

本資料は、平成 25 年 9 月 12 日付の欧州議会の決定¹において提示された、「EU における遺伝資源へのアクセス及びその利用から生ずる利益の公正かつ衡平な配分に関する欧州議会及び理事会規則（案）」²（平成 24 年 10 月 4 日公表）に対する修正内容の案を見え消し（追記箇所：下線、削除箇所：取り消し線）の形で記載したものである。

1（以下のファイルの P211～）

<http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+TA+20130912+SIT+DOC+WORD+V0//EN&language=EN>

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[http://www.europarl.europa.eu/registre/docs_autres_institutions/commission_europeenne/com/2012/0576/COM_COM\(2012\)0576_EN.pdf](http://www.europarl.europa.eu/registre/docs_autres_institutions/commission_europeenne/com/2012/0576/COM_COM(2012)0576_EN.pdf)

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

[Having regard to the Convention on Biological Diversity and to the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization,](#)

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 Committee¹,

Having regard to the opinion of the Committee of the Regions²,

Acting in accordance with the ordinary legislative procedure,

Whereas:

¹ OJ C , , p. .

² OJ C , , p. .

(-1) The Union has put in place an ‘EU Biodiversity Strategy to 2020’, which commits it to stepping up its contribution to averting global biodiversity loss by 2020 .

(1) A broad range of users and suppliers~~players~~ in the Union, including academic 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. Research and development activities imply not only the study and analysis of the genetic or biochemical composition of genetic resources but also measures to generate innovation and practical applications. The successful implementation of the Nagoya Protocol also depends on the way in which users and suppliers of genetic resources or traditional knowledge associated with genetic resources are able to negotiate agreed conditions for the promotion of biodiversity conservation in accordance with the ‘EU biodiversity strategy to 2020’.

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

(2a) The Union recognises the interdependence of all countries with regard to genetic resources for food and agriculture, as well as the special nature and importance of those resources for achieving food security worldwide and for the sustainable development of agriculture in the context of poverty alleviation and climate change, and acknowledges the fundamental role of the International Treaty on Plant Genetic Resources for Food and Agriculture and the FAO Commission on Genetic Resources for Food and Agriculture in this regard.

(2b) 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. In this context, a study of the immense biodiversity to be found in deep marine ecosystems is an emerging and highly promising area of research with a view to the discovery of genetic resources offering potential applications for a wide range of purposes.

(2c) It is recognised practice to exchange all plant genetic resources for food and agriculture for the purposes of research, breeding and training under the terms and conditions of the Standard Material Transfer Agreement (SMTA) established under the International Treaty on Plant Genetic Resources for Food and Agriculture (ITPGRFA) as determined in the Memorandum of Understanding for the establishment of the European Genebank Integrated System (AEGIS); in accordance with Article 4.3 of the Nagoya Protocol, it is acknowledged that such a practice is supportive of, and does not run counter to, the objectives of the Convention and the Nagoya Protocol.

(3) Traditional knowledge that is held by indigenous and local communities may provide important lead information for the scientific discovery of potentially valuable~~interesting~~ genetic or biochemical properties of genetic resources , including the knowledge, innovations and practices of indigenous and local communities

embodying traditional lifestyles that are relevant for the conservation and sustainable use of biological diversity. The rights of such communities, as laid down in Convention No. 169 of the International Labour Organisation on Indigenous and Tribal Peoples and also set out in the UN Declaration on the Rights of Indigenous Peoples adopted by the UN General Assembly in 2007 should be respected and Union implementing measures should facilitate that aim.

(3a) It is important to recall that, according to the European Patent Convention, plant and animal varieties as well as biological processes for the production of plants and animals are not patentable. When inventions are based on genetic resources or on components of genetic resources, applications for a patent covering, inter alia, those resources, products, including derivatives, and processes derived from the use of biotechnology, or traditional knowledge associated with the genetic resources, should indicate the resources and their origin should be provided to the relevant authorities and transmitted to the competent authority. The same obligation should apply to new plant variety rights.

(3b) Competence and responsibility for the practical implementation of measures to safeguard indigenous and local communities within the Union in access and benefit-sharing arrangements would remain with Member States and their courts.

