Department
for Environment
Food & Rural Affairs

Guidance on the UK Access and Benefit Sharing Regulations

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Contents

Using this guidance

Purpose: This document has been produced by the Department for the Environment, Food and Rural Affairs (Defra) to provide guidance[1] on the provisions and implementation of the UK's Access and Benefit Sharing ('ABS') Regulations.

Intended use: This guidance document is not legally binding; its sole purpose is to assist citizens, academia, and businesses in the application of the ABS Regulations. It does not prejudge any future position of HM Government on this matter.

This guidance document does not replace, add to, or amend the provisions of the ABS Regulations. It should not be considered in isolation but used together with the regulations. If you have any questions regarding the content of this guidance, please contact Defra at abs@defra.gov.uk.

Regional coverage: The ABS Regulations are applicable throughout the United Kingdom of Great Britain and Northern Ireland. The ABS Regulations do not extend to the Overseas Territories or to the Crown Dependencies.

Application of the ABS Regulations: The ABS Regulations apply to the utilisation of genetic resources and traditional knowledge associated with the utilisation of the genetic resources (see Section 3).

Legislative primacy: Whilst this guidance document provides clarity on meeting the ABS Regulations, it is always the responsibility of UK users to comply with the provider country's legislation. If the provider country is not a Party to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation ('Nagoya Protocol'), or does not have applicable legislation in place to cover a particular activity or genetic resource, then the ABS Regulations will not be applicable. However, the user must still comply with any other applicable national laws of the provider country.

In this guidance:

- '**must'** indicates a legal obligation;
- '**should**' indicates good practice advised; and
- '**may**' indicates discretionary actions in the light of the context and circumstances.

[1] Defra acknowledges the EU Commission Guidance document C (2020)8759 dated 14 December 2021 *Guidance document on the scope of application and core obligations of Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 2014 on the compliance measures for users from the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilisation in the Union*, on which this guidance is based.

1. Background

The Nagoya Protocol is an international, supplementary agreement to the Convention on Biological Diversity ('CBD').

The CBD has three main objectives: the conservation of biological diversity; the sustainable use of the components of biological diversity; and the fair and equitable sharing of the benefits arising out of the utilization of genetic resources (Article 1 CBD). The Nagoya Protocol provides the legal framework for the effective implementation of the third objective.

Regulation (EU) No 511/2014 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 in the Union (hereafter referred to as 'the retained EU Regulation') was adopted in April 2014 and came into force for the EU and its member states alongside the Nagoya Protocol on 12 October 2014. The UK is no longer part of the EU and this Regulation has been retained as UK law (see below).

The Commission Implementing Regulation (EU) 2015/1866 (hereafter referred to as 'the retained EU Implementing Regulation') came into force on 9 November 2015 and lays down detailed rules for the implementation of the retained EU Regulation. The UK is no longer part of the EU and this Regulation has been retained as UK law (see below).

The Nagoya Protocol (Compliance) Regulations 2015 (Statutory Instrument 2015/821) put in place the measures needed for the UK to implement and enforce the EU Regulation and elements of the Nagoya Protocol.

The retained EU Regulation and the retained EU Implementing Regulation were amended by two statutory instruments which came into force in the UK on 1 January 2021:

- The Nagoya Protocol (Compliance) (Amendment) (EU Exit) Regulations 2018/1393 and
- The Environment and Wildlife (Legislative Functions) (EU Exit) Regulations 2019/473

The above legislation collectively is referred to below as the 'ABS Regulations'.

2. Glossary

Genetic resources: The ABS Regulations apply to genetic resources which are defined as '*genetic material of actual or potential value'* (Article 3(2) of the retained EU Regulation; Article 2 of the CBD). 'Genetic material' means '*any material of plant, animal, microbial or other origin containing functional units of heredity'* (Article 3(1) of the retained EU Regulation).

Utilisation of genetic resources: Utilisation means '*to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention'* (Article 3(5) of the retained EU Regulation). Utilisation, in part or in full, must take place in the UK for the ABS Regulations to be applicable.

Research and development: The term 'research and development' is not defined in the Nagoya Protocol or the ABS Regulations. Within this guidance, utilisation in terms of the ABS Regulations applies to either research i.e. the focus on the discovery or examination of specific genetic and / or biochemical traits; or research and development i.e. which leads to the development of a product. In this guidance, the terms 'research and development' and 'utilisation' are interchangeable.

User: This means **'***a natural or legal person that utilises genetic resources or traditional knowledge associated with genetic resources'* (Article 3(4) of the retained EU Regulation). This is independent of the users' size or of the intent of the use (public sector or private, commercial or non-commercial, profit or non-profit) and thus may apply to individuals, including researchers, and to organisations such as government departments, universities or other research organisations, as well as to small and medium sized enterprises and multinational companies, which utilise genetic resources or traditional knowledge associated with genetic resources.

Traditional knowledge associated with genetic resources (aTK): This means '*traditional knowledge held by an indigenous or local community that is relevant for the utilisation of genetic resources and that is as such described in the mutually agreed terms applying to the utilisation of genetic resources'* (Article 3(7) of the retained EU Regulation). There is no internationally accepted definition of traditional knowledge, but Parties to the Nagoya Protocol which regulate access to traditional knowledge associated with genetic resources should have a domestic definition of traditional knowledge. To be in scope of the ABS Regulations, aTK must be related to the utilisation of genetic resources and it must be covered by the relevant mutually agreed terms[2].

In this guidance, when 'genetic resources' are referred to, this should be read as also including 'traditional knowledge associated with genetic resources', where appropriate.

Provider country: The term 'provider country' is not defined in the ABS Regulations but for the purposes of this guidance it refers to the country of origin of the genetic resource or a Party that has acquired the genetic resource in accordance with the Convention (see Article 5 of the Nagoya Protocol). The ABS Regulations only apply to genetic resources from provider countries which are Parties to the Nagoya

[2] See also paragraphs 9, 11 and 21 of the retained EU Regulation.

Protocol and have established applicable access measures which cover the genetic resource in question.

Access: For the purposes of this guidance, access means the acquisition of genetic resource or of aTK from a Party to the Nagoya Protocol. Article 6 of the Protocol states '*access to genetic resources for their utilization shall be subject to the prior informed consent of the Party providing such resources that is the country of origin of such resources or a Party that has acquired the genetic resources in accordance with the Convention, unless otherwise determined by that Party'*.

