Federal Office
for Agriculture and Food

INFORMATION AND
COORDINATION CENTRE
BIOLOGICAL DIVERSITY

Implementation of the Nagoya Protocol in the EU

Workshop "Pre-breeding materials: a grey zone between Genetic Resources and Cultivars – Introduction on regulatory aspects and protection of Intellectual Property",
15th March 2023, University of Applied Sciences, Dresden, Germany

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INFORMATION AND COORDINATION CENTRE BIOLOGICAL DIVERSITY

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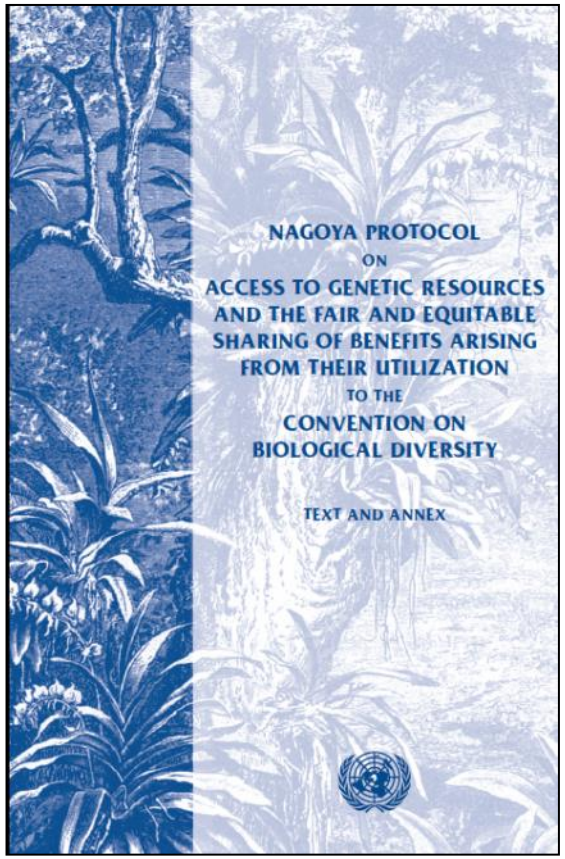
1. Nagoya Protocol- overview



Legal framework for ABS

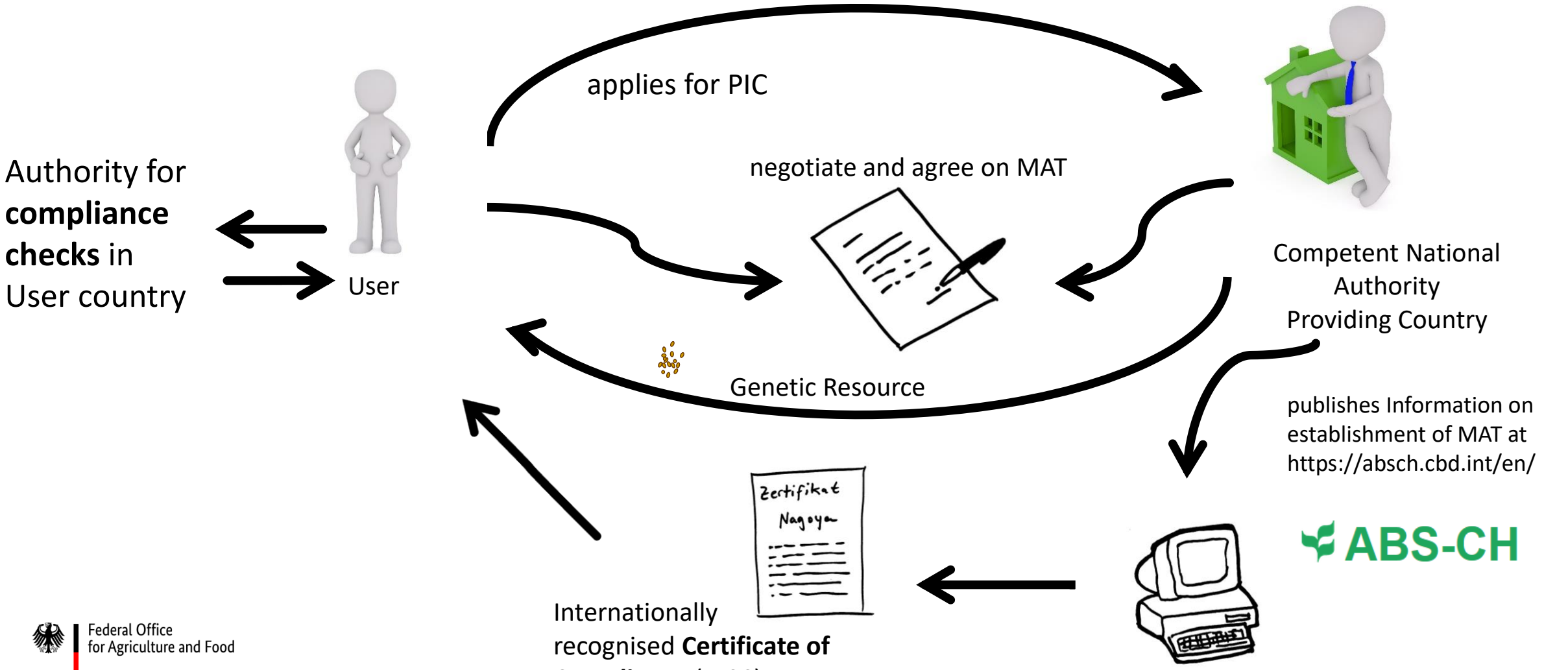
- implements the **ABS provisions of the CBD**
- covers **genetic resources** and **associated traditional knowledge**
- entered into force on **12 October 2014**