(4) The main international instrument governing access to and use of genetic resources is the Convention on Biological Diversity (the Convention). Council Decision 93/626/EEC of 25 October 1993 concerning the Convention on Biological Diversity³ approved the Convention on behalf of the Union.

(4a) Genetic resources should be preserved in situ and used 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 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'), adopted on 29 October 2010 by the Parties to the Convention. As parties to the Convention, the Union and most of its Member States have signed the Nagoya Protocol. Capacity to effectively implement that Protocol should be supported

(4b) Benefit-sharing should be seen in a context where biodiversity-rich developing countries dominate the provision of genetic resources, while users are mainly found in developed countries. In addition to having the potential to contribute to conservation and the sustainable use of biodiversity, access and benefit-sharing can also contribute to poverty eradication and environmental sustainability and thereby to progress towards the Millennium Development Goals, as acknowledged in the preamble of the

³ OJ L 309, 13.12.1993, p. 1.

Nagoya Protocol. The implementation of the Nagoya Protocol should also aim to realise that potential.

(4c) The right to food, laid down in Article 25 of the Universal Declaration of Human Rights and Article 11 of the International Covenant on Economic, Social and Cultural Rights, as well as the right to the enjoyment of the highest attainable standard of health recognised in Article 12 of the International Covenant on Economic, Social and Cultural Rights, are of superior importance and should always be protected.

(4d) As is the case with genetic resources, traditional knowledge associated with such resources is largely concentrated in developing countries, in particular in indigenous and local communities. The rights of such communities laid down in Convention No 169 of the International Labour Organisation on Indigenous and Tribal Peoples and also set out in the UN Declaration on the Rights of Indigenous Peoples adopted by the UN General Assembly in 2007 should be respected and Union implementing measures should facilitate this.

(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 facilitate access to genetic resources, for environmentally sound uses by other Parties, over which they hold sovereign rights. It also makes it mandatory for all Parties to take measures to share in a fair and equitable way the results of research and development and the benefits arising from the commercial and other utilization of genetic resources with the Party providing these resources. Such sharing shall be upon the prior informed consent requirement of the country of origin of this resource and the benefits shall be based on mutually agreed terms. The Convention also addresses access and benefit-sharing in relation to the knowledge, innovations and practices of indigenous and local communities relevant for the conservation and sustainable use of biological diversity. Genetic resources should, indeed, be utilized in a balanced and sustainable manner and local communities legitimately involved, for it is only in that way that opportunities, developments, and benefits arising from their utilization can be shared fairly and equitably among all Parties.

(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 (the Nagoya Protocol) is an international treaty adopted on 29 October 2010 by the Parties to the Convention⁴. The Nagoya Protocol further details~~significantly expands~~ the general rules of the Convention on access and monetary and non-monetary benefit-sharing for the utilisation and subsequent commercialisation~~use~~ of genetic resources and traditional knowledge associated with genetic resources.

⁴ Annex I to Document UNEP/CBD/COP/DEC/X/1 of 29 October 2010..

- (7) Council Decision xxxx/xx/EU of [date] on the conclusion 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 Diversity⁵ approved the Nagoya Protocol 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. Nonetheless, nothing in the Nagoya Protocol prevents Parties to it from extending its principles to activities taking place in such marine areas.

- (8) It is important to set out a clear and sound framework for implementing the Nagoya Protocol and the relevant provisions of the Convention that should support its main objective, notably the conservation of biological diversity, the sustainable use of its components and the fair and equitable sharing of the benefits arising from the utilization of genetic resources. This includes preventing enhance opportunities available for nature based research and development activities in the Union. It is also essential to prevent the use of illegally acquired genetic resources or traditional knowledge associated with genetic such resources in the Union. It is also essential to enhance opportunities available for nature-based research and development activities in the Union, in particular by improving the conditions for legal certainty in connection with the use of genetic resources and traditional knowledge and to support the effective implementation of benefit sharing commitments set out in mutually agreed terms between providers and users.

(8a) Utilisation of illegally acquired genetic resources, or subsequent commercialisation of products based on such resources or associated traditional knowledge should be prohibited.

