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 (Text with EEA relevance)

CHAPTER I

SUBJECT MATTER, SCOPE AND DEFINITIONS

Article 1

Subject matter

This 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 (the 'Nagoya Protocol'). The effective implementation of this 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 (the 'Convention').

Article 2

Scope

1 This Regulation applies to genetic resources over which States exercise sovereign rights and to traditional knowledge associated with genetic resources that are accessed after the entry into force of the Nagoya Protocol for the Union. It also applies to the benefits arising from the utilisation of such genetic resources and traditional knowledge associated with genetic resources.

2 This Regulation does not apply to genetic resources for which access and benefit-sharing is governed by specialised international instruments that are consistent with, and do not run counter to the objectives of the Convention and the Nagoya Protocol.

3 This Regulation is without prejudice to Member States' rules on access to genetic resources over which they exercise sovereign rights within the scope of Article 15 of the Convention, and to Member States' provisions on Article 8(j) of the Convention concerning traditional knowledge associated with genetic resources.

4 This Regulation applies to genetic resources and traditional knowledge associated with genetic resources to which access and benefit-sharing legislation or regulatory requirements of a Party to the Nagoya Protocol are applicable.

5 Nothing in this Regulation shall oblige a Member State to supply information the disclosure of which it considers contrary to the essential interests of its security.

Article 3

Definitions

For the purposes of this Regulation, the definitions of the Convention and the Nagoya Protocol as well as the following definitions apply:

(1) ‘genetic material’ means any material of plant, animal, microbial or other origin containing functional units of heredity;

(2) ‘genetic resources’ means genetic material of actual or potential value;

(3) ‘access’ means the acquisition of genetic resources or of traditional knowledge associated with genetic resources in a Party to the Nagoya Protocol;

(4) ‘user’ means a natural or legal person that utilises genetic resources or traditional knowledge associated with genetic resources;

(5) ‘utilisation of genetic resources’ means to conduct research and development on the genetic and/or biochemical composition of genetic resources, including through the application of biotechnology as defined in Article 2 of the Convention;

(6) ‘mutually agreed terms’ means the contractual arrangements concluded between a provider of genetic resources, or of traditional knowledge associated with genetic resources, and a user, that set out specific conditions for the fair and equitable sharing of benefits arising from the utilisation of genetic resources or of traditional knowledge associated with genetic resources, and that may also include further conditions and terms for such utilisation as well as subsequent applications and commercialisation;

(7) ‘traditional knowledge associated with genetic resources’ means traditional knowledge held by an indigenous or local community that is relevant for the utilisation of genetic resources and that is as such described in the mutually agreed terms applying to the utilisation of genetic resources;

(8) ‘illegally accessed genetic resources’ means genetic resources and traditional knowledge associated with genetic resources which were not accessed in accordance with the national access and benefit-sharing legislation or regulatory requirements of the provider country that is a Party to the Nagoya Protocol requiring prior informed consent;

(9) ‘collection’ means a set of collected samples of genetic resources and related information that is accumulated and stored, whether held by public or private entities;

(10) ‘association of users’ means an organisation, established in accordance with the requirements of the Member State in which it is located, that represents the interests of users and that is involved in developing and overseeing the best practices referred to in Article 8 of this Regulation;

(11) ‘internationally recognised certificate of compliance’ means a permit or its equivalent issued at the time of access as evidence that the genetic resource it covers has been accessed in accordance with the decision to grant prior informed consent, and that mutually agreed terms have been established for the user and the utilisation specified therein by a competent authority in accordance with Article 6(3)(e) and Article 13(2) of the Nagoya Protocol, that is made available to the Access and Benefit-sharing Clearing House established under Article 14(1) of that Protocol.

CHAPTER II

USER COMPLIANCE

Article 4

Obligations of users

1 Users shall exercise due diligence to ascertain that genetic resources and traditional knowledge associated with genetic resources which they utilise have been accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements, and that benefits are fairly and equitably shared upon mutually agreed terms, in accordance with any applicable legislation or regulatory requirements.