Biotechnology: This is referenced within the definition of 'utilisation' but is not defined in the ABS Regulations. For guidance, the definition of biotechnology as stated in Article 2 of the Nagoya Protocol will be used - '*any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use'.*

Derivatives: Article 2 of the Nagoya Protocol defines the term 'derivatives' as '*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'.*

3. Scope of the ABS Regulations

To establish whether the ABS Regulations are applicable or not, UK users should initially consider the following generic scope requirements:

1. Does the material meet the definition of a genetic resource? And is the genetic resource non-human[3]?
2. Was the provider country a Party to the Nagoya Protocol at the time of access?
3. If yes, did the provider country exercise sovereign rights over the genetic resource (to include having legislation in place) at the time of access which is applicable to access and utilisation of the genetic resource in question?
4. Was the genetic resource accessed on or after 12 October 2014[4]?
5. Does the utilisation of the genetic resource constitute 'research and development'? In other words, does it create new insight into the characteristics of the genetic resource which is of (potential or real) benefit to the further process of product development?
6. Is the genetic resource and its utilisation **not** covered by those Specialised International ABS Instruments recognised within the ABS Regulations (see Article 2 of retained EU Regulation 511/2014 and Article 4(2) and (4) of the Nagoya Protocol)[5]?
7. Does utilisation of the genetic resource take place, in part or in full, within the UK?

If the answer is yes to all the above, then the activity is in scope of the ABS Regulations. If no to any of the above, then the activity is likely to be out of scope of the ABS Regulations. If users are unable to provide a definitive response to any of the above, then they should contact Defra (abs@defra.gov.uk) or the Office for Product Safety and Standards (OPSS) for further advice (https://www.gov.uk/guidance/abs#contact-us).

The ABS Clearing House provides details on whether a provider country is a Party to the Nagoya Protocol and on its legislation.

Although the ABS Regulations do not apply to genetic resources accessed from provider countries which are not Party to the Nagoya Protocol, these countries may have applicable national ABS legislation, to which those accessing and utilising genetic resources and aTK must adhere.

Note that at least part of the utilisation of the genetic resource must also be conducted within the UK to be in scope of the ABS Regulations. In cases where the utilisation process is split across different jurisdictions, where at least one part of the utilisation process occurs in the UK, the ABS Regulations will apply. The ABS Regulations will therefore not be applicable if a company commercialises in the UK a product that it has developed through utilisation of genetic resources (the entire process of research and development) outside of the UK.

[3] See also chapter 3.3.2

[4] The ABS Regulations are applicable from 12 October 2014 onwards but note that the user's legal obligations on articles 4, 7 and 9 of the retained EU Regulation became applicable from 12 October 2015 onwards.

[5] For example, the Pandemic Influenza Preparedness Framework and the International Treaty on Plant Genetic Resources in Food and Agriculture.

3.1 Geographic scope

The ABS Regulations apply to genetic resources from provider countries which are Parties to the Nagoya Protocol and have established applicable access (and benefit sharing) measures relevant to the genetic resource and / or aTK in question at the time of access.

In some cases, despite the best efforts of the intended user, the provider country of a specific genetic resource cannot be determined. Therefore, there is no means of determining whether the provider country is a Party to the Protocol, nor whether it has appropriate access legislation in place to legislate for the genetic resource in question. Under the ABS Regulations, the user may proceed with the utilisation of the genetic resource but:

- The user should retain evidence of checks undertaken to determine the provider country of the genetic resource in question.
- Should new information come to light that allows the provider country to be subsequently identified, then the user must agree prior informed consent (PIC) and mutually agreed terms (MAT), or discontinue utilisation, in accordance with Article 4(5) of the retained EU Regulation – on the premise that at the time of access the provider country was a Party to the Nagoya Protocol and had appropriate access legislation in place.

A particular way of indirectly accessing genetic resources is through ex-situ collections in the provider country of these genetic resource. If the country in question is a Party to the Protocol, has in place access legislation for the genetic resource and if they are accessed from the collection after the entry into force of the Protocol, utilisation falls within the scope of the ABS Regulations, regardless of when the resources were collected/ added to the collection.

3.2 Temporal scope

The ABS Regulations apply to genetic resources and / or aTK over which Parties to the Nagoya Protocol exercise sovereign rights and are accessed from the entry into force of the Nagoya Protocol (12 October 2014 onwards).

Genetic resources accessed prior to the 12 October 2014 fall outside the scope of the ABS Regulations even if utilisation of those genetic resources occurs after that date.

Some Parties to the Nagoya Protocol may have put in place national rules that apply also to genetic resources accessed before its entry into force. Utilisation of those genetic resources would be outside the scope of the ABS Regulations. However, national legislation or regulatory requirements of the provider country still apply, and any mutually agreed terms entered into should be respected, even if not covered by the ABS Regulations.

Note that Articles 4 (obligations of users), 7 (monitoring user compliance), and 9 (checks on user compliance) of the retained EU Regulation became applicable one year after the date of entry into force of the Nagoya Protocol. The legal obligations

for users to comply with these articles became applicable therefore on 12 October 2015. As an example, the obligation under Article 4 of the retained EU Regulation to exercise due diligence came into force on 12 October 2015.

3.3 Material scope

Specialised International ABS Instruments (SII): In accordance with Article 4(4) of the Nagoya Protocol and the ABS Regulations, SII prevail in respect of the specific genetic resources covered by the SII and for the purpose of that instrument, if it is consistent with and does not run counter to the objectives of the CBD and the Protocol. The ABS Regulations recognise the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) and the WHO's Pandemic Influenza Preparedness Framework (PIPF)[6] as SII. The ABS Regulations will therefore not be applicable if:

- The genetic resource covered by the SII is accessed in a country that is a Party to that agreement and to the Nagoya Protocol.
- The genetic resource is covered by the SII and is utilised for purposes in accordance with the SII.

Human genetic resources are not included in the framework of the Convention on Biological Diversity or Nagoya Protocol and are therefore out of scope of the ABS Regulations[7]. However, genetic resources **such as pathogens and microbiota**, may be in scope. See also Chapter 6.1 and 6.2.

Digital Sequence Information (DSI) is out of scope of the ABS Regulations. Note that the provider country's ABS legislation may contain DSI associated terms, conditions, and obligations and so users might be subject to bilateral obligations.

