NAGOYA PROTOCOL GUIDANCE

Loughborough University

The Nagoya Protocol is an international agreement establishing a legal framework to govern access to **GENETIC RESOURCES** and ensure that benefits arising from the use of these resources are shared fairly.

The recent EU regulation 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' (EU) 511/2014 is part of UK law under The Nagoya Protocol (Compliance) Regulations 2015. The requirement to conduct R&D in accordance with these Regulations is reinforced by the BBSRC guidance on Safeguarding Good Scientific Practice.

This means that in certain cases, UK researchers who use genetic resources which originated outside of the UK, such as plants, animals, microbes, biomass and even food waste in R&D are now legally obliged to follow a number of steps in terms of permits, permissions, record-keeping and due diligence declarations.

The protocol does **not** apply to:

- human genetic resources
- genetic resources covered by specialised ABS treaties that are supportive of the CBD

Full guidance on ABS implementation is available from The Office for Product Safety and Standards, BEIS

1. Scope

There are four considerations detailed below to determine if a specific use of genetic resources is covered by the EU Regulation. **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.

1.1 Geography

Is the provider country a Party to the Nagoya Protocol?
List of current Parties - Users should also refer to the ABS Clearing House which 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

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' 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 resource is in scope if they meet all other criteria. Please note that the UK does not regulate access to its own genetic resources. **If you are exclusively working with resources which originated in the UK, you do not need to take any further action.**
- 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.

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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

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

1.2 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.

1.3 Type of Material

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

Are the GR human?

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

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.

1.4. Intended Use of Material

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:

- 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;
- 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;
- Handling/storing biological material and describing its phenotype (e.g. in a botanical collection) without undertaking R&D
- 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.

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

- Find out more information about the provider country by accessing their profile on the ABS Clearing House. 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.
- 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.
- 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 as a 'due diligence' record.
- Researchers should be aware that some countries have domestic ABS legislation which must still be followed even if they are not a Party to the NP and/or the genetic material being used doesn't fall under the scope of the EU Regulation.
  Full details of individual countries with respect to their domestic legislation and whether they are Parties to the NP.

3. If my use of genetic resources is within the scope of the EU Regulations, what do I need to do?

(Based on EU commission notice 2016/C 313/01)

- Obtain 'Prior Informed Consent' (PIC) – a permit which outlines the permitted use - from the provider country before research activities begin.

- 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.

- 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.

- 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:

  - date and place of access to GR
  - a description of the GR
  - the source from which the GR were directly obtained
  - any existing rights and obligations relating to access and benefit sharing
  - access permits, if applicable
  - mutually agreed terms, if applicable

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- 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 –

  1. Market approval or authorisation is sought
  2. A 'notification required prior to placing for the first time on the Union market' is made
  3. Placing on the Union market for the first time (where no prior market approval, authorisation or notification is required)
  4. 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 1, 2 or 3
  5. 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
- An online platform for the submission of due diligence declarations, called DECLARE, is now operational. New users of the system will be required to create an account.

Reference: https://www.york.ac.uk/staff/research/external-funding/contracts/legal-and-intellectual-property-advice/nagoya-protocol/#tab-4