WORKSHOP:
Access and Benefit Sharing, Practical Advice
Introduction (slides 1-20)
Questions/Answers (slides 21-30)

Wednesday, 4 September 2019
Innsbruck, Austria

Bruno DAVID

Pierre FABRE Laboratories
Toulouse, FRANCE

Pierre Fabre

GREEN MISSION
Pierre Fabre

First steps in Plant sourcing…

- **Protected species** (CITES, National, Regional, Local laws…)
- **Properties issues** (authorization of the land owner)
- **Plant health control legislations**
- **Custom regulations**
- **Regulations on Biodiversity** Access and **B**enefit **S**haring **(A.B.S.)**

David B (2018). New regulations for accessing plant biodiversity samples, what is ABS? *Phytochem. Rev.*, **17**: *1211–1223*

Calendar of biodiversity laws

* Andean Community Decision n° 391 (Bolivia, Colombia, Ecuador + Venezuela)

Convention on Biological Diversity Enforcement

Genetic resources broadest sense

1996

1998

2000

2002

2004

Genetic resources narrow sense !

TK

29 December 1993

Free access no regulation

Genetic resources + traditional knowledge regulated access for R&D !

Nagoya Protocol + European Regulation 511/2014 on Compliance Enforcements

Implementation of ABS regulation EU member states + elsewhere

Genetic resources broadest sense

TK

12 October 2014

Genetic + biological resources + traditional knowledge Regulated access for R&D

118 countries have ratified the Nagoya Protocol

Pierre Fabre

David B (2018). New regulations for accessing plant biodiversity samples, what is ABS? *Phytochem. Rev.*, **17**: *1211–1223*

International & national levels

International agreements applicable only to the signatory countries

Convention on Biological Diversity

Nagoya Protocol

Regulations applicable directly to users of GR or TK

Infranational regulations

Examples: New Caledonian Provinces ABS regulations in France

National regulations

Examples: Brazilian or French national ABS regulations

Supranational regulations

Examples: Andean Community Decision n° 391 + European Regulation 511/2014

Documents not legally binding, indicative for users of GR or TK

Eur. Commission guidance 2016/C 313

Best practices guides…

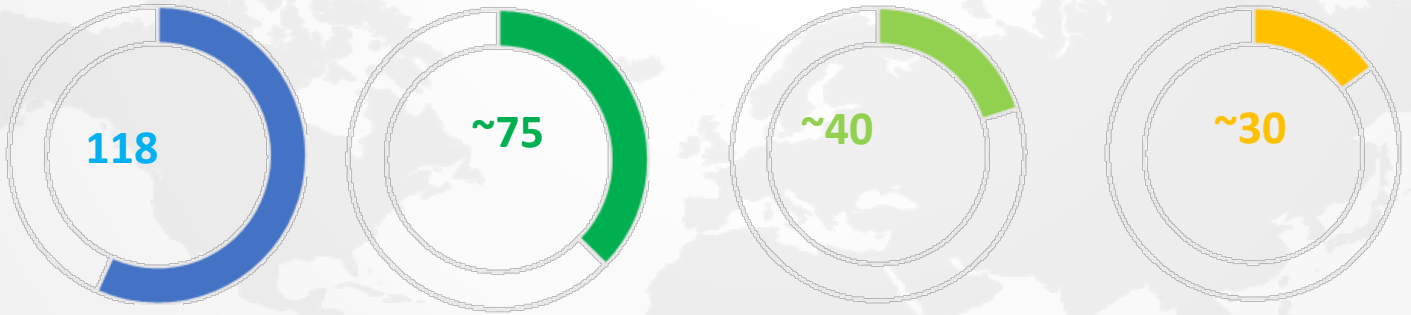
David B (2018). New regulations for accessing plant biodiversity samples, what is ABS? *Phytochem. Rev.*, **17**: *1211–1223*

Nagoya Protocol *vs* ABS national laws

120 ratifications (to date) :