3 pillars:

Access shall be subject to „Prior Informed Consent“ (PIC)
Benefits shall be shared upon „Mutually Agreed Terms“ (MAT)
Compliance Obligations of Contracting Parties

Cover page of the Nagoya Protocol booklet.

1. Nagoya Protocol – overview bilateral approach



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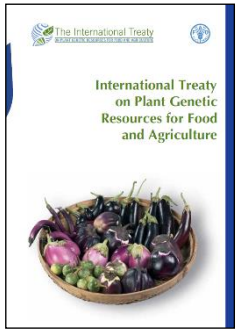
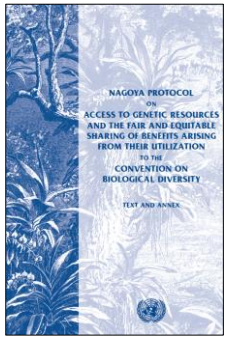
1. Nagoya Protocol - how does it relate to the Plant Treaty



International Treaty on Plant Genetic Resources for Food and Agriculture

since 2004

155 Contracting Parties



Nagoya Protocol on Access to Genetic Resources and Benefit Sharing

since 2014

138 Contracting Parties

- **Multilateral System** for facilitated access and Benefit Sharing for about 60 important crops (ANNEX I)
- Established in harmony with the CBD
- **Standard Material Transfer Agreement (SMTA)**
  - Only for research, breeding and training for food and feed
  - **Benefit-Sharing** Terms included in **SMTA**

Monitoring via Treaty-Secretariat, each signed SMTA to be reported to the Secretariat

- **Bilateral System:** Each access to a genetic resource has to be negotiated with the Country of Origin
- **Individual ABS-Regulations** of Contracting Parties
- **Individual Benefit-Sharing**-Contracts (case-by-case) between user and Providing Country

