Office for Product Safety & Standards

The Nagoya Protocol on Access and Benefit Sharing (ABS) in the UK

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Content

- Who we are
- Background of Nagoya Protocol
- The Regulations
- What it means for “users”
- Approach to Enforcement
- Case Studies and Q&A

Who we are

DEFRA

- Policy lead
- National Focal Point (NFP)

BEIS – Office for Product Safety and Standards

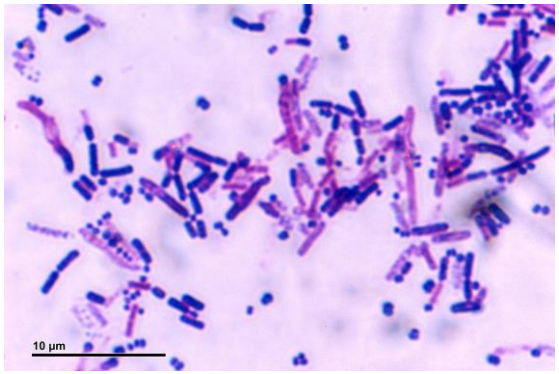
- Competent National Authority (CNA)
- Implementation and enforcement
- Technical and product based regulations with environmental focus

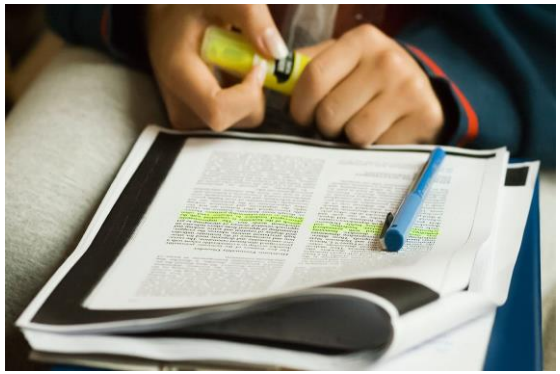
ABS simply explained

By the ABS Capacity Development Initiative

https://youtu.be/09zflWUIKTQ?list=PLFxz19cUN2XISQiFjv5K16u8wmDowHiET

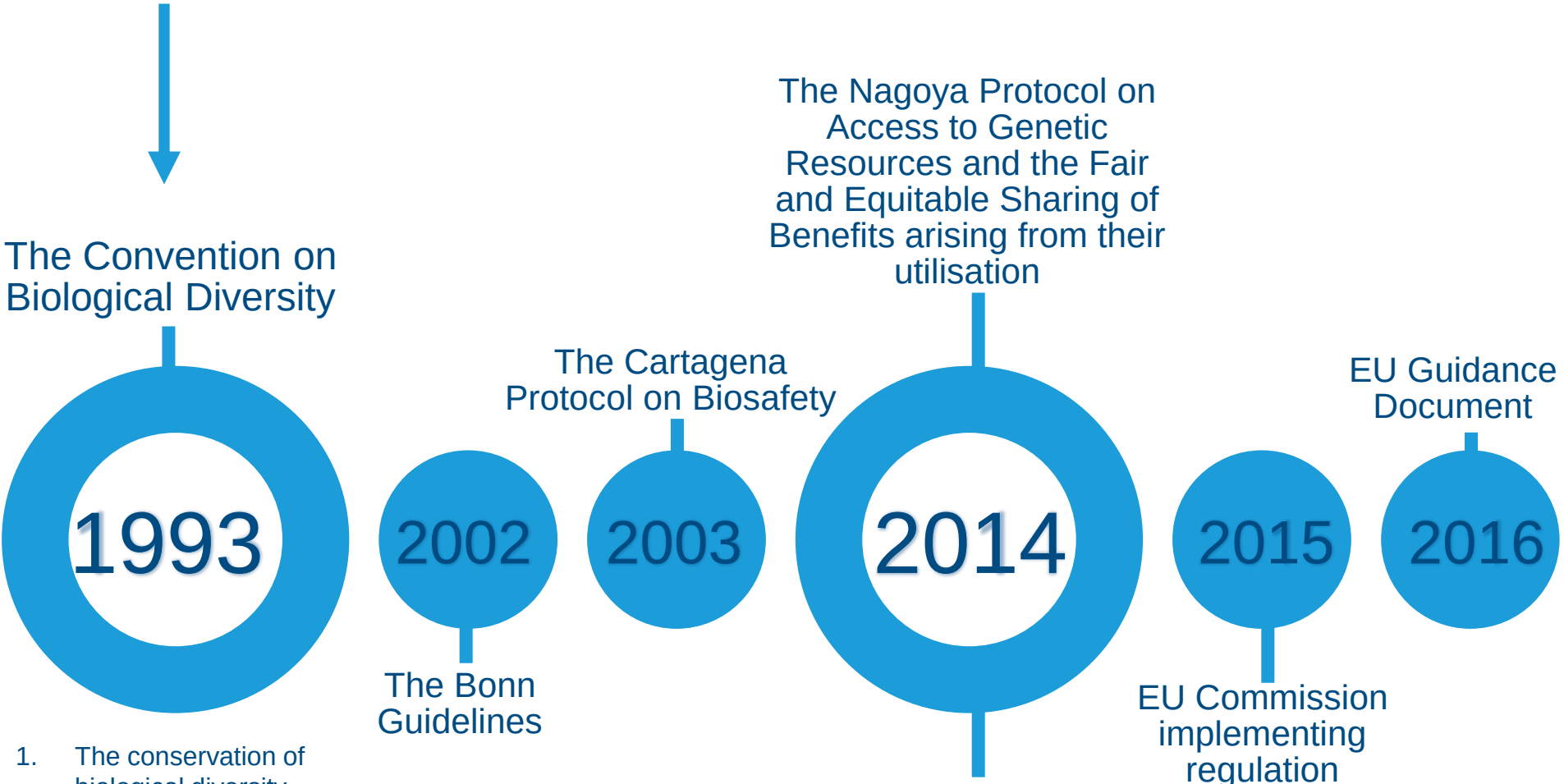
The Value of Biodiversity and Traditional Knowledge





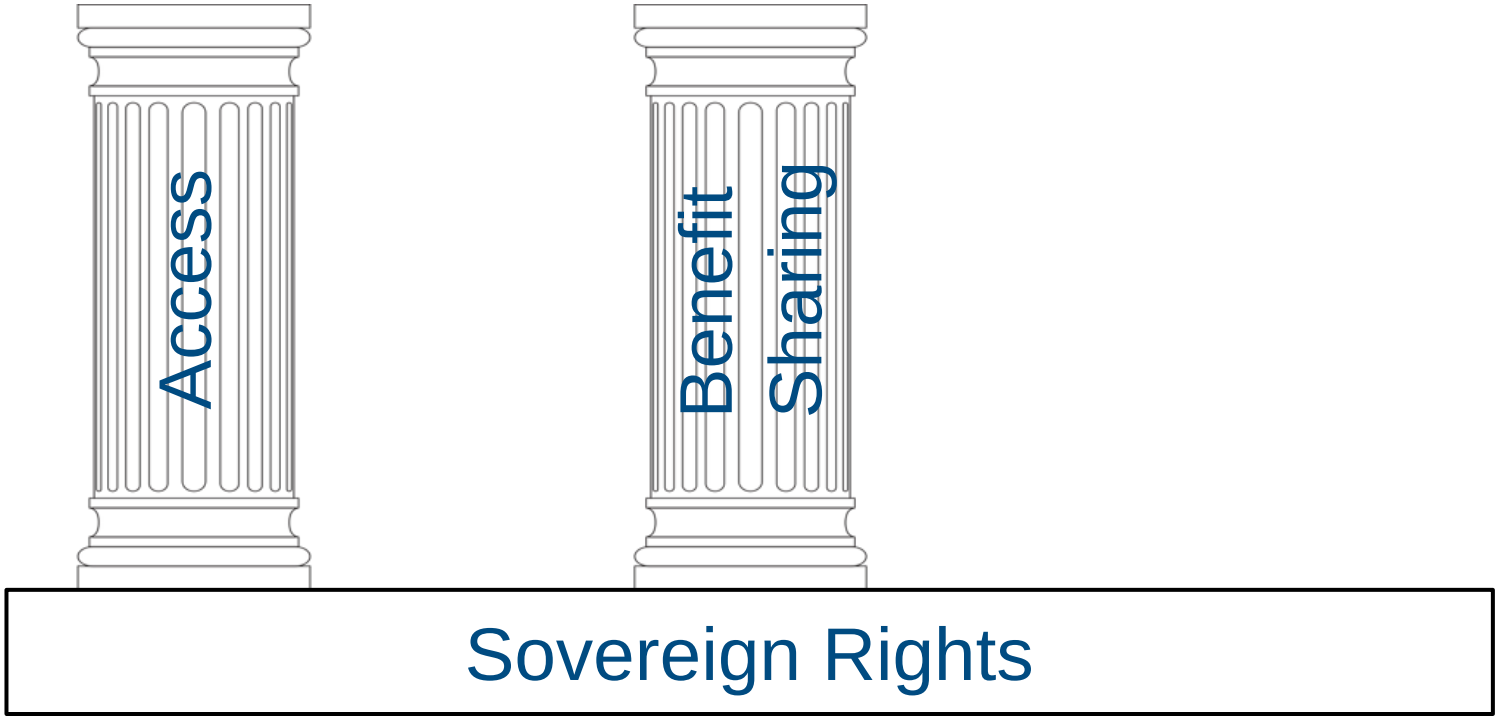
Many countries felt that their biodiversity and traditional knowledge were being exploited.

