COMMISSION IMPLEMENTING REGULATION (EU) 2015/1866

of 13 October 2015

laying down detailed rules for the implementation of Regulation (EU) No 511/2014 of the European Parliament and of the Council as regards the register of collections, monitoring user compliance and best practices

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) No 511/2014 of the European Parliament and of the Council of 16 April 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 [1], and in particular Article 5(5), Article 7(6) and Article 8(7) thereof,

Whereas:

(1) Regulation (EU) No 511/2014 establishes rules governing compliance with access and benefit-sharing for genetic resources and traditional knowledge associated with genetic resources in accordance with the provisions of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (the 'Nagoya Protocol'). The effective implementation of that Regulation will also contribute to the conservation of biological diversity and the sustainable use of its components, in accordance with the provisions of the Convention on Biological Diversity.

(2) Articles 5 and 8 of Regulation (EU) No 511/2014 provide for voluntary tools, namely registered collections and best practices, to assist users in complying with their due diligence obligation. Identifying and registering collections which effectively apply measures that result in supplying genetic resources and related information only with documentation providing evidence of legal access and ensuring the establishment of mutually agreed terms, where required, is expected to assist users in complying with that obligation. Users which obtain genetic resources from a collection included in the register should be considered to have exercised due diligence as regards the seeking of information. Identifying and recognising as best practices measures that are particularly suitable for achieving compliance with the system of implementation of the Nagoya Protocol, at an affordable cost and with legal certainty, is also expected to assist users in fulfilling the due diligence obligation. The effective implementation of a recognized best practice by users should be considered by the competent authorities in their checks on user compliance. In order to ensure uniform conditions for the implementation of those provisions, detailed rules are required regarding the procedures to be followed in the case of a request for registration of a collection or part thereof and regarding recognition of best practices.

(3) Where an applicant wishing to be included in the register is a member of a network of collections, it is useful that such applicant provides information on any other collections or parts thereof from the same network that were or are the subject of an application in other Member States. In order to facilitate the fair and consistent treatment of applicants in different Member States, when verifying the collections or parts thereof, the competent authorities of the Member States that have been made aware of such applications in relation to different collections or parts thereof within a network should consider exchanging information with the authorities of those Member States in which applications have been made by other members of the network.

(4) Regulation (EU) No 511/2014 applies to genetic resources and to traditional knowledge associated with genetic resources. The material for the utilisation of which a due diligence declaration is required includes: genetic resources, traditional knowledge associated with genetic resources and a combination of both.

(5) In order to ensure uniform conditions for the implementation of provisions on monitoring user compliance, detailed rules are required regarding the declarations to be made by recipients of funding for research involving the utilisation of genetic resources and traditional knowledge associated with genetic resources, as well as

[1] OJ L 150, 20.5.2014, p. 59.

regarding the declarations to be made by users at the stage of final development of a product developed via the utilisation of genetic resources and traditional knowledge associated with genetic resources.

(6) When monitoring user compliance at the stage of research funding, it is important to ensure that recipients of funding understand their obligations under Regulation (EU) No 511/2014 and that they exercise due diligence. It is equally important to provide information to the Access and Benefit-Sharing Clearing House ('ABS Clearing House'), and to ensure that such information is useful for the functioning and implementation of the Nagoya Protocol. Where an internationally recognised certificate of compliance is not available, other relevant information should be submitted. In order to balance the objectives of submitting useful information to the ABS Clearing House and of not overburdening the recipients of funding for research, only information which is essential for the identification of genetic resources should be exchanged at this check-point.

(7) The monitoring of user compliance is effective when carried out in the Member State where the utilisation takes place. It is therefore appropriate that the declaration of due diligence is submitted to the competent authority of the Member State where the recipient of funding is established, as this is where the research involving utilisation of genetic resources and traditional knowledge associated with genetic resources typically takes place.