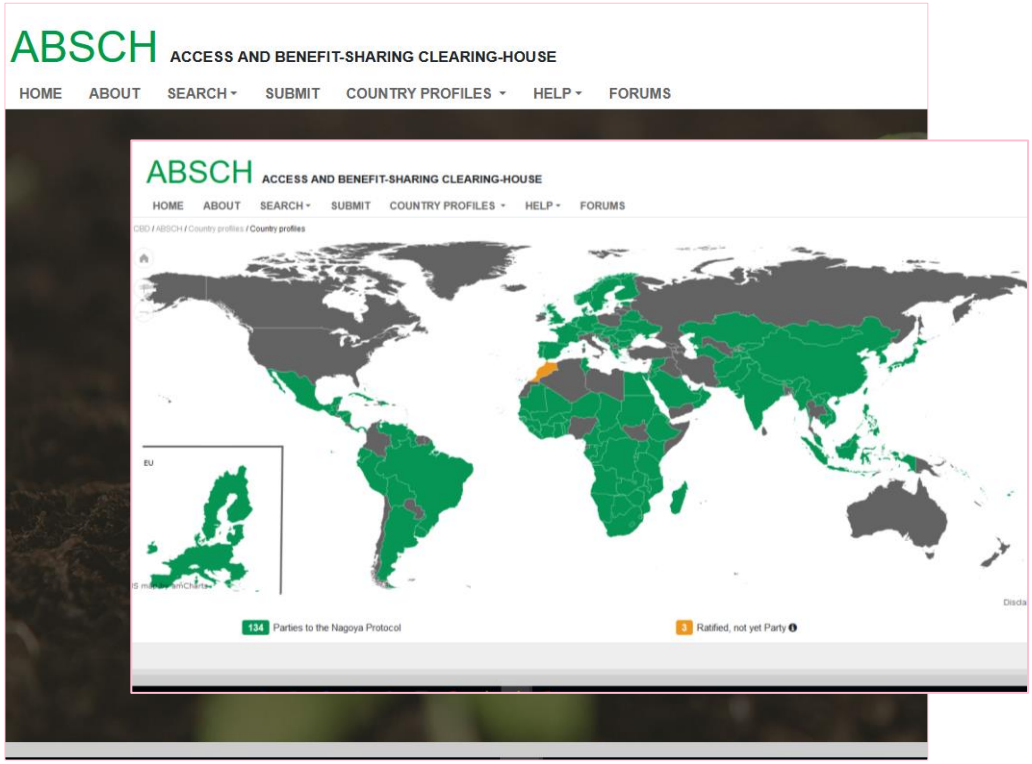
- **Monitoring obligations** of countries, where uses take place have to be checked

Material in scope of the Treaty is exempted from the Nagoya Protocol!

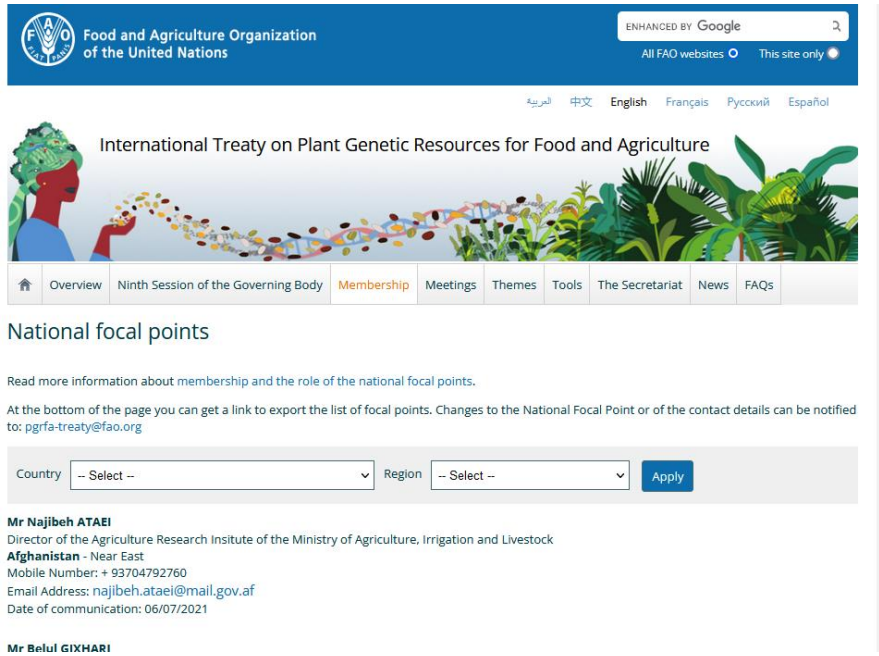
Bundesanstalt für Landwirtschaft und Ernährung

1. Nagoya Protocol and Plant Treaty – where to find contact persons

https://absch.cbd.int/en/countries/status/party



https://www.fao.org/plant-treaty/countries/national-focal-points/en/



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2. Nagoya Protocol - What does the EU regulate?

