Discussion paper for the stakeholder meeting of 9 December 2014

Background

Regulation (EU) No 511/2014 (hereafter: the basic Regulation) 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 ('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 ('Convention').

The Commission is tasked with adopting implementing provisions in relation to Articles 5, 7, and 8 of the basic Regulation. For the purpose of the implementing regulation the competent authorities are the competent authorities designated by Member States in accordance with Article 6 of the basic Regulation. The implementing act is expected to enter into force in October 2015. Its draft provisions are summarised below.

Voluntary tools to assist compliance

Articles 5 and 8 of the basic Regulation provide for voluntary tools to assist users in complying with their due diligence obligation. This includes identifying and registering collections as suppliers of genetic resources that effectively apply measures restricting the supply of samples of genetic resources to third persons with documentation providing evidence of legal access, and who ensure the establishment of mutually agreed terms, where required. This also includes identifying and recognising as best practice measures that 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. In order to ensure uniform conditions for the implementation of those provisions, detailed provisions 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.

Monitoring user compliance

To ensure uniform implementation of the basic Regulation, it is necessary to clarify the conditions for implementing the provisions on monitoring user compliance as regards the declarations to be made (1) by recipients of research funding involving the utilisation of genetic resources and traditional knowledge associated with genetic resources as well as (2) 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.

In order to identify the final stage of utilisation in different sectors, the stage of final development of a product under Article 7(2) of the basic Regulation needs to be determined. The final stage of utilisation, meaning the stage of final development of a product can be identified with legal clarity at the time (1) when either market approval is sought or, (2) when

a notification required prior to placing for the first time on the Union market is made or, (3) where neither market approval nor a notification are required, at the time of placing for the first time on the Union market a product developed via the utilisation of genetic resources and/or traditional knowledge associated with genetic resources.

In some sectors the person utilising genetic resources and traditional knowledge associated with genetic resources may not be the one requesting market approval, 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 declaration should, in those cases, be made by the person selling or in any other form transferring the result of the utilisation to another person that carries out those activities. Effective monitoring of user compliance within the Union must also address cases where the result of the utilisation is sold or in any other form transferred outside the Union without placing a product on the Union market.

In order to ensure consistency of treatment of products placed on the Union market, the declaration should also be made when the development of a product has taken place outside the Union.

The triggering events for the due diligence declaration at the stage of final development of a product are mutually exclusive. This declaration will therefore only have to be made once.

Substance

Article 5 of the basic Regulation - register of collections

Register of collections

As to the register of collections, established based on Article 5 of the basic Regulation, it will have to include the following information (per collection and part thereof):

(a) a registration code assigned by the Commission;

(b) name and contact details of the collection or part thereof;

(c) name and contact details of the holder of the collection or part thereof;

(d) type of collection;

(e) competent authority of a Member State, which verified the collection or part thereof;

(f) date of inclusion of the collection or part thereof into the register;

(g) other existing identifier of the collection, where available;

(h) where applicable, date of removal of the collection or part thereof from the register.

Request for inclusion in the register of collections

A request for inclusion of a collection or a part thereof in the register will have to contain the basic information about the collection, i.e.: name of the collection (or part thereof), identifier (if available), address and website. Further, the request will have to contain information on the holder of the collection (or a part thereof), so similarly as above: name, address, e-mail address and telephone number, as well as information on legal personality.

In a situation where only part of a collection is to be included in the register, the description and the distinctive (biological) features of that part will have to be specified.

Further, the applicant will be asked to provide information on the type of the collection, having the choice to tick one or more of the following boxes:

(a) Animal ☐
  (i) Sperm/semen ☐
  (ii) Ovule ☐
  (iii) Vertebrates ☐
  (iv) Invertebrates ☐
(b) Plants and similar ☐
  (i) Plants/seeds ☐
  (ii) Algae ☐
(c) Microorganisms ☐
  (i) Cyanobacteria ☐
  (ii) Bacteria ☐
(d) Fungi ☐
(e) Viruses ☐
(f) Nucleic acids ☐
(g) Other – (specification)

Following a request for inclusion, the collection holder will have to notify the competent authority of any changes which influence the collection's capacity to comply with the criteria set out in Article 5(3) of the basic Regulation and of any changes in the information previously submitted to the competent authority (as described above).