Gabon, Jordan, Rwanda, Seychelles, Mexico, Laos, India, Fiji, Ethiopia, Panama, Mauritius, South Africa, Albania, Micronesia, Botswana, Syria, Mongolia, Comoros, Honduras, Tajikistan, Ivory Coast, Bissau Guinea, Indonesia, Bhutan, Norway, Egypt, Myanmar, Burkina Faso, Benin, Kenya, Guyana, Vietnam, Hungary, Denmark, Namibia, European Union (16 May 2014), Samoa, Spain, Guatemala, Uganda, Belarus, Vanuatu, Niger, Burundi, Gambia, Madagascar, Mozambique, Sudan, Peru, Switzerland, Uruguay (14 July 2014), Malawi, United Arab Emirates, Guinea, Marshall Islands, Lesotho, Dominican Republic, Cambodia, DR Congo, Congo, Kyrgyzstan, Kazakhstan, Liberia, Mauritania, Croatia, Cuba, Philippines, Djibouti, Pakistan, Slovakia, Togo, UK, Senegal, Germany, Czech Republic, Zambia, Finland, China, Belgium, Bulgaria, Netherlands, Moldova, France, Mali, Sweden, Swaziland, Bolivia, Luxembourg, Sierra Leone, Cameroon, Malta, Argentina, Antigua and Barbuda, Sao Tome and Principe, Qatar, Angola, Zimbabwe, Ecuador, Chad, Lebanon, Tanzania, Afghanistan, Palau, Austria, Central African Republic, Tuvalu, Saint Kitts and Nevis, Venezuela, Serbia, Malaysia, Estonia, Nepal, Eritrea, Romania, Maldives, Ghana …

International enforcement of Nagoya Protocol on 12 October 2014



Countries Parties to Nagoya Protocol

Countries with ABS regulation

Countries with ABS Procedures

Countries with access formalities

David B (2018). New regulations for accessing plant biodiversity samples, what is ABS? *Phytochem. Rev.*, **17**: *1211–1223*

The 3 key questions:

① Is there an ABS regulation enforced in the Source Country to Date ?

NO

YES

② Restricted access for the planned Utilisation ?

NO

YES

FREE ACCESS

ACCESS TO BE NEGOTIATED

③ Is the European Regulation 511/2014 applicable ?

For EU users + 10 cumulative conditions → Due Diligence Declaration(s)

- External funding received for your research
- Before commercialisation of GR/TK derived products

✱ Cf. slides #14/15 about cumulative conditions !

YES

DUE DILIGENCE DECLARATION(S) TO BE DONE

David B (2018). New regulations for accessing plant biodiversity samples, what is ABS? *Phytochem. Rev.*, **17**: *1211–1223*

Application of ABS regulations

Apply to

- Genetic resources (GR) subject to R&D = Plants, fungi, animals, microorganisms
- Wild or cultivated/farmed GR
- Traditional knowledge associated with GR
- Collections of GR
- GR or TK accessed where states exercise sovereign rights after national laws enforcement