Access

- **not** implemented at EU level
- Individual country measures

Member State	Remarks
Bulgaria	
Croatia	
Denmark	without Greenland
Finland	only traditional knowledge
France	
Malta	
Spain	
Sweden	only traditional knowledge

Benefit Sharing

- not implemented at EU level
- subject to contractual agreements
- confidential

Compliance

- Implementation at EU level
- Regulation (EU) 511/2014


EN Official Journal of the European

REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAME

of 16 April 2014

on compliance measures for users from the Nagoya Protocol on Access the Fair and Equitable Sharing of Benefits Arising from their Utili

(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 pa

ng regard to the proposal from the European Commission,

mission of the draft legislative act to the national parliaments,

opinion of the European Economic and

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2. Nagoya Protocol - What does the EU regulate?

Objective of EU ABS-Regulation: ensure that benefits from genetic resources are shared fairly and equitably with the country providing these resources

- Regulation (EU) 511/2014 ("**EU ABS Regulation**")
- Commission Implementing Regulation (EU) 2015/1866 ("**Implementing Regulation**")
- **Guidance document** on scope and obligations of Reg (EU) 511/2014, *new version published in 2020*

See also Webpage of the EU Commission:

https://environment.ec.europa.eu/topics/nature-and-biodiversity/sharing-natures-genetic-resources_en

3. Compliance Rules in the EU

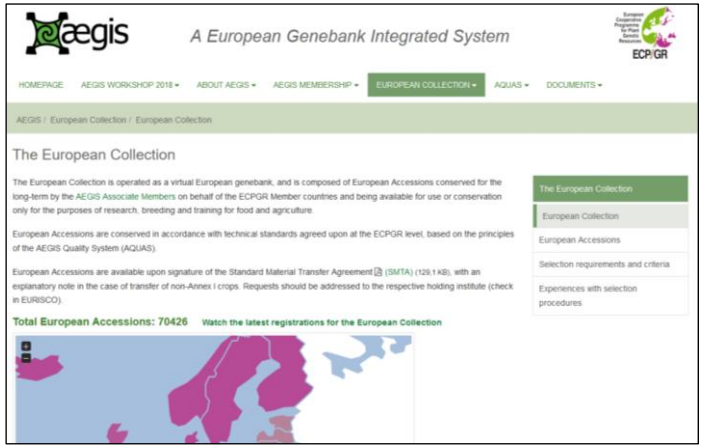
Important definitions

- **‘User’** means a natural or legal person that utilises genetic resources or traditional knowledge associated with genetic resources (Article 3(4) of the Regulation)
- **‘Utilisation of genetic resources’** means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention (Article 3(5) of the Regulation)
- **‘Access’** means the acquisition of genetic resources or of traditional knowledge associated with genetic resources in a Party to the Nagoya Protocol (Article 3(3) of the Regulation)

3. Compliance Rules in the EU

Obligations of users (Art. 4 EU ABS Regulation)

- Users shall **exercise due diligence** to ascertain that they have accessed GR / TK in accordance with applicable ABS regulations (of NP Parties)
- Users shall seek, keep and transfer to subsequent users the Internationally Recognized **Certificate of compliance** (IRCC) or other relevant documents of the providing country
- If users have **insufficient information** or are **uncertain about the legality** of access and utilization, they shall obtain an access permit or its equivalent and establish mutually agreed terms, or **discontinue utilisation**.
- Non-Annex-I material received via SMTA from a Party to the Nagoya Protocol: due diligence is regarded as fulfilled (e.g. via AEGIS)
- Users shall keep the information for 20 years after the end of use



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3. Compliance Rules in the EU

Monitoring via due dilligance declarations (Art. 7 EU ABS Regulation)

Checkpoint 1: at the stage of research funding

- no distinction between public and private funding
- after first instalment of funding and after GR/aTK have been obtained, but no later than final report