Biodiversity threatened by climate change and human activity



https://www.cbd.int/

Background



The Convention on Biological Diversity

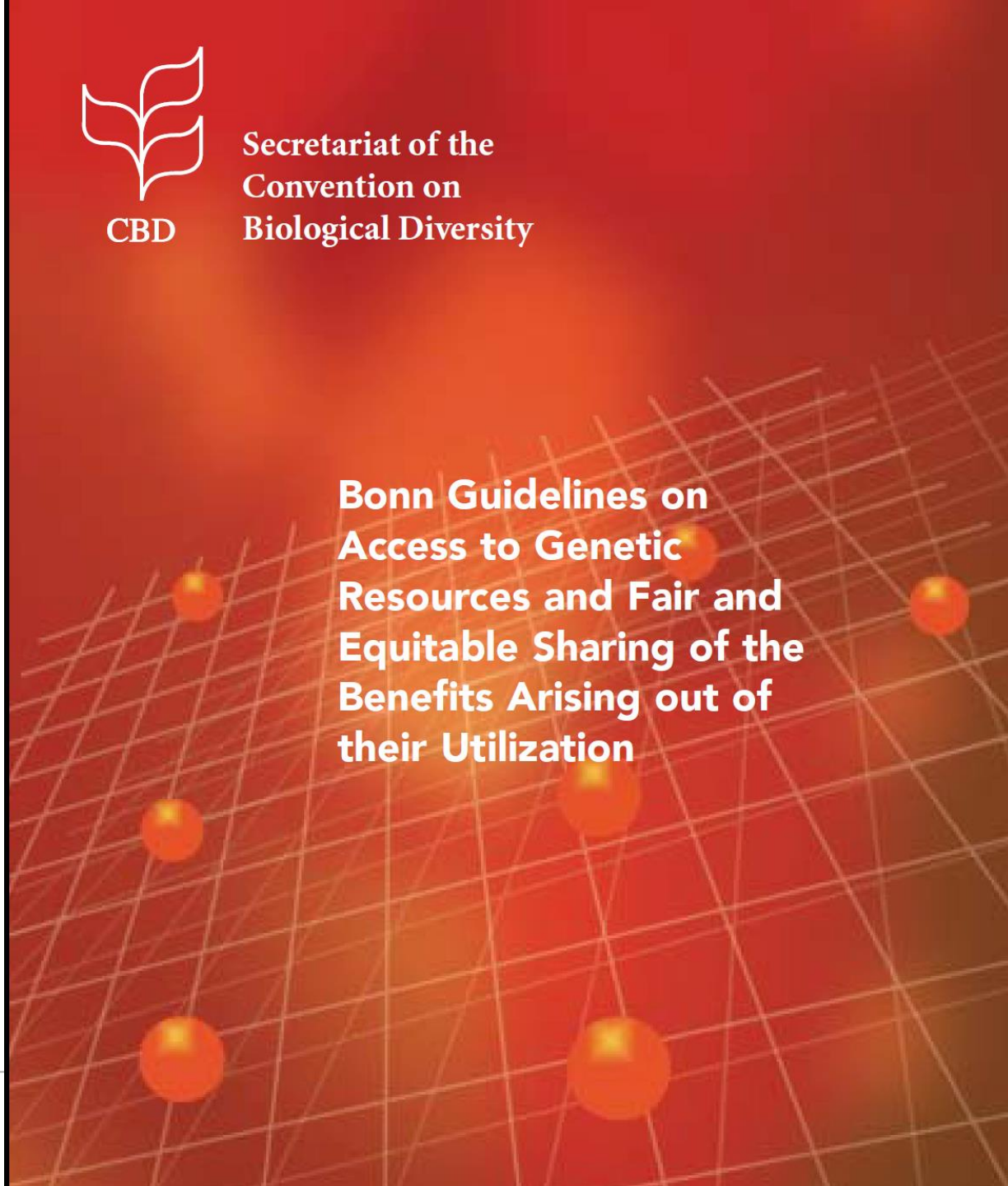
1993

2002

The Bonn Guidelines

1. The conservation of biological diversity,
2. The sustainable use of the components of biological diversity,
3. The fair and equitable sharing of the benefits arising out of the utilisation of genetic resources

https://www.cbd.int/



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

(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 particular Article 192(1) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee [1],

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure [2],

Whereas:

(1) The main international instrument providing a general framework for the conservation and sustainable use of biological diversity and the fair and equitable sharing of the benefits arising from the utilisation of genetic resources is the Convention on Biological Diversity, approved on behalf of the Union in accordance with Council Decision 93/626/EEC [3] (the 'Convention').