(8b) The framework created by this Regulation is needed also to maintain and increase trust between Parties, indigenous and local communities, and stakeholder groups 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 should only apply to new acquisitions or new utilisations of genetic resources and traditional knowledge associated with genetic resources that ~~are accessed~~ take place or commence after the entry into force of the Nagoya Protocol for the Union.

- (10) 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 International Treaty on Plant Genetic Resources for Food and Agriculture⁶ approved that Treaty on behalf of the Union. That Treaty constitutes a specialized international access and benefit-sharing instrument that should not be affected by the rules implementing the Nagoya Protocol.

⁵ OJ

⁶ OJ L 378, 23.12.2004, p. 1.

- (11) It is important to define, in accordance with the Nagoya Protocol, that ~~use-utilisation~~ of genetic resources refers to research and development on the genetic or biochemical composition of ~~samples of genetic resources~~. Research and development should be understood to mean the investigation and study of the genetic or biochemical composition of genetic resources in order to establish facts and reach conclusions, including the creation of innovations and practical applications.~~material, which includes research and development on isolated compounds extracted from genetic material that was accessed in a Party to the Nagoya Protocol.~~
- (12) It seems important to recall CBD Decision II/11 paragraph.2 – as confirmed by CBD Decision X/1, paragraph 5 – that reaffirms the exclusion of human genetic resources from the framework of the Convention.
- (13) There is currently no internationally agreed definition on "traditional knowledge associated with genetic resources" or on "holding" such knowledge by an indigenous and local community. International definitions of those terms and concepts are being negotiated in the Intergovernmental Committee of the World Intellectual Property Organization. Therefore, 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 an effective implementation of the Nagoya Protocol, all users of genetic resources and traditional knowledge associated with such resources should have to exercise due diligence to ascertain that the genetic resources and associated traditional knowledge used were accessed in accordance with applicable legal requirements and to ensure that, ~~where relevant~~, benefits are shared. However, given the diversity of users within the Union it is not appropriate to oblige all users to take the same measures for exercising due diligence. ~~Therefore, only minimum features of due diligence measures should be set out.~~ The specific choices taken by users on the tools and measures applied for exercising 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 relevant for access and benefit-sharing should be limited in time, consistent with the time-span for an eventual 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 not only lead to fair benefit-sharing, but also contribute to the Nagoya Protocol's wider objective of contributing to the conservation of biological diversity.
- (15) The due diligence obligation should apply to all users irrespective of their size, including to micro-enterprises and small and medium-sized companies. Excluding these actors from the system would entirely undermine its effectiveness. It would also run against the international obligations of the Union under the Nagoya Protocol. However, the Regulation should offer a range of measures and tools to enable micro-enterprises and small and medium-sized companies to comply with their obligations at low 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 with high legal certainty and at low costs. Users should be enabled to build on existing access and benefit sharing codes of conduct developed for the academic sector and different industries. Associations of users should be able to request that the Commission determines 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 collective of the Parties to the Nagoya Protocol.~~
- (17) Users should declare at identified points in the chain of activities that ~~constitute use that~~ they have exercised due diligence, and provide evidence to that effect. Suitable points for such declarations are upon the establishment of prior informed consent and mutually agreed terms, upon receipt/receiving of public research funding, when applying for intellectual property rights at relevant national, regional or international institutions, funds, where a market approval for a product developed on the basis of genetic resources is requested or at the time of commercialisation where a market approval is not required. Notably, the declaration made upon applying for intellectual property rights or ~~occasion of~~ requesting market approval would not constitute part of the approval procedure as such and would be directed to competent authorities established under this Regulation.
- (18) Collecting of genetic resources in the wild is mostly undertaken by private collectors and companies, often serving commercial for non-commercial purposes, and by academic-by university based researchers or ~~collectors~~ scientific institutions serving non-commercial purposes. In the vast majority of cases and in almost all sectors, access to newly collected genetic resources is gained through intermediaries, collections, or agents that acquire genetic resources in third countries, both commercially and non-commercially. This Regulation should ensure that the provisions of mutually agreed terms for the initial access relevant for third party transfer are followed by all parties involved. In many cases subsequent utilisation or commercialisation could require new prior mutually agreed terms.
- (19) Most Collections are ~~major~~ the most accessible suppliers of genetic resources and traditional knowledge associated with genetic resources ~~used~~ 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 Union ~~trusted~~ registered collections should be set in place. It ~~would~~ ensures that collections registered at Union level included in the register of Union trusted collections effectively apply measures to only supply samples of genetic resources to third persons with documentation providing evidence of legal acquisition and the establishment of mutually agreed terms, where required. A system of Union ~~trusted~~ registered collections should substantially lower the risk that illegally acquired genetic resources are ~~used~~ utilised in the Union. Competent authorities of Member States would verify if a collection meets the requirements for recognition as a Union registered trusted collection, including demonstrating the capacity to respect the broad objectives of the Nagoya Protocol in terms of achieving a fair and equitable sharing of the benefits arising from the utilisation of genetic resources and contributing to the conservation of biodiversity.