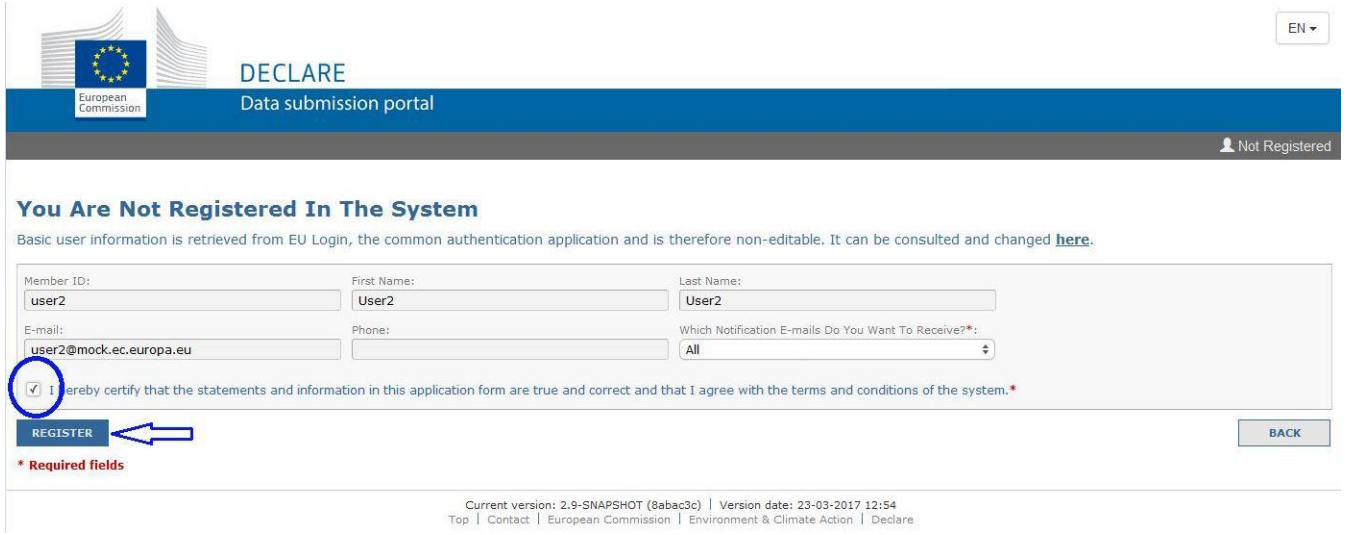
⇨ Template for ddd: see Annex II of Commission Implementing Regulation (EU) No 2015/18663

Checkpoint 2: at the stage of final development of a product

⇨ Template for ddd: see Annex III of Commission Implementing Regulation (EU) No 2015/18663

3. Compliance Rules in the EU

https://circabc.europa.eu/ui/group/3f466d71-92a7-49eb-9c63-6cb0fadf29dc/library/03ade20f-c623-4c96-a4fe-6d71408cb76e/details?download=true



DECLARE:

- EU-wide web-based tool
- enables users of genetic resources to submit **d**ue **d**iligence **d**eclarations to the relevant competent authorities responsible for their implementation
- enables competent authorities to transfer non-confidential information from the **ddd**'s to the ABS Clearing House