The Trade and exchange of genetic resources as commodities are outside the scope of the ABS Regulations. The Protocol does not regulate issues related to trade. If there is no utilisation of the genetic resource, the ABS Regulations do not apply.

Note however, that if a user intends to conduct research and development on a genetic resource which originally entered the UK as a commodity e.g. freshwater fish from a pet shop, the intended use has changed, and such new use may fall within the scope of the ABS Regulations. In this case, the user should contact the provider country and establish whether PIC and MAT are required (and if yes, they must obtain the necessary permits and establish MAT). If users intend to acquire and bring a genetic resource commodity into the UK for the purposes of utilisation, then the generic scope requirements set out previously in this chapter should be determined.

[6] The PIP Framework applies only to influenza viruses with human pandemic potential and specifically does not apply to seasonal influenza viruses.
[7] This is confirmed by CBD COP Decision II/11 (para. 2) and CBD COP Decision X/1 (para. 1(5)), specifically for ABS).

3.4 Personal scope

A person or entity that only **transfers** genetic resources/aTK is not a user in the meaning of the ABS Regulations. However, an entity, such as a collection, may be required to transfer ABS information (including that listed under Article 4(3) of the retained EU Regulation) to subsequent users, subject to contractual obligations agreed at the time of access.

Similarly, a person or entity that only **commercialises** products which have been developed based on utilisation of genetic resources/aTK is not a user in the meaning of the ABS Regulations – regardless of where the development of the product took place. However, such an entity may be subject to contractual obligations entered into when the material was accessed, which may include benefit sharing and/or regulatory requirements in the country of utilisation.

> The ABS Regulations will not apply if a company commercialises in the UK a product that it has developed through the utilisation of genetic resources which took place solely outside of the UK.

It is common practice that research and development activities are carried out by **subcontractors, toll manufacturers or service providers** (in the following referred to jointly as 'service providers'). Among others, many universities and small and medium-sized enterprises (SMEs) provide specialised services in this regard. Such services may include, for example, DNA and protein sequence determination, DNA or protein synthesis and identification of bioactive compounds and extraction methods. Although such service providers may be carrying out activities that would normally qualify them as users under the ABS Regulations, under certain conditions the obligations for due diligence could rest with the entity which is subcontracting the work ('service requestor').

Thus, all activities carried out by service providers potentially falling in scope of the ABS Regulations, when performed at the request of the service requestor, would not qualify them as users in the meaning of the retained EU Regulation if the following conditions are met, and are explicitly set out in the service agreement:

(i) The service provider can only perform the activities as listed and specifically described in the service agreement, and is not granted the right to perform any other research and development or exploitation activities on the genetic resources provided or the results obtained by performing the services under the service agreement;

(ii) The service provider has the obligation to return or destroy all material and all information pertaining to the research and development at the end of the service agreement. If a copy is kept for archiving purpose, the entity subcontracting the service will be informed thereof;

(iii) The service provider is not granted any rights on the genetic resources or any proprietary rights related to the results obtained by performing the services under the service agreement;

(iv) The service provider does not have the right to transfer material or information to any third party or another country and has an obligation to keep all information

received and generated under the service agreement confidential (including no right to publish); and

(v) The service requestor has the obligation to comply with all obligations under the retained EU Regulation related to the material provided to the service provider.

If these conditions are met, it is the service requestor that is considered to be the user in the meaning of the ABS Regulations.

Genetic resources may be acquired indirectly from **third parties or intermediaries**, such as from a culture collection or other specialised companies or organisations with a similar function. These are not 'providers' within the context of this guidance. Accessing genetic resources from intermediaries does not abrogate the users' responsibility to meet their due diligence obligations (see Chapter 4 on due diligence). The user should determine whether:

- New PIC and MAT is required to access and utilise the genetic resource.
- The intermediary has already obtained PIC and MAT from the provider country which covers access to and utilisation of the genetic resource.
- The PIC and MAT in place allows for the intermediary to transfer, share or sell the genetic resource to the user and covers the subsequent utilisation.

If the intermediary cannot provide such evidence, or the PIC / MAT does not cover the intended utilisation of the new user, then the user should go back to the to the provider country and establish both (PIC and MAT).

Note that even if the intermediary or third party is located in a country which is not a Party to the Nagoya Protocol, the user is still expected to meet their due diligence obligations and any obligations to the provider country. The intermediary would also be expected to comply with any such obligations to the provider country.

3.5 Utilisation

The term utilisation within this guidance can apply to research i.e. the focus on the discovery or examination of specific genetic and / or biochemical traits; or research and development i.e. which leads to the development of a product.

Users should consider the following basic principles when determining whether the activity can be defined as utilisation:

- The identification, taxonomic description, characterisation or description of a genetic resource is not utilisation and is out of scope.
- However, the identification, taxonomic description, characterisation or description of a genetic resource when combined with research on specific genetic and/or biochemical properties of the genetic resource will qualify as utilisation in the meaning of the ABS Regulations.
- Research which leads to the discovery of specific genetic and/or biochemical properties is utilisation.
- The creation of new insight into the characteristics of the genetic resource which is of (potential or real) benefit to the further process of product development is utilisation.

Guidance examples of activities falling under the definition of ‘utilisation’ and therefore in scope of the ABS Regulations:

- Research on a genetic resource leading to the isolation of a biochemical compound used as a new ingredient (active or not) incorporated into a cosmetic product.
- Breeding programme to create a new plant variety based on landraces or naturally occurring plants.
- Genetic modification creation of a genetically modified animal, plant, or microorganism containing a gene from another species.
- Creation or improvement of yeasts, resulting from human action through a research and development process, to be used in manufacturing processes.

Guidance examples of activities which are not considered as utilisation and therefore would not fall within scope of the ABS Regulations:

- Supply and processing of relevant raw materials for subsequent incorporation in a product where the properties of the biochemical compound contained in the genetic resource are already known and therefore no research and development is carried out such as, for example, supply and processing of Aloe Vera, Shea nut or butter, rose essential oils, etc. for further incorporation into cosmetics.
- Genetic resources as testing/reference tools: At that stage the genetic material is not the object of the research in itself but only serves to confirm or verify the desired features of other products developed or under development. This may include laboratory animals used to test their reaction to medical products, or laboratory reference material (including reference strains), reagents and samples of proficiency tests or pathogens used for testing the resistance of plant varieties. See also Section 6.4.
- Handling and storing of biological material and describing its phenotype.
- The application of biotechnology in a way which does not make the genetic resource in question the object of research and development. For example, the use of yeasts in the brewing of beer, where no research and development is carried out on the yeast, and it is used ‘as is’ in the process of brewing, is not to be considered as utilisation of that genetic resource.

