ANNEX

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of

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 *Utilisation* in the Union

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 192(1) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national Parliaments,

Having regard to the opinion of the European Economic and Social Committee[1],

Having regard to the opinion of the Committee of the Regions[2],

Acting in accordance with the ordinary legislative procedure,

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1 OJ C , , p. .
2 OJ C , , p. .

Whereas:

(1) A broad range of ***users and suppliers*** in the Union, including academic, ***university and non-commercial*** researchers and companies from different sectors of industry, use genetic resources for research, development and commercialisation purposes; some also use traditional knowledge associated with genetic resources.

(2) Genetic resources represent the gene pool in both natural and cultivated or domesticated ***species*** and play a significant and growing role in many economic sectors, including food production, forestry, ***and the*** development of medicines, ***cosmetics and*** bio-based sources of ▌energy. ***Genetic resources play a significant role in the implementation of strategies designed to restore damaged ecosystems and safeguard endangered species.***

(3) Traditional knowledge that is held by indigenous and local communities may provide important lead information for the scientific discovery of interesting genetic or biochemical properties of genetic resources, ***including knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity***.

(4) The main international instrument ***providing a general framework for the conservation, sustainable use of biodiversity and the fair and equitable sharing of the benefits arising out of the utilisation*** of genetic resources is the Convention on Biological Diversity (***"***Convention***"). In accordance with*** Council Decision 93/626/EEC[1] the Convention ***was*** approved ▌on behalf of the Union.

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1 ***Council Decision 93/626/EEC of 25 October 1993 concerning the conclusion of the Convention on Biological Diversity (***OJ L 309, 13.12.***1993***, p. 1***).***

(4a) ***Genetic resources should be preserved in situ and utilised in sustainable ways and the benefits arising from their utilisation should be shared fairly and equitably. This would contribute to poverty eradication and, thereby, to achieving the United Nations Millennium Development Goals, as acknowledged in the preamble of the Nagoya Protocol. The implementation of the Nagoya Protocol should also aim to realise that potential.***

(5) The Convention recognises that ***States*** have sovereign rights over natural resources found within their jurisdiction and the authority to determine access to their genetic resources. The Convention imposes an obligation on all Parties to ***endeavour to create conditions to*** facilitate access to genetic resources***, for environmentally sound uses by other Parties,*** over which they ***exercise*** sovereign rights. It also makes it mandatory for all Parties to take measures ***with the aim of sharing*** in a fair and equitable way the results of research and development and the benefits arising from the commercial and other ***utilisation*** of genetic resources with the Party providing ***such*** resources. Such sharing ***is to*** be upon mutually agreed terms. The Convention also addresses access and benefit-sharing in relation to the knowledge, innovations and practices of indigenous and local communities ***which are*** relevant for the conservation and sustainable use of biological diversity.

(6) 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") is an international treaty adopted on 29 October 2010 by the Parties to the Convention[3]. The Nagoya Protocol ***further elaborates*** the general rules of the Convention on access and ***monetary and non-monetary*** benefit-sharing ***in relation to utilisation*** of genetic resources and traditional knowledge associated with genetic resources.

(7) ***In accordance with*** Council Decision ***.../2013/EU***[4*] the Nagoya Protocol ***was approved*** on behalf of the Union.

(7a) The Nagoya Protocol applies to genetic resources falling within the scope of Article 15 of the Convention as opposed to the wider scope of Article 4 of the Convention. This implies that the Nagoya Protocol does not extend to the full jurisdictional scope of Article 4, such as to activities taking place in marine areas beyond national jurisdiction. Research on genetic resources is gradually being extended into new areas, especially the oceans, which are still the planet's least explored and least well-known environments. The deep ocean in particular represents the last great frontier on the planet and is attracting growing interest in terms of research, prospecting and resource exploration.

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3 Annex I to Document UNEP/CBD/COP/DEC/X/1 of 29 October 2010.

4 ***Council Decision .../2013/EU of ... on the conclusion, on behalf of the Union, 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.***

* ***OJ: please insert the number, date and the publication reference for the Decision in doc. 6852/13.***

(8) It is important to set out a clear and sound framework for implementing the Nagoya Protocol that should ***contribute to the conservation of biological diversity and sustainable use of its components, the fair and equitable sharing of the benefits arising from the utilisation of genetic resources and poverty eradication while at the same time enhancing*** opportunities available for nature-based research and development activities in the Union. It is also essential to prevent the ***utilisation in the Union of*** genetic resources or traditional knowledge associated with genetic resources ***which were not accessed in accordance with the national access and benefit-sharing legislation or regulatory requirements of a Party to the Nagoya Protocol*** and to support the effective implementation of benefit-sharing commitments set out in mutually agreed terms between providers and users. ***It is also essential to improve the conditions for legal certainty in connection with the utilisation of genetic resources and traditional knowledge associated with genetic resources.***

(8a) The framework created by this Regulation will contribute to maintaining and increasing trust between Parties as well as stakeholders, including indigenous and local communities, involved in access and benefit-sharing of genetic resources.