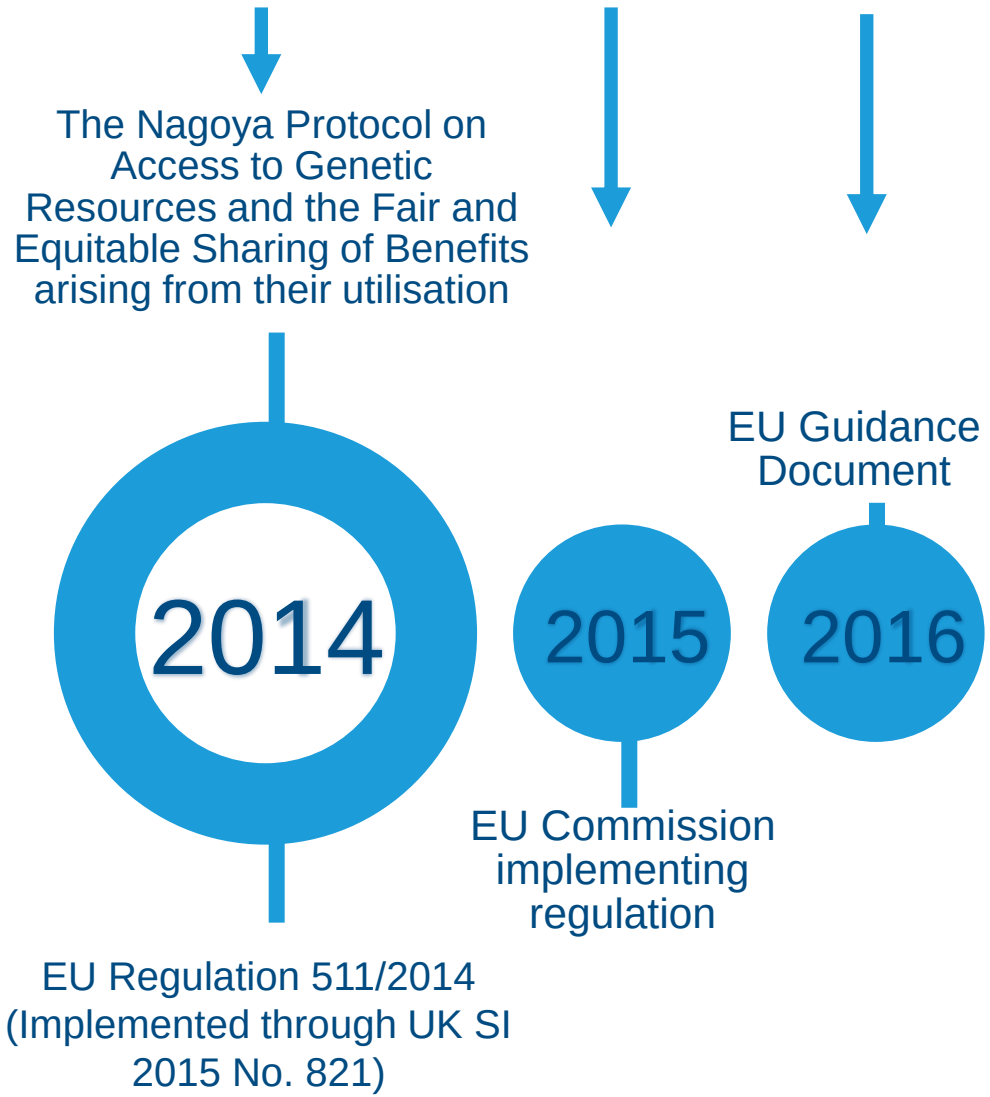
(2) The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from Their Utilization to the Convention on Biological Diversity [4] (the 'Nagoya Protocol') is an international treaty adopted on 29 October 2010 by the Parties to the Convention. The Nagoya Protocol further elaborates upon the general rules of the Convention on access to genetic resources and sharing of monetary and non-monetary benefits arising from the utilisation of genetic resources and traditional knowledge associated with genetic resources ('access and benefit-sharing'). In accordance with Council Decision 2014/283/EU [5], the Nagoya Protocol was approved on behalf of the Union.

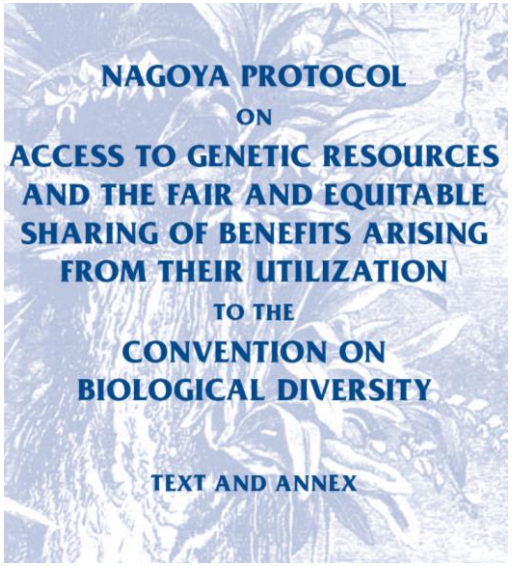
(3) A broad range of users and suppliers in the Union, including academic, university and non-commercial researchers and companies from different sectors of industry, use genetic resources for research, development and commercialisation purposes. Some also use traditional knowledge associated with genetic resources.

(4) Genetic resources represent the gene pool in both natural and domesticated or cultivated species and play a significant and growing role in many economic sectors, including food production, forestry, and the development of medicines, cosmetics and bio-based sources of energy. Furthermore, genetic resources play a significant role in the implementation of strategies designed to restore damaged ecosystems and safeguard endangered species.

(5) Traditional knowledge that is held by indigenous and local communities could provide important lead information for the scientific discovery of interesting genetic or biochemical properties of genetic resources. Such traditional knowledge includes knowledge, innovations and practices, of indigenous and local communities embodying traditional lifestyles, relevant for the conservation and sustainable use of biological diversity.

[1] OJ C 161, 6.6.2013, p. 73.
[2] Position of the European Parliament of 11 March 2014 (not yet published in the Official Journal) and decision of the Council of 14 April 2014.
[3] Council Decision 93/626/EEC of 25 October 1993 concerning the conclusion of the Convention on Biological Diversity (OJ L 309, 13.12.1993, p. 1).
[4] Annex I to Document UNEP/CBD/COP/DEC/X/1 of 29 October 2010.
[5] Council Decision 2014/283/EU of 14 April 2014 on the conclusion, on behalf of the Union, of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (see page 231 of this Official Journal).





National Access Measures (Optional for party countries)

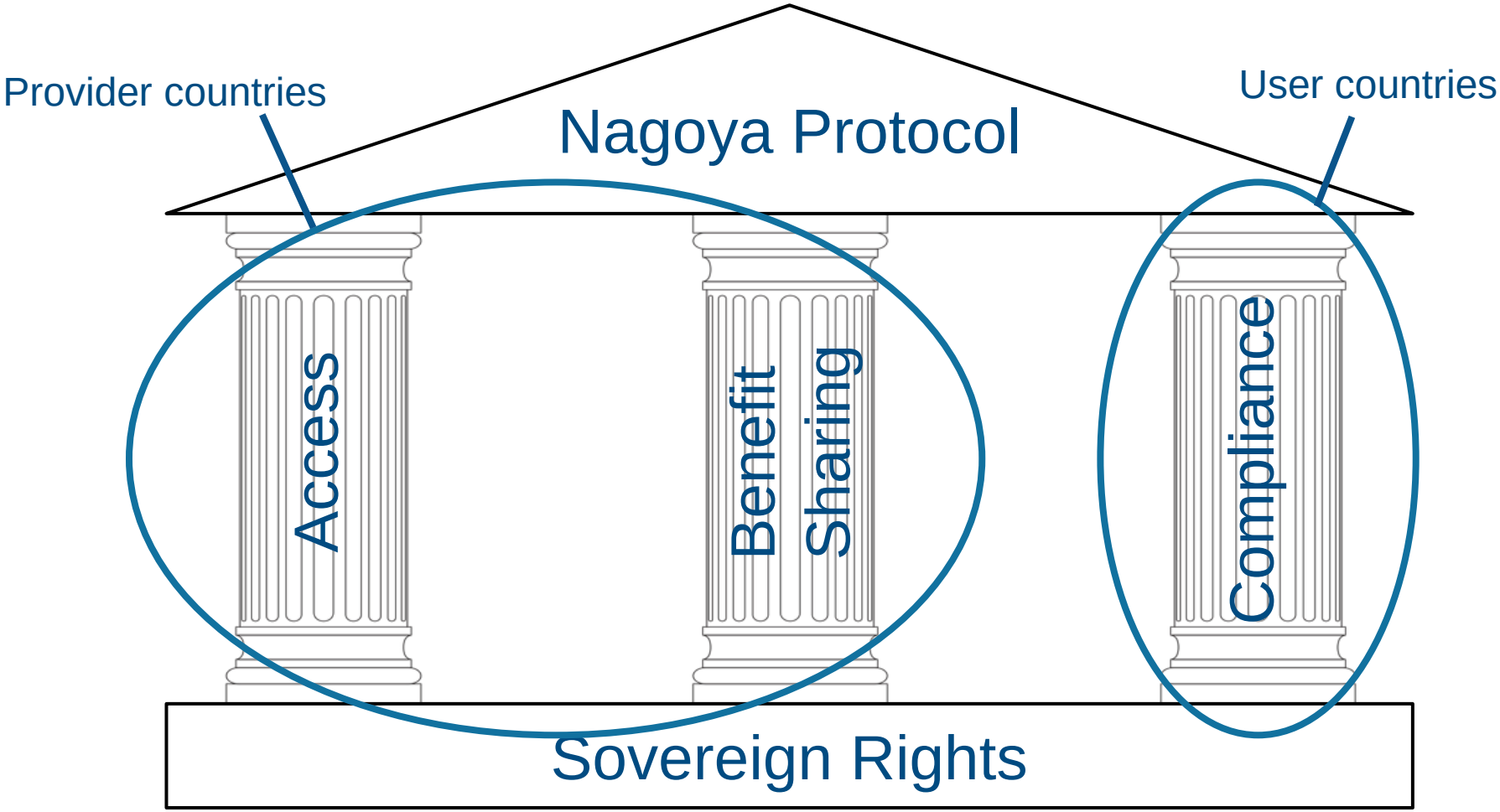
- Countries can choose to exercise sovereign rights over their GRs/aTK
- PIC/MAT/equivalent
- **The UK does not have national access measures**

