, including contact details:
Name:
Address:
E-mail:
Telephone:
Website, where available:

3. 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.

Where this box is ticked, please indicate the unique identifier of the internationally recognised certificate of compliance:
Please go to point 1 of Part D.

(b) Where the box in point (a) has not been ticked, please fill in the following information:

(i) Place of access:
 Confidential

EU Regulation No. 511/2014 in detail

MONITORING OF USERS (Article 7, continued)

Declarations upon receipt of research funding have to include information on

- the user making the declaration
- the GR or TKaGR
- place of access to the GR or TKaGR
- identifiers of PIC or equivalents
- source of research grant (public or private)

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ANNEX II
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EU Regulation No. 511/2014 in detail

Recognition of BEST PRACTICE (Article 8)

Voluntary Codes of Conduct on ABS including user specific tools and measures (= Best Practice) shall help to exercise due diligence (and, thereby, to build trust in providing countries)

→ *called for by the Nagoya Protocol*

EU Regulation No. 511/2014 in detail

Recognition of BEST PRACTICE (Article 8)

Voluntary Codes of Conduct on ABS including user specific tools and measures (= Best Practice) shall help to exercise due diligence (and, thereby, to build trust in providing countries)

→ *called for by the Nagoya Protocol*

Provisions in EU Reg. 511/2014 :

- Associations of users and other stakeholders may apply to the European Commission for the recognition of their Best Practices
- Users that apply such recognized Best Practice might experience less intensive checks by their competent national authorities

EU Regulation No. 511/2014 in detail

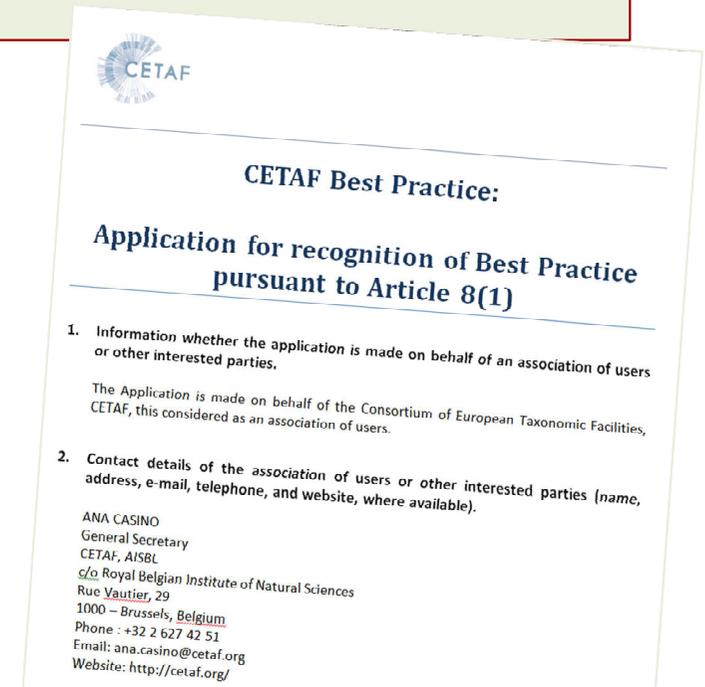
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→ called for by the Nagoya Protocol

CETAF's Code of Conduct and Best Practices on ABS:

- submitted to the Commission in Feb 2016



The image shows a document titled 'CETAF Best Practice: Application for recognition of Best Practice pursuant to Article 8(1)'. The document is a form with a header containing the CETAF logo and the title. Below the title, there are two numbered sections. Section 1 asks for information on whether the application is made on behalf of an association of users or other interested parties, and provides a statement that the application is made on behalf of the Consortium of European Taxonomic Facilities, CETAF, considered as an association of users. Section 2 asks for contact details of the association of users or other interested parties, including name, address, e-mail, telephone, and website. At the bottom of the form, contact information for ANA CASINO, General Secretary of CETAF, AISBL, is provided, including the address at the Royal Belgian Institute of Natural Sciences, Rue Vautier, 29, 1000 - Brussels, Belgium, and contact details for phone, email, and website.

