

Using genetic resources for R&D - an overview of the legislation at international, European and national level

- The **Convention on Biological Diversity (CBD)** is a global agreement with three main objectives: 1) The conservation of biological diversity, 2) the sustainable use of the components of biological diversity and 3) the fair and equitable sharing of the benefits arising out of the utilisation of genetic resources
- 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**' is an international agreement designed to provide a legal framework to ensure that the 'third objective' of the CBD – that benefits arising from the use of genetic resources are shared fairly – is achieved. It establishes a legal framework governing access to genetic resources and the traditional knowledge associated with them.
- **EU Regulation 511/2014** and associated **Implementing Regulation 2015/1866** provides compliance measures for users in the EU, detailing steps which users are legally obliged to follow when genetic resources, and associated traditional knowledge, originally from a country which is a Party to the Nagoya Protocol are used in research and development. The scope of the EU Regulations is summarised below.
- **UK Statutory Instrument 2015 No. 821 "The Nagoya Protocol (Compliance) Regulations 2015"** grants powers to enforce the EU Regulation in the UK.

The legislation is implemented and enforced in the UK by the Office for Product Safety and Standards, part of the Department for Business, Energy and Industrial Strategy (BEIS).

How do I know if my use of genetic resources is within the scope of the EU Regulation?

Based on EU commission notice 2016/C 313/01 available at <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C..2016.313.01.0001.01.ENG&toc=OJ:C:2016:313:TOC>

There are **4 considerations** to determine if a specific use of GR is covered by the EU Regulation:

1 - GEOGRAPHY/STATUS OF PROVIDER COUNTRY

1a) Is the provider country a Party to the Nagoya Protocol? A list of current Parties is available at <https://www.cbd.int/information/parties.shtml#tab=2> and users should also refer to the ABS Clearing House at <https://absch.cbd.int/> as this is constantly being updated.

- If the provider country is a Party to the Nagoya Protocol then resources from that country *are in scope if they meet all other criteria*
- If the provider country is not a Party to the Nagoya Protocol then resources from that country *are not in scope*

1b) Does the provider country have applicable access measures in place? All Parties to the Nagoya Protocol are required to make their legislative, administrative and policy measures on ABS available on a searchable database called the 'ABS Clearing House' at <https://absch.cbd.int/> although as an interim measure until the ABSCH is fully populated, users should contact the National Focal Point of a Party to confirm that their entry is fully updated in cases where this is not clear.

- If the provider country has established access measures which include the GR in question, the resources *is in scope if they meet all other criteria*
- If the provider country has not established access measures, or the measures do not include the GR in question, the activity *is not in scope*. The only exception to this is where GR (and particularly TK associated with the GR) come from an indigenous local community – in this case it is always *best practice* to mutually agree terms for access which take the views of the community into account even if it is not specifically required by national legislation.

1c) Does the GR fit within the geographic scope covered by the Nagoya Protocol?

- GR which are found beyond areas of national jurisdiction (e.g. the high seas or areas covered by the Antarctic Treaty System) *are not in scope*
- GR over which a State exercises sovereign rights (e.g. taken from the geographical area of that country where its laws apply) *are in scope if they meet all other criteria*

1d) Where is utilisation of the GR taking place?

- GR which are utilised outside of the EU *are not in scope*
- GR which are utilised in the EU *are in scope if they meet all other criteria*

2 - TIMINGS

2a) Were the GR accessed and utilised before or after the Nagoya Protocol entered into force?

- GR accessed and utilised after the 12th Oct 2014 *are in scope if they meet all other criteria*. This may apply to GR accessed *indirectly from an intermediary* depending on whether they meet all other criteria **and** on the conditions attached to the GR when passing from the provider country to the intermediary.
- If GR are accessed from an ex situ collection *in the country of origin* after 12th Oct 2014, they are *in scope regardless* of when they were added to that collection, *assuming all other criteria are met*.
- GR accessed before the 12th Oct 2014 *are not in scope* even if they are *utilised* after that date.

3 - THE TYPE OF MATERIAL

3a) Are the GR covered by an existing 'specialised international ABS instrument'?

- GR that **are** covered by specialised agreements which have already established ABS conditions, such as the International Treaty on Plant Genetic Resources for Food and Agriculture or the WHO's Pandemic Influenza Preparedness Framework *are not in scope*.
- GR which are **not** already covered by any other legal agreements designed to ensure access in specific situations *are in scope if they meet all other criteria*

3b) Are the GR human?