4. User obligations

Article 4(1) of the retained EU Regulation states '*Users shall exercise due diligence to ascertain that the genetic resources and traditional knowledge associated with genetic resources which they utilise have been accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements, and that benefits are fairly and equitably shared upon mutually agreed terms, in accordance with any applicable legislation or regulatory requirements'.*

The core user obligations under Article 4 of the retained EU Regulation and Articles 5 and 6 of the retained EU Implementing Regulation are to:

a) Exercise due diligence.
b) Seek and keep the information relevant to ABS for 20 years after the end of the period of utilisation, and transfer this to subsequent users.
c) Submit a due diligence declaration at the stage of research funding.
d) Submit a due diligence declaration at the stage of final development of a product.

Users must fulfil all obligations (where applicable) to be considered as compliant.

The user must provide documentary evidence to satisfy the due diligence requirement of the ABS Regulations. This evidence must show compliance with the provider country's applicable ABS legislation or regulatory requirements. The evidence can include internationally recognised certificates of compliance (IRCC), PIC, MAT, or other such documentation to indicate the date and time of access, location of access, and description of the genetic resource (see Article 4 of the retained EU Regulation for further clarity).

Note that the Office for Product Safety and Standards (OPSS) is responsible for enforcing compliance with the ABS Regulations. OPSS are using their legal authority to request information when they request entities to evidence why they are out of scope. By evidencing to OPSS why they are out of scope, users are evidencing how they are compliant with the ABS Regulations. See chapter 7.3.

Issues arising when meeting user obligations. Occasionally, users face difficulties in their attempts to demonstrate evidence of meeting their user obligations.

Scenario	Guidance
Lack of available information or uncertainty about the legality of access and utilisation.	Article 4 (5) of the retained EU Regulation states that '*When the information in their (the user's) possession is insufficient or uncertainties about the legality of access and utilisation persist, users shall obtain an access permit or its equivalent and establish mutually agreed terms or discontinue utilisation*'. See also Chapter 3.1

When can I proceed with utilisation?	Users should not proceed with utilisation until they have complied with the requirements of the provider country's ABS legislative requirements (to include PIC and / or MAT as relevant).
What happens if I can't establish PIC and / or MAT, or there are significant delays in agreeing them?	If there is a known, legislative requirement to establish and agree PIC and / or MAT (as relevant), no access (or utilisation) can proceed until they have been agreed, regardless of any delays encountered.
I don't know if the provider country has implemented relevant national ABS measures.	In cases where the user is unsure whether a provider country has implemented relevant national ABS measures, the user should: 1. Check the country profile on the ABS-CH website (https://absch.cbd.int/en/) 2. Contact the relevant National Focal Point (NFP) and retain evidence of correspondence (or evidence of attempts to engage in correspondence) 3. Check the provider country's national websites.
I have tried to contact the NFP and checked the legislative requirements on the ABS clearing house but I am still unsure as to whether I can proceed with access and utilisation.	If the user is still not sure whether a provider country has implemented relevant national ABS measures, the user should seek further advice from OPSS (https://www.gov.uk/guidance/abs#contact-us) or Defra (abs@defra.gov.uk).

Compliance with the due diligence obligation should ensure that the necessary information related to the genetic resource and/or aTK is available throughout the value chain. This, in turn, will enable all users to know of and respect rights and obligations attached to the genetic resource and/or aTK. If a user – no matter at which step in the value chain – takes reasonable measures in the seeking, keeping, and transferring of information, the user will be compliant with the due diligence obligation under the ABS Regulations.

4.1 Due diligence declarations

There are two stages at which a due diligence declaration is to be submitted by the user. For each stage, the contents of the required declaration are specified in annexes to the retained EU Implementing Regulation. Further guidance on submitting a due diligence declaration in the UK is available on the following website: https://www.gov.uk/guidance/abs.

Due diligence declaration at the stage of research funding.

The first stage (defined in Article 7(1) of the retained EU Regulation) concerns the research stage, when a research project involving utilisation of genetic resources/ aTK is subject to external funding in the form of a grant[8]. The retained EU Implementing Regulation clarifies that 'funding for research' means any financial contribution by means of a grant to carry out research, whether from commercial or non-commercial sources. It does not cover internal budgetary resources of private or public entities.

The retained EU Implementing Regulation clarifies in Article 5(2) the timing for filing such a declaration. The declaration must 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, but in any case, no later than at the time of the final report (or in absence of such report, at the project's end). When drafting a collaboration agreement, consideration should be given to the identification of an individual who will be responsible for making the declaration.

Due diligence declaration at the stage of final development of a product.

The second stage at which a due diligence declaration must be submitted by users is the stage of final development of a product developed via the utilisation of genetic resources/aTK. The declaration shall be made only once, prior to the first of the events listed in Article 6 of the retained EU Implementing Regulation[9] occurring:

(a) market approval or authorisation is sought for a product developed via the utilisation of genetic resources and aTK;

(b) a notification required prior to placing for the first time on the UK market is made for a product developed via the utilisation of genetic resources and aTK;

(c) placing on the UK market for the first time a product developed via the utilisation of genetic resources and aTK for which no market approval, authorisation or notification is required;

(d) the result of the utilisation is sold or transferred in any other way to a natural or legal person within the UK in order for that person to carry out one of the activities referred to in points (a), (b) and (c);

(e) the utilisation in the UK has ended and its outcome is sold or transferred in any other way to a natural or legal person outside the UK.

'Placing on the UK market' means the first making available of a product developed via utilisation of genetic resource(s) and aTK on the UK market, where 'making available' means the supply by any means, for distribution, consumption or use on the UK market in the course of a commercial activity, whether in return for payment or free of charge. Placing on the market does not include pre-commercial trials, including clinical, field or pest resistance trials.