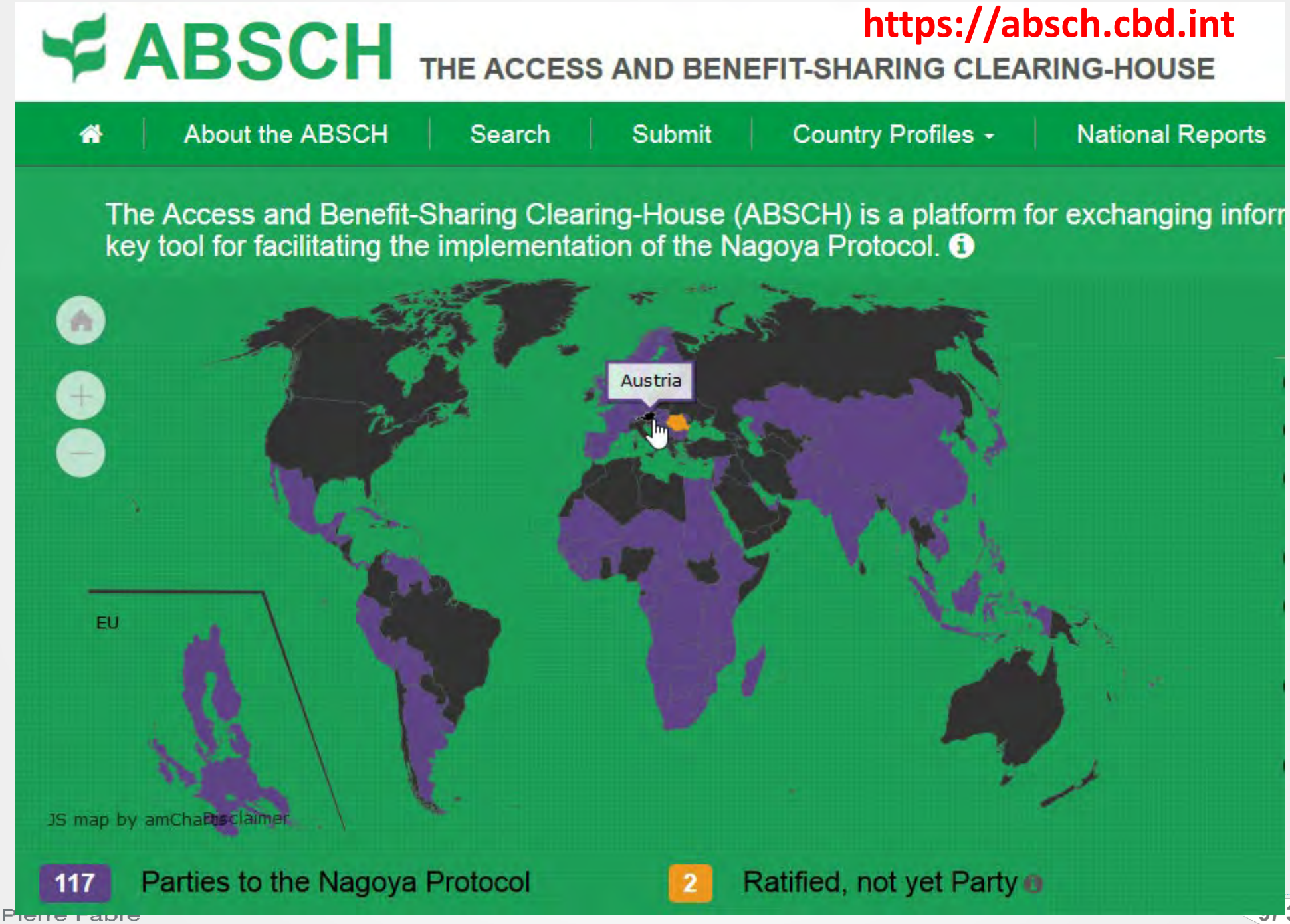
Does not apply to

- GR or TK accessed before national laws enforcement
- GR from areas beyond national jurisdictions
  International waters, space, Antarctic (to date)
- Commodities* in the absence of R&D
  * Except in some countries e.g. Brazil
- *Ex-situ* collections
  * Except *ex-situ* collections on which countries have claims e.g. Brazil
- Human genetic resources
- GR used as tool or reference
- Unintentional access (microorganisms)
- Digital Sequence Information (to date)

David B (2018). New regulations for accessing plant biodiversity samples, what is ABS? *Phytochem. Rev.*, **17**: *1211–1223*

How to get information on contacts and regulations ?

→ **https://absch.cbd.int**


ABSCH
https://absch.cbd.int
THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE
About the ABSCH
Search
Submit
Country Profiles
National Reports
The Access and Benefit-Sharing Clearing-House (ABSCH) is a platform for exchanging inform
key tool for facilitating the implementation of the Nagoya Protocol.
Austria
EU
JS map by amCha
Disclaimer
117
Parties to the Nagoya Protocol
2
Ratified, not yet Party

https://absch.cbd.int

ABSCH THE ACCESS AND BENEFIT-SHARING CLEARING-HOUSE

Convention on Biological Diversity

About the ABSCH | Search | Submit | Country Profiles | National Reports

CBD > ABSCH > Country Profiles > Austria

Austria

Party to the Nagoya Protocol

- 1 ABS National Focal Point
- 1 Competent National Authority
- 2 Legislative, Administrative or Policy Measure
- 0 ABS Procedure
- 0 National Model Contractual Clause
- 0 Internationally Recognized Certificates of Compliance
- 2 National Websites or Databases
- 0 Checkpoint