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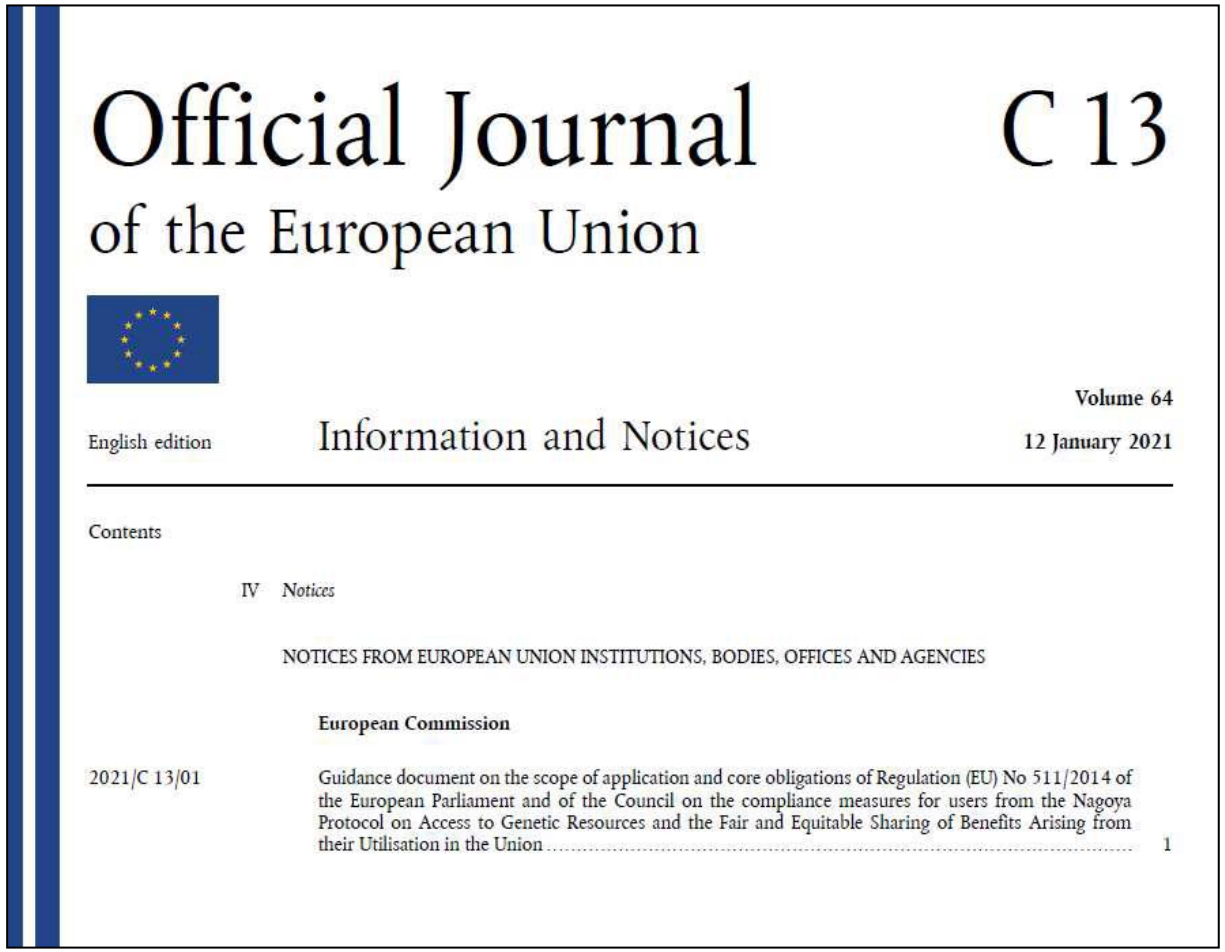
4. Guidance Document on the scope of application



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Annex I:

OVERVIEW OF CONDITIONS FOR APPLICABILITY OF THE EU ABS REGULATION

Annex II:

SPECIFIC GUIDANCE ON THE CONCEPT OF UTILISATION

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4. Guidance Document

Annex 1: Overview of conditions for applicability of the EU ABS Regulation

		Within scope *	Outside of scope
Geographic scope (provenance of GR **)	*Access in*	Areas within a country's jurisdiction	Areas beyond national jurisdiction or covered by Antarctic Treaty System
	Provider country is	Party to the Nagoya Protocol	Not a Party to the Protocol
	Provider country has	Applicable access legislation	No applicable access legislation
Temporal scope	*Access*	On or after 12 October 2014	Before 12 October 2014
Material scope	*Genetic resources*	Not covered by a specialised international ABS instrument	Covered by a specialised international ABS instrument (e.g. ITPGRFA)
		Non-human	Human
		Obtained as commodities but subsequently subject to R & D	Used as commodities
	Utilisation	R & D on genetic and/or biochemical composition	No such R & D
Personal scope		Natural or legal persons utilising GR	Persons only transferring GR or commercialising products based on it
Geographic scope (Utilisation)	*Research & Development*	Within the EU	*Exclusively* outside of the EU

* *To be within the scope, all conditions must be fulfilled.*
** *GR = genetic resource; to be read as also including 'traditional knowledge associated with genetic resources', where appropriate.*

Source: Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014, **page 31**

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4. Guidance document – Examples

Taxonomy

Where is the border between „utilisation“ in the sense of the Regulation and „no utilsation“?