The definition of the term '**result of the utilisation'** (see Article 6(3) of the retained EU Implementing Regulation) makes it clear that the user is under the obligation to

[8] According to Article 5(5) of the retained EU Implementing Regulation, funding for research — in the context of submitting due diligence declarations at the first checkpoint — is to be understood as 'any financial contribution by means of a grant to carry out research, whether from commercial or non-commercial sources. It does not cover internal budgetary resources of private or public entities.
[9] As amended by SI 2018 No.1393 The Nagoya Protocol (Compliance) (Amendment) (EU Exit) Regulations 2018

file a due diligence declaration for the result of utilisation only if the next person in the value chain can manufacture a product based on the result of utilisation and no further utilisation takes place. The different actors in the value chain may have to communicate with each other to establish who the last user in the value chain is. Such communication might also be required in situations involving changes of intent — for example, when a downstream actor changes plans and decides not to conduct any utilisation activities after all, but places a product containing the genetic resources in question (such as shampoo) on the market. In this case the previous actor would need to file a due diligence declaration.

Example of 'result of the utilisation' *- A UK company obtains an access permit for the utilisation of plants from a country which is a Party to the Protocol and has applicable access measures in place. Research is being conducted on the samples obtained. Through the research, the company identifies a new active ingredient derived from the plant. The material is then transferred, together with all the relevant information defined in Article 4(3) of retained EU Regulation, to another UK company where further development on the product takes place. The second company enters into a license agreement with a third company. That technology transfer does not require any further research and development. Given that the third company does not carry out any research and development, and is therefore not a user in the sense of the ABS Regulations, it is for the second company to file a due diligence declaration at the checkpoint 'final stage of development of a product'. In this case, that stage has been reached when the result of utilisation is sold or transferred to a natural or legal person within the UK (i.e. to the third company) for the purpose of placing a product on the UK market (Article 6(2)(d) of the retained EU Implementing Regulation).*

Example of 'outcome of utilisation' *- A UK company obtains an access permit for utilisation of plants from a country which is a Party to the Protocol and has applicable access measures in place. Research is being conducted on the samples obtained. Through the research the company identifies a new active ingredient derived from the plant. The material is then transferred, together with all the relevant information as defined in Article 4(3) of the retained EU Regulation, to another UK company where further development on the product takes place. The second company decides not to continue with the development of the product but sells the outcome of their activities to a company based in the EU, which may intend to carry out further research and development. The second company files a due diligence declaration at the checkpoint 'final stage of development of a product'. In this case that stage has been reached when the utilisation in the UK has ended and the outcome of utilisation is sold or transferred to a natural or legal person outside of the UK (i.e. to the EU company) — regardless of the future activities undertaken by the company outside of the UK (Article 6(2)(e) of the retained EU Implementing Regulation).*

Transfers between entities of the same company, are not considered as transfer within the meaning of Article 6 of the retained EU Implementing Regulation, therefore filing of a due diligence declaration is not required.

Publication of scientific papers is also not considered as a sale or transfer of the result or outcome of the utilisation within the meaning of Article 6 of the retained EU

Implementing Regulation, and therefore the filing of a due diligence declaration is not required. However, the general due diligence obligation may still apply, if all the conditions for applicability of the ABS Regulations are met. In that case, the obligation to seek, keep and to transfer relevant information to subsequent entities rests with the author(s) of the scientific paper or their entities.

5. Registered collections

Where genetic resources are obtained from a collection registered (entirely or partly) within the UK under Article 5 of the retained EU Regulation, the user is considered to have exercised due diligence as regards the seeking of information as far as the genetic resource from (the relevant, registered part of) that collection are concerned. Being considered to have exercised due diligence as regards the seeking of information means that the user will not be expected to enquire about ('seek') the information listed in Article 4(3) of the retained EU Regulation. Users should be aware that when the intended utilisation changes, there may be a need to seek new or updated PIC from the provider country and establish MAT for the new use, if it is not covered by the PIC and MAT obtained and relied upon by the registered collection.

The obligation to supply the genetic resource together with all the relevant information rests with the holder of the registered collection. However, the duty to keep and transfer this information rests with the user. Similarly, the requirement to submit due diligence declarations also rests with the user. A collection should keep any genetic resource for which the provider country cannot be identified separate from the registered part, using whatever storage or labelling system is appropriate, as distribution of such material would not comply with conditions set up in Article 5(3) b of the retained EU Regulation.

If a user accesses genetic resources from a collection that does not have registered status, the obligation remains with the user to exercise due diligence and seek the necessary permissions and negotiate MAT with the provider country. The user should request information, such as provider country and date of collection, from the collection itself.

Storing genetic resources in a collection. The act of storage of genetic resources in a UK-based collection (whether obtained from in situ conditions, from a market or shop in the provider country, or from an ex-situ collection) does not involve research and development on the genetic or biochemical composition of the genetic resource and is therefore not in scope of the ABS Regulations. However, acquisition of these genetic resources should be done in line with the legal requirements of the country where the material is collected.

Before storing acquired genetic resources in a collection, collection holders might verify the identity of these genetic resources and assess their health status and the presence of pathogens. These activities form an integral part of collection management and are considered as related to (or carried out in support of) such management. They are thus not considered to be utilisation in the meaning of the ABS Regulations.

General good practice for collection holders upon receiving material is to check if the original permit for collecting genetic resources (where required) allows supply to third-party users and, if this is the case, to make the information on the permit available for potential users and to supply it together with any material to the potential users. If the permit does not allow the transfer of material to third parties, the material cannot be made available, but it can be marked in the catalogue with a reference to the Competent National Authority (CNA) that issued the original permit,

so that the potential user can contact that CNA to either seek a new permit and negotiate a new contract (MAT) for access to the collection material or for access to a genetic resource in the provider country.

It is possible that genetic resources are present in a collection without PIC and / or MAT. General good practice for collection holders is to support users through seeking, keeping and transferring the necessary information, recalling that the user has the responsibility under the ABS Regulations to exercise due diligence for their utilisation.

6. Sector specific issues

This chapter gives additional guidance on specific issues which frequently arise. The chapter is not able to comment on every sector or related topic to which the ABS Regulations may or may not be applicable. Users should always apply the generic scope requirements as set out in Chapter 3 or contact the OPSS or Defra for additional clarification.

6.1 Health

UK organisations should consult with OPSS and / or Defra as soon as possible in all cases concerning the transfer of genetic resources in respect of present or imminent emergencies that threaten or damage human, animal or plant health.

