ANNEX I

Information to be provided with a request for inclusion in the register of collections pursuant to Article 3(1)

PART A

Information to be included in the register

Pursuant to Article 3(1) the information to be provided with a request for inclusion in the register of collections is as follows:

1. Information on the holder of the collection (name, type of entity, address, e-mail, telephone number).

2. Information on whether the application concerns a collection or part of a collection.

3. Information on the collection or the relevant part thereof (name; identifier (code/ number), where available; address (es), website, where available; link to the collection's online database of genetic resources, where available).

4. A brief description of the collection or the relevant part thereof.

   Where only part of a collection is to be included in the register, details on the relevant part(s) and its(their) distinctive features should be provided.

5. Collection category

   The application should provide information on the category to which the collection or part thereof belongs.

Table of categories

		Specificities					
		Entire specimens (1)	Parts				
			Seeds, sexual spores, or embryos	Gametes ♀	Somatic cells	Nucleic acids	Other parts (2)
Animal	Vertebrate						
	Invertebrate						
Plants							
Algae							
Protista							
Fungi							
Bacteria							
Archaea							
Viruses							
Other groupings (3)							

Notes
(1) When no particular parts of a specimen are concerned, refer to the appropriate cell of 'entire specimens'.
(2) 'Other parts' include asexual reproductive parts, vegetative reproduction structures, such as stem, cutting, tuber, rhizomes.
(3) 'Other groupings' include slime molds, etc.

PART B

Evidence of the capacity of the collection or of the relevant part thereof to comply with Article 5(3) of Regulation (EU) No 511/2014

Any of the following documentation may be attached (or linked) to the application as evidence of the capacity of the collection or the relevant part thereof to comply with Article 5(3) of Regulation (EU) No 511/2014:

(a) codes of conduct, guidelines or standards, whether national or international, developed by associations or organisations, and adhered to by the collection, and information relating to the collection's instruments for the application of those codes of conduct, guidelines or standards;

(b) relevant principles, guidelines, codes of conduct or manuals of procedures, developed and applied within the collection, and any additional instruments for their application;

(c) certification of the collection under relevant schemes, whether national or international;

(d) information about participation of the collection in any international collection networks, and about associated applications for inclusion in the register of collections filed by partner collections in other Member States (optional);

(e) any other relevant documentation.

ANNEX II

Template for a due diligence declaration to be submitted at the stage of research funding pursuant to Article 5(2)

PART A

Information to be transmitted to the ABS Clearing House pursuant to Article 7(3) of Regulation (EU) No 511/2014

If the information provided is confidential within the meaning of Article 7(5) of Regulation (EU) No 511/2014, please provide it nonetheless, tick the respective box and provide the justification for confidentiality at the end of this Annex.

If you marked as confidential essential information (such as about the genetic resources or traditional knowledge associated with genetic resources, access place, form of utilisation), without which the record would not be published on the website of the ABS Clearing House, this information will not be shared with the ABS Clearing House, but it may be passed on directly to the competent authorities of the provider country.

At least one declaration is required per grant received, i.e. different recipients under one grant may choose to submit either individual declarations or a joint declaration, through the project coordinator.

I am making this declaration for the utilisation of:

Please tick the appropriate box or boxes:

☐ Genetic resources

☐ Traditional knowledge associated with genetic resources

1. Subject matter of the research or identification code of the grant:

   ☐ Confidential

2. Recipient or recipients of funding, including contact details:

   Name:

   Address:

   E-mail:

   Telephone:

   Website, where available:

3. Information on exercise of due diligence:

   (a) ☐ An internationally recognised certificate of compliance (i) was issued for my (entity's) access or (ii) covers the terms of this access to the genetic resource(s) and traditional knowledge associated with genetic resources.

   Where this box is ticked, please indicate the unique identifier of the internationally recognised certificate of compliance:

   Please go to point 1 of Part B.

   (b) Where the box in point (a) has not been ticked, please fill in the following information:

   (i) Place of access:

   ☐ Confidential

(ii) Description of the genetic resources or traditional knowledge associated with genetic resources utilised; or unique identifier(s), where available:

☐ Confidential

(iii) Identifier of access permit or its equivalent ([1]), where available:

☐ Confidential

Please go to point 2 of Part B.