Compliance measures (Compulsory for party countries)

UK obligations:

- Due diligence
- Seek, keep and transfer
- Due-diligence declarations

Background


Provider countries
User countries
Nagoya Protocol
Access
Benefit Sharing
Compliance
Sovereign Rights

Assessing scope (EU Regulation)

- Utilisation

Applies to genetic resources (GRs) accessed in countries that:

- have ratified the Nagoya Protocol
- regulate access to genetic resources/traditional knowledge through established access measures

And where the GRs are:

- accessed after 12 October 2014
- not already governed by specialised international instruments (e.g. PIP Framework, ITPGRFA)

Always check the provider country access measures (even if out of scope of the compliance measures)

Examples of in-scope activities

Utilisation: *research and development on the genetic or biochemical composition of the genetic resource, including through the application of biotechnology*

Examples:

- **Research** on a genetic resource leading to the isolation of a biochemical compound used as a new ingredient incorporated into a pharmaceutical product
- **Creation or improvement** of GRs used in a manufacturing process
- **Genetic modification** - creation of a genetically modified organism containing a gene from another species

Examples of out of scope activities

- **Maintenance and management** of a collection for conservation purposes
- Genetic resources as **testing tools** (GR is not the subject of the research)
- Using **vectors** to introduce foreign material to a host organism
- Using GRs as **biofactories**
- Using existing **lab strains** established before the Nagoya Protocol/compliance measures
- Utilisation of **Human** GRs

Example activities

Pathogens

- Generally in-scope
- Note extensions in public health emergencies
- Exemptions on material covered under the PIP framework.

Intentionality of Access

- Pests and pathogenic organisms introduced unintentionally into the UK are out of scope.
- Intentional access overseas is in-scope.

Example activities

Product development

- In-scope if involving R&D on a GR
- Processing or product formulation (simply mixing ingredients without R&D) is out of scope.

Clinical trials

- Can be in-scope if trials inform R&D or further product development.

Screening

- Out of scope.
- However, utilisation on selected samples can be in-scope.

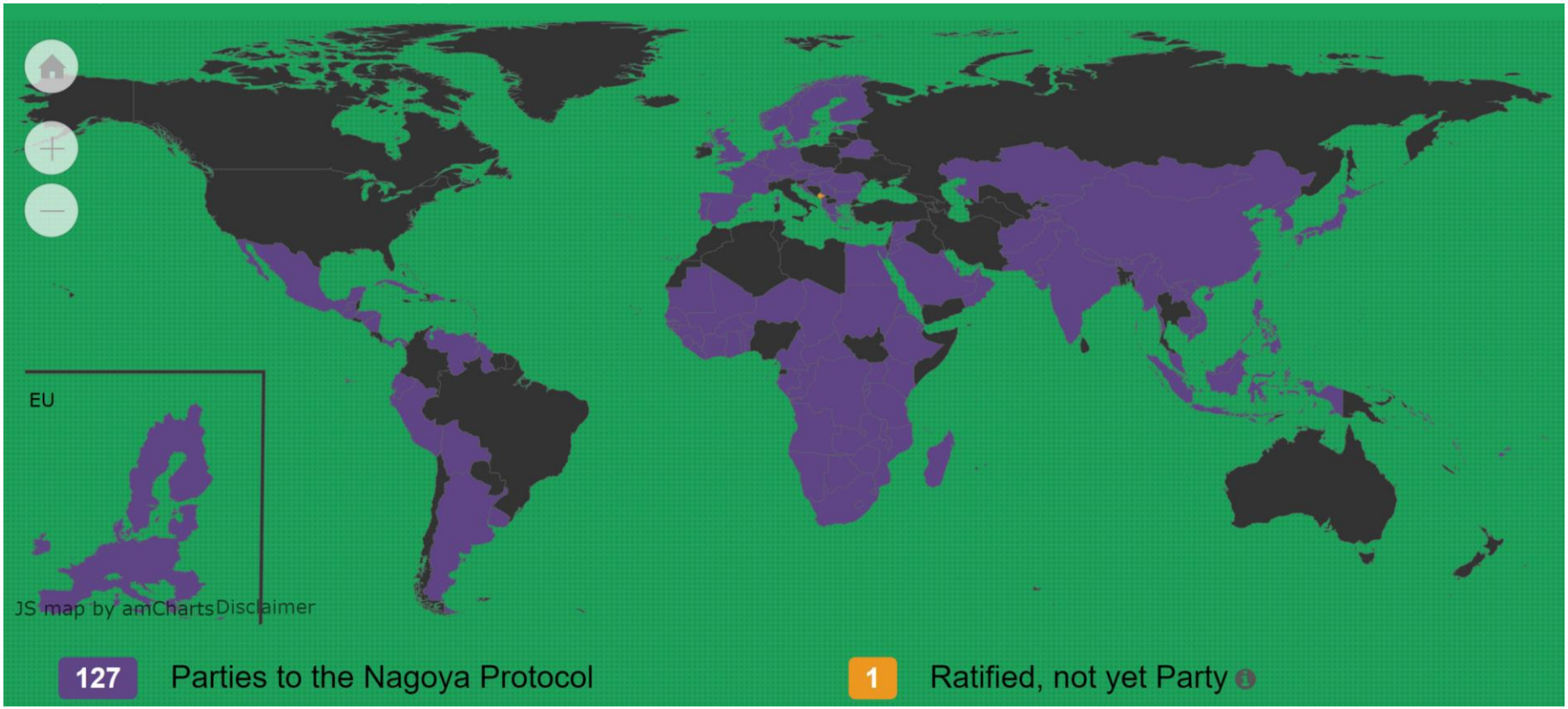
What are the obligations?

- Exercise due-diligence
- Seek, keep and transfer
- Due-diligence declaration – stage of research funding
- Due-diligence declaration – stage of final product development

Identify GR to access

Exercise due diligence

ABS Clearing House



https://absch.cbd.int/

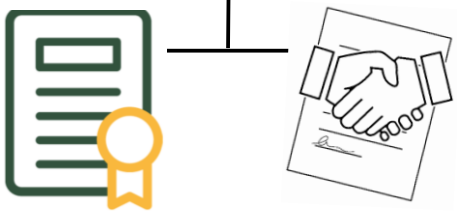
Kenya

Party Status:	**Party to the Nagoya Protocol**
Entered into force on:	**12 Oct 2014**
Ratification on:	**07 Apr 2014**
Signatory:	**Signed on 01 Feb 2012**
CBD Country Profile:	www.cbd.int/countries/?country=ke

+ ABS National Focal Point (NFP) 1
+ Competent National Authority (CNA) 1
+ Legislative, Administrative or Policy Measure (MSR) 11
+ ABS Procedure (PRO) 1
+ National Model Contractual Clause (NMCC) 0
+ Internationally Recognized Certificates of Compliance (IRCC) 38
+ National Websites or Databases (NDB) 1
+ Checkpoint (CP) 9
+ Checkpoint Communiqué (CPC) 0
+ Interim National Reports on the Implementation of the Nagoya Protocol (NR) 1

What does that mean for users?