CETAF

CETAF Best Practice:

Application for recognition of Best Practice pursuant to Article 8(1)

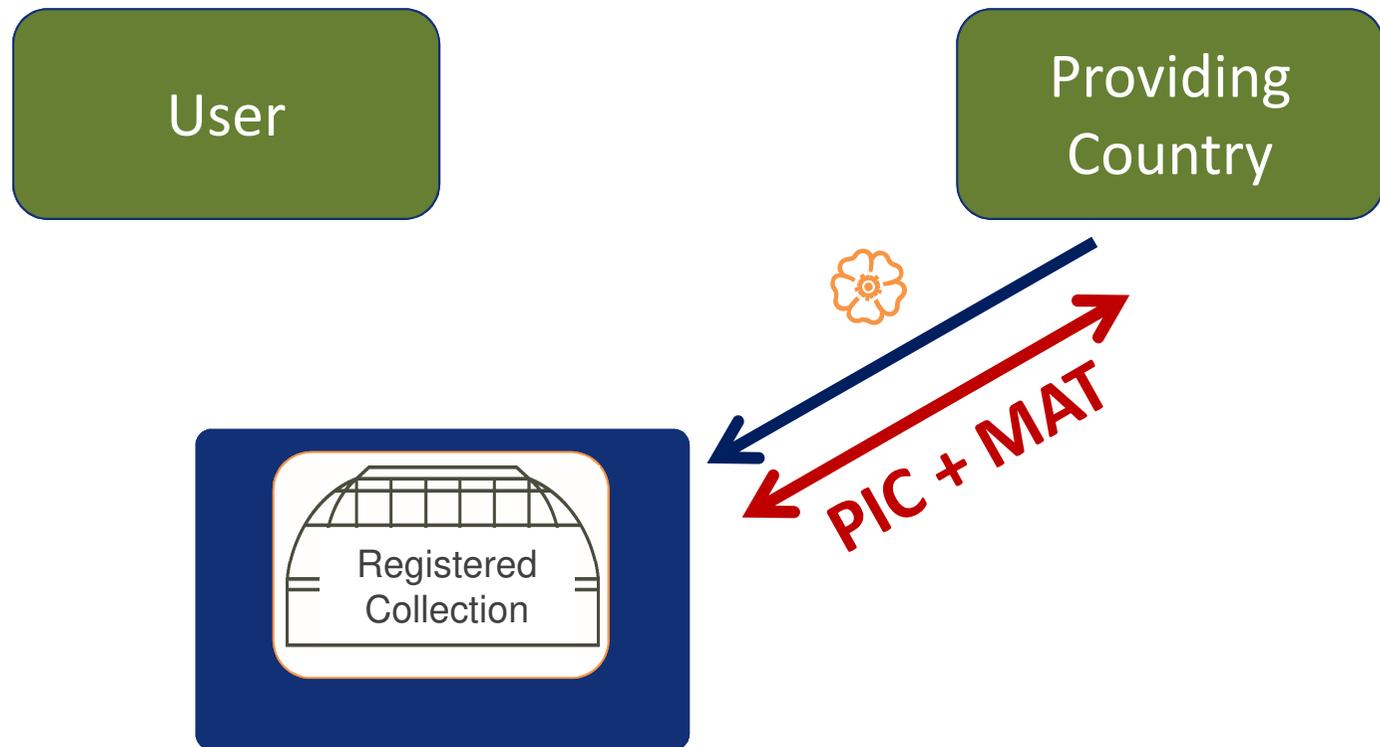
1. Information whether the application is made on behalf of an association of users or other interested parties.
The Application is made on behalf of the Consortium of European Taxonomic Facilities, CETAF, this considered as an association of users.
2. Contact details of the association of users or other interested parties (name, address, e-mail, telephone, and website, where available).