PART B

Information not to be transmitted to the ABS Clearing House

1. I declare that I will keep and transfer to subsequent user(s) a copy of the internationally recognised certificate of compliance as well as information on the content of the mutually agreed terms relevant for subsequent users.

   Please go to point 3.

2. I declare that I am in possession of the following information, which I will keep and transfer to subsequent user(s):

   (a) date of access;

   (b) person or entity having granted prior informed consent, where applicable;

   (c) person or entity to whom prior informed consent was granted (where applicable), if not granted directly to me or my entity;

   (d) mutually agreed terms, where applicable;

   (e) the source from which I or my entity obtained the genetic resource and traditional knowledge associated with genetic resources;

   (f) presence or absence of rights and obligations relating to access and benefit-sharing, including rights and obligations regarding subsequent applications and commercialisation.

3. Where the genetic resource(s) was(were) obtained from a registered collection, please provide the registration code of the collection:

4. The research grant is funded by the following sources:

   Private ☐ Public ☐

5. Member State(s) in which the research involving utilisation of genetic resources and traditional knowledge associated with genetic resources takes place or has taken place:

Confidentiality

If you have declared that some information is confidential within the meaning of Article 7(5) of Regulation (EU) No 511/2014, please state the reasons for each piece of information for which you have declared that confidentiality applies:

Date:

Place:

Signature ([2]):

([1]) Evidence of the decision to grant prior informed consent or approval for access to genetic resources and traditional knowledge associated with genetic resources.

([2]) Signature of the recipient of funding or individual responsible within the research institution.

ANNEX III

Template for a due diligence declaration to be submitted at the stage of final development of a product pursuant to Article 6(1)

PART A

Information to be transmitted to the ABS Clearing House pursuant to Article 7(3) of Regulation (EU) No 511/2014

If the information provided is confidential within the meaning of Article 7(5) of Regulation (EU) No 511/2014, please provide it nonetheless, tick the respective box and provide the justification for confidentiality at the end of this Annex.

If you marked as confidential essential information (such as about the genetic resources or traditional knowledge associated with genetic resources, access place, form of utilisation) without which the record would not be published on the website of the ABS Clearing House, this information will not be shared with the Clearing House but it may be passed on directly to the competent authorities of the provider country.

If the utilisation has involved more than one genetic resource or any traditional knowledge associated with genetic resources, please provide relevant information for each genetic resource or any traditional knowledge utilised.

I declare that I have fulfilled the obligations under Article 4 of Regulation (EU) No 511/2014. I am making this declaration for the utilisation of:

Please tick the appropriate box or boxes:

☐ Genetic resources

☐ Traditional knowledge associated with genetic resources

1. Name of the product or description of the result of the utilisation ([1]) or description of the outcome of the utilisation ([2]):

   ☐ Confidential

2. Contact details of the user:

   Name:

   Address:

   E-mail:

   Telephone:

   Website, where available:

3. The declaration is made on the occasion of the following event:

   Please tick the appropriate box:

   ☐ (a) market approval or authorisation is sought for a product developed via the utilisation of genetic resources and traditional knowledge associated with genetic resources;

   ☐ (b) a notification required prior to placing for the first time on the Union market is made for a product developed via the utilisation of genetic resources and traditional knowledge associated with genetic resources;

([1]) 'Result of the utilisation of genetic resources and traditional knowledge associated with genetic resources' means products, precursors or predecessors to a product, as well as parts of products to be incorporated into a final product, blueprints or designs, based on which manufacturing and production could be carried out without further utilisation of the genetic resource and traditional knowledge associated with genetic resources.

([2]) Where the utilisation in the Union has ended and its outcome is sold or transferred in any other way to a natural or legal person outside the Union.

☐ (c) placing for the first time on the Union market a product developed via the utilisation of genetic resources and traditional knowledge associated with genetic resources, 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 Union in order for that person to carry out one of the activities referred to in points (a), (b) and (c);

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

4. Information on exercise of due diligence:

(a) ☐ An internationally recognised certificate of compliance (i) was issued for my (entity's) access or (ii) covers the terms of this access to the genetic resource(s) and traditional knowledge associated with genetic resources.

Where this box is ticked, please indicate the unique identifier of the internationally recognised certificate of compliance:

Please go to point 2 of Part B.

