Pre-access triage form - use of genetic resources in Research and Development (R&D)

The purpose of this triage form is to help researchers identify responsiblities and necessary actions with respect to EU Regulation 511/2014 **and** any domestic ABS legislation of Provider Countries when accessing genetic resources and associated traditional knowledge for utilisation in R&D. This form is intended to provide basic support but does not constitute legal advice. It is designed to guide users through a series of questions which should be addressed in the order listed below. Abbreviations and sources of further information are listed at the bottom of the form.

		In or Out of Scope of EU 511/2014	Issues for user to address
	1. What type of activity is it?		
1a	Utilisation - defined as 'R&D on the genetic and/or biochemical composition of genetic resources'. Work funded internally.	**Out of scope but see issues for user to address**	User is responsible for ensuring the requirements of any domestic ABS legislation in the provider country are met - user should contact the National Focal Point of the provider country (details on the ABS Clearing House).
1b	Utilisation - defined as 'R&D on the genetic and/or biochemical composition of genetic resources'. Work funded by a grant.	**Potentially in scope - see issues for user to address then move to Question 2**	Is it a Collaborative Project? The collaboration agreement should make clear which institute/department will take responsibility for ABS issues. This is usually the Project Manager but each partner institute should have appropriate record keeping in place to demonstrate that their ABS obligations have been fulfilled.
1c	Contract science which involves utilisation - defined as 'R&D on the genetic and/or biochemical composition of genetic resources'.	**Potentially in scope - see issues for user to address then move to Question 2**	The contract should state who will take responsibility for ABS issues.
1d	Supply/processing/scale up/product development which does not meet the definition of 'utilisation'	**Out of scope but see issues for user to address**	User is responsible for ensuring the requirements of any domestic ABS legislation in the provider country are met - user should contact the National Focal Point of the provider country (details on the ABS Clearing House).
1e	Use of genetic resources as a reference tool or for phenotypic description (i.e. as part of a botanical collection)	**Out of scope but see issues for user to address**	User is responsible for ensuring the requirements of any domestic ABS legislation in the provider country are met - user should contact the National Focal Point of the provider country (details on the ABS Clearing House).
	2. What type of materials do you intend to use?		
2a	Human genetic material	**Out of scope but see issues for user to address**	Users must act in accordance with the Human Tissue Act 2004 and any other relevant UK Regulations.
2b	Non-human genetic material including plant, animal and microbial material	**Potentially in scope - see issues for user to address then move to Question 3**	In addition to meeting the requirements of any relevant ABS legislation, users may also need to consider any other relevant UK Regulations including Plant Health controls and CITES protection for endangered species.
2c	Food waste / material which entered the UK as a commodity	**Potentially in scope - see issues for user to address then move to Question 3**	If there has been a change of use to an activity which fits the definition of utilisation, and all other criteria are in scope of EU 511/2014 (see Questions 1,3,4 & 5 to confirm this), the activity is in scope. Even if the utilisation does not meet the scope of EU 511/2014, domestic ABS legislation in the provider country may apply. User is responsible for ensuring the requirements of any domestic ABS legislation in the provider country are met - user should contact the National Focal Point of the provider country (details on the ABS Clearing House).
2d	Material covered by a specialised ABS instrument such as the Plant Genetic Resources for Food and Agriculture Treaty	**Out of scope if the provider country is a Contracting Party to the specialised ABS instrument and utilisation is exclusively linked to the remit of that specialised ABS instrument; potentially in scope if not. In this latter situation, move to Question 3**	Further details available from http://www.fao.org/plant-treaty/en/
2e	Digital sequence information or artificial sequences synthesised without access to physical genetic resources	**Out of scope but see issues for user to address**	User is responsible for ensuring the requirements of any domestic ABS legislation in the provider country are met - user should contact the National Focal Point of the provider country (details on the ABS Clearing House).
	3. When did you access the materials?		
3a	Materials received before 12th October 2014	**Out of scope but see issues for user to address**	User must ensure that any conditions attached to their access to the materials are adhered to. If this is a new use of materials received during a previous R&D activity, the user may wish to alert the provider to the intended new use as a courtesy. User is also responsible for ensuring the requirements of any domestic ABS legislation in the provider country are met - user should contact the National Focal Point of the provider country (details on the ABS Clearing House).
3b	Materials received after 12th October 2014	**Potentially in scope - move to question 4**	
	4. Which country did the materials originate from?		
4a	A country which is a Party to the Nagoya Protocol and has established legislative, policy and/or administrative measures relating to ABS	**Potentially in scope - see issues for user to address then move to Question 5**	User should check the provider country's status on the ABS Clearing House and make contact with the National Focal Point of the provider country to confirm the requirements of domestic ABS legislation before proceeding.
4b	A country which is a Party to the Nagoya Protocol but has not yet established legislative, policy and/or administrative measures relating to ABS	**Out of scope but see issues for user to address**	User should check the provider country's status on the ABS Clearing House and make contact with the National Focal Point of the provider country to determine if domestic ABS legislation is in place before proceeding.