ANA CASINO
General Secretary
CETAF, AISBL
c/o Royal Belgian Institute of Natural Sciences
Rue Vautier, 29
1000 - Brussels, Belgium
Phone : +32 2 627 42 51
Email: ana.casino@cetaf.org
Website: <http://cetaf.org/>

EU Regulation No. 511/2014 in detail

REGISTER OF COLLECTIONS (Article 5)

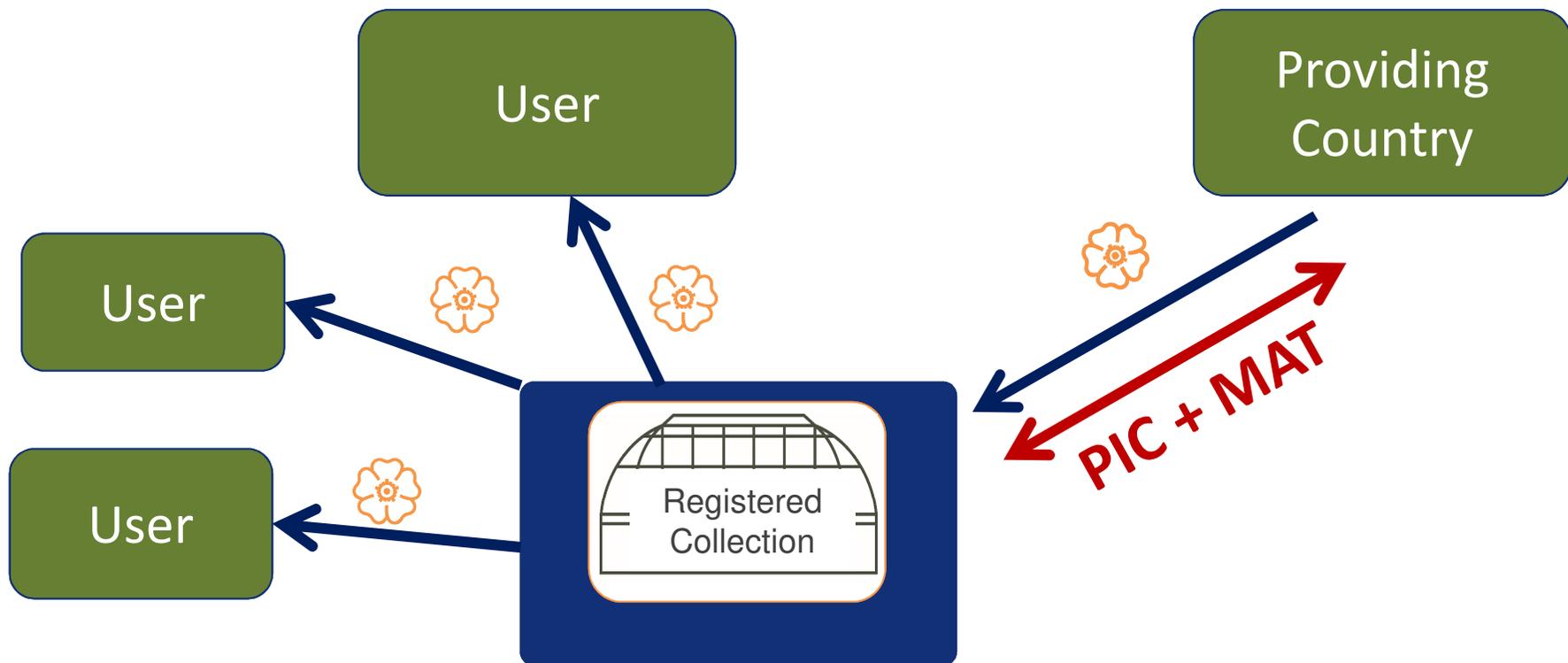
Intention: **Collections fulfil due diligence obligations** (i.e. obtain PIC and MAT) and thereby **help other users**, who obtain GR from the collection, to comply with the Regulation.