2 Genetic resources and traditional knowledge associated with genetic resources shall only be transferred and utilised in accordance with mutually agreed terms if they are required by applicable legislation or regulatory requirements.

3 For the purposes of paragraph 1, users shall seek, keep and transfer to subsequent users:

a the internationally-recognised certificate of compliance, as well as information on the content of the mutually agreed terms relevant for subsequent users; or

b where no internationally-recognised certificate of compliance is available, information and relevant documents on:

(i) the date and place of access of genetic resources or of traditional knowledge associated with genetic resources;

(ii) the description of the genetic resources or of traditional knowledge associated with genetic resources utilised;

(iii) the source from which the genetic resources or traditional knowledge associated with genetic resources were directly obtained, as well as subsequent users of genetic resources or traditional knowledge associated with genetic resources;

(iv) the presence or absence of rights and obligations relating to access and benefit-sharing including rights and obligations regarding subsequent applications and commercialisation;

(v) access permits, where applicable;

(vi) mutually agreed terms, including benefit-sharing arrangements, where applicable.

4 Users acquiring Plant Genetic Resources for Food and Agriculture (PGRFA) in a country that is a Party to the Nagoya Protocol which has determined that PGRFA under its management and control and in the public domain, not contained in Annex I to the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA), will also be subject to the terms and conditions of the standard material transfer agreement for the purposes set out under the ITPGRFA, shall be considered to have exercised due diligence in accordance with paragraph 3 of this Article.

5 When the information in their possession is insufficient or uncertainties about the legality of access and utilisation persist, users shall obtain an access permit or its equivalent and establish mutually agreed terms, or discontinue utilisation.

6 Users shall keep the information relevant to access and benefit-sharing for 20 years after the end of the period of utilisation.

7 Users obtaining a genetic resource from a collection included in the register of collections within the Union referred to in Article 5(1) shall be considered to have exercised due diligence as regards the seeking of information listed in paragraph 3 of this Article.

8 Users acquiring a genetic resource that is determined to be, or is determined as likely to be, the causing pathogen of a present or imminent public health emergency of international concern, within the meaning of the International Health Regulations (2005), or of a serious cross-border threat to health as defined in the Decision No 1082/2013/EU of the European Parliament and of the Council[(1)], for the purpose of public health emergency preparedness in not yet affected countries and response in affected countries, shall fulfil the obligations listed in paragraph 3 or 5 of this Article at the latest:

a one month after the imminent or present threat to public health is terminated; or

b three months after commencement of utilisation of the genetic resource;

whichever is the earlier.

Should the obligations listed in paragraph 3 or 5 of this Article not be fulfilled by the deadlines laid down in points (a) and (b) of the first subparagraph of this paragraph, utilisation shall be discontinued.

In the event of a request for market approval or the placing on the market of products deriving from utilisation of a genetic resource as referred to in the first subparagraph, the obligations listed in paragraph 3 or 5 shall apply entirely and without delay.

In the absence of prior informed consent having been obtained in a timely manner and mutually agreed terms having been established, and until an agreement is reached with the provider country concerned, no exclusive rights of any kind will be claimed by such a user to any developments made via the use of such pathogens.

Specialised international access and benefit-sharing instruments as mentioned in Article 2 remain unaffected.

Article 5

Register of collections

1 The Commission shall establish and maintain a register of collections within the Union (‘the register’). The Commission shall ensure that the register is internet-based and is easily accessible to users. The register shall include the references of the collections of genetic resources, or of parts of those collections, identified as meeting the criteria set out in paragraph 3.

2 A Member State shall, upon request by a collection holder under its jurisdiction, consider the inclusion of that collection, or a part of it, in the register. After verifying that the collection, or a part of it, meets the criteria set out in paragraph 3, the Member State shall notify the Commission without undue delay of the name and contact details of the collection and of its holder, and of the type of collection concerned. The Commission shall without delay include the information received in the register.