(9) In order to ensure legal certainty, it is important that the rules implementing the Nagoya Protocol ***apply*** only ▌to genetic resources ***over which States exercise sovereign rights within the scope of Article 15 of the Convention, and to*** traditional knowledge associated with genetic resources ***within the scope of the Convention, which*** are accessed after the entry into force of the Nagoya Protocol for the Union.

(10) ***The Nagoya Protocol establishes that each Party, in the development and implementation of its access and benefit-sharing legislation or regulatory requirements, is to consider the importance of genetic resources for food and agriculture ("GRFA") and their special role for food security. In accordance with*** Council Decision 2004/869/EC of 24 February 2004 concerning the conclusion, on behalf of the European Community, of the International Treaty on Plant Genetic Resources for Food and Agriculture ***("ITPGRFA")[5] the ITPGRFA was*** approved ▌on behalf of the Union. ***The ITPGRFA*** constitutes a ***specialised*** international access and benefit-sharing instrument ***within the meaning of Article 4 (4) of the Nagoya Protocol*** that should not be affected by the rules implementing the Nagoya Protocol.

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5 OJ L 378, 23.12.2004, p. 1.

(10a) Many Parties, in the exercise of their sovereign rights, have determined that PGRFA under their management and control and in the public domain, not contained in Annex I, will also be subject to the terms and conditions of the standard material transfer agreement (sMTA) for the purposes set out under the ITPGRFA.

(10aa) The implementation of the Nagoya Protocol should be done in a way that is mutually supportive with other international instruments that do not run counter to its objectives or to those of the Convention.

(10b) The Convention defines, in its Article 2, "domesticated species" as any species in which the evolutionary process has been influenced by humans to meet their needs and "biotechnology" as any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use. The Nagoya Protocol defines, in its Article 2, "derivatives" as a naturally occurring biochemical compound resulting from the genetic expression or metabolism of biological or genetic resources, even if it does not contain functional units of heredity.

(10c) ***Article 8(b) of the Nagoya Protocol establishes that each party is to pay due regard to cases of present or imminent emergencies that threaten or damage human, animal or plant health, as determined nationally or internationally. On 24 May 2011, the Sixty-fourth World Health Assembly adopted the Pandemic Influenza Preparedness Framework for the sharing of influenza viruses and access to vaccines and other benefits ("PIP Framework"). The PIP Framework applies only to influenza viruses with human pandemic potential and specifically does not cover seasonal influenza viruses. The PIP Framework constitutes a specialised international access and benefit-sharing instrument consistent with the Nagoya Protocol that should not be affected by the rules implementing the Nagoya Protocol.***

(10d) ***It is important to include in this Regulation the definitions from the Nagoya Protocol and the Convention that are necessary for the implementation of this regulation by users. It is important that the new definitions contained in the Regulation, which are not included in the Convention or in the Nagoya Protocol, are consistent with the definitions of the Convention or the Nagoya Protocol. In particular the term "user" should be consistent with the Nagoya Protocol term "utilisation of genetic resources".***

(10e) ***The Nagoya Protocol establishes the obligation to promote and encourage biodiversity-related research, and in particular with non-commercial intent.***

(12) It ***is*** important to recall ***paragraph 2 of Decision II/11 of the Conference of the Parties to the Convention which reaffirms that*** human genetic resources ***are not included within*** the framework of the Convention.

(13) There is currently no internationally agreed definition ***of*** "traditional knowledge associated with genetic resources"**.** ***Without prejudice to the competence and responsibility of the Member States for matters relating to traditional knowledge associated with genetic resources and the implementation of measures to safeguard indigenous and local communities' interests***, in order to ensure flexibility and legal certainty for providers and users, this Regulation should make reference to traditional knowledge associated with genetic resources as described in benefit-sharing agreements.