IRCC



Provider Country can upload documents to ABSCH to create IRCC

Identify GR to access

Access Measures

Exercise due diligence

Access

No Access Measures

Keep correspondence and documentation for 20 years and transfer to subsequent users

Information to be collected under article 4

IRCC – inc. content of MAT

or

Required:

Date & place of access

Description of GR & aTK

Source obtained and subsequent users

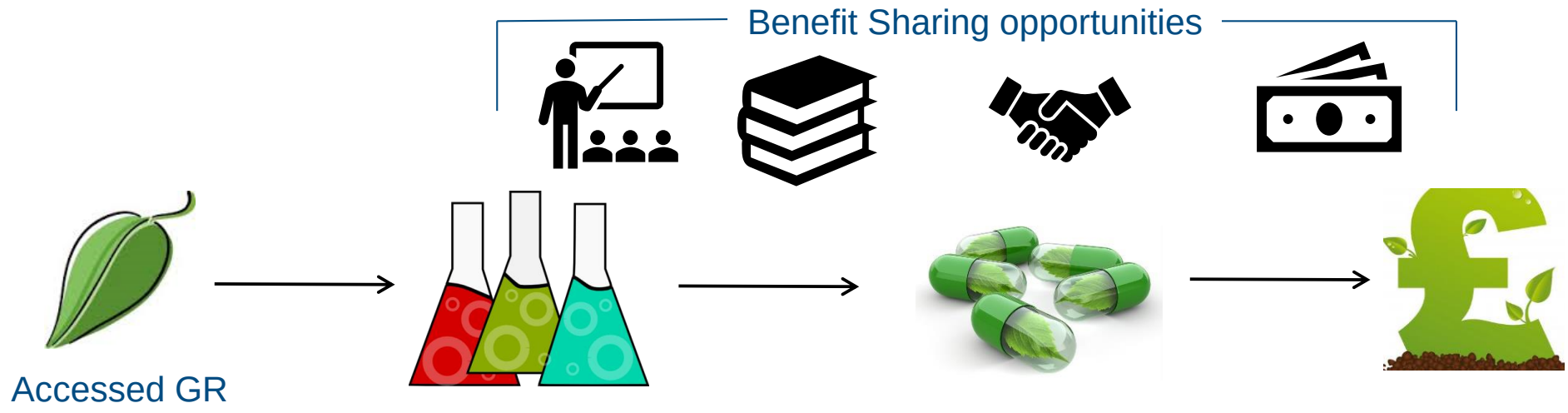
If applicable:

Rights and obligations

Access permits

MAT

Keep correspondence and documentation for 20 years and transfer to subsequent users



www.gov.uk/abs

What happens on the 1st Jan 2021?

- The UK will remain party to the Nagoya Protocol
- Current user obligations will remain the same
- New procedure for submitting due-diligence declarations
- New procedure for applying for best practice and registered collection recognition
- Current EU Best Practices and Registered Collections will no longer be recognised in the UK

Approach to Enforcement

Regulators' Code

Support compliance & growth

Engage with those we regulate

Base our activity on risk

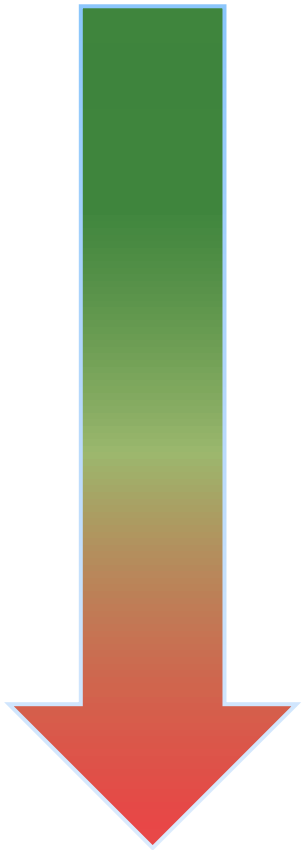
Share information

Offer clear guidance

Be transparent

We do not take enforcement action just because an organisation asks a question or highlights a problem

Approach to Enforcement



- Education
- Advice and Guidance
- Enforcement undertaking

- Warning Letter
- Compliance / Stop Notice
- Variable Monetary Penalties

- Court Action
- Publishing of Sanctions (legally required)

Enforcement to Date

We are currently conducting enforcement audits

Current Process:

Require a list of all projects that involve the utilisation of genetic resources as defined in the EU Regulation 511/2014 requested prior to visit.

Select a specific example(s) based upon risk and ask for further information to check for compliance with articles 4 (Due Diligence, Seek/Keep/Transfer information) and 7 (Submit Due Diligence Declarations)

Provide feedback after meeting on compliance and any remedial actions or sanctions issued.

What is Due Diligence?

Thoroughness and best possible efforts to determine that GRs/aTK have been legally accessed.

- We will look for what judgements and decisions have been made when exercising due-diligence with evidence where appropriate
- Greater care should be applied to riskier activities
- Stay up to date with relevant information if the situation is unclear

Best Practice and Registered Collections

Best Practice Recognition

- Procedures, tools or mechanisms, developed and overseen by associations of users
- Ensure compliance when effectively implemented

CETAF

Consortium of European Taxonomic Facilities (CETAF)
Code of Conduct and Best Practice for Access and Benefit-Sharing

Registered Collections

- Standardised procedures for exchanging GR
- Provide GR legal certainty

Case Studies

1. Utilisation of bacteria GR samples from Nigeria
2. Updating existing agreements involving utilisation of GR from a country where national access measures are being introduced
3. Requirements for transferring GR from the EU to the UK (and vice versa) and how this may change after the Transition Period