- Human GR *are not in scope*
- Non-human GR *are in scope if they meet all other criteria*

3c) Are the GR commodities?

- Commodities traded for direct consumption or for use as ingredients in food and drink products (i.e. to be used only as a commodity) *are not in scope – ie use as a commodity*
- GR which originally entered the EU as commodities but the intended use changes and R&D is undertaken on the GR *are in scope if they meet all other criteria*. This would apply to nutraceuticals (e.g. dried leaf powder), food (e.g. oranges) and food waste (e.g. coffee grounds) if used for R&D.

4 - INTENDED USE

4a) Are the GR being utilised for R&D?

- GR which have been accessed for any use other than R&D *are not in scope*.
Four examples of situations which are **not** in scope are: 1) **supply/processing of raw materials** where the properties are already known and no new R&D is carried out - e.g. supply of aloe vera for incorporation into cosmetics; 2) **GR as testing/reference tools** - where the GR itself is not the object of R&D but is used to confirm/verify the desired features of products which are undergoing R&D; 3) **Handling/storing** biological material **and describing** its phenotype (e.g. in a botanical collection) without undertaking R&D and 4) **using a GR** whose action is already known '**as is**' without undertaking R&D on the GR itself - such as the use of yeast in brewing.
- R&D is taken to include basic and applied research, non-profit and commercial research. Any scientific activity which goes beyond the mere description of a GR is likely to constitute research and fit within the definition of utilisation. Utilisation of a GR or its derivatives for the purposes of R&D

even if no commercial output can be envisaged at the time *is therefore in scope if all other criteria are met.*

Important: all steps have to be in scope – if a resource is not in scope at any step listed above, it is not covered by EU 511/2014. However, even if a country is not yet Party to the Nagoya Protocol and therefore outside the scope of EU 511/2014, other relevant ABS legislation in that country must be complied with.

2. If my use of genetic resources *might be* within the scope of the EU Regulation, what do I need to do?

You need to conduct a ‘due diligence review’ – this means to assess the GR you intend to use and reach a decision on whether it is in or out of scope of the EU Regulation. You can do this by following the steps outlined below:

1. Find out more information about the provider country by accessing their profile on the ABS Clearing House at <https://absch.cbd.int/>. If you are unsure about whether the provider country has established access measures based on the information available on the ABS Clearing House, you should contact that country’s named ABS National Focal Point to confirm and keep a record of their response.
2. Review the ‘scope’ criteria systematically to determine if there is any reason that the GR you wish to use does not fall within the scope of the EU Regulations.
3. Even if you decide that the GR you wish to use does *not* fall within the scope of the EU Regulations, keep a record of your actions and the decision you have reached as a ‘due diligence’ record.

3. If my due diligence review shows that my intended use of genetic resources *is* within the scope of the EU Regulation, what do I need to do?

Based on EU commission notice 2016/C 313/01 available at http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.C_.2016.313.01.0001.01.ENG&toc=OJ:C:2016:313:TOC

1. Obtain ‘Prior Informed Consent’ (PIC) – a permit which outlines the permitted use - from the provider country before research activities begin.
2. Negotiate ‘Mutually Agreed Terms’ (MAT) – a contract between the provider country and the user – which outlines terms of use, timeframes, permissions regarding transfer of material to third parties and benefit sharing arrangements before research activities begin.
3. Throughout the period of use, conduct and maintain records of due diligence. Due diligence involves gathering and using information in a systematic way to demonstrate that the necessary information related to a GR is available *all throughout the value chain while in the European Union*. This will include your initial steps to determine if a GR is in scope of the EU Regulations and any discussions you have had with a provider country’s National Focal Point.
4. **Do not** transfer GR to any third party unless your PIC & MAT give you permission to do so. To demonstrate compliance with the EU Regulations, users are required to *seek, keep and transfer to subsequent users* key information **either** by (1) referring to an international certificate of compliance (IRCC) associated with their access to the GR **or** (2) seeking and acquiring the necessary information. The **key information** users must *seek, keep and transfer to subsequent users if they are permitted to do so* is:

1. date and place of access to GR
2. a description of the GR
3. the source from which the GR were directly obtained
4. any existing rights and obligations relating to access and benefit sharing
5. access permits, if applicable
6. mutually agreed terms, if applicable

Users are required to keep any information relevant to access and benefit sharing for a 20 year period after the end of the period of utilisation.