(14) With a view to ensuring ***the*** effective implementation of the Nagoya Protocol, all users of genetic resources and traditional knowledge associated with ***genetic*** resources should ▌exercise due diligence to ascertain that ▌genetic resources and ▌traditional knowledge ***associated with genetic resources*** were accessed in accordance with applicable legal ***or regulatory*** requirements and to ensure that, where relevant, benefits are ***fairly and equitably shared. In that context, competent authorities should accept internationally recognised certificates of compliance as evidence that the genetic resources covered were legally accessed and that mutually agreed terms were established for the user and the utilisation specified therein. The specific choices made*** by users on the tools and measures ***to apply in order to exercise*** due diligence should be supported through the recognition of best practices as well as complementary measures in support of sectoral codes of conduct, model contractual clauses▌ and guidelines with a view to increasing legal certainty and reducing costs. The obligation on users to keep information ***which is*** relevant for access and benefit-sharing should be limited in time ***and in accordance*** with the time-span for ***potential*** innovation.

(14a) ***The successful implementation of the Nagoya Protocol depends on users and providers of genetic resources or of traditional knowledge associated with genetic resources negotiating mutually agreed terms that lead to fair benefit-sharing and contribute to the Nagoya Protocol's wider objective of contributing to the conservation and sustainable use of biological diversity. Users and providers are also encouraged to raise awareness of the importance of genetic resources and of traditional knowledge associated with genetic resources.***

(15) The due diligence obligation should apply to all users irrespective of their size, including micro, small and medium-sized ***enterprises. This*** Regulation should offer a range of measures and tools to enable micro, small and medium-sized ***enterprises*** to comply with their obligations at ***an affordable*** cost and with high legal certainty.

(16) Best practices developed by users should play an important role in identifying due diligence measures that are particularly suitable for achieving compliance with the system of implementation of the Nagoya Protocol ***at an affordable cost and*** with high legal certainty ▌. Users should ▌ build on existing access and benefit-sharing codes of conduct developed for the academic ***and university and non-commercial research sectors*** and different industries. Associations of users should be able to request that the Commission ***determine*** whether a specific combination of procedures, tools or mechanisms overseen by an association may be recognised as best practice. Competent authorities of the Member States should consider that the implementation of a recognised best practice by a user reduces that user's risk of non-compliance and justifies a reduction in compliance checks. The same should apply to best practices adopted by ▌ the Parties to the Nagoya Protocol.

(17) ***The Nagoya Protocol establishes that the check-points must be effective and should be relevant to the utilisation of genetic resources. At*** identified points in the chain of activities that constitute ***utilisation users should declare and provide evidence when requested*** that they have exercised due diligence. ***One suitable point*** for such ***a declaration is when research funds are received. Another suitable point is at the final stage of the utilisation, that means at the stage of final development of a product before requesting*** market approval for a product developed ***via the utilisation of genetic resources or traditional knowledge associated with such resources or at the stage of final development of a product before first placing on the Union's market*** where a market approval is not required. ***In order to ensure the effectiveness of check-points, while at the same time increase legal certainty for users, implementing powers should be conferred on the Commission in accordance with Article 291(2) of the Treaty of the Functioning of the European Union. The Commission should make use of those implementing powers to determine the stage of final development of a product in accordance with the Nagoya Protocol in order to identify the final stage of utilisation in different sectors.***

(17a) ***It is important to acknowledge that the Access and Benefit-Sharing Clearing House would play an important role in implementing the Nagoya Protocol. In accordance to Article 14 and 17 of the Nagoya Protocol information would be submitted to the Access and Benefit-Sharing Clearing House as part of the internationally recognised certificate of compliance process. The competent authorities should cooperate with the Access and Benefit-Sharing Clearing House to ensure that the information is exchanged to facilitate the monitoring by the competent authorities of the compliance of users.***

(18) ***The collection*** of genetic resources in the wild is mostly undertaken for non-commercial purposes by ***academic,*** university ***and non-commercial*** researchers or collectors. In the vast majority of cases and in almost all sectors, ▌newly -collected genetic resources ***are accessed*** through intermediaries, collections, or agents that acquire genetic resources in third countries.

(19) Collections are major suppliers of genetic resources and traditional knowledge associated with genetic resources ***utilised in the Union. As suppliers they can play an important role in helping other users in the chain of custody to comply with their obligations. In order to do so a system of registered*** collections ***within the Union*** should be set in place ***through the establishment of a voluntary register of collections to be maintained by the Commission. This system*** would ensure that collections included in the register ▌ effectively apply measures to only supply samples of genetic resources to third persons with documentation providing evidence of legal ***access*** and the establishment of mutually agreed terms, where required. A system of ***registered*** collections ***within the Union*** should substantially lower the risk that ***genetic resources which were not accessed in accordance with the national access and benefit- sharing legislation or regulatory requirements of a Party to the Nagoya Protocol are utilised*** in the Union. Competent authorities of Member States would verify if a collection meets the requirements for recognition as ***a*** collection ***for inclusion in the register***. Users that ***obtain*** a genetic resource from a collection ***included*** in the ▌ register should be considered to have exercised due diligence as regards the seeking of all necessary information. This should prove particularly beneficial for academic, ***university and non-commercial*** researchers as well as small and medium -sized enterprises ***and contribute to a reduction in administrative and compliance requirements***.