(8) The unnecessary multiplication of due diligence declarations should be avoided. Therefore, a declaration made by recipients of research funding may cover more than one genetic resource or any traditional knowledge associated with genetic resources. A single declaration may also be made by several users jointly conducting research involving the utilisation of genetic resources and traditional knowledge associated with genetic resources funded by one grant. In this context, a special role should be given to the project co-ordinator, who should be responsible for submitting the declarations on behalf of the users concerned. In the light of Article 12 of Regulation (EU) No 511/2014, the competent authority receiving the declarations submitted by the project co-ordinator should exchange the information with its counterparts in the other Member States concerned.

(9) In order to monitor user compliance under Article 7(2) of Regulation (EU) No 511/2014, the final stage of utilisation, meaning the stage of final development of a product should be determined. The stage of final development of a product can be identified with legal certainty as having been completed at the time when either market approval or authorisation is sought or a notification required prior to placing for the first time on the Union market is made or, where neither market approval or authorisation nor a notification is required, at the time of 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. In some cases, it may not be the user that is requesting market approval or authorisation, making a notification or placing a product for the first time on the Union market. In order to effectively address all activities that utilise genetic resources and traditional knowledge associated with genetic resources within the Union, the due diligence declaration should, in those cases, be made by the user selling or transferring in any other way the result of the utilisation. Effective monitoring of user compliance within the Union should also address cases where the utilisation has ended in the Union and its outcome is sold or transferred in any other way outside the Union without placing a product on the Union market.

(10) Those different events that give rise to the due diligence declaration by the user at the stage of final development of a product are exclusive of each other, and therefore the declaration should only be made once. As the stage of final development of a product is reached before any of those events occur, the due diligence declaration should be made prior to the first event occurring.

(11) The information provided in the due diligence declarations is to be submitted by the competent authorities to the ABS Clearing House pursuant to Article 7(3) of Regulation (EU) No 511/2014. Where an internationally recognised certificate of compliance is not available, other relevant information provided in accordance with Article 17(4) of the Nagoya Protocol, as specified in Article 4(3)(b) of Regulation (EU) No 511/2014, should be submitted. In order to ensure efficient operation of the Nagoya Protocol and the ABS Clearing House in particular, only information which will facilitate the monitoring by the competent national authorities referred to in Article 13(2) of the Nagoya Protocol should be exchanged.

(12) A due diligence declaration is required only for genetic resources or traditional knowledge associated with genetic resources obtained from a Party to the Nagoya Protocol that has established relevant access and benefit-sharing legislation or regulatory requirements pursuant to Article 6(1) and Article 7 of the Nagoya Protocol.

(13) In the light of the novelty of measures introduced, it is appropriate to review this Regulation. In this context, the reports referred to in Article 16(1) of Regulation (EU) No 511/2014 may prove useful and therefore should be taken into account, where available.

(14) The measures provided for in this Regulation are in accordance with the opinion of the ABS Committee,

HAS ADOPTED THIS REGULATION:

Article 1

Subject matter

This Regulation lays down detailed rules concerning the implementation of Articles 5, 7 and 8 of Regulation (EU) No 511/2014 which refer to the register of collections, the monitoring of user compliance, and to best practices.

Article 2

Register of collections

The register established by the Commission in accordance with Article 5 of Regulation (EU) No 511/2014 shall include the following information for each collection or part thereof:

(a) a registration code assigned by the Commission;

(b) name given to the collection or part thereof and its contact details;

(c) name and contact details of the holder;

(d) category of the collection or part thereof;

(e) short description of the collection or part thereof;

(f) link to database, where available;

(g) institution within competent authority of the Member State that verified the capacity of the collection to comply with Article 5(3) of Regulation (EU) No 511/2014;

(h) date of inclusion in the register;

(i) other existing identifier, where available;

(j) where applicable, date of removal from the register.

Article 3

Request for inclusion in the register and notification to the Commission

1. A request for inclusion of a collection or a part thereof in the register, referred to in Article 5(2) of Regulation (EU) No 511/2014, shall contain the information specified in Annex I to this Regulation.

