CETAF Legislation and Regulations Liaison Group

The European ABS Legislation

CETAF WORKSHOP ON ABS - Berlin, 25 June 2016

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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 the **Convention on Biological Diversity** (since 1992).
Basic Principles of the legal framework

National Access laws

National laws on users
Basic Principles of the legal framework

National Access laws

National laws on users

Implementation of compliance checks

- EU Regulation 511/2014
- Implementing Regulation 2015/1866
Basic Principles of the legal framework

National Access laws

National laws on users

- EU Regulation 511/2014
- Implementing Regulation 2015/1866
- National Implementation
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

  
  [Link](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
  
  [Link](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

- 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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- 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 its 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):

<table>
<thead>
<tr>
<th>In place or planned</th>
<th>Not intended</th>
<th>Maybe</th>
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<tbody>
<tr>
<td>• Bulgaria</td>
<td>• Austria</td>
<td>• Cyprus</td>
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<td>• Malta</td>
<td>• Sweden</td>
<td>• Portugal</td>
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<tr>
<td>• Netherlands (only overseas territories)</td>
<td>• UK</td>
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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

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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
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EU Regulation No. 511/2014 in detail

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EU Regulation No. 511/2014 in detail

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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
EU Regulation No. 511/2014 in detail

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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/](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
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**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).

**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.
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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 […]

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CETAF Legislation and Regulations Working Group
EU Regulation No. 511/2014 in detail

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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
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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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→ 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

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→ 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
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Details on 7(1) are provided in Implementing Regulation 2015/1866:
EU Regulation No. 511/2014 in detail

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→ 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
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)
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)

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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

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)

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

➢ submitted to the Commission in Feb 2016
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

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[Diagram showing the flow of users obtaining PIC and MAT from a registered collection]

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EU Regulation No. 511/2014 in detail

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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
EU Regulation No. 511/2014 in detail

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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

Nov 2012 – Sept 2013:
Debates in EU Council, Parliamentary Committees and Parliament

March – April 2014
Regulation 511/2014 adopted by Parliament and Council

20 May 2014
Regulation 511/2014 published in Official Journal

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

May 2013: Position paper incl. amendments to draft Regulation

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

CETAF WORKSHOP ON ABS - Berlin, 25 June 2016

CETAF Legislation and Regulations Working Group
Side Note 4: A short history of the EU ABS legislation
...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

80% of the world’s described biodiversity

CETAF Legislation and Regulations Working Group

www.cetaf.org

EXPLORING AND DOCUMENTING DIVERSITY IN NATURE

Through a network of 50+ natural history collections