Case Study 1. Utilisation of bacteria samples from Nigeria

UK user

Genetic resource

Provider country

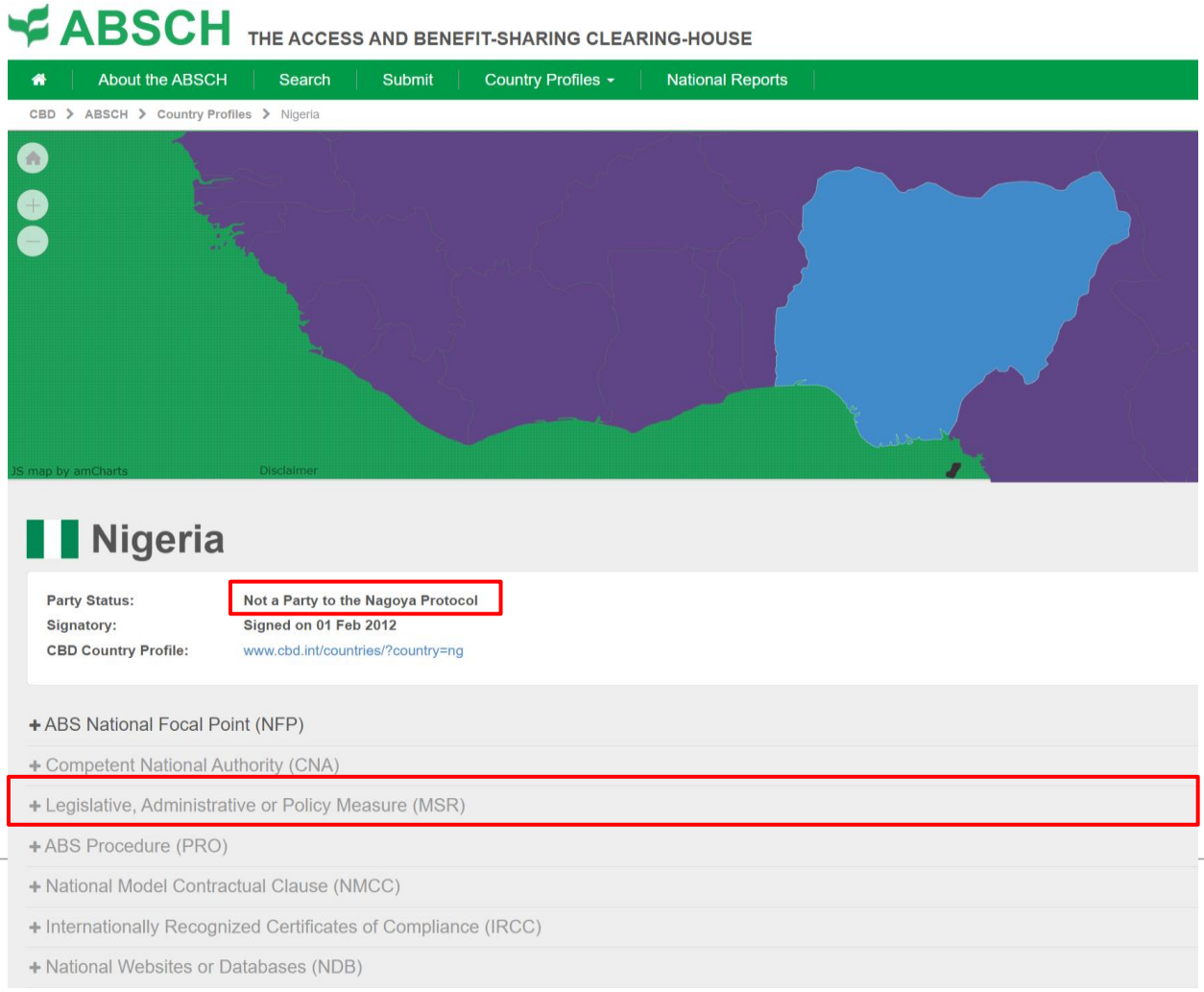
Case Study 1. Utilisation of bacteria samples from Nigeria

Users should exercise due diligence and assess whether they are **in scope** of the UK compliance measures

- ☑ Date of access
- ☑ Type of material
- ☑ Intended use
- ☑ Place of access

Case Study 1. Utilisation of bacteria samples from Nigeria

Check whether the country is **party to the Nagoya Protocol** & whether there are **national access measures** (if yes, comply with these)



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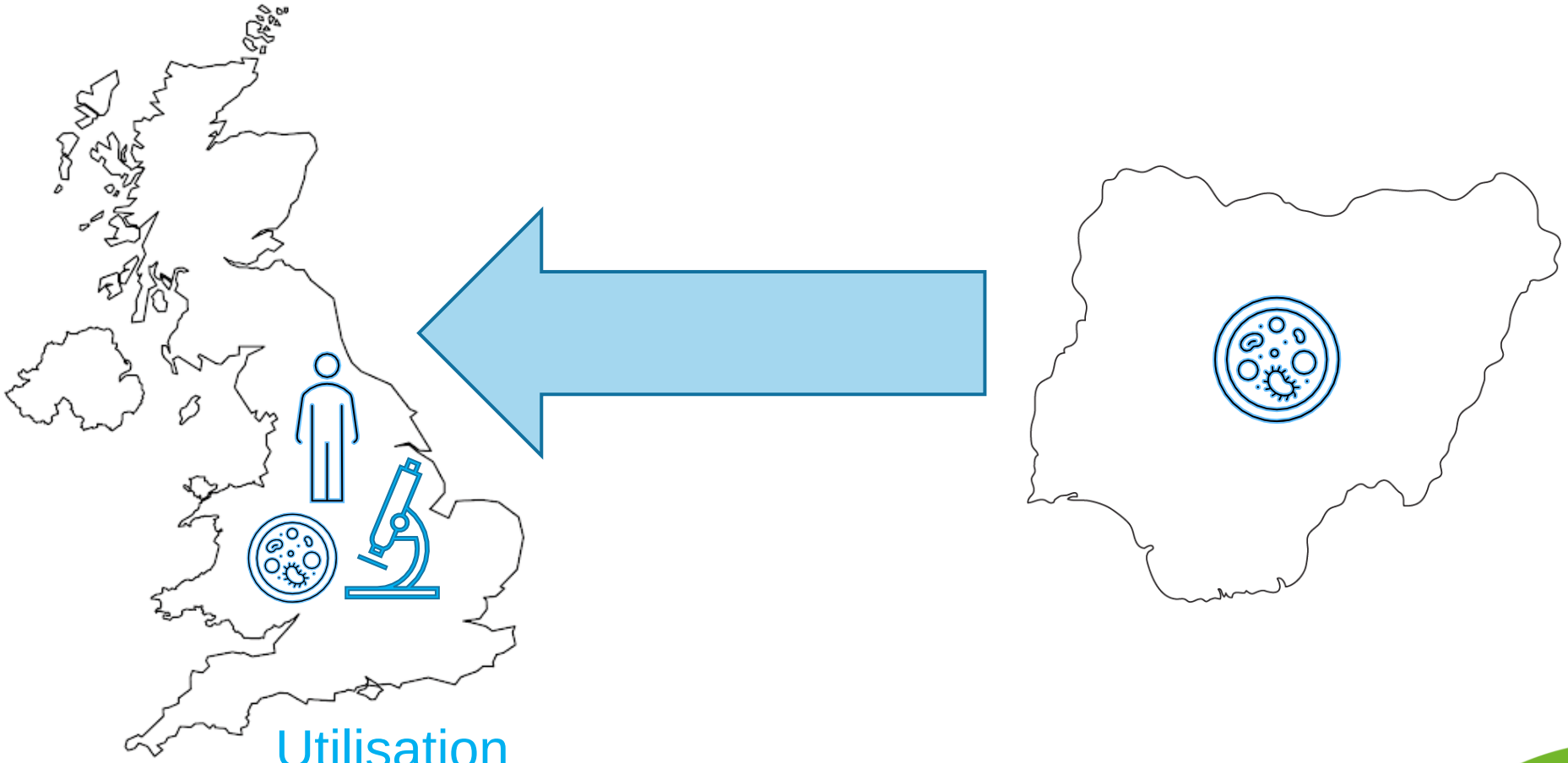

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Case Study 2. Updating existing agreements involving utilisation of GR from a country where national access measures are being introduced

UK user

Genetic resource

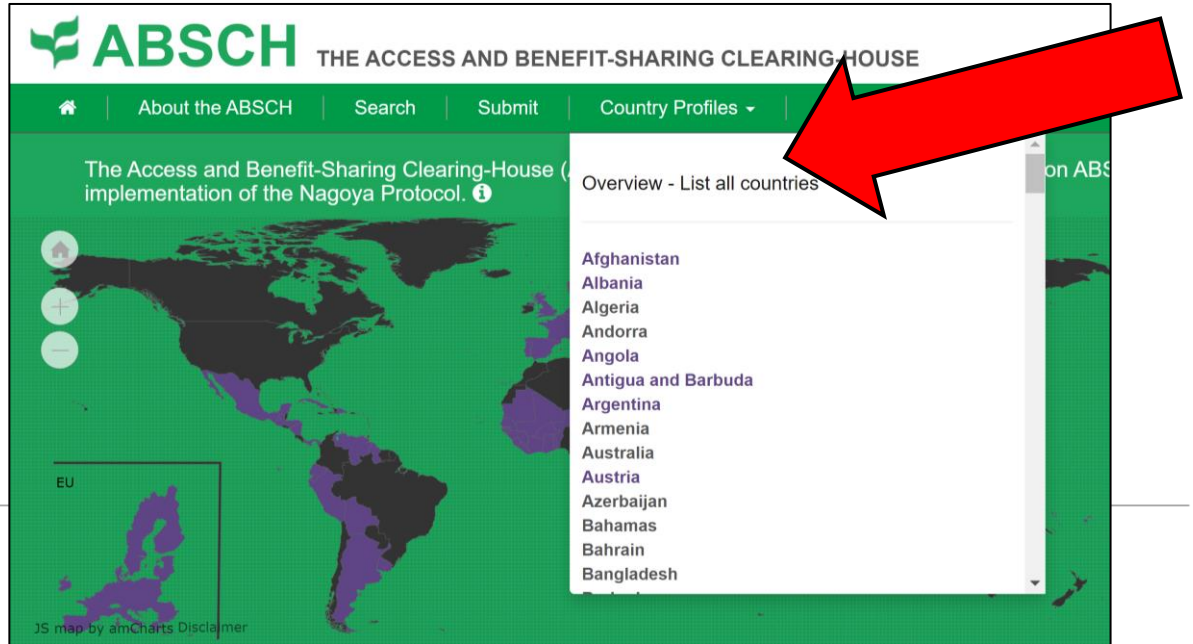
Provider country

Case Study 2. Updating existing agreements involving utilisation of GR from a country where national access measures are being introduced