Following the inclusion in the register of a collection or a part thereof, the collection holder shall notify the competent authority of any significant changes that influence the collection's capacity to comply with the criteria set out in Article 5(3) of Regulation (EU) No 511/2014 and of any changes to the information previously submitted on the basis of Part A of Annex I to this Regulation.

2. Where an applicant is a member of a network of collections, when applying for inclusion of a collection or a part thereof in the register, the applicant may inform the competent authorities about any other collections or parts thereof from the same network that were or are the subject of an application in other Member States for inclusion in the register.

When verifying the collections or parts thereof, the competent authorities of Member States that have been made aware of such applications, shall consider exchanging information with the competent authorities of those Member States where the other applications from the network have been made.

3. The verification referred to in Article 5(2) of Regulation (EU) No 511/2014 may include the following:

(a) on-the-spot checks;

(b) examination of selected documentation and records of a collection or part thereof, which are relevant for demonstrating compliance with Article 5(3) of Regulation (EU) No 511/2014;

(c) examination of whether selected samples of genetic resources and related information of the collection concerned have been documented in accordance with Article 5(3) of Regulation (EU) 511/2014;

(d) examination of whether the collection holder has the capacity to consistently supply genetic resources to third persons for their utilisation in accordance with Article 5(3) of Regulation (EU) No 511/2014;

(e) interviews with relevant persons, such as the collection holder, staff, external verifiers, and users obtaining samples from that collection.

4. For the purposes of the notification referred to in Article 5(2) of Regulation (EU) No 511/2014, the competent authority shall provide the Commission with the information submitted by the collection holder on the basis of Part A of Annex I to this Regulation. The competent authority shall notify the Commission of any subsequent changes to that information.

Article 4

Checks on registered collections and remedial actions

1. The verification referred to Article 5(4) of Regulation (EU) No 511/2014 by the competent authorities shall be effective, proportionate and capable of detecting cases of non-compliance with Article 5(3) of that Regulation. It shall be conducted on the basis of a periodically reviewed plan developed using a risk-based approach. The plan should provide for a minimum level of checks and allow for differentiation in the frequency of checks.

2. Where there are substantiated concerns that a collection or part thereof included in the register no longer meets the criteria set out in Article 5(3) of Regulation (EU) No 511/2014, the competent authority shall carry out additional verification.

3. The verification referred to in paragraph 1 and 2 may include the following:

(a) on-the-spot checks;

(b) examination of selected documentation and records of a collection or part thereof, which are relevant for demonstrating compliance with Article 5(3) of Regulation (EU) No 511/2014;

(c) examination of whether selected samples of genetic resources and related information have been documented and supplied to third persons for their utilisation in accordance with Article 5(3) of Regulation (EU) No 511/2014;

(d) interviews with relevant persons, such as the collection holder, staff, external verifiers, and users obtaining samples from that collection.

4. The collection holder and its staff shall provide all assistance necessary to facilitate the verification referred to in paragraphs 1, 2 and 3.

5. Remedial actions or measures referred to in Article 5(4) of Regulation (EU) No 511/2014 shall be effective and proportionate and address shortcomings which, if left unaddressed, would permanently compromise the capacity of a registered collection to comply with Article 5(3) of that Regulation. They may require the collection holder concerned to put in place additional tools or to improve its capacity to apply existing tools. The collection holder shall report to the competent authority on the implementation of the identified remedial actions or measures.

Article 5

Due diligence declaration at the stage of research funding

1. A recipient of funding for research involving the utilisation of genetic resources and traditional knowledge associated with genetic resources shall make the due diligence declaration requested pursuant to Article 7(1) of Regulation (EU) No 511/2014 to the competent authority of the Member State in which the recipient is established. If the recipient is not established in the Union and the research is carried out in the Union, the due diligence declaration shall be made to the competent authority of the Member State in which the research is carried out.