Austria

Party Status:	**Party to the Nagoya Protocol**
Entered into force on:	**18 Oct 2018**
Ratification on:	**20 Jul 2018**
Signatory:	**Signed on 23 Jun 2011**
CBD Country Profile:	www.cbd.int/countries/?country=at

https://absch.cbd.int

– ABS National Focal Point (NFP) 1

Ms. Andrea H. Nouak

Division I/9 - International Environmental Affairs Federal Ministry of Sustainability and Tourism Stubenbastei 5 A-1010 Vienna

ABS NATIONAL FOCAL POINT | AUSTRIA | ABS-NFP-AT-209978-16 | 19 JAN 2018

– Competent National Authority (CNA) 1

Federal Minister for Sustainability and Tourism

Only designated competent national authority for the country

COMPETENT NATIONAL AUTHORITY | AUSTRIA | ABSCH-CNA-AT-240481-2 | SINGLE CNA FOR THE COUNTRY | 29 MAY 2019

– Legislative, Administrative or Policy Measure (MSR) 5

Select the ABS Measures to be displayed in the overview

☑ 1. **Commission Implementing Regulation (EU) 2015/1866 of 13 October 2015 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 compliance and best practices**

REGIONAL / MULTILATERAL | LAW | LEGALLY BINDING | COMPLIANCE | ENTRY INTO FORCE: 09 NOV 2015

☑ 2. **EU ABS Regulation - 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**

REGIONAL / MULTILATERAL | LAW | LEGALLY BINDING | COMPLIANCE | ENTRY INTO FORCE: 09 JUN 2014

In practice:

① Identification and contact with the biodiversity National Competent Administration (NCA)

② Negotiation with NCA

Biodiversity National Competent Authorities of the source country

Prior Informed Consent (PIC)

Mutually Agreed Terms (MAT)

User of GR or TK Academics or Industries

Benefit Sharing

③ **Access**

Provider of GR or TK in practice: University, enterprise, local community…

③ **Delivery of Permit by National Competent Authority**

ABS Clearing House
CBD Secretary
(Montreal, Canada)

④ **Registration of access permit**

⑤ **Delivery of Internationally Recognized Certificate of Compliance (IRCC)**

⑥ **Controls**

* ⑦ **Due Diligence Declaration**

National Competent Authorities of the User's country (EU)

European **Commission**

Take-home message: ABCD of ABS

A ***ACCESS*** **Negotiate access with source country**

Nations are sovereign → free access, authorisation, permits…

B ***BENEFIT SHARING*** **Sharing according to agreed terms**

C ***COMPLIANCE***

Controls, sanctions by EU member state where research is conducted

Art 4, 7 & 9 European Regulation

D ***DILIGENCE***

Conformity / European Regulation (cf. * for conditions of application page 14 &15)

Annex II when external funding of research on GR e-portal « *declare* »

Annex III before commercialization of GR derived product e-portal « *declare* »

Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union

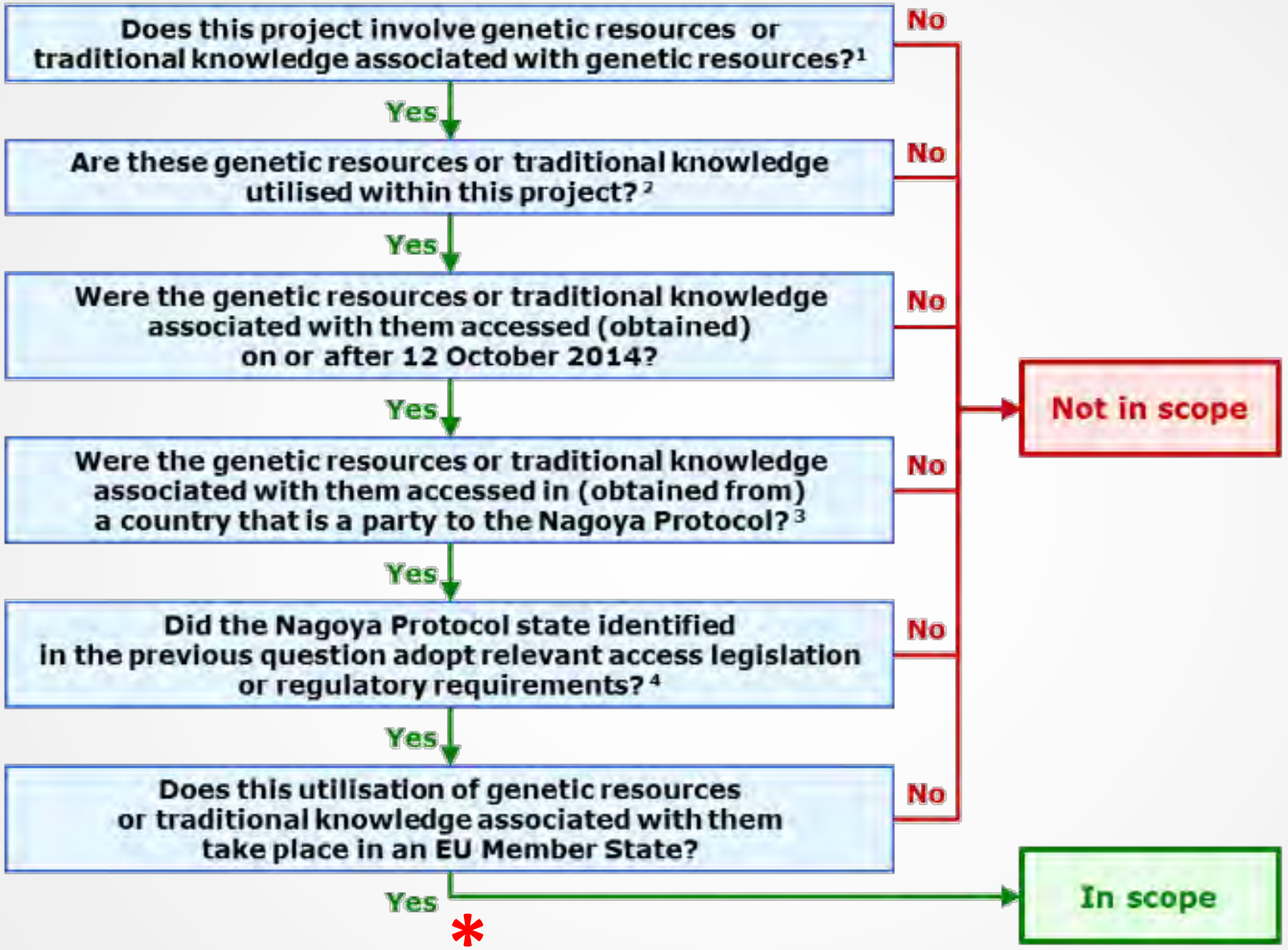
(2016/C 313/01)