- Pure identification of organisms

=> outside the scope

- Investigation of special properties and get “new insides” on the genetic and/or biochemical composition of the genetic resource

=> inside the scope

(see page 39ff)

4. Guidance document – Examples

Unintentionally introduced genetic resources

- e.g. Microbes or small organisms „travelling“/„associated“ with GR‘s

Pests/Pathogenes (see p. 10)

- not in scope, if introduced unintentionally
- in scope, if established in a Party to the NP

Other associates species (see p. 11)

- Not seen outside scope, user is advised to ask the providing country

Invasive Species (see p. 6)

- if „established“ in a country, the ABS obligations of that country have to be followed

4. Guidance document – Examples

Acquisition and utilisation of commodities

- GR may be acquired as a commodity, directly or via a third person/entity:

  Trade and exchange of genetic resources as commodities (such as agricultural, fisheries or forestry products – whether for direct consumption or as ingredients, e.g. in food and drink products) fall outside the scope of the Regulation.

  But:

  If such GR are utilised according to the definition

  => Utilisation is in scope (see chapter 2.3.1.3, p. 9)

4. Guidance document – Examples

Utilisation of commercial plant varieties

- Research and breeding with commercial plant varieties, that has been (legally) placed on the market
  - legally protected by a plant variety right in accordance with the provisions of Council Regulation (EC) No 2100/94 or in accordance with national provisions
  - registered in a national or common catalogue of varieties of agricultural plant and vegetable species
  - variety has been entered in any other public or private list according to EU legislation and/or international standards containing officially recognized denomination and description
- Generally: when a new variety is protected by a plant variety right according to the UPOV Convention, including under Regulation (EC) No 2100/94 on Community Plant Variety Rights

=> Not in scope (see p. 52 of Guidance document)

4. Guidance document – Examples

Use of a crop wild relative, landrace or farmer's variety in a breeding programme

"A plant breeder accesses a crop wild relative *in situ* or a landrace or farmer's variety(20) from farmers' fields and uses this material in a breeding programme to introduce useful traits in commercial breeding materials.

A breeding activity using such material (in scope of the EU ABS Regulation) is considered utilisation in the meaning of the EU ABS Regulation. Due diligence obligations therefore apply. The user needs to submit a due diligence declaration when a new variety is registered or placed on the market…"

(see example on p. 54)

4. Guidance document – Examples

Species listed in Annex I of the ITPGRFA …

…may be in scope, if they are not „under management and control of Parties and in public domain, but be found in „in situ-conditions“ (e.g. landraces/ farmer‘s varieties from farmer‘s fields).
In those cases Article 12.3.h of the Plant Treaty is applicable. Therefore, you should first contact the National Focal Point of the ITPGRFA of the respective country to ask, which national legislation is applicable for this PGRFA. If the country is a contracting Party to the Nagoya Protocol it may be the case that PIC and MAT is required.

=> In such cases the EU-ABS-Regulation is applicable (see box at page 28)

5. Monitoring Compliance – Example Germany

Compliance checks under Regulation (EU) No 511/2014 are always organized at the **national level**.