EU Regulation No. 511/2014 in detail

REGISTER OF COLLECTIONS (Article 5)

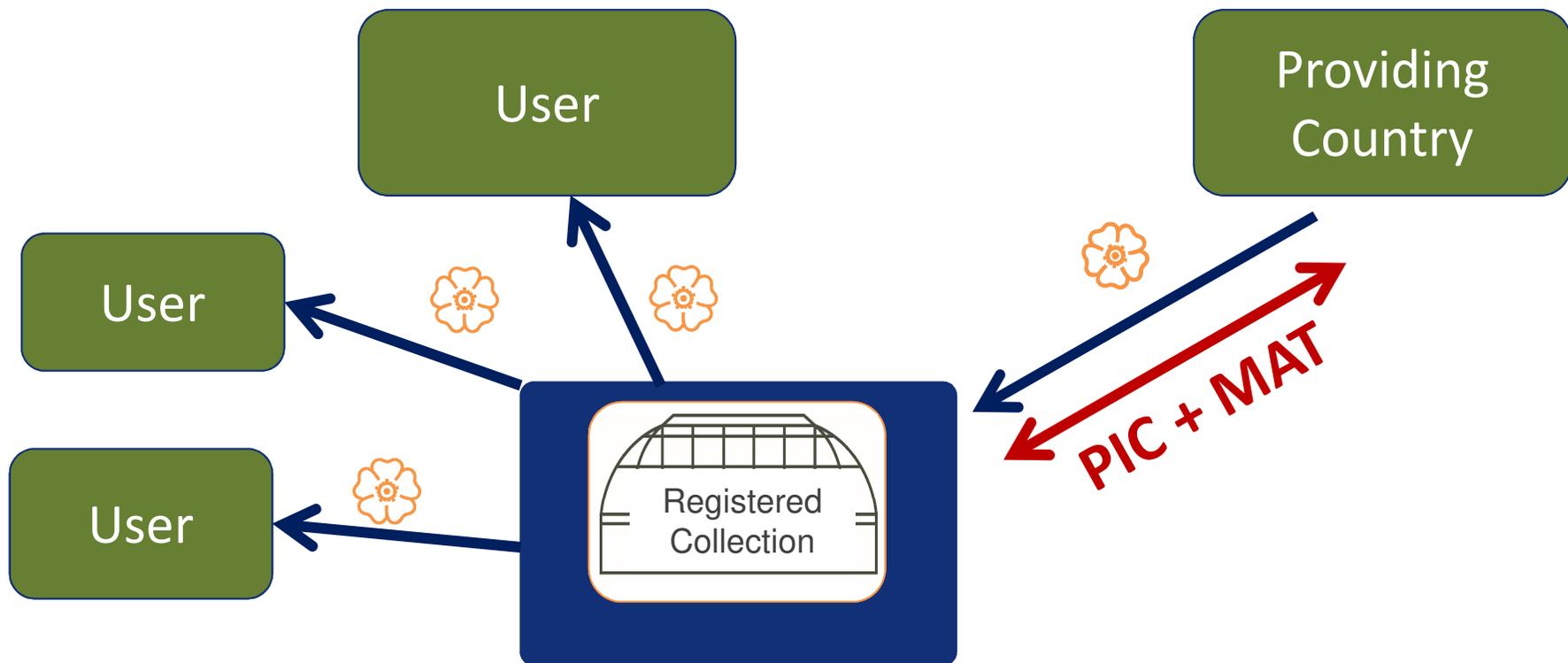
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EU Regulation No. 511/2014 in detail