If GR are in scope of compliance measures in force in the UK, check:

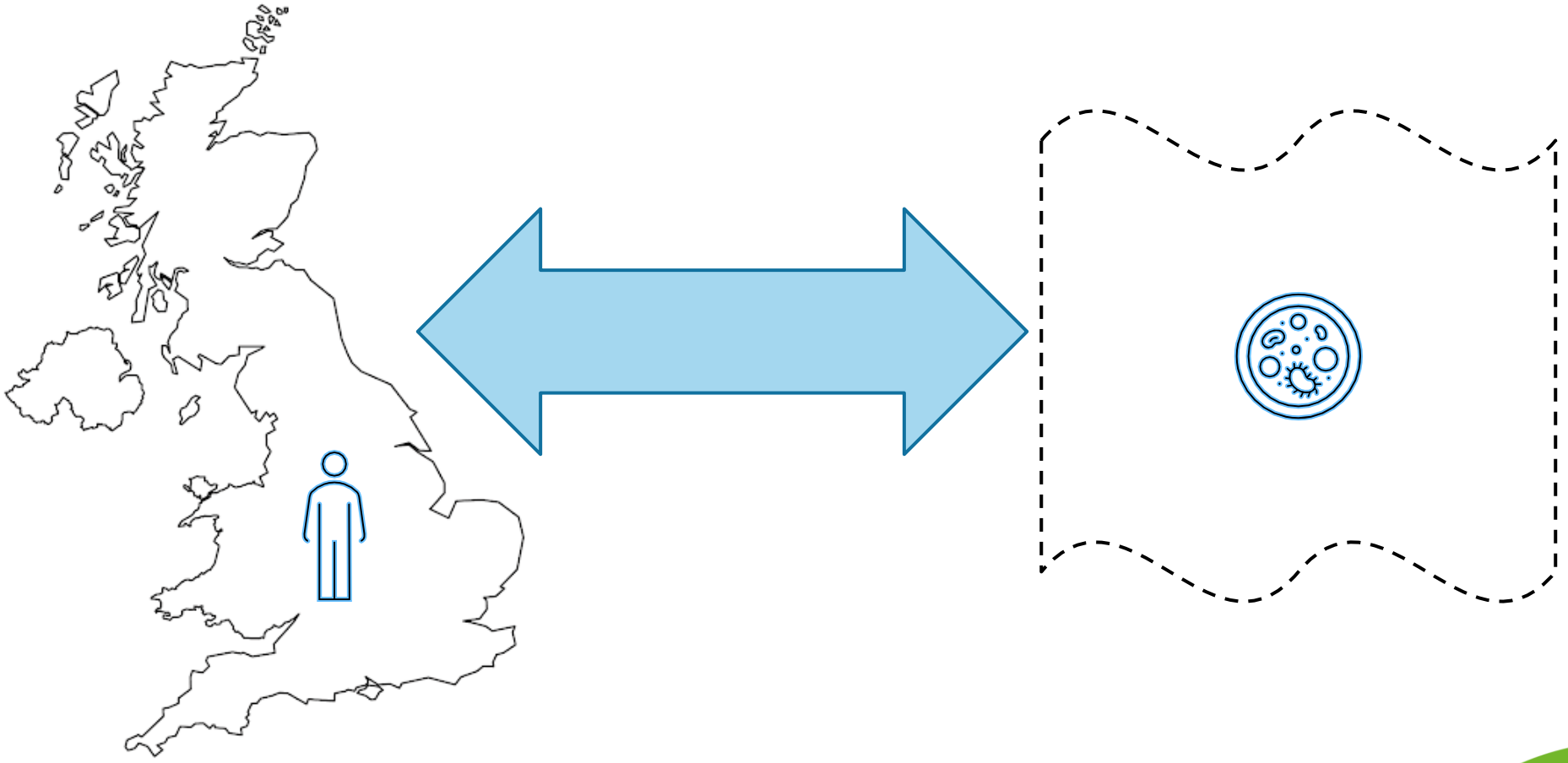
- Is the country **party to the Nagoya Protocol**?
- Are **national access measures** in place?