Article 8(b) of the Nagoya Protocol requires Parties to pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health. This can refer to a genetic resource that is determined to be the pathogen causing a present or imminent public health emergency of international concern as defined within the International Health Regulations (2005)[10]. It can also refer to an event or situation which threatens serious damage to human welfare in a place in the UK, as defined by the Civil Contingencies Act (2004)[11]. This is reflected in the ABS Regulations through:

- Recognition of SII (see paragraph 3.3.1), namely the PIPF and the ITPGRFA.
- The ABS Regulations are not applicable if:
  - The genetic resource covered by the SII is accessed in a country that is a Party to that instrument and to the Nagoya Protocol, and
  - The genetic resource is covered by the SII and is utilised for purposes in accordance with the SII.
- In addition, Article 4 of the retained EU Regulation further addresses pathogens of a present or imminent public health emergency or threat and allows for delays in submission of due diligence declarations to either:
  - One month after the imminent or present threat to public health is terminated; or
  - Three months after commencement of utilisation of the genetic resource; whichever is the earlier.

Subject to temporal and geographic scope conditions and the application of the PIPF or any other SIIs that may be recognised by the UK in the future, pathogens are in scope of the ABS Regulations. See also chapter 6.2.

[10] WHO IHR link: International Health Regulations (2005) Third Edition (who.int)
[11] CCA legislation link: Civil Contingencies Act 2004 (legislation.gov.uk)

6.2 Intentionality of access

The UK does not have legislation in place which, under the Nagoya Protocol, governs the access to, and utilisation of, its sovereign genetic resource [12]. Whilst 'intentionality of access' is not defined within the ABS Regulations, there is a requirement to provide guidance to stakeholders in this matter.

The ABS Regulations apply to those genetic resources which are deliberately acquired and brought into the UK, and to which the generic scope requirements are applicable (see Chapter 3), for utilisation purposes. Users should ensure that PIC and MAT (where relevant) provide for predictable possibilities i.e. intended or subsequent utilisation of commodities, contaminants, derivatives or associated organisms (to include pathogens, parasites, pests or microbiota). If in doubt, users should re-engage with the provider country and if necessary, agree new PIC and MAT (as may be required in the case of accessing human microbiota).

The ABS Regulations do not apply to those genetic resources which arrive unintentionally, or are introduced unintentionally, into the UK, such as alien species. genetic resources once established in the UK, to include alien species and biocontrol organisms, are not subject to the ABS Legislation as the UK does not legislate for access to and utilisation of its sovereign genetic resources. Utilisation may therefore take place on those genetic resources and their associated organisms without recourse to the ABS Regulations.

6.3 Derivatives

The definition of utilisation in the Nagoya Protocol and the retained EU Regulation applies to '*research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology'* (Article 2(c) of the Nagoya Protocol, Article 3(5) of the retained EU Regulation). Biotechnology, in turn, is defined in the CBD as '*any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use'* (Article 2 of the CBD, see also Article 2(d) of the Nagoya Protocol). Thus, through the concept of 'biotechnology', the definition of utilisation is interlinked with the definition of 'derivatives' in Article 2(e) of the Nagoya Protocol, which clarifies that 'derivative' means '*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'*. However, the definition does not cover material such as synthetic gene segments. Examples of derivatives include proteins, lipids, enzymes, and organic compounds such as flavonoids, essential oils or resins from plants. Some such derivatives may no longer contain functional units of heredity.

Derivatives are referred to in the definition of biotechnology, which in turn is mentioned in the definition of utilisation, but no corresponding reference is to be found in the substantive provisions of the Protocol, including those related to utilisation, which ultimately determine its scope of application. Access to derivatives is covered by the retained EU Regulation when it also includes genetic resources for utilisation, e.g. when access to a derivative is combined with access to a genetic resource from which that derivative was or is obtained or when research and

[12] A UK or non-UK based organisation will not need to agree PIC and MAT to access and utilise UK sovereign genetic resources.

development to be carried out on such derivatives is addressed in mutually agreed terms transferred to the user.

In other words, there needs to be an ascertainable level of continuity between a derivative and the genetic resource from which it was obtained for research and development activities on derivatives to fall in the scope of the retained EU Regulation.

Such continuity is considered to exist in the following situations:

- The research and development activities conducted using a derivative form part of a research project covering the genetic resource and include obtaining the derivative.
- A user has obtained the derivative or commissioned a third party to obtain the derivative from a genetic resource in a research collaboration or as a specific service (e.g. under a service agreement).
- The derivative is acquired from a third party and it is transferred with PIC and MAT conditions that cover the respective research and development activities using the derivative.

Such continuity does not exist if the derivative is acquired from a third party as a product available on the market and it is transferred without PIC and MAT conditions that cover research and development activities on the derivative. As a consequence, any research and development that is merely using derivatives that are traded and obtained as commodities (such as the harvest or waste products of agriculture, forestry, aquaculture and alike, including oils, molasses, starches, and other refinery products, animal by-products such as milk, silk, wool grease, beeswax), without PIC and MAT attached or without any access to a specific genetic resource, would not be considered as being within the scope of the retained EU Regulation.

6.4 Taxonomy

The taxonomic identification of biological or genetic resources, by morphological or molecular analysis, including through the use of DNA sequencing, does not constitute utilisation in the meaning of the ABS Regulations, as it does not involve the discovery of specific genetic and/or biochemical properties, nor does it ‘create new insight into characteristics of the genetic resource which is of (potential or real) benefit to the further process of product development’. There is no difference whether the taxonomic identification points to a previously named entity or an unnamed entity.

6.5 Characterisation (to include gene expression)

If characterisation and comparison do not involve the discovery of specific genetic and/or biochemical functions, it does not ‘create new insight into characteristics of the genetic resource which is of (potential) benefit to the further process of product development’. In such cases, characterisation does not qualify as utilisation in the meaning of the ABS Regulations.

Characterisation can also include **gene expression**. Research in both commercial and non-commercial settings may be specifically performed to discover the expression of genes, both by morphological and biochemical means. Alternatively, research may seek the genetic background of traits of interest, to analyse which

genes, gene complexes or regulatory sequences and mechanisms governing their expression are involved. Such trait analysis, even if carried out for non-commercial purposes, is considered to fall within scope of the ABS Regulations. However, examination of morphological characteristics alone without inclusion of the genetic influences on the morphology is not considered to be research and development on the genetic and biochemical composition of the organism (i.e. genetic function) and is out of scope.