ANNEX I

Overview of conditions for applicability of the EU ABS Regulation

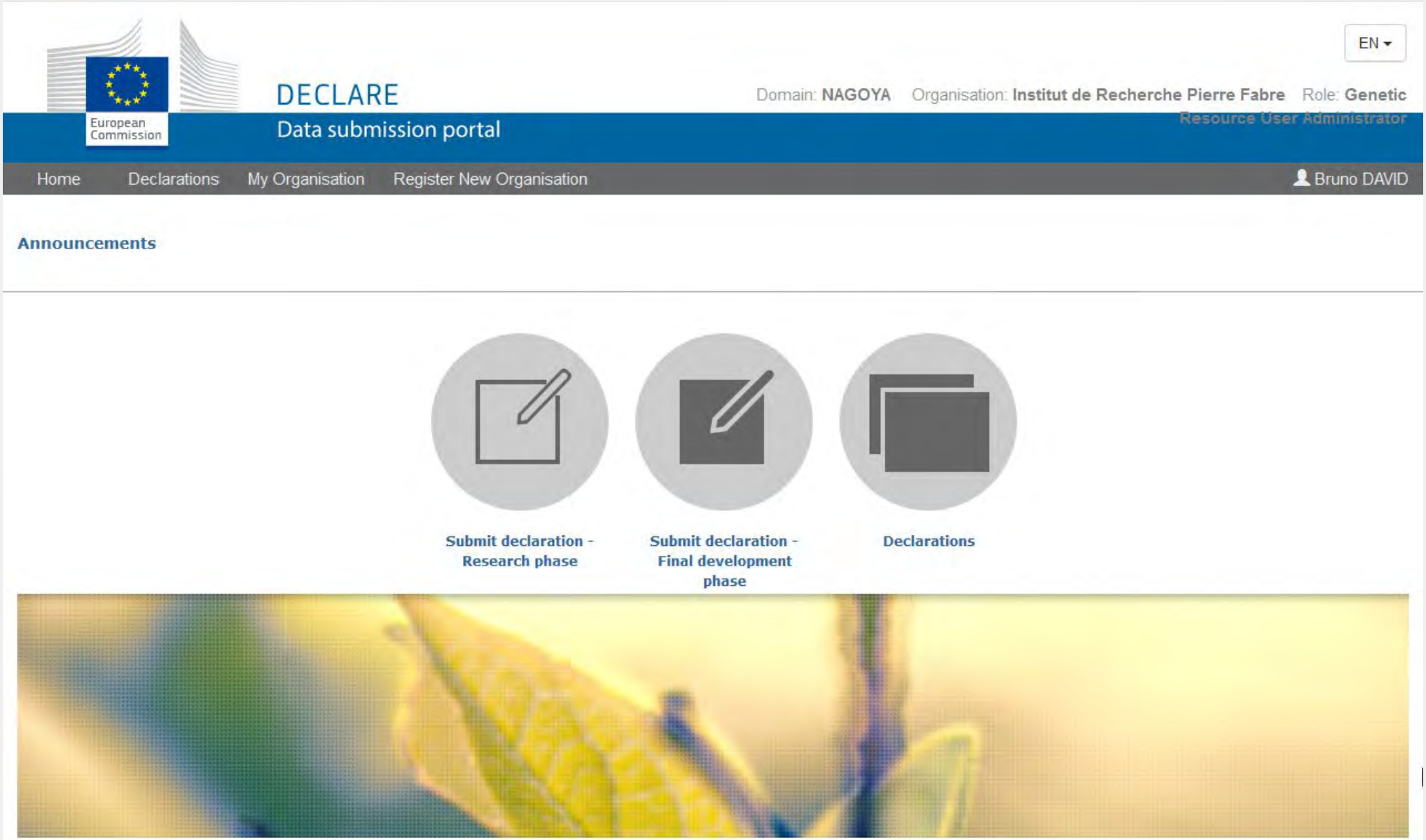
		Within scope (cumulative conditions (*))	Outside of scope
Geographic scope (provenance of GR (**))	*Access in …*	Areas within a country's jurisdiction	Areas beyond national jurisdiction or covered by Antarctic Treaty System
	Provider country is …	Party to the Nagoya Protocol	Not a Party to the Protocol
	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
		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)	*R & D …*	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.



http://ec.europa.eu/research/participants/docs/h2020-funding-guide/cross-cutting-issues/ethics_en.htm

https://webgate.ec.europa.eu/declare/web



https://webgate.ec.europa.eu/declare/web

DUE DILIGENCE DECLARATION AT THE STAGE OF RESEARCH FUNDING

pursuant to Article 5 of Regulation 2015/1866

Institut de Recherche Pierre Fabre - France

General Contact Email: -

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.

If you marked as confidential essential information (such as about access place), without which the record would not be published on 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 am making this declaration for the utilisation of*:

- ☐ Genetic resources
- ☐ Traditional knowledge associated with genetic resources

Subject matter of the research or identification code of the grant*:

☐ Confidential

Translation for publishing to the ABS Clearing House (EN, FR or ES)

https://webgate.ec.europa.eu/declare/web

INFORMATION ON EXERCISE OF DUE DILIGENCE

Your declaration can cover one or more genetic resources. If it covers multiple genetic resources subject to different permits, you can add to your declaration references to more permits.

Information: You can see both types of permits now. Once you choose one of them, this will no longer be the case but you can still add as many permits (of different types) as required by using **Add IRCC Permit** or **Add National Permit** buttons.