3 In order for a collection or a part of a collection to be included in the register, a collection shall demonstrate its capacity to:

a apply standardised procedures for exchanging samples of genetic resources and related information with other collections, and for supplying samples of genetic resources and related information to third persons for their utilisation in line with the Convention and the Nagoya Protocol;

b supply genetic resources and related information to third persons for their utilisation only with documentation providing evidence that the genetic resources and the related information were accessed in accordance with applicable access and benefit-sharing legislation or regulatory requirements and, where relevant, with mutually agreed terms;

c keep records of all samples of genetic resources and related information supplied to third persons for their utilisation;

d establish or use unique identifiers, where possible, for samples of genetic resources supplied to third persons; and

e use appropriate tracking and monitoring tools for exchanging samples of genetic resources and related information with other collections.

4 The Member States shall regularly verify that each collection or part of a collection under their jurisdiction included in the register meets the criteria set out in paragraph 3.

Where there is evidence, on the basis of information provided pursuant to paragraph 3, that a collection or a part of a collection included in the register does not meet the criteria set out in paragraph 3, the Member State concerned shall, in dialogue with the collection holder concerned and without undue delay, identify remedial actions or measures.

A Member State which determines that a collection or a part of a collection within its jurisdiction no longer complies with paragraph 3 shall inform the Commission thereof without undue delay.

Upon receipt of that information, the Commission shall remove the collection or the part of the collection concerned from the register.

5 The Commission shall adopt implementing acts to establish the procedures for implementing paragraphs 1 to 4 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 14(2).

Article 6

Competent authorities and focal point

1 Each Member State shall designate one or more competent authorities to be responsible for the application of this Regulation. Member States shall notify the Commission of the names and addresses of their competent authorities as of the date of entry into force of this Regulation. Member States shall inform the Commission without undue delay of any changes to the names or addresses of the competent authorities.

2 The Commission shall make public, including via the internet, a list of the competent authorities of the Member States. The Commission shall keep the list up-to-date.

3 The Commission shall designate a focal point on access and benefit-sharing responsible for liaising with the Secretariat of the Convention with regard to matters covered by this Regulation.

4 The Commission shall ensure that the Union bodies established under Council Regulation (EC) No 338/97[(2)] contribute to the achievement of the objectives of this Regulation.

Article 7

Monitoring user compliance

1 The Member States and the Commission shall request all recipients of research funding involving the utilisation of genetic resources and traditional knowledge associated with genetic resources to declare that they exercise due diligence in accordance with Article 4.

2 At the stage of final development of a product developed via the utilisation of genetic resources or traditional knowledge associated with such resources, users shall declare to the competent authorities referred to in Article 6(1) that they have fulfilled the obligations under Article 4 and shall simultaneously submit:

a the relevant information from the internationally-recognised certificate of compliance; or

b the related information as referred to in Article 4(3)(b)(i)-(v) and Article 4(5), including information that mutually agreed terms were established, where applicable.

Users shall further provide evidence to the competent authority upon request.

3 The competent authorities shall transmit the information received on the basis of paragraphs 1 and 2 of this Article to the Access and Benefit-Sharing Clearing House, established under Article 14(1) of the Nagoya Protocol, to the Commission and, where appropriate, to the competent national authorities referred to in Article 13(2) of the Nagoya Protocol.

4 The competent authorities shall cooperate with the Access and Benefit-Sharing Clearing House to ensure the exchange of the information listed in Article 17(2) of the Nagoya Protocol for monitoring the compliance of users.

5 The competent authorities shall take due account of the respect of confidentiality of commercial or industrial information where such confidentiality is provided for by Union or national law to protect a legitimate economic interest, in particular concerning the designation of the genetic resources and the designation of utilisation.

6 The Commission shall adopt implementing acts to establish the procedures for implementing paragraphs 1, 2 and 3 of this Article. In those implementing acts, the Commission shall determine the stage of final development of a product in order to identify the final stage of utilisation in different sectors. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 14(2).