(20) Competent authorities of Member States should check whether users comply with their obligations ***and have obtained prior informed consent and established*** mutually agreed terms ▌. Competent authorities should also keep records of the checks made and relevant information should be made available in accordance with Directive 2003/4/EC[6].

(21) Member States should ensure that infringements of the rules ***implementing*** the Nagoya Protocol ▌ are sanctioned by means of effective, proportionate and dissuasive penalties.

(22) Taking into account the international character of access and benefit-sharing transactions, competent authorities of the Member States should cooperate ***with each other***, with the Commission, and with ***the competent national*** authorities of third countries ***in order*** to ***ensure that users*** comply with ***this Regulation and support an effective application of the rules*** implementing the Nagoya Protocol.

(22a) The Union and the Member States should act in a proactive manner to ensure the objectives of the Nagoya Protocol are achieved in order to increase resources to support conservation of biological diversity and the sustainable use of its components globally.

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(24) The Commission and the Member States should take appropriate complementary measures to enhance the effectiveness of ***the implementation of*** this Regulation and to lower costs, particularly where this would benefit academic, ***university and non-commercial*** researchers and small and medium -sized enterprises.

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6 ***Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information*** (OJ L 41, 14.2.2003, p. ***6)***.

(27) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council[7].

(28) ***Since the*** objectives of this Regulation, ***namely*** to support the fair and equitable sharing of ***the*** benefits ***arising*** from the ***utilisation*** of genetic resources ***in accordance with the Nagoya Protocol*** cannot be ***sufficiently*** achieved by the Member States ▌ and can therefore, by reasons of their scale and to ensure ***the*** functioning of the internal market, be better achieved at Union level, ***the*** Union may ▌ adopt measures, in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary to achieve ***this objective.***

(29) The date of entry into force of this Regulation should be directly correlated to the entry into force of the Nagoya Protocol for the Union in order to ensure equal conditions at Union and global levels in activities related to access and benefit-sharing of genetic resources,

HAVE ADOPTED THIS REGULATION:

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7 ***Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (***OJ L 55, 28.2.2011, p. 13***).***

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 Utilisation to the Convention on Biological Diversity ("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 (***"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.***

2a. This Regulation shall be 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.

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

3a. 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 ***shall*** apply:

▌

(2) "genetic material" means any material of plant, animal, microbial or other origin containing functional units of heredity;

(3) "genetic resources" means genetic material of actual or potential value;

(4) "access" means the acquisition of genetic resources or of traditional knowledge associated with genetic resources in a Party to the Nagoya Protocol ▌***;***

(5) "user" means a natural or legal person ***utilising*** genetic resources or traditional knowledge associated with genetic resources;

(6) ***"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***;

(7) "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***;

(8) "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;

(8a) "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 requirement 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 ▌***;***

(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 the establishment of mutually agreed terms 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 the Nagoya 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***.

1a. 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.

2. ***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 ***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 related 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.

2a. ***Users acquiring PGRFA in a country that is a Party to the Nagoya Protocol and which has determined, that PGRFA under its management and control and in the public domain, not contained in Annex I of the 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 the due diligence requirements set out in paragraph 2 of this Article.***

2b. ***When the information in their possession is not sufficient 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.***

3. Users shall keep the information relevant for access and benefit-sharing for twenty years after the end of the period of ***utilisation***.

4. 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 2.***

5. *Users acquiring a genetic resource that is determined to be the causing pathogen or likely to be the causing pathogen of a present or imminent public health emergency of international concern, in the sense of the International Health Regulations (2005) or of a serious cross-border threat to health as defined in the Decision of the European Parliament and of the Council on serious cross-border threats to health, 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 2 or 3 at the latest*

(a) one month after the imminent or present threat for public health is terminated or

(b) three months after commencement of utilisation of the genetic resource

or discontinue utilisation.

The condition that is fulfilled first will apply.

In case of request of market approval or placing on the market of products deriving from utilisation of such a genetic resource, obligations listed in paragraph 2 or 3 apply entirely and without delay.

In the absence of Prior Informed Consent timely obtained and Mutually Agreed Terms established and until an agreement is reached with the provider country, 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 Commission shall ensure that the*** register ***is*** internet-based ***and*** easily accessible to users. ***It*** 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 part of it, held by that collection holder*** in the ▌ register of ▌ collections ***within the Union***. After verifying that the collection ***or 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 type ***of collection concerned***. The Commission shall without delay include the information thus received ***in*** the ▌ register ▌ .

