AN INTRODUCTION TO THE NAGOYA PROTOCOL

What is the Nagoya Protocol?

The Nagoya Protocol on Access and Benefit Sharing (ABS) is a 2010 supplementary agreement to the 1992 Convention on Biological Diversity (CBD). The Protocol aims to prevent unregulated commercial exploitation of the world’s naturally occurring genetic resources, and contribute to the conservation and sustainable use of biodiversity, to ensure resulting benefits are distributed equitably and fairly and that there is no restriction on their future use.


From 12 October 2014 anyone who wishes to access genetic resources (GR) and/or the associated traditional knowledge (aTK) from a country that is party to the Nagoya Protocol and has access and benefit sharing (ABS) legislation will be required to comply with these regulations.

What is/is NOT covered by the Nagoya Protocol?

<table>
<thead>
<tr>
<th>IS covered by the Protocol</th>
<th>IS NOT covered by the Protocol</th>
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<tbody>
<tr>
<td>Genetic resources (GR) that are covered by the CBD, and the benefits arising from their utilisation.</td>
<td>Human GR</td>
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<tr>
<td>Animal GR</td>
<td>Mouse derived cell line</td>
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<tr>
<td>Plant GR</td>
<td>GR used as bulk commodities (such as agriculture, fisheries or forestry products, whether for direct consumption or as ingredients)</td>
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<tr>
<td>Microbial GR</td>
<td>GR acquired prior to the entry into force of the Nagoya Protocol (12 October 2014)</td>
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<td>Biomass GR</td>
<td>GR for which access and benefit sharing is governed by specialised ABS-international treaty agreements that are supportive of the CBD (such as the International Treaty on Plant Genetic Resources for Food and Agriculture <a href="http://www.fao.org/plant-treaty/en/">http://www.fao.org/plant-treaty/en/</a>).</td>
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<tr>
<td>Food waste</td>
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<tr>
<td>Other (essentially non-human) genetic resources and associated traditional knowledge (aTK)</td>
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The Protocol only covers access to GR in countries where sovereign rights are exercised (i.e. the Arctic or high seas are covered by other treaties). Every country holds rights to GR in its territory so any researcher (or business) based in another country wishing to access GR requires permission.
How do I determine if my research falls within the scope of the associated EU regulation (EU) 511/2014?

Please note that further guidance is available at http://www.marinegeneticresources.org/

There are four considerations to determine if a specific use of genetic resources is covered by the EU Regulation (EU) 511/2014.

i. Geographic scope - Is the provider country a Party to the Nagoya Protocol?

ii. Temporal scope - Were the genetic resources (GR) accessed and utilised before or after the Nagoya Protocol entered into force (12 October 2014)?

iii. Material scope – Are the genetic resources (GR) covered by an existing ‘specialised international ABS instrument’? Are the GR human? Are the GR commodities?

iv. Personal Scope (Intended Use) - Are the GR being utilised for R&D?

Note: all steps have to be in scope – if a resource is not in scope at any of the steps 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.

What should I do if my use of genetic resources might be within the scope of the EU Regulations?

1. Find out more information about the relevant national laws, procedures and contacts in the provider country by accessing their profile on the ABS Clearing House.

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 as a ‘due diligence’ record.

4. No further action is required in terms of adherence to the EU Regulations. However please note that some nations may have their own ABS legislation (unrelated to the Nagoya Protocol) that must be followed.

What do I have to do If my use of genetic resources is within the scope of the EU Regulations?

(Note: Prior to taking any action, the Business Development Officer should be consulted for guidance and advice specific to your particular circumstances. The following information is provided as a general guide to the process.)

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. Do not transfer GR to any third party unless your PIC & MAT give you permission to do so.

4. The PIC and MAT should be deposited in the ABS Clearing House. Records of due diligence should be maintained throughout the period of use. Due diligence can be demonstrated by an internationally recognised certificate of compliance (IRCC) which is either issued for the user, or the user can rely on it because the particular utilisation is covered by the terms of the IRCC.

5. There are two check points in the research and development phase where users of genetic resources must submit a due diligence declaration:
Checkpoint 1: when in receipt of research funding in the form of a grant, for work involving utilisation of genetic resources and/or aTK. The declaration should be made after the first instalment of funding has been received and all the genetic resources and aTK that are utilised in the funded project have been obtained, and no later than at the time of the final report or project end; and

Checkpoint 2: at the stage of final development of a product developed via the utilisation of genetic resources and/or aTK with such resources. The conditions under which this declaration would be required are outlined in the Implementing Regulation (EU) 2015/1866.

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.

Due diligence declarations should be submitted to the Competent National Authority (CNA) of the country where the utilisation takes place. Parties to the Nagoya Protocol are listed at https://www.cbd.int/abs/nagoya-protocol/signatories/. Where research and development is undertaken in the UK, due diligence declarations should be submitted to the regulator (Regulatory Delivery) using the online application, DECLARE.

Note that users are required to retain all the above information for a period of 20 years following the end of the period of use of the GR.

What are the penalties for non-compliance?
Non-compliance may result in civil sanctions (or criminal sanctions in serious cases or in the event of continual non-compliance). The regulator may impose compliance notices and monetary penalties.

Who should I contact within the University for further advice on the Nagoya Protocol and associated EU regulation?
Your Business Development Officer (BDO) will be able to provide further guidance on the implementation of the Nagoya Protocol and adherence to EU 511/2014.