Internationally recognized certificate of compliance (IRCC)

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 *:

ABSCH-IRCC- Select an IRCC code

Type the two-letter country code of the IRCC identifier followed by '-' then followed by the first numbers/letters of the IRCC identifier.

E.g.: "in" will search all IRCCs from India; "in-2378" will search all IRCCs from India with the identifier number starting with "2378"

National permit

Please fill in the following information :

Place of access *:

...

☐ Confidential

Description of the genetic resources or traditional knowledge associated with genetic resources utilised; or unique identifier(s), where available *:

☐ Confidential

Translation for publishing to the ABS Clearing House (EN, FR or ES)

Identifier of access permit or its equivalent, where available *:

☐ Confidential

https://webgate.ec.europa.eu/declare/web

Part B - Information not to be transmitted to the ABS Clearing House

☐ **I declare that I will keep and transfer to subsequent user(s) a copy of the internationally recognized certificate(s) of compliance referred above as well as information on the content of the mutually agreed terms relevant for subsequent users.** *

☐ **In relation to national permit(s) referred above, I declare that I am in possession of the following information, which I will keep and transfer to subsequent user(s):** *

(a) date of access;
(b) person or entity having granted prior informed consent, where applicable;
(c) person or entity to whom prior informed consent was granted (where applicable), if not granted directly to me or my entity;
(d) mutually agreed terms, where applicable;
(e) the source from which I or my entity obtained the genetic resource and traditional knowledge associated with genetic resources;
(f) presence or absence of rights and obligations relating to access and benefit-sharing, including rights and obligations regarding subsequent applications and commercialisation.

Where the genetic resource(s) was(were) obtained from a registered collection, please provide the registration code of the collection ⓘ

The research grant is funded by the following sources *:

☐ Private
☐ Public

Member State(s) in which the research involving utilisation of genetic resources and traditional knowledge associated with genetic resources takes place or has taken place *:

☐ Select all

Place of Declaration *:

Cancel

Save

https://webgate.ec.europa.eu/declare/web

DUE DILIGENCE DECLARATION AT THE STAGE OF FINAL DEVELOPMENT OF A PRODUCT

pursuant to Article 6 of Regulation 2015/1866

Institut de Recherche Pierre Fabre - France

General Contact Email: -

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.

☐ **I declare that I have fulfilled the obligations under Article 4 of Regulation (EU) No 511/2014.** * ℹ

I am making this declaration for the utilisation of: *

☐ Genetic resources
☐ Traditional knowledge associated with genetic resources

This declaration concerns *

○ **Product**
○ **Result of the utilisation** ℹ
○ **Outcome of the utilisation** ℹ

INFORMATION ON EXERCISE OF DUE DILIGENCE

Your declaration can cover one or more genetic resources. If it covers multiple genetic resources subject to different permits, you can add to your declaration references to more permits.

Information: You can see both types of permits now. Once you choose one of them, this will no longer be the case but you can still add as many permits (of different types) as required by using **Add IRCC Permit** or **Add National Permit** buttons.

Question 1

"We frequently have guest researchers from biodiversity-rich countries who bring plant material from their country to our institute in order to do collaborative research with us, usually ending up with a joint publication. Is it also necessary for us (i.e. for the Academic hosts) to contact the respective national focal point in such cases?"

- ✓ It's depends on the source country and on the national regulations.
- ✓ The biodiversity source countries may have no regulation as countries are free to implement access law or not.
- ✓ When Access is regulated inform the National Competent Authority
- ✓ Welcoming a student is considered as Benefit Sharing.

Question 2

"Does the Nagoya Protocol also apply for herbal samples that are for example purchased from local markets?"

- ✓ It's depends in which country you buy the plant (on the local market) and the origin of the plant. Some countries (*e.g.* Brazil) have ABS regulations which claim Benefit Sharing on their resources accessed abroad (*ex-situ*).

Question 3

"A German company/university is working on an US Plant.
The plant was purchased in the United States on December 15, 2015.
A phytochemical study and some biological assays are conducted.

- ✓ Does European Regulation 511-2014 apply?
- ✓ What are the administrative requirements?"