3. In order for a collection ***or 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. 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 part of a collection*** included in the ▌ register ▌ does not ***meet*** the ***criteria*** set out in paragraph 3, the Member State concerned shall without ***undue*** delay identify remedial actions ***or measures*** in dialogue with the ▌ collection ***holder*** concerned.

A Member State which determines that a collection or 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 a collection from the ***register.***

6. The Commission shall ▌ adopt implementing acts, to establish the procedures for implementing paragraphs 1 to ***4. Those*** implementing acts shall be adopted in accordance with the examination procedure referred to in Article 15(2).

Article 6

Competent authorities and focal point

1. Each Member State shall designate one or more competent authorities 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 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 on 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.***

3a. The Commission shall ensure that the Union bodies established under Council Regulation (EC) No 338/97 contribute to the achievement of the objectives of this Regulation[8].

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[8] ***OJ L 61, 3.3.1997, p. 1.***

Article 7

Monitoring user compliance

1. 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(2)(b) i)-v) and 4(2b), including information that mutually agreed terms were established, where applicable.

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

3. Competent authorities shall transmit to the ***Access and Benefit-Sharing Clearing House the global information-sharing portal established under Article 14(1) of the Nagoya Protocol, to the Commission and, as appropriate, to the competent national authorities referred to in Article 13(2) of the Nagoya Protocol*** the information received on the basis of paragraphs 1 and 2. ▌

3a. 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.

3b. The competent authorities shall take due account of the respect of confidentiality of commercial or industrial information where such confidentiality is provided for by national or Union law to protect a legitimate economic interest, notably concerning the designation of the genetic resources and the designation of utilisation.

4. The Commission shall ▌ adopt implementing acts, to establish the procedures for implementing paragraphs 1, 2 and 3 of this Article. ***In this implementing act, the Commission shall determine the stage of final development of a product in order to identify the final stage of utilisation in different sectors. This implementing act*** shall be adopted in accordance with the examination procedure referred to in Article 15(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,*** the Commission determines that the specific combination of procedures, tools or mechanisms, when effectively implemented by a user, enables the user to comply with its obligations ***under*** Articles 4 and 7, ▌ 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 fail to comply with their obligations under this Regulation, the Commission shall examine in dialogue with the relevant association of users, 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*** best practices recognised by the Commission in accordance with paragraph 2 of this Article and ▌, in another section, ***list*** 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 15(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.

1a. Member States shall ensure that the checks in paragraph 1 are effective, proportionate and dissuasive and detect cases of non-compliance with the Regulation by users.

▌

3. ***These checks 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 ***may*** include [redacted]:

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

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

[redacted]

d) examination of instances where a user was obliged to make declarations under Article 7.

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

[redacted]

6. Users shall offer all assistance necessary to facilitate the performance of the checks referred to in paragraph 1 [redacted].

7. Without prejudice to Article 11, where, following the checks referred to in paragraph 1 [redacted], 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 [redacted], Member States may ***also*** take immediate interim measures [redacted].

[redacted]

Article 10

Records of checks

1. The competent authorities shall keep 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(7) ▌ for at least five years. ▌

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 measures necessary to ensure that they are implemented.

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

▌

3. ***By…****, Member States shall notify the rules referred to in paragraph 1 to the Commission ▌ and shall notify it without delay of any subsequent amendments ***thereto***.

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* ***OJ: please insert the date: one year after the date of entry into force of the Nagoya Protocol for the Union***

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 on 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 14

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*** understand their obligations ***and 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;***

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

Article 15

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.

1. [redacted]

4. 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 15a

Consultation Forum

The Commission shall ensure a balanced participation of representatives of 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 forum shall be established by the Commission.

Article 16

Reports and review

1. ***By ...*** [*] ***and every five years thereafter, unless otherwise determined in accordance with Article 29 of the Nagoya Protocol,*** Member States shall submit to the Commission ▌ a report on the application of this Regulation.

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

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[*] ***OJ: please insert the date: three years after the date of entry into force of this Regulation.***

3. Every ten 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 ***to achieve 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 serving as the meeting of the Parties to the Nagoya Protocol on the measures ***taken by*** the Union ▌ to implement ***compliance measures with*** the Nagoya Protocol.

Article 17

Entry into force and application

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

1a. 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 specifying the date on which the Nagoya Protocol enters into force for the Union. This Regulation shall apply from that date.

2. Articles 4, 7, and 9 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 …,

For the European Parliament	*For the Council*
The President	*The President*