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

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

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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 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

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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.

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(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.

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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;