Article 8

Best practices

1 Associations of users or other interested parties may submit an application to the Commission to have a combination of procedures, tools or mechanisms, developed and overseen by them, recognised as a best practice in accordance with the requirements of this Regulation. The application shall be supported by evidence and information.

2 Where, on the basis of evidence and information provided pursuant to paragraph 1 of this Article, the Commission determines that the specific combination of procedures, tools

or mechanisms, when effectively implemented by a user, enables that user to comply with its obligations under Articles 4 and 7, it shall grant recognition as best practice.

3 An association of users or other interested parties shall inform the Commission of any changes or updates made to a best practice for which recognition was granted in accordance with paragraph 2.

4 If there is evidence of repeated or significant cases where users implementing a best practice have failed to comply with their obligations under this Regulation, the Commission shall examine, in dialogue with the relevant association of users or other interested parties, whether those cases indicate possible deficiencies in the best practice.

5 The Commission shall withdraw the recognition of a best practice when it has determined that changes to the best practice compromise a user's ability to comply with its obligations under Articles 4 and 7, or when repeated or significant cases of non-compliance by users relate to deficiencies in the best practice.

6 The Commission shall establish and keep up-to-date an internet-based register of recognised best practices. That register shall, in one section, list the best practices recognised by the Commission in accordance with paragraph 2 of this Article, and, in another section, list the best practices adopted on the basis of Article 20(2) of the Nagoya Protocol.

7 The Commission shall adopt implementing acts to establish the procedures for implementing paragraphs 1 to 5 of this Article. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 14(2).

Article 9

Checks on user compliance

1 The competent authorities referred to in Article 6(1) shall carry out checks to verify whether users comply with their obligations under Articles 4 and 7, taking into account that the implementation by a user of a best practice in relation to access and benefit-sharing, recognised under Article 8(2) of this Regulation or under Article 20(2) of the Nagoya Protocol, may reduce that user's risk of non-compliance.

2 Member States shall ensure that the checks carried out pursuant to paragraph 1 are effective, proportionate, dissuasive and detect cases of user non-compliance with this Regulation.

3 The checks referred to in paragraph 1 shall be conducted:

a in accordance with a periodically reviewed plan developed using a risk-based approach;

b when a competent authority is in possession of relevant information, including on the basis of substantiated concerns provided by third parties, regarding a user's non-compliance with this Regulation. Special consideration shall be given to such concerns raised by provider countries.

4 The checks referred to in paragraph 1 of this Article may include an examination of:

a the measures taken by a user to exercise due diligence in accordance with Article 4;

b documentation and records that demonstrate the exercise of due diligence in accordance with Article 4 in relation to specific use activities;

c instances where a user was obliged to make declarations under Article 7.

On-the-spot checks may also be carried out, as appropriate.

5 Users shall offer all assistance necessary to facilitate the performance of the checks referred to in paragraph 1.

6 Without prejudice to Article 11, where, following the checks referred to in paragraph 1 of this Article, shortcomings have been detected, the competent authority shall issue a notice of remedial action or measures to be taken by the user.

Depending on the nature of the shortcomings, Member States may also take immediate interim measures.

Article 10

Records of checks

1 The competent authorities shall keep, for at least five years, records of the checks referred to in Article 9(1), indicating, in particular, their nature and results, as well as records of any remedial actions and measures taken under Article 9(6).

2 The information referred to in paragraph 1 shall be made available in accordance with Directive 2003/4/EC.

Article 11

Penalties

1 Member States shall lay down the rules on penalties applicable to infringements of Articles 4 and 7 and shall take all the measures necessary to ensure that they are applied.

2 The penalties provided for shall be effective, proportionate and dissuasive.

3 By 11 June 2015, Member States shall notify to the Commission the rules referred to in paragraph 1 and any subsequent amendments thereto without delay.