For the purposes of the notification of the collection by a competent authority to the Commission (i.e. the notification referred to in Article 5(2) of the basic Regulation), a competent authority will have to provide the Commission with a signed confirmation that the collection or part thereof has been verified by them and found to meet the criteria set out in Article 5(3) of the basic Regulation. Competent authorities will have to notify the Commission of any subsequent changes to the information submitted to them by the collection (as described above).

In addition, the act will specify the indicative documents demonstrating the capacity of a collection or a part thereof to comply with the requirements of Article 5(3) of the basic Regulation, such as:

1. Codes of conduct, manuals of procedures, etc.
2. Model contracts.
3. ISO certification or other certification system.
4. Indication of compliance with standards of a relevant standardisation organisation.

Frequency and nature of checks on collections

Competent authorities will have to carry out the verification referred to in Article 5(4) of the basic Regulation regularly, at least once every three years per collection or part thereof.

Where there are substantiated concerns that a collection included in the register does not meet the criteria set out in Article 5(3) of the basic Regulation, the competent authority will have to carry out additional verification.

For this verification to be effective, proportionate and capable of detecting cases of non-compliance with Article 5(3) of the basic Regulation, it will have to include the following, as appropriate:

(a) on-the-spot checks;

(b) examination of documentation and records of a collection and of the collection holder, which are relevant for demonstrating compliance with Article 5(3) of the basic Regulation;

(c) examination of whether samples of genetic resources and related information of the collection concerned have been properly documented;

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

Further, the collection holder and its staff will have to provide all assistance necessary to facilitate the performance of the verification referred above.

Remedial actions

Remedial actions or measures referred to in Article 5(4) of the basic Regulation can be any of the following:

(a) revision of the measures taken by the collection in order to comply with Article 5(3) of the basic Regulation;

(b) additional verification or third-party verification of compliance with Article 5(3) of the basic Regulation;

(c) requirement of additional reports from the collection holder on significant changes or updates in the collection, in order to comply with Article 5(3) of the basic Regulation.

The competent authority can take immediate interim measures.

Article 7 of the basic Regulation – monitoring user compliance

Due diligence declaration at the stage of research funding

The declaration requested by Member States and the Commission referred to in Article 7(1) of the basic Regulation is to be made upon first receipt of research funding by the recipients of research funding involving the utilisation of genetic resources and/or traditional knowledge associated with them by way of submitting a completed form. The draft templates for these forms are in Annex A and B to this discussion paper.

If at the time of first receipt of research funding, the recipient has not yet obtained the genetic resource and/or traditional knowledge associated with genetic resources involved in the utilisation, the request referred to in Article 7(1) of the basic Regulation will have to specify the point in time at which the declaration will be made. That point in time will have to be at the latest when the recipient of research funding involving utilisation of genetic resources has obtained the genetic resources and /or traditional knowledge associated with genetic resources.

Where research funding is provided from both public and private sources, a separate declaration for the privately funded part will not be requested.

Where a Member State determines that the declaration is not to be made directly to the competent authority responsible for the transmission under Article 7(3) of the basic Regulation (transmission to the ABS Clearing House), the designated addressee of the declaration will have to submit a copy of the declaration to that competent authority without undue delay.

Where research funding is provided by both the Union and by one or several Member States, the declaration will have to be submitted to the competent authority of the Member State in whose territory the recipient of research funding is established.

Where research funding is provided exclusively by the Union, the declaration will have to be submitted to the funding institution which provided the research funding. That institution will have to forward a copy of the declaration to the competent authority of the Member State in whose territory the recipient of research funding is established.