– check **ABSCH** and contact **NFP/CNA** if unclear



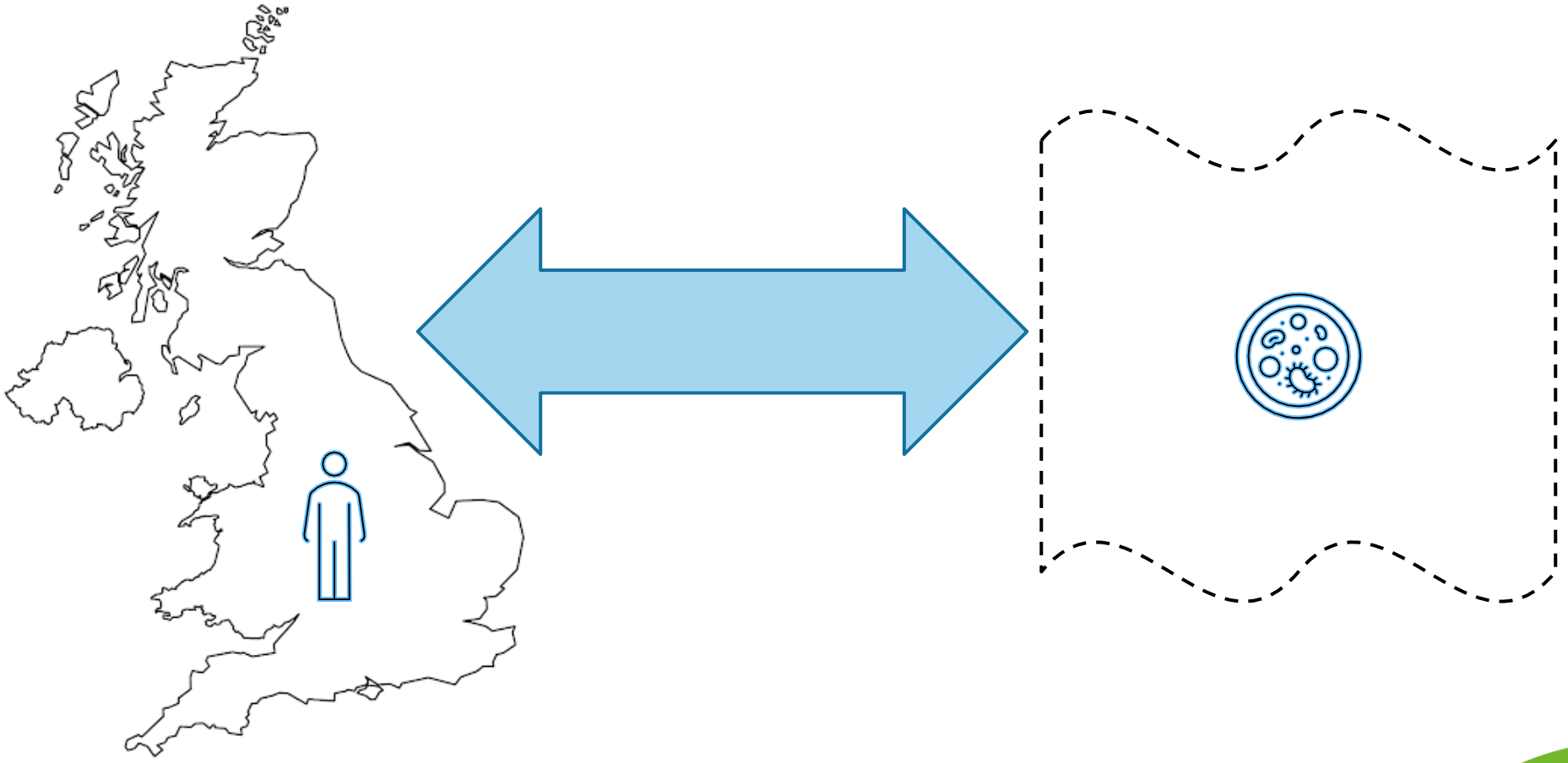
*If GR have already been accessed

The compliance measures in force in the UK do not apply retrospectively – Check requirements with provider country



*If new GR will be accessed

If the provider country is party to the Nagoya Protocol **and** has national access measures in place, users must take steps to **comply with these** before utilisation can begin in the UK



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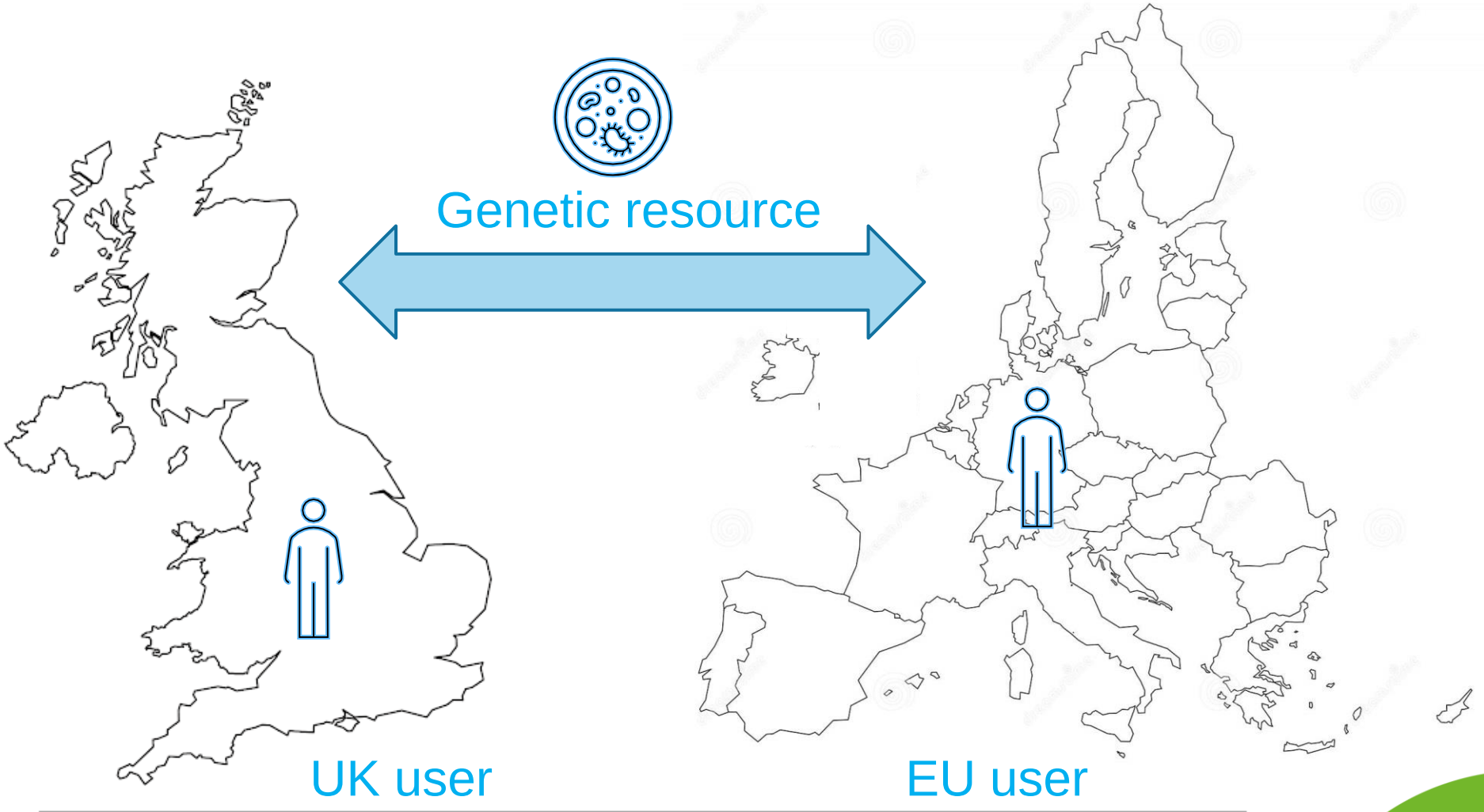

Case Study 3. Requirements for transferring GR from the EU to the UK (and vice versa) and how this may change after the Transition Period (*assuming in scope of UK compliance measures*)

If **utilisation has not ended** – will **not trigger a due diligence declaration**

If **utilisation has ended** - may trigger the obligation to **submit due diligence declarations**

Remember: **operate within terms of the MAT**

Case Study 3. Requirements for transferring GR from the EU to the UK (and vice versa) and how this may change after the Transition Period (*assuming in scope of UK compliance measures*)

Submit a declaration if:

Utilisation in the UK has ended & its outcome is sold/transferred to a natural/legal person outside the UK

Submitted Questions

Scope

- *I would like to understand specific regulations and associated terms and conditions when conducting collaborative research with international partners involving animal and microbial products.*
- *I'd be grateful if the webinar could include information on the application of the Nagoya Protocol to clinical isolate samples.*
- *How long does a non-native plant need to have been present in a non-native country to be excluded from Nagoya?*
- *How does this relate to historical material, e.g. cell lines?*

Submitted Questions

Scope continued…

- *Which microorganisms are of concern for the Nagoya Protocol & ABS, all microorganisms whatever their origin e.g. clinical, veterinary, food, environment?*
- *How to proceed with samples without commercial prospect (current and future), such as specimens collected for barcoding, 16S and18S-sequencing or basic research? Does Nagoya apply in full and if yes how are academic PIs expected to comply with this?*
- *I have an interest in the regulations surrounding the use of bacteria picked up locally, e.g. on beaches, for commercial purposes*

Submitted Questions

User Obligations

- *Material transfer requirements? How does this apply to material transfer agreements?*
- *If genetic sequences are used from Genbank or the like - does this need to be declared?*

Registered Collections

- *We have a historical library of plant extracts, all collected long before 2012 - how can we get this registered as a collection?*
- *Are there any details on the ability of culture collections to register in the UK, post – Transition Period?*

Support for users

LinkedIn Forum:
[Nagoya Protocol on Access and Benefit Sharing: Compliance Forum]

- www.gov.uk/abs
- https://www.ethicalbiotrade.org/
- https://learnnagoya.com/
- http://nagoyaprotocol.myspecies.info/
- https://community.abs-sustainabledevelopment.net/

Recording of previous ABS webinar:
https://www.youtube.com/watch?v=5rjRgKGBlXc&feature=youtu.be

opss.enquiries@beis.gov.uk

Office for Product
Safety & Standards

Thank you!

Any Questions?

OPSS.enquiries@beis.gov.uk