6.6 Acquisition of animals by farmers (animal breeding)

Farmers routinely, and at a large scale, buy animals, semen or embryos from commercial providers, including importers, to maintain the value of their farm herd for production purposes. When farmers acquire animals, semen and embryos for direct production purposes only, and no forms of research and development are undertaken, such activities do not represent utilisation and do not trigger obligations under the ABS Regulations.

6.7 Phylogenetic analysis

This makes use of a plethora of methods of analysis which can be performed on all kinds of data that have a presumed ancestor-descendant relationship: e.g. in linguistics, or, in a biological context, morphological and chemical aspects, nucleotide sequences, or in general ‘characters’.

Research involving phylogenetic analysis using genetic resources may therefore be aimed at identifying variation in identity (‘passport data’ in the terminology of germplasm collections or gene banks) of the species within and between populations and be similar to taxonomic identification. Similarly, it may be aimed at identifying such variation between species or taxa above species such as genus, tribe or family and grouping the analysed entities. Where such activity does not entail research and development into the genes, and the function of the genes or DNA sequences (if known at all) is neither investigated nor of interest, it is out of scope of the ABS Regulations. However, if research is carried out on the function of the genes, then such activity falls within the scope of the ABS Regulations.

6.8 Large scale screening

Large scale screening means an activity which involves the evaluation of usually large numbers of genetic resource samples against a specific criterion. The process is frequently automated and involves questions of a binary nature (i.e. does this sample match the criterion, or not?). The objectives of the activity are (a) to screen out the vast majority of samples which are not of interest to and will not be used for the research project (‘negative’); and (b) identify the few samples which may have the potential for further research within the terms of the project (‘positive’). Such a type of screening activity, which is based on simple binary questions and resolved by identical tests performed on multiple samples in a standardised way to screen out the majority of them, would not fall in scope of the ABS Regulations on the basis that it does not amount to utilisation of a genetic resource. It does not constitute ‘research and development’ as understood in the context of the regulations, since no added scientific insight in relation to the screened-out samples is created.

When, however, a researcher starts to look in more depth into the genetic resource which have been identified for further study by the binary process, such activity could fall within the scope of the ABS Regulations. Such further research moves beyond the application of standardised binary questions and follows a more individualised testing regime. It is also no longer focused on screening out certain samples but is concentrated on identifying the qualities and properties of those genetic resources which have been selected. The activity of looking more in depth at a genetic resource most typically requires more time than screening. Given that such research creates additional knowledge and new insight into the genetic and/or biochemical composition of those genetic resources, it amounts to utilisation, and so falls within scope of the ABS Regulations. This step when a researcher starts to look at the genetic resource more in depth can be regarded as the first step in a research and development chain.

The distinction between screening activities and more in-depth analysis may not always be clear-cut. Users should identify the end of screening activities and the beginning of any subsequent research activities, and keep records of this, as part of their due diligence obligation, for potential checks by the UK's competent authority.

6.9 Testing and reference tools

The application of genetic resources as **testing or reference tools** is not considered to constitute utilisation in the meaning of the ABS Regulations, and therefore does not fall within its scope. This is because the material is not the object of the research but only serves to confirm or verify features of other genetic resources or products. In addition, the use of genetic resources as attractants, e.g. for monitoring pests and potential pests to determine whether control actions may be needed, is also not considered utilisation in the context of the ABS Regulations.

Examples of such testing/reference tools are:

- laboratory animals used to test their reaction to medical products.
- pathogens used for testing the resistance of plant varieties.
- pathogens used for testing biocontrol and bio stimulant agents.
- bacteria used for testing the effectiveness of compounds that are candidates for new antibiotics against those bacteria.

Although the application of genetic resources as testing/reference tools is not considered utilisation in the meaning of the ABS Regulations, research and development may have been carried out on those genetic resources with the aim of turning them into (or improving their application as) testing or reference tools. As such, this research and development would fall under the scope of the ABS Regulations.

6.10 Vectors

Vectors (e.g. insects or micro-organisms) may be used to introduce foreign material (e.g. pathogens or genes) into host organisms. Typically, specimens of such vectors have been developed to facilitate such introduction, and in many cases a research and development programme does not involve any other changes to the vector than the incorporation of the genetic material to be introduced in the target plant. In such cases, the use of the vector or host does not constitute utilisation of such host

organisms or vectors in the context of the ABS Regulations. However, the study of introduced genetic material constitutes utilisation of those gene sequences in the meaning of the ABS Regulations. Also, the activity of optimising the performance of a vector or host qualifies as utilisation in the meaning of the ABS Regulations.

6.11 Biofactory

Genetic resources may be exploited to produce active compounds, which are subsequently extracted. This use of a genetic resource as a biofactory does not amount to utilisation in the meaning of the ABS Regulations, since it does not involve research and development on the genetic and/or biochemical composition of this genetic resource. However, if it is combined with research and development on the genetic and/or biochemical composition of that genetic resource, e.g. to discover specific genetic and/or biochemical functions that may optimise compound production, this research would qualify as utilisation in the meaning of the ABS Regulations.

6.12 Laboratory strain

A laboratory strain is a living organism or virus that has particular and invariant properties that make it unique, most typically for research purposes, and is available for mass production and transfer to third parties. A ‘laboratory strain’ therefore is usually characterised by the fact that it is:

- Genetically defined (at least for traits of interest), and with low or no genetic heterozygosity, often inbred or clonal. However, older laboratory strains may be defined by their phenotype rather than by their genotype.
- Distinct from the original strain or parental materials isolated from in situ conditions or obtained from a public culture collection, characterized by a genetic and/or biochemical composition that has been intentionally created or conserved.

In addition, laboratory strains can be:

- Managed under a record of laboratory maintenance over several generations, with a publicly traceable history regarding ancestry and/or pedigree: and/or
- Shared by laboratories/researchers. Laboratory strains are often maintained and sold by laboratories or farms that guarantee the purity of the line and with a health monitoring report. They may be certified as SPF (specific pathogen free), SOPF (specific and opportunistic pathogen free) or Germ free.

Laboratory strains created prior to entry into force of the Nagoya Protocol fall outside the scope of the ABS Regulations for temporal reasons.

Isolation of genetic material from the environment and its subsequent modification is in scope of the ABS Regulations.

A researcher who creates a strain (which may over time become a new laboratory strain) based on material in scope of the ABS Regulations is a user in the meaning of the regulations.