Where research is funded exclusively by private sources, the declaration is to be submitted to the competent authority of the Member State in whose territory the recipient of research funding is established.

Where the recipient of research funding provided by the Union and/or by one or several Member States is not established in the Union, the declaration is to be made to the funding institution. This funding institution will transmit it to the competent authority of the Member State in whose territory it is established.

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

For utilisation of genetic resources, users will have to make the declaration referred to in Article 7(2) of the basic Regulation by submitting to the competent authority a completed form, a draft template set out in Annex C to this discussion paper.

For utilisation of traditional knowledge associated with genetic resources, users will have to make the declaration referred to in Article 7(2) of the basic Regulation by submitting to the competent authority a completed form, a draft template of which is set out in Annex D to this discussion paper.

The declarations referred above are to be made only once. Depending on the circumstances, they will have to be made when any of the following events occurs for the first time:

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

(c) placing for the first time on the Union market a product developed via the utilisation of genetic resources and/or traditional knowledge associated with genetic resources, for which no market approval or notification is required;

(d) the result of the utilisation is sold or in any other form transferred 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 result of the utilisation is sold or in any other form transferred to a natural or legal person outside the Union.

Where the utilisation has taken place outside of the Union, the declaration is to be made to the competent authority of the Member State through which the product enters the Union.

A voluntary declaration may also be made where the utilisation is permanently ended without finalising the development of a product or where the user considers that the stage of final development of a product has been reached.

Placing for the first time on the Union market is to be understood as the supply by any means, irrespective of the technique used, for distribution or use in the course of a commercial activity, whether in return for payment or free of charge including for incorporation into a final product, for further processing or refinement prior to placing on the market.

Transmission of information to the ABS Clearing House

For the purposes of Article 7(3) of the basic Regulation, the competent authorities will have to transmit to the addressees specified in Article 7(3) of that Regulation the information received on the basis of part A of Annexes (here part A of Annex A, B, C and/or D to this discussion paper), unless the information is confidential. The competent authorities will have to transmit the information received without undue delay and at the latest one month after the information was received.

Competent authorities will also have to transfer the information to the ABS Clearing House where they have received the information from funding institutions in cases where research

funding is provided exclusively by the Union and where the recipient of funding is established outside of the Union.

Article 8 of the basic Regulation – best practices

Application for recognition of a best practice

An application by associations of users or other interested parties submitted in accordance with Article 8(1) of the basic Regulation is to be made to the Commission by providing the information and documentation specified (see below). In particular, an application submitted by other interested parties which do not represent users, will have to include details on the legitimate interest in developing and overseeing a combination of procedures, tools or mechanisms, which, when effectively implemented by users, enables these users to comply with their obligations under Articles 4 and 7 of the basic Regulation.

Information required to be submitted with an application for recognition of best practice

The information provided will have to include the indication whether the application is received from associations of users or from other interested parties. An association of users needs to describe the organization and its structure. Other interested parties need to specify why *at least one* of the following conditions is fulfilled: (1) they have legitimate interest in the subject matter of the basic Regulation (and provide the reasons for), (2) they either access, collect, transfer, or commercialise genetic resources or traditional knowledge associated with genetic resources, which must be further detailed.

The association of users or the other interested party will be required to provide contact details (name, address, e-mail, telephone, website, where available).

Further, the applicants will be required to state whether they are established in accordance with the requirements of the Member State, in which they are located (including providing supporting evidence and information). In such a case, the applicants are asked to specify their legal nature.

The applicants are also required to provide a description of the combination of procedures, tools or mechanisms they have developed, which, when effectively implemented, enable users to comply with their obligations under Articles 4 and 7 of the basic Regulation and how they will ensure the oversight[1] of the procedures, tools or mechanisms referred above.

Further, the applicants are to provide information on Member States, in which they are located and in which they operate, including information on Member States, where the users implementing a best practice overseen by them operate.