- ✓ The European Regulation does not apply because US are not a party to the NP. The EU regulation applies only when the country of origin is a party to the NP. (Cf. slides #14/15 about cumulative conditions !)
- ✓ No obligation from a legal point of view. However it is essential to keep the proof of the origin of the plant, its date of access and the activities carried out, in order to be able to justify every dates of access + source countries.

Question 4

"How does one determine the monetary value of indigenous / traditional knowledge if in the event the knowledge leads to the discovery and commercialization of a pharmaceutical? This is required for determining share of benefits with knowledge holders."

- ✓ The value is generally determined during the negotiation between researchers and Biodiversity National Competent Authorities + indigenous/traditional representatives. Most of the time a % of the profit generated in the commercialisation of the TK associated genetic resource is negotiated.
- ✓ Therefore the value of the Traditional Knowledge (TK) depends on the profit made at the world level.
  Each country being sovereign over its own Genetic Resources (GR) + TK can therefore decide how to regulate and value its own GR and TK.

Question 5

"An African company sells a derivative/extract from a local plant to a German company B which produce via a well known process (*e.g.* by hydrogenation), a semi-synthetic compound.
The German company sells as an ingredient this compound.
Obligations?"

- ✓ The German company must be in compliance with national ABS law and check whether the source country is party to the Protocol.
- ✓ The product is a "derivative" in the sense of Nagoya.
- ✓ If we consider that the German company manufactures a new ingredient without R&D at the process level = outside the scope of the European Regulation = no due diligence.
- ✓ The new ingredient is no longer a "derivative" (naturally occurring) = outside the scope of the EU Regulation even if one considers characterization as R&D.

Question 6

"A French laboratory had access to a French genetic resource before the Biodiversity national law (for example July 2016) and conducted biological research still on the cosmetic field. The resource is harvested in the wild in France. Obligations at the French level?

- ✓ European level ?
- ✓ If cultivated?"

- ✓ When access before National ABS law no obligation !
- ✓ French national ABS Law is enforced + fully applicable since 1 July 2017
- ✓ No DDD obligations.

Question 7

"A Swiss company wants to develop a food supplement from Nepal. The plant is cultivated and sold abroad by a local company."

- ✓ Is an enforced + fully applicable National ABS law in Nepal ?
- ✓ Request before the local company an official certificate stating the legacy of the intended use as food supplement .

Question 8

"A UK laboratory accessed an aqueous extract of gentian flower (*Gentiana lutea*) in Switzerland on May 26, 2015.
R&D work aims to find moisturizing properties.
The ingredient, if developed, is intended to be marketed.
Obligations toward source country, with regards to EU Regulation ?"

- ✓ Obligations in this country? On the date indicated, access has not yet been regulated, so there is no obligation. However, since February 1, 2016, it is necessary to document and notify (voluntarily or before commercialization) the uses, but no declaration procedure or prior authorization is necessary. For benefit sharing, Switzerland encourages voluntary approaches.
- ✓ Switzerland has ratified the Nagoya Protocol on July 11, 2014, there is a decree of March 21, 2014 and an order of December 11, 2015, which came into force on February 1, 2016.
- ✓ EU DDD ? NO: Access is prior to the date of full application of the European Regulation. (Cf. slides #14/15 about cumulative conditions !)

Question 9

"Preparation of new essential oils to create new fragrance ingredients
Plant parts (cultivated or wild species) are imported by a perfumery company. New essential oils are being extracted. Volatile compounds are purified and identified.
Steps to be taken: at the supplier country level? at the European level ?"

- ✓ The extraction of new essential oils and purification of volatile compounds from a genetic resource and the assessment of their potential as new fragrance ingredients constitute R&D on the biochemical composition of the genetic resource.
- ✓ Check the ABS regulations of the source country
- ✓ Check if EU Regulation DDD applicable?

Question 10

"On January 2, 2018, parts of plants (of cultivated or wild species) are imported by a lab directly from wholesaler from Spain."

- ✓ Plants parts are genetic resources.
- ✓ The Spanish APA regulation is applicable since March 15, 2017 because the accesses are prior to this date.
- ✓ This study constitutes an access within the meaning of the European Regulation 511/2014.