

Edge Hill University

Nagoya Protocol

Checklist

This checklist should be used to determine whether the research activity that you are conducting is within the scope of the Nagoya Protocol (NP). Please fill out the checklist and return it to the Research Office (RO) for review. Please note that the RO do not expect you to know the answer to all of the questions or to conduct significant investigation to be able to answer the questions as this can be done once the background information has been obtained.

If the answer to **all** of the following questions is Yes, the project or activity is likely to be within the scope of the NP and RO will discuss with you the further action points. If the answer to any of these questions is No the project or activity will be deemed to be outside the scope of the NP. However, further action may still be required as the provider country may still have some access and benefit sharing legislation which we will still need to comply with if utilising the GR (see Q5 below).

<u>Question</u>	<u>Explanation</u>	<u>Yes?</u>	<u>No?</u>	<u>Maybe? Please provide further detail.</u>
1. Does the project or activity involve non-human Genetic Resources (GR) taken (by you or others) from outside of the UK?	<p>The term "Genetic Resources" includes genetic material of actual or potential value. GR covers material containing functional units of heredity [e.g. genes or DNA] or their derivatives (e.g. proteins, lipids, enzymes).</p> <p>GR can also include any relevant traditional knowledge associated (aTK) with their use. aTK is traditional knowledge held by an indigenous/local community that is relevant for the utilisation of GR.</p>			

<p>2. Does the project or activity involve the utilisation of GR for Research and Development (R&D)?</p>	<p>The EU's guidance on the NP clarifies that "research" should be defined as "the systematic investigation into and the study of materials and sources in order to establish facts and reach new conclusions. It also defines R&D as "creative work undertaken on a systematic basis in order to increase the stock of knowledge, including knowledge of man, culture and society, and the use of the stock of knowledge to devise new applications."</p> <p>Any scientific activity which goes beyond the mere description of a GR is likely to constitute research.</p> <p>If the project involves R&D on the genetic and/or biochemical composition of GR, including through the application of biotechnology as defined in Article 2 of the Convention on Biological Diversity (CBD), you should answer Yes to this question.</p> <p>"Biotechnology" as defined in Article 2 of the CBD means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use.</p>			
<p>3. Is the provider country a party to the NP?</p>	<p>You can check this by consulting the Access and Benefit Clearing House website. https://absch.cbd.int/</p> <p>If the provider country is a party to the NP, then the resources from that country are in scope if they meet all other criteria.</p>			

	If the provider country is not a party to the NP, then resources from that country are not in scope.			
4. Is the utilisation taking place within the EU?	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.			
5. Does the provider country have applicable access measures in place?	You can check this by consulting the Access and Benefit Clearing House website. https://absch.cbd.int/ 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 aTK associated with the GR) comes 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. If it is unclear whether the provider country has access measures, we will need to contact the National Focal Point to obtain clarification.			
6. Does the GR fit within the geographic scope covered by the NP?	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.			

7. Were the GR accessed after the NP entered into force?	<p>GR accessed 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.</p> <p>GR accessed before the 12th Oct 2014 are not in scope even if they are utilised after that date.</p>			
8. Are the GR covered by an existing "specialised international ABS instrument"?	<p>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.</p> <p>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.</p>			
9. Are the GR human?	<p>Human GR are not in scope</p> <p>Non-human GR are in scope if they meet all other criteria</p>			
10. Are the GR commodities?	<p>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.</p>			

	<p>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.</p>			
<p>11. Are the GR being utilised for R&D on the genetic and/or biochemical composition of GR?</p>	<p>“Utilisation” means “to conduct R&D on the genetic and/or biochemical composition of GR.”</p> <p>GR which have been accessed for any use other than R&D are not in scope.</p> <p>Four examples of situations which are not in scope are:</p> <ul style="list-style-type: none"> • 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. 			

	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.			
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