A newly created strain remains in scope of the regulations if it is not publicly available to others for research and development purposes.

Before the strain is made publicly available to others, the developer of the laboratory strain needs to submit a due diligence declaration (end of utilisation process).

If the strain has become a new laboratory strain and is shared by laboratories/researchers, its further use is out of scope of the regulations.

However, contractual agreements agreed in PIC and MAT concerning benefit sharing resulting from further use of newly developed laboratory strains need to be respected.

6.13 Crossing and selection

Where genetic resources falling in scope of the ABS Regulations are introduced for the purpose of crossing and selection, the resulting research and development falls within the scope of the ABS Regulations, which triggers due diligence obligations.

Such obligations may concern activities undertaken by many actors, including private breeding companies, public research institutions, farmer-breeders and hobby breeders, as well as actors improving insect populations or microbial species. Farmers and breeders are often trading or exchanging breeding stock of rare and traditional animal breeds and plant varieties amongst themselves, most often within the country but sometimes across borders. They may also be members of traditional seed networks, breeders' associations or breeders' networks (usually at national level). Exchange of breeding material largely takes place between farmers and/or hobbyists, often within the network/association, and contributes to the conservation of the specific breed or variety. Such trade or exchange for the purpose of maintenance and conservation of rare or traditional breeds and varieties is considered to be out of scope of the ABS Regulations. However, if the activities involve crossing and selection for the purpose of improving or changing the properties of established breeds and varieties, such activities will qualify as utilisation and hence fall within the scope of the ABS Regulations. For example, rare sheep breeds have been improved to render these breeds resistant to the scrapie disease.

7. Additional advice to stakeholders to aid compliance with the UK's ABS regulations

This chapter provides UK users of genetic resources with additional advice which, when implemented effectively, should support compliance with the ABS Regulations. Different sectors will have different approaches to managing compliance based on the level of risk. Organisations should have in place proportionate and appropriate measures relevant to the activities undertaken and the sector involved. This may range from processes to ensure appropriate documentation is acquired, retained and shared, to procedures for establishing projects in scope of the regulations and governance structures ensuring employees are aware of their responsibilities for compliance. What is useful and practical for one sector may not be for another.

7.1 Information management checklist

Where practicable, users are encouraged to develop, implement, and maintain the following:

1. A list of personnel within the organisation responsible for compliance with the ABS Regulations.
2. To assist in providing evidence of due diligence, a centralised spreadsheet, system or database listing those projects involving access to and utilisation of genetic resources.
3. Internal guidance and procedures on seeking, keeping, and transferring all relevant project documentation
4. Project or programme documentation may include:
    a. Details of the genetic resource involved
    b. Date and place of access / acquisition
    c. Utilisation purposes
    d. IRCC, PIC, MAT, MTA or equivalent
    e. Where practicable, evidence why a project is out of scope of the ABS Regulations
    f. Evidence of issues encountered when dealing with provider parties to include correspondence with a provider country's NFP or CNA, inability to establish and / or clarify the provider country's legislative requirements etc.
5. Internal guidance on awareness raising to include through relevant training

7.2 Best Practice and Registered Collections

The ABS Regulations recognise that best practices developed by users play an important role in identifying due diligence measures. Practices are particularly suitable for achieving compliance with the system of implementation of the Nagoya Protocol at an affordable cost and with a high level of legal certainty. Furthermore, the implementation of a recognised best practice by a UK user reduces that user's risk of non-compliance and justifies a reduction in compliance checks by the OPSS.

The retained EU Regulation emphasises that collections are major suppliers of genetic resources and play an important role in helping other users in the chain of custody to comply with their obligations. It calls for the establishment of a voluntary

register of collections to be put in place in the UK (see Article 5). A system of registered collections within the UK should substantially lower the risk that genetic resources which were not accessed in accordance with the national access and benefit-sharing legislation or regulatory requirements of a Party to the Nagoya Protocol are utilised in the UK.

The retained EU Implementing Regulation sets out the procedures and criteria for UK organisations to apply for recognition of best practice and to request the registration of a collection in the UK. Where applicable, users are therefore encouraged to have best practice recognised or to register a collection in the UK as further evidence of compliance with the ABS Regulations. Further details, to include the application process, can be found on the OPSS website: https://www.gov.uk/guidance/abs.

7.3 Evidentiary considerations for being out of scope of the UK's ABS regulations

OPSS are using their legal authority to request information when they request entities to evidence why they are out of scope. By evidencing to OPSS why they are out of scope, users are evidencing how they are compliant with the ABS Regulations.

Table 1 below provides an overview of the potential reasons why a project may be considered to be out of scope of the ABS Regulations, together with examples for being out of scope. Please note this list is not exhaustive and other evidence may be permissible. See Chapter 3 for further information. To discuss case-specific queries, please contact OPSS: OPSS.enquiries@beis.gov.uk.

Generic scope elements	**Reasons for consideration as being out of scope**	**Examples of evidence which could be used to prove a project is out of scope**
Temporal scope	The genetic resource was accessed prior to 12 October 2014.	• Material Transfer Agreements (MTAs) • Postal records • Receipts • Invoices • Letters / correspondence with the collection / intermediary through which material was obtained • Research proposals • Published articles

Geographic scope	The provider country of the genetic resource is not a Party to the Protocol. The provider country does not have applicable access legislation in place. The genetic resource is in an area beyond national jurisdiction.	• MTAs • Research proposals • Letters / correspondence with the collection / intermediary through which material was obtained • Link to the ABS CH • Correspondence with the NFP
Material scope	The material does not meet the definition of a genetic resource. The genetic resource is human. The genetic resource (and its utilisation) is covered by an SII. [The material is DSI.]	• MTAs • Research proposals • Progress reports (to funders) • Patent applications • Published articles • [Links to and correspondence with websites / databases where DSI is obtained from]
Utilisation scope	The utilisation is identification. Research and development is not being conducted on the genetic and / or biochemical composition of the genetic resources. The research and development (utilisation) of the genetic resource does not create new insight into the characteristics of the genetic resource which is of (potential or real) benefit to the further process of product development.	• MTAs • Research proposals • Progress reports (to funders) • Published articles • Contract agreements
Place of utilisation	The utilisation of the genetic resources takes place outside of the UK.	• MTAs • Research proposals • Progress reports (to funders) • Contract agreements
User status	The utilisation is being conducted by a service provider (on behalf of the user).	• Contract agreements