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)

REGULATION (EU) No 511/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

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(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)],

After consulting the Committee of the Regions,

Acting in accordance with the ordinary legislative procedure[(2)],

Whereas:

(1) The main international instrument providing a general framework for the conservation and sustainable use of biological diversity and the fair and equitable sharing of the benefits arising from the utilisation of genetic resources is the Convention on Biological Diversity, approved on behalf of the Union in accordance with Council Decision 93/626/EEC[(3)] (the 'Convention').

(2) 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[(4)] (the 'Nagoya Protocol') is an international treaty adopted on 29 October 2010 by the Parties to the Convention. The Nagoya Protocol further elaborates upon the general rules of the Convention on access to genetic resources and sharing of monetary and non-monetary benefits arising from the utilisation of genetic resources and traditional knowledge associated with genetic resources ('access and benefit-sharing'). In accordance with Council Decision 2014/283/EU[(5)], the Nagoya Protocol was approved on behalf of the Union.

(3) 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

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genetic resources for research, development and commercialisation purposes. Some also use traditional knowledge associated with genetic resources.

(4) Genetic resources represent the gene pool in both natural and domesticated or cultivated 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. Furthermore, genetic resources play a significant role in the implementation of strategies designed to restore damaged ecosystems and safeguard endangered species.

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

(6) 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 thereto to endeavour to create conditions to facilitate access to genetic resources, over which they exercise sovereign rights, for environmentally sound uses by other Parties to the Convention. The Convention also makes it mandatory for all Parties thereto 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 commercial and other utilisation of genetic resources with the Party to the Convention that provided those resources. Such sharing is to take place 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.

(7) 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, in order to 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.

(8) The Nagoya Protocol applies to genetic resources, over which States exercise sovereign rights, falling within the scope of Article 15 of the Convention as opposed to the wider scope of Article 4 of the Convention. That implies that the Nagoya Protocol does not extend to the full jurisdictional scope of Article 4 of the Convention, 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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(9) 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 the 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.

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

(11) 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.

(12) The Nagoya Protocol requires each Party thereto, in the development and implementation of its access and benefit-sharing legislation or regulatory requirements, 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[(6)], the International Treaty on Plant Genetic Resources for Food and Agriculture (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.

(13) Many Parties to the Nagoya Protocol, in the exercise of their sovereign rights, have decided that Plant Genetic Resources for Food and Agriculture (PGRFA) under their management and control and in the public domain, not listed in Annex I to the ITPGRFA, are also to be subject to the terms and conditions of the standard material transfer agreement (sMTA) for the purposes set out under the ITPGRFA.

(14) The Nagoya Protocol should be implemented in a manner that is mutually supportive with other international instruments that do not run counter to the Protocol's objectives or to those of the Convention.

(15) In Article 2 of the Convention, the terms 'domesticated species' are defined 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

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systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use. In Article 2 of the Nagoya Protocol, the term 'derivatives' is defined 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.

(16) The Nagoya Protocol requires each Party thereto 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 (the 'PIP Framework'). The PIP Framework applies only to influenza viruses with human pandemic potential and specifically does not apply to seasonal influenza viruses. The PIP Framework constitutes a specialised international access and benefit-sharing instrument that is consistent with the Nagoya Protocol and that should not be affected by the rules implementing the Nagoya Protocol.

(17) 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 this Regulation, which are not included in the Convention or in the Nagoya Protocol, are consistent with the definitions of the Convention and the Nagoya Protocol. In particular, the term 'user' should be consistent with the definition of 'utilization of genetic resources' from the Nagoya Protocol.

(18) The Nagoya Protocol lays down an obligation to promote and encourage research related to biological diversity, in particular research with non-commercial intent.

(19) 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.

(20) 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.

(21) 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 whether genetic resources and traditional knowledge associated with genetic resources have been 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

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established for the user and the utilisation specified therein. The specific choices made by users as regards 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-frame for potential innovation.

(22) 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 and equitable 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.

(23) 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 a high level of legal certainty.

(24) 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 a high level of legal certainty. Users should build on existing access and benefit-sharing codes of conduct developed for the academic, university and non-commercial research sectors and different industries. Associations of users should be able to request that the Commission determine whether it is possible for a specific combination of procedures, tools or mechanisms overseen by an association to 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.

(25) Under the Nagoya Protocol 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 utilisation, meaning 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, where market approval is not required, at the stage of final development of a product before first placing it on the Union market. In order to ensure the effectiveness of check-points, while at the same time increasing legal certainty for users, implementing powers should be conferred on the Commission