Users that acquire a genetic resource from a collection listed in the Union register should be considered to have exercised due diligence as regards the seeking of all necessary information. This should prove particularly beneficial for academic researchers as well as small and medium sized enterprises.

- (19a) Union registered collections should adhere to the objective of the Nagoya Protocol. They should contribute to awareness raising and capacity-building, in line with that Protocol's Articles 21 and 22, to the extent that the resources at their disposal so permit. Competent authorities may consider providing funding to collections for such activities. Every Union registered collection should seek to contribute to efforts to document traditional knowledge associated with genetic resources, in cooperation with indigenous and local communities, authorities, anthropologists and other actors, as appropriate. Such knowledge should be handled with full respect for relevant rights. Information on such knowledge should be publicised when this serves and does not in any way contravene or hamper the protection of relevant rights .
- (20) Competent authorities of Member States should check whether users comply with their obligations. In that context, competent authorities should accept internationally recognised certificates of compliance as evidence that the genetic resources covered were legally acquired and that mutually agreed terms were established. When an international certificate is not available, other legally acceptable forms of compliance should be considered evidence that the genetic resources covered were legally acquired and that mutually agreed terms were established. Competent authorities should also keep records of the checks made and relevant information should be made available in accordance with Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information.⁷
- (21) Member States should ensure that infringements of the rules constituting the system of implementation of the Nagoya Protocol by users 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 between themselves, with the Commission, and with authorities of third countries to comply with their duties within the system for implementing the Nagoya Protocol.
- (22a) The Union should act in a proactive manner to ensure the objectives of the Nagoya Protocol regarding global multilateral benefit-sharing mechanisms are achieved in order to increase resources to support conservation of biological diversity and the sustainable use of its components globally.
- (23) A Union platform on access and fair and equitable benefit-sharing should enable discussions on and contribute to the streamlining of access conditions in Member States, the design and performances of access and benefit sharing regimes, simplified access and benefit-sharing for non-commercial research, access and benefit-sharing practices of collections in the Union, access of Union stakeholders in third countries and the sharing of best practices. The Union platform should fully respect Member State competences and aim to ensure, as appropriate, the involvement of indigenous and local communities in accordance with the Nagoya Protocol.

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OJ L 41, 14.2.2003, p. 26.

- (24) The Commission and the Member States should take appropriate complementary measures to enhance the effectiveness of implementing this Regulation and to lower costs, particularly where this would benefit academic researchers and small and medium sized enterprises.
- (25) In order to take into account the inherently international character of access and benefit-sharing activities, the Commission should also consider whether cooperation with third countries or regions could support an effective application of the system created for implementing the Nagoya Protocol.
- (26) The date of entry into force of this Regulation should be directly correlated to the entry into force of the Nagoya Protocol in order to ensure equal conditions at the Union and global levels in activities related to access and benefit sharing of genetic resources. The Nagoya Protocol will enter into force on the ninetieth day after the deposit of the fiftieth instrument of ratification, acceptance, approval or accession by States or regional economic integration organisations that are Parties to the Convention.
- (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 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 powers⁸.
- (28) The objectives of this Regulation are to minimise the risk that illegally genetic resources or traditional knowledge associated with genetic resources are used in the Union, and to support the fair and equitable sharing of benefits resulting from the use of genetic resources or traditional knowledge associated with genetic resources upon mutually agreed terms. These cannot be achieved by the Member States individually, and can therefore, by reasons of their scale and to ensure functioning of the internal market, be better achieved at Union level. The Union may therefore 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 its objectives.