(b) Where the box in point (a) has not been ticked, please fill in the following information:

(i) Place of access:

☐ Confidential

(ii) Description of the genetic resource or traditional knowledge associated with genetic resources utilised, or unique identifier(s), where available:

☐ Confidential

(iii) Date of access:

☐ Confidential

(iv) Identifier of access permit or its equivalent [1], where available:

☐ Confidential

(v) Person or entity who granted prior informed consent:

☐ Confidential

(vi) Person or entity to whom the prior informed consent was granted:

☐ Confidential

(vii) Is the utilisation of genetic resources and traditional knowledge associated with genetic resources subject to mutually agreed terms?

Yes ☐ No ☐

☐ Confidential

Please go to point 1 of Part B.

[1] Evidence of the decision to grant prior informed consent or approval for access to genetic resources and traditional knowledge associated with genetic resources.

PART B

Information not to be transmitted to the ABS Clearing House

1. Information on exercise of due diligence:

   (a) Direct source of the genetic resource and the traditional knowledge associated with genetic resources:

   (b) Are there any restrictions in the mutually agreed terms limiting the possible utilisation of the genetic resource(s) or the traditional knowledge associated with genetic resources, e.g. allowing for non-commercial utilisation only?

   Yes ☐ No ☐ Not applicable ☐

   (c) Have there been rights and obligations agreed regarding subsequent applications and commercialisation in the mutually agreed terms?

   Yes ☐ No ☐ Not applicable ☐

2. If the genetic resource(s) was(were) obtained from a registered collection, please provide the registration code of the collection:

3. If you are implementing a best practice recognised under Article 8 of Regulation (EU) No 511/2014, please provide the registration number:

4. Which category best describes your product (optional)?

   ☐ (a) cosmetics

   ☐ (b) medicinal products

   ☐ (c) food and beverage

   ☐ (d) biological control

   ☐ (e) plant breeding

   ☐ (f) animal breeding

   ☐ (g) other, please specify:

5. Member State(s) in which the utilisation of genetic resources and traditional knowledge associated with genetic resources has taken place:

6. Member State(s) in which the product is to be placed on the market, following the procedure for approval, authorisation or notification referred to in Article 6(2)(a) and (b) of Commission Regulation (EU) 2015/1866 or placed on the market in accordance with Article 6(2)(c) of that Regulation:

Confidentiality

If you have declared that some information is confidential within the meaning of Article 7(5) of Regulation (EU) No 511/2014, please state the reasons for each piece of information for which you have declared that confidentiality applies:

Date:

Place:

Signature ([1]):

([1]) Signature of the person legally responsible for the stage of final development of a product.

ANNEX IV

Information to be provided with an application for recognition of best practice pursuant to Article 8(1)

Pursuant to Article 8(1) the information to be provided with the application for recognition of best practice is as follows:

1. Information whether the application is made on behalf of an association of users or other interested parties.

2. Contact details of the association of users or other interested parties (name, address, e-mail, telephone, and website, where available).

3. If the application is made by an association of users, the following should be provided:

   (a) evidence of being established in accordance with the requirements of the Member State in which the applicant is located;

   (b) description of the organisation and structure of the association.

4. If the application is made by other interested parties, the reasons for having legitimate interest in the subject matter of Regulation (EU) No 511/2014 should be explained.

5. The information provided should describe how the applicant is involved in developing measures and policies related to genetic resources, or how the applicant accesses, collects, transfers or commercialises genetic resources and traditional knowledge associated with genetic resources.

6. Description of the combination of procedures, tools or mechanisms, developed by the applicant, which, when effectively implemented, enable users to comply with the obligations provided for in Articles 4 and 7 of Regulation (EU) No 511/2014.

7. Description of how the overseeing of the procedures, tools or mechanisms referred to in point 6 will be carried out.

8. Information on Member State(s) in which the applicant is located and in which it operates.

9. Information on Member State(s) where the users implementing the best practice overseen by the association or the other interested party operate.

List of supporting documents related to points 5 and 6:

(a) list of relevant personnel working for organization applying or any sub-contractors, with description of their duties related to the development and overseeing of best practices;

(b) declaration of absence of conflict of interest, on the part of applicant and any sub-contractors, in developing and overseeing the combination of procedures, tools or mechanisms ([1]);

(c) where tasks related to development of best practices or overseeing such practices or both are sub-contracted, description of those tasks.

([1]) Payment of fees or voluntary contributions by users to an association should not be considered as creating a conflict of interest.