The supporting information to be provided includes:

1. List of competent personnel with copies of CVs, accompanied by a description of their duties.

2. Where tasks are sub-contracted, description of these tasks and evidence that all subcontractors meet the relevant requirements listed.

[1] E.g. including record keeping system or control system.

3. Declaration of absence of conflict of interest in overseeing the implementation of the combination of procedures, tools or mechanisms.

4. Description of the written policies and procedures for avoidance of conflict of interest at organisational and individual level, which may include third party audits.

5. Copies of financial statements for the last two financial years or other substantiating documents where financial statements are not required due to the legal status of the applicant.

Applicants will have to send a copy of the application and supporting documentation to the competent authority of the Member State in which they are located at the time when the application is submitted to the Commission.

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

The Commission will have to inform the applicant if additional information or documents are required in order to carry out the assessment of the application. The applicant is required to submit any additional information and documents requested to the Commission without undue delay and provide at the same time a copy of these documents to the competent authority of the Member State in which the applicant is located.

The competent authority of a Member State which receives a copy of an application submitted in accordance with this Article may provide comments to the Commission within two months of receiving the copy of the application.

Recognition and withdrawal of recognition as best practice

Where the Commission makes a decision to grant recognition as best practice under Article 8(2) of the basic Regulation or to withdraw the recognition of a best practice under Article 8(5) of that Regulation, it will have to inform the association of users or other interested parties respectively, as well as the competent authority of the Member State, in which the association or other interested parties are located of that decision without undue delay. The Commission will have to publish that decision in the register established under Article 8(6) of the basic Regulation.

Information on subsequent changes to a recognised best practice

Where the Commission is informed of any changes or updates in accordance with Article 8(3) of the basic Regulation and taking into consideration comments received from the competent authorities of the Member State in which the applicant is located, as well as information received as a result of checks carried out under Article 9 of the basic Regulation (see below), it will have to assess the following:

(a) whether the change or update made to the combination of procedures, tools or mechanisms still enable users to comply with their obligations under Articles 4 and 7 of the basic Regulation;

(b) whether the association of users or the other interested parties are still able to fulfil their oversight functions to ensure that, when effectively implemented, the combination of procedures, tools or mechanisms enables the user to comply with its obligations under Articles 4 and 7 of the basic Regulation.

Where information is provided to the Commission based on Article 8(3) of the basic Regulation, a copy of that information is to be submitted by the applicant to the competent

authority of the Member State in which the applicant is located. Where competent authorities wish to submit comments to the Commission regarding changes or updates made to the recognised best practice, they will have do so within two months of receiving the information.

Competent authorities will have to inform the Commission without undue delay of any information resulting from checks carried out based on Article 9 of the basic Regulation indicating non-compliance with Articles 4 and 7 of this Regulation as these may indicate possible deficiencies in the best practice.

Deficiency in best practice

Where the Commission receives information regarding repeated or significant cases of non-compliance with Articles 4 and 7 of the basic Regulation by a user implementing a best practice, the Commission will have to request the association of users or the other interested parties to submit observations regarding the alleged non-compliance within two months. The association of users or other interested parties will have to submit a copy of those observations and supporting documentation to the competent authority of the Member State in which they are located. Where a competent authority wishes to submit observations to the Commission regarding this submission, they will have do so within two months of receiving a copy of these documents. The result of this examination is to be conclusive and to include recommendations regarding measures to be taken, which may include a recommendation to withdraw recognition of the best practice.

Where the Commission examines possible deficiencies in a best practice and cases of non-compliance with the obligations in Articles 4 and 7 of the basic Regulation, the association of users or the other interested parties subject to examination will have to co-operate with the Commission and assist the Commission in its actions. The Commission will have to consider the need for remedial actions to be taken by the association of users or the other interested parties. Where the association of users or the other interested parties subject to examination fail to cooperate with the Commission and to provide the necessary information and documents, the Commission may, without further consideration, withdraw recognition of a best practice.