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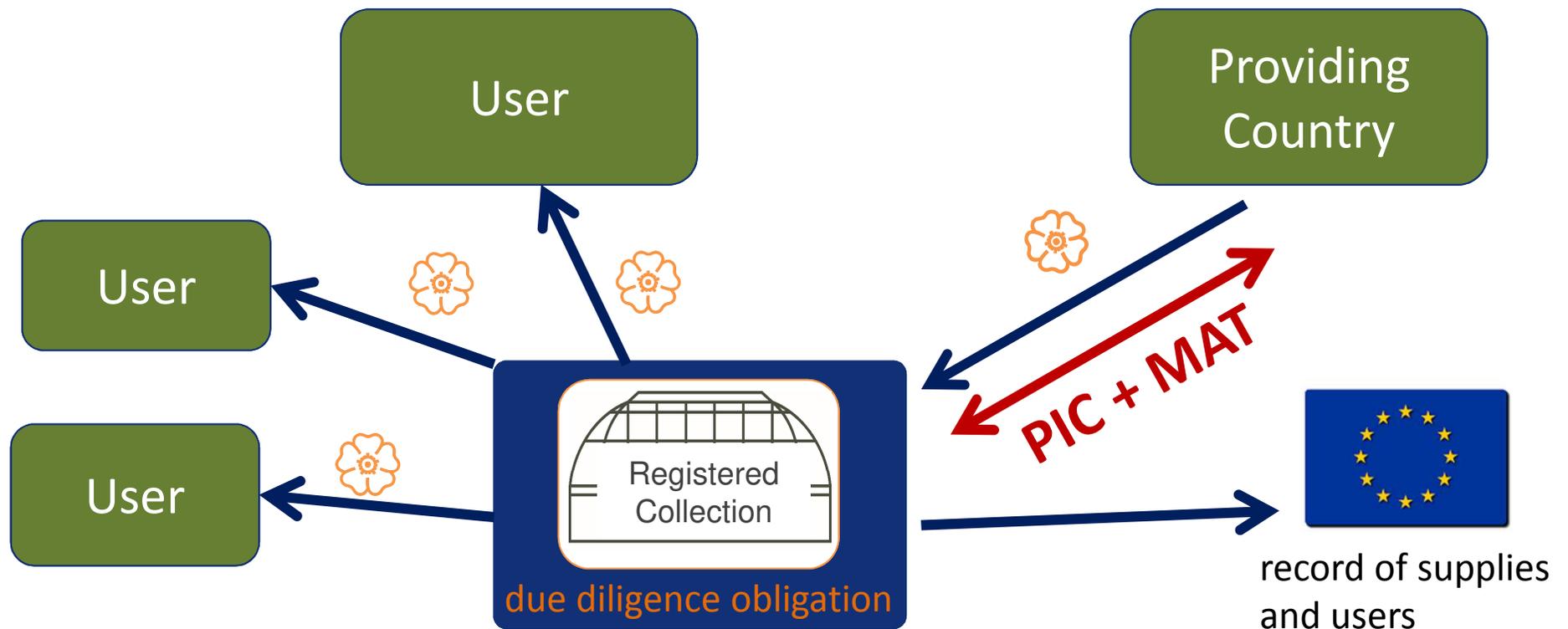
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EU Regulation No. 511/2014 in detail

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EU Regulation No. 511/2014 in detail

REGISTER OF COLLECTIONS (Article 5)

Intention: **Collections fulfil due diligence obligations** (i.e. obtain PIC and MAT) and thereby **help other users**, who obtain GR from the collection, to comply with the Regulation.

Procedure:

- Collections may apply (voluntarily!) to their Competent National Authorities for inclusion in the register and demonstrate capacity to
 - apply standardised procedures for exchanges
 - provide evidence that proposed utilisation of third is within existing laws
- Registered collections will be checked regularly by the CNA

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→ *so far, no immediate benefits for the collections foreseen
(except – maybe – an increase in recognition and trust)*

Side Note 4: A short history of the EU ABS legislation

...and CETAF's engagement

Oct 2012

European Commission (DG Environment) publishes legislative proposal, accompanied by impact assessment and background study;

First stakeholder consultation meeting

Since 2012: Active participation in meetings of the Commission, Council and Parliament

Nov 2012 – Sept 2013:

Debates in EU Council, Parliamentary Committees and Parliament

May 2013: Position paper incl. amendments to draft Regulation

March – April 2014

Regulation 511/2014 adopted by Parliament and Council

2013-2015: Development of CETAF Code of Conduct on ABS and presentation at different occasions, e.g. at COP12 in Korea