CHAPTER III

FINAL PROVISIONS

Article 12

Cooperation

The competent authorities referred to in Article 6(1) shall:

(a) cooperate with each other and with the Commission in order to ensure that users comply with this Regulation;

(b) consult, if appropriate, with stakeholders on the implementation of the Nagoya Protocol and this Regulation;

(c) cooperate with the competent national authorities referred to in Article 13(2) of the Nagoya Protocol in order to ensure that users comply with this Regulation;

(d) inform the competent authorities of other Member States and the Commission of any serious shortcomings, detected by means of the checks referred to in Article 9(1), and of the types of penalties imposed in accordance with Article 11;

(e) exchange information on the organisation of their system of checks for monitoring user compliance with this Regulation.

Article 13

Complementary measures

The Commission and Member States shall, as appropriate:

(a) promote and encourage information, awareness-raising and training activities to help stakeholders and interested parties to understand their obligations arising from the implementation of this Regulation, and of the relevant provisions of the Convention and the Nagoya Protocol in the Union;

(b) encourage the development of sectoral codes of conduct, model contractual clauses, guidelines and best practices, particularly where they would benefit academic, university and non-commercial researchers and small and medium-sized enterprises;

(c) promote the development and use of cost-effective communication tools and systems in support of monitoring and tracking the utilisation of genetic resources and traditional knowledge associated with genetic resources by collections and users;

(d) provide technical and other guidance to users, taking into account the situation of academic, university and non-commercial researchers and of small and medium-sized enterprises, in order to facilitate compliance with the requirements of this Regulation;

(e) encourage users and providers to direct benefits from the utilisation of genetic resources towards the conservation of biological diversity and the sustainable use of its components in accordance with the provisions of the Convention;

(f) promote measures in support of collections that contribute to the conservation of biological diversity and cultural diversity.

Article 14

Committee procedure

1 The Commission shall be assisted by a committee. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.

2 Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

3 Where the committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) of Regulation (EU) No 182/2011 shall apply.

Article 15

Consultation forum

The Commission shall ensure a balanced participation of representatives of the Member States and other interested parties in issues related to the implementation of this Regulation. They shall meet in a consultation forum. The rules of procedure of that consultation forum shall be established by the Commission.

Article 16

Reports and review

1 Unless an alternative interval for reports is determined, as referred to in Article 29 of the Nagoya Protocol, Member States shall submit to the Commission a report on the application of this Regulation by 11 June 2017 and every five years thereafter.

2 Not later than one year after the time-limit for submission of reports referred to in paragraph 1, the Commission shall submit to the European Parliament and to the Council a report on the application of this Regulation, including a first assessment of the effectiveness of this Regulation.

3 Every 10 years after its first report the Commission shall, on the basis of reporting on, and experience with the application of, this Regulation, review the functioning and effectiveness of this Regulation in achieving the objectives of the Nagoya Protocol. In its review the Commission shall, in particular, consider the administrative consequences for public research institutions, micro, small or medium-sized enterprises and specific sectors. It shall also consider the need to review the implementation of the provisions of this Regulation in light of developments in other relevant international organisations.

4 The Commission shall report to the Conference of the Parties to the Convention serving as the meeting of the Parties to the Nagoya Protocol on the measures taken by the Union to implement compliance measures in respect of the Nagoya Protocol.

Article 17

Entry into force and application

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

2 As soon as possible following the deposit of the Union's instrument of acceptance of the Nagoya Protocol, the Commission shall publish a notice in the *Official Journal of the European Union* specifying the date on which the Nagoya Protocol will enter into force for the Union. This Regulation shall apply from that date.

3 Articles 4, 7, and 9 of this Regulation shall apply one year after the date of entry into force of the Nagoya Protocol for the Union.

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

Done at Strasbourg, 16 April 2014.

For the European Parliament

The President

M. SCHULZ

For the Council

The President

D. KOURKOULAS

(**1**) Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

(**2**) Council Regulation (EC) No 338/97 of 9 December 1996 on the protection of species of wild fauna and flora by regulating trade therein (OJ L 61, 3.3.1997, p. 1).