5. File due diligence declarations if appropriate. There are **two checkpoints** defined in the EU Regulations which trigger the requirement for a due diligence declaration to be submitted by the user of the GR:

- **Checkpoint 1.** At the stage of **research funding in the form of a grant** – *after* the first instalment of funding has been received and all the GR to be utilised in the funded project have been obtained.
- **Checkpoint 2.** At the stage of **final development of a product** – only *once*, at the *first* event from the list below for a product developed through utilisation of GR –
 - a) *Market approval or authorisation* is sought
 - b) A '*notification required prior to placing for the first time on the Union market*' is made
 - c) *Placing on the Union market for the first time* (where no prior market approval, authorisation or notification is required)
 - d) The *output of the utilisation of GR is sold or transferred within the Union* to a natural or legal person who intends to carry out an activity listed in a, b or c
 - e) The *utilisation in the Union has ended* and the *output of the utilisation* is sold or transferred to a natural or legal person *outside the Union*
- Blank templates of due diligence declarations, which list the information required at each of the checkpoints, are available in Annexe II and Annexe III of Commission Implementing Regulation EU 2015/1866 at <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32015R1866>
- Due diligence declarations should be submitted to the Competent National Authority (CNA) of the country where the utilisation takes place. Where utilisation is undertaken in the UK, due diligence declarations can be submitted to The Office for Product Safety & Standards (previously Regulatory Delivery) using the [online application, DECLARE](#). See <https://www.gov.uk/guidance/abs> for more information.

Key terms

Access: the acquisition of genetic resources from a country which is Party to the Nagoya Protocol.

Access and benefit sharing (ABS): the fair and equitable sharing of the benefits arising out of the utilization of genetic resources.

Biotechnology: Any technology application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.

Collection: a set of collected samples of genetic resources and related information that is accumulated and stored, whether held by public or private entities

Derivative: A naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.

Genetic resource (GR): genetic material of *actual or potential* value – *when GR are referred to in this document, this also includes any relevant traditional knowledge associated with their use. GR also extends to derivatives of that resource.*

In situ & Ex situ: "In-situ" genetic resources are those found within ecosystems and natural habitats. "Ex-situ" genetic resources are those found outside their normal ecosystem or habitat, such as in botanical gardens or seed banks, or in commercial or university collections - these collections may be held in the country of origin or another country.

Provider country: the country of origin of genetic resources – this is the country which possesses the genetic resources in *in-situ* conditions (i.e. as part of the natural habitat, not as part of a botanical collection).

Traditional knowledge associated with genetic resources (TK): traditional knowledge held by an indigenous/local community that is relevant for the utilisation of GR.

User: A natural or legal person (i.e. an individual or their institute) which is accessing the GR with the intention of utilisation.

Utilisation of GR: to conduct R&D on the genetic and/or biochemical composition of GR or their derivatives including through the application of biotechnology. This includes commercial and non-commercial (academic) research

Where can I get more information?

The Office for Product Safety and Standards, BEIS - the UK's Competent National Authority for Access and Benefit Sharing <https://www.gov.uk/guidance/abs>

ABS Clearing House provides access to a wide range of resources, including an online 'help' facility <https://absch.cbd.int/>

CBD sector-specific resources developed for agricultural, pharmaceutical, food & drink, IB, botanicals & cosmetics sectors are available at <https://www.cbd.int/abs/policy-brief/default.shtml/>

ABS Capacity Development Initiative has developed a range of resources including fact sheets:

<http://www.abs-initiative.info/abs-simply-explained/nagoya-protocol/> and short videos

<http://www.abs-initiative.info/knowledge-center/multimedia/>

Union for Ethical Biobanking (UEBT) provides recent (2016) and succinct overviews, guidance, policies and case studies on access and benefit at <http://ethicalbiobanking.org/resources/#6>; including a particularly helpful summary of scope and due diligence implications of EU regulation 511/2014

<http://ethicalbiobanking.org/dl/EU%20ABS%202016%20r.pdf>

BBSRC guidance for researchers – see Annexe 1 in this document updated Sept 2016 for guidance for BBSRC-funded researchers on their obligations relating to the Nagoya Protocol:

<http://www.bbsrc.ac.uk/about/policies-standards/good-scientific-practice/>

Guidance document updated 28th March 2018 by Wendy Lawley, HVCfP Network Manager.

This guidance is intended to provide users with a basic introduction to ABS Legislation and the obligations placed on UK users of genetic resources. It does not constitute legal advice and users should seek further information and support as appropriate in order to fully understand and fulfil their obligations.