The **competent authority** in Germany is the **Federal Agency for Nature Conservation**

Bundesamt für Naturschutz

- responsible for the application of the EU ABS Regulation
- provides legally binding information on the implementation of the EU ABS Regulation in Germany
- conducts compliance checks
  - according to a **risk based control plan** which is periodically reviewed and adapted
  - if there are substantiated **concerns** that an infringement of the EU ABS Regulation has occurred (e.g. raised by provider countries)

5. Monitoring Compliance – Example Germany

Stepwise approach:

1. Request for Information via questionaire

1st round
Questionnaire with general questions regarding

- level of awareness
- preparedness to fulfill the due diligence obligations
- sourcing of GR & their origin
- type of research undertaken

2nd round
Specific questions with the aim of

- clarification of open questions
- ensuring common understanding
- possibly requesting copies of necessary documents

3rd round
Depending on the information received,

- further questions may be asked
- An on-site inspections may be conducted
- The check may be concluded

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5. Monitoring Compliance – Example Germany

Stepwise approach:

1. Request for Information via questionaire
   - including on-the-spot checks, as appropriate

2. In case the user has not fulfilled his due diligence obligations, the BfN
   - adopts the necessary orders to remedy the breaches
   - may in individual cases seize the unlawfully-utilised genetic resou
     or
   - prohibit specific utilisation activities/publication of research results.

3. In case of non-compliance, penalties are foreseen:
   - Provides for a level of fines up to 50,000 €
   - Additionally, an absorption of profits is possible

If the user complies with the orders adopted the measures taken will be rescinded

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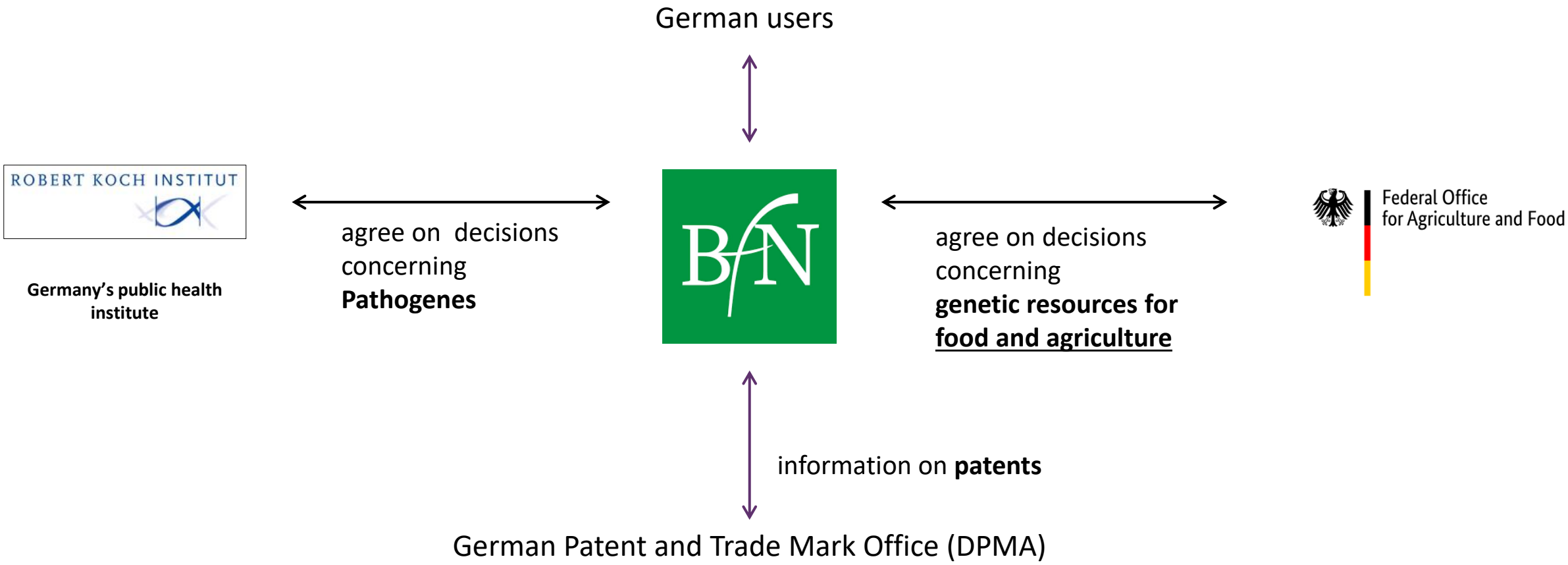
5. Monitoring Compliance – Example Germany



Thank you.

Contact

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