2. The due diligence declaration shall be made by submitting the completed template set out in Annex II. It shall be made after the first instalment of funding has been received and all the genetic resources and traditional knowledge associated with genetic resources that are utilised in the funded research have been obtained, but no later than at the time of the final report, or in absence of such report, at the project end. The time of submission of such declaration may be further specified by the national authorities.

3. Where the same research project is funded from more than one source or involves more than one recipient, the recipient(s) may decide to make only one declaration. That declaration shall be submitted by the project co-ordinator to the competent authority of the Member State in which the project co-ordinator is established. If the project co-coordinator is not established in the Union and the research is carried out in the Union, the due diligence declaration shall be made to the competent authority of one of the Member States in which the research is carried out.

4. Where the competent authority that receives the declaration referred to in paragraphs 2 and 3 is not responsible for its transmission pursuant to Article 7(3) of Regulation (EU) No 511/2014, it shall forward that declaration to the competent authority responsible for such transmission without undue delay.

5. For the purposes of this Article and Annex II, '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

Article 6

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

1. For the utilisation of genetic resources and traditional knowledge associated with genetic resources users shall make the due diligence declaration pursuant to Article 7(2) of Regulation (EU) No 511/2014 to the competent authority of the Member State in which the user is established. That declaration shall be made by submitting the completed template set out in Annex III to this Regulation.

2. The due diligence declaration referred to in paragraph 1 shall only be made once, prior to the first of the following events occurring:

(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;

(c) placing on the Union market for the first time 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 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.

3. For the purposes of this Article and Annex III, 'result of the utilisation' 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.

4. For the purposes of this Article and Annex III, 'placing on the Union market' means the first making available of a product developed via utilisation of genetic resources and traditional knowledge associated with genetic resources on the Union market, where making available means the supply by any means, for distribution, consumption or use on the Union 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, nor the making available of unauthorised medicinal products in order to provide treatment options for individual patients or groups of patients.

Article 7

Transmission of information

1. In accordance with Article 7(3) of Regulation (EU) No 511/2014, and unless the information is confidential within the meaning of Article 7(5) of Regulation (EU) No 511/2014, the competent authorities shall transmit to the ABS Clearing House the information received on the basis of Part A of Annexes II and III to this Regulation without undue delay and at the latest one month after the information has been received.

2. Where essential information, such as on the user and utilisation, on the place of access, or on the genetic resource, without which the record could not be published on the ABS Clearing House, is considered confidential, the competent authorities shall consider instead transmitting that essential information directly to the competent national authorities referred to in Article 13(2) of the Nagoya Protocol.

3. In accordance with Article 7(3) of Regulation (EU) No 511/2014, the competent authorities shall transmit to the Commission the information received on the basis of Annexes II and III to this Regulation, unless such information is confidential within the meaning of Article 7(5) of Regulation (EU) No 511/2014.

4. Where the Commission is not provided access to this information on a permanent basis through electronic means, such transmission shall be made once every six months, starting from 9 November 2016.

Article 8

Application for recognition of a best practice

1. An application submitted in accordance with Article 8(1) of Regulation (EU) No 511/2014 shall be made to the Commission by providing the information and supporting documentation specified in Annex IV to this Regulation.

2. An interested party that does not represent users but is involved in the access, collection, transfer or commercialisation of genetic resources or in developing measures and policy related to genetic resources shall provide with its application information, as specified in Annex IV to this Regulation, on its legitimate interest in developing and overseeing a combination of procedures, tools or mechanisms, which, when effectively implemented by a user, enables that user to comply with the obligations provided for in Articles 4 and 7 of Regulation (EU) No 511/2014.

3. The Commission shall send a copy of the application and supporting documentation to the competent authorities of all the Member States.

4. The competent authorities may submit comments to the Commission regarding the application within two months of receiving the documents referred to in paragraph 3.

5. The Commission shall acknowledge receipt of an application and provide the applicant with a reference number within 20 working days from the date of receipt of the application.