4c	A country which is not a Party to the Nagoya Protocol but is a Party to the Convention on Biological Diversity	**Out of scope but see issues for user to address**	User should check the provider country's status on the ABS Clearing House and make contact with the National Focal Point of the provider country to determine if domestic ABS legislation is in place before proceeding.
4d	A country which is not a Party to the Nagoya Protocol or the Convention on Biological Diversity	**Out of scope but see issues for user to address**	User should check the Provider Country's status on the ABS Clearing House and, if a National Focal Point has been designated, make contact with them to determine if domestic ABS legislation is in place before proceeding.
4e	Provider country is not known	**Potentially in scope - see issues for user to address then return to the top of Question 4.**	User is responsible for confirming which country the material originated from and then deciding which of the above four options applies before continuing. The genetic resource must not be utilised if the provider country cannot be confirmed.
	5. What is the current source of the genetic material?		
5a	Direct supply from the country of origin which is a Party to the Nagoya Protocol and has established legislative, policy and/or administrative measures relating to ABS	**If all other criteria are in scope of EU 511/2014 (see Questions 1-4 to confirm this), the activity is in scope.**	User should liase with the Provider Country's National Focal Point/Competant National Authority to obtain Prior Informed Consent and establish Mutually Agreed Terms for access. User should see Regulatory Delivery's guidance page for details of how to comply with UK requirements.
5b	Sourced from a botanical garden or other collection outside of the country of origin.	**If all other criteria are in scope of EU 511/2014 (see Questions 1-4 to confirm this), the activity is in scope.**	User should confirm with the source what uses are permitted and liase with the Provider Country's National Focal Point/Competant National Authority if required to obtain new Prior Informed Consent and establish new Mutually Agreed Terms for access. User should see https://www.gov.uk/guidance/abs for details of how to comply with UK requirements. User must not initiate utilisation until all ABS requirements have been fulfilled.
5c	Sourced from a UK retailer (e.g. garden centre, grocery shop, healthfood shop)	**If all other criteria are in scope of EU 511/2014 (see Questions 1-4 to confirm this), the activity is in scope.**	User should confirm with the source which country the material originated from and if any permission is in place for utilisation. User should liase with the Provider Country's National Focal Point/Competant National Authority if required to obtain new Prior Informed Consent and establish new Mutually Agreed Terms for access. User should see https://www.gov.uk/guidance/abs for details of how to comply with UK requirements. User must not initiate utilisation until all ABS requirements have been fulfilled.
5d	Sourced from a third party e.g. colleague or collaborator	**If all other criteria are in scope of EU 511/2014 (see Questions 1-4 to confirm this), the activity is in scope.**	User should confirm with the source which country the material originated from and if any permission is in place for utilisation. User should liase with the Provider Country's National Focal Point/Competant National Authority if required to obtain new Prior Informed Consent and establish new Mutually Agreed Terms for access. User should see https://www.gov.uk/guidance/abs for details of how to comply with UK requirements. User must not initiate utilisation until all ABS requirements have been fulfilled.

6. And finally - is there any Traditional Knowledge linked to your intended utilisation of the genetic resource?
Although there may be no legal obligation to do so, in order to use a genetic resource which falls within the scope of EU 511/2014 or the domestic legislation of the provider country, it is good practice to consider appropriate means of acknowledging the contribution of traditional knowledge holders and sharing benefits. This should be done before obtaining Prior Informed Consent and establishing Mutually Agreed Terms.

Sources of further information referred to in this form:

https://absch.cbd.int/
https://www.gov.uk/guidance/abs
https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/use-tissue-research/
https://www.gov.uk/guidance/plant-health-controls
https://www.gov.uk/guidance/cites-imports-and-exports
http://www.fao.org/plant-treaty/en/

Abbreviations and technical terms:

R&D - Research and Development; this includes non-commercial academic research

ABS - Access (to genetic resources) and Benefit Sharing

CITES - Convention on International Trade in Endangered Species of Wild Fauna and Flora

PIC - Prior Informed Consent; a permit granting permission to utilise genetic resources for a particular purpose

MAT - Mutually Agreed Terms; the contract or agreement outlining the permitted use(s) of a genetic resource

NFP - National Focal Point; the representative of a country who provides information to potential users of genetic resources originating from that country

CNA - Competant National Authority - the representative of a country who can formally grant access to genetic resources originating from that country

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