20 May 2014

Regulation 511/2014 published in Official Journal

Side Note 4: A short history of the EU ABS legislation

...and CETAF's engagement

2014: Commission launches discussion paper and draft articles for an Implementing Regulation
Stakeholder meeting on 9 Dec 2014

Jan 2015 – Oct 2015:

Commission and Member States discuss and draft the implementing regulation including its annexes

9 November 2015:

Entry into force of the Commission's Implementing Regulation

Dec 2015 / Jan 2016:

Draft Guidance on Scope of the Regulation
Consultation Forum meeting on 21 Jan 2016

April 2016: Guidance Doc to be published

Jan 2015:

Position paper on the draft implementing regulation

During 2015: *Lobbying by CETAF members via national contacts*

Dec '15/ Jan '16:

Participation in Stakeholder Meeting, written comments on Guidance Doc.

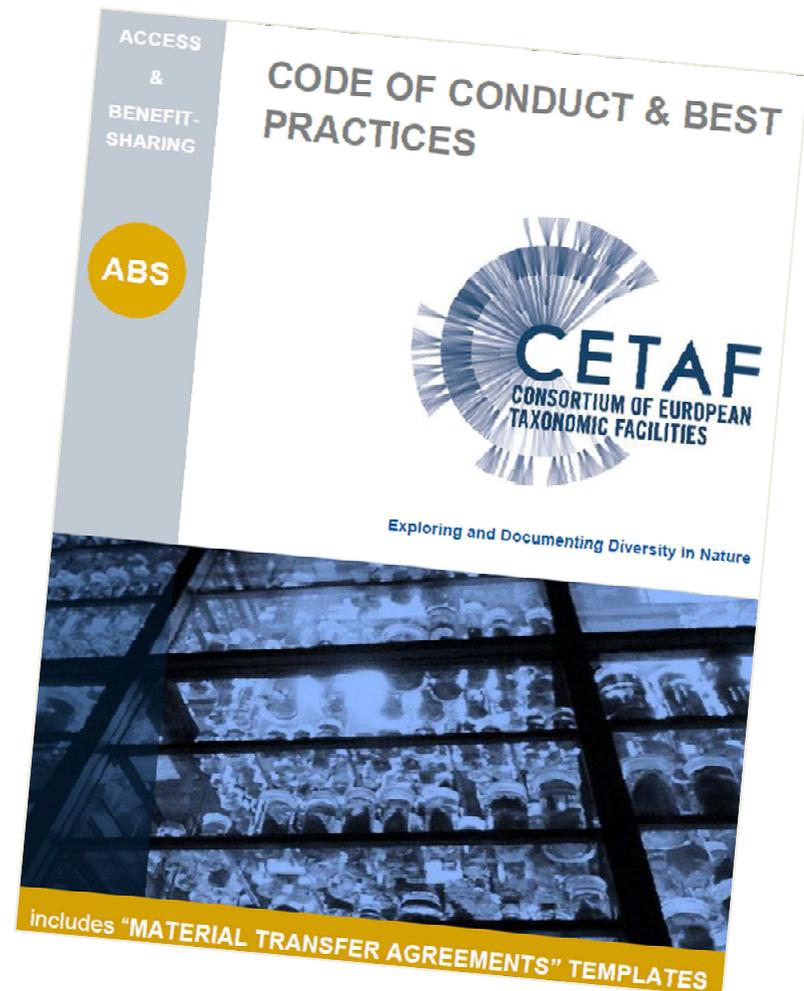
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...and CETAF's engagement

Oct 2015:

*CETAF Code of Conduct &
Best Practices published !!!*

See <http://cetaf.org/taxonomy/publications...>
... and the next presentations.



THANK YOU FOR YOUR ATTENTION!

The European ABS Legislation

CETAF WORKSHOP ON ABS - Munich, 24 February 2016



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