The Commission shall provide the applicant with an indicative time limit within which a decision on the application will be taken.

The Commission shall inform the applicant if additional information or documentation is required in order for it to carry out the assessment of the application.

6. The applicant shall submit to the Commission any additional information and documentation requested without undue delay.

7. The Commission shall send a copy of the documents referred to in paragraph 6 to the competent authorities of all the Member States.

8. The competent authorities may submit comments to the Commission regarding the information or documentation referred to in paragraph 6 within two months of receiving the copy of those documents.

9. The Commission shall inform the applicant each time it revises the indicative time limit within which a decision on the application will be taken due to the necessity to obtain additional information or documents for the assessment of the application.

The Commission shall inform the applicant in writing of the status of the assessment of the application at least every six months.

Article 9

Recognition and withdrawal of recognition as best practice

1. Where the Commission decides to grant recognition as best practice under Article 8(2) of Regulation (EU) No 511/2014 or to withdraw the recognition of best practice under Article 8(5) of that Regulation, the Commission shall inform of that decision without undue delay the association of users or the other interested parties, as well as the competent authorities of the Member States.

2. The Commission shall state reasons for its decision to grant recognition as best practice or to withdraw the recognition of best practice and it shall publish that decision in the register established under Article 8(6) of Regulation (EU) No 511/2014.

Article 10

Information on subsequent changes to a recognised best practice

1. Where the Commission is informed, pursuant to Article 8(3) of Regulation (EU) No 511/2014, of any changes or updates made to a recognized best practice, the Commission shall send a copy of that information to the competent authorities of all the Member States.

2. The competent authorities may submit comments to the Commission regarding such changes or updates within two months of receiving the information.

3. The Commission shall assess, taking into consideration the comments referred to in paragraph 2 of this Article, whether the changed or updated combination of procedures, tools or mechanisms still enables users to comply with their obligations provided for in Articles 4 and 7 of Regulation (EU) No 511/2014.

4. The competent authorities shall inform the Commission without undue delay of any information resulting from checks carried out pursuant to Article 9 of Regulation (EU) No 511/2014 indicating non-compliance with Articles 4 and 7 of that Regulation, which may indicate possible deficiencies in the best practice.

Article 11

Deficiency in best practice

1. Where the Commission receives substantiated information regarding repeated or significant cases of non-compliance with Articles 4 and 7 of Regulation (EU) No 511/2014 by a user implementing a best practice, the Commission shall request the association of users or the other interested parties to submit observations regarding the alleged non-compliance and whether those cases indicate possible deficiencies in the best practice.

2. Where the association of users or the other interested parties submit observations, they shall do so within three months.

3. The Commission shall examine those observations and any supporting documentation and send copies thereof to the competent authorities of all the Member States.

4. The competent authorities may submit comments to the Commission regarding those observations and supporting documentation within two months of receiving the copy of those documents.

5. Where the Commission examines possible deficiencies in a best practice and cases of non-compliance with the obligations provided for in Articles 4 and 7 of Regulation (EU) No 511/2014, as referred to in Article 8(4) of that Regulation, the association of users or the other interested parties subject to examination shall co-operate with the Commission and assist it in its actions. Where the association of users or the other interested parties subject to examination fails to do so, the Commission may, without further consideration, withdraw recognition of the best practice.

6. The results of the examination carried out by the Commission shall be conclusive and shall include any remedial actions to be taken by the association of users or the other interested parties. The examination may also result in a decision to withdraw recognition of the best practice.

Article 12

Review

The Commission shall review the functioning and effectiveness of this Regulation, taking into account the experience gathered in its implementation and with a view to its potential revision. Such review should consider the impact of this Regulation on micro, small and medium-sized enterprises, public research institutions and specific sectors, as well as relevant developments at the international level, in particular those related to the ABS Clearing House.

Article 13

Entry into force

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 13 October 2015.

For the Commission
The President
Jean-Claude JUNCKER

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.