⁸ OJ L 55, 28.2.2011, p. 13.

HAVE ADOPTED THIS REGULATION:

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 (the Nagoya Protocol).

(1a) The objective of this Regulation is the fair and equitable sharing of the benefits arising from the utilisation of genetic resources, thereby contributing to the conservation of biological diversity and the sustainable use of its components, in accordance with the objectives of the Convention on Biological Diversity (‘the Convention’).

(1b) This Regulation lays down obligations for users of genetic resources and traditional knowledge associated with genetic resources. The system for implementing the Nagoya Protocol established by this Regulation also includes arrangements for facilitating user compliance with their obligations and a framework for monitoring and control arrangements to be drawn up and put in place by the Member States of the Union. This Regulation also includes provisions encouraging activities by relevant actors to raise awareness of the importance of genetic resources and traditional knowledge associated with genetic resources and related access and benefit-sharing issues, as well as activities contributing to capacity-building in developing countries, in line with the Nagoya Protocol's provisions.

Article 2

Scope

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 use utilisation of such genetic resources and to traditional knowledge associated with genetic resources.

This Regulation does not apply to genetic resources for which access and benefit-sharing is governed by a specialised international instrument to which the Union is a Party.

This Regulation does not apply to genetic resources from a country of origin which decided not to adopt domestic access rules in conformity with the requirements of the Nagoya Protocol in place or to commodity trade in general. Due regard should be paid to useful and relevant ongoing work or practices under other international organisations.

Article 3

Definitions

For the purposes of this Regulation, the following definitions apply:

(1) "Nagoya Protocol" means 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;

(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, or derivatives thereof;

~~(3a)~~ 'derivative' means 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;

~~(3)~~~~(4)~~ "access" means the acquisition of genetic resources or of traditional knowledge associated with genetic resources in a Party to the Nagoya Protocol in accordance with the applicable domestic access and benefit-sharing legislation or regulatory requirements of that Party.

~~(4)~~~~(5)~~ "user" means a natural or legal person utilising genetic resources or traditional knowledge associated with genetic resources or who subsequently commercialises genetic resources or products based on genetic resources or traditional knowledge associated with genetic resources;

~~(6)~~ "~~use~~-utilisation of genetic resources" means to conduct research and development on the genetic or biochemical composition of genetic resources including through the application of biotechnology;

~~(6a)~~ 'commercialisation' means for the purposes of this Regulation the making available of a product on the Union market;

~~(6b)~~ 'biotechnology' means any technological application that uses biological systems, living organisms, or derivatives thereof, to make or modify products or processes for specific use;

~~(5)~~~~(7)~~ "mutually agreed terms" means the contractual arrangement concluded between a provider of genetic resources or of traditional knowledge associated with genetic resources and a user of such resources or knowledge, that sets out specific conditions for the fair and equitable sharing of benefits arising from such use, and that may also include further conditions and terms for the use of such resources or knowledge;

~~(8)~~ "traditional knowledge associated with genetic resources" means traditional knowledge held by an indigenous or local community that is relevant for the use of genetic resources and that is as such described in the mutually agreed terms applying to the use of genetic resources;

~~(8 a)~~ 'illegally acquired genetic resources' means genetic resources and traditional knowledge associated with genetic resources acquired in contravention of the applicable international and national law on access and benefit-sharing in the country of origin;

~~(6)~~(9) "collection" means an ensemble of collected samples of genetic resources and related information that is accumulated, stored, and taxonomically identified, whether owned by public or private entities;

~~(7)~~(10) "association of users" means a legal person representing the interests of users that is involved in developing and overseeing best practices under Article 8 of this Regulation.

~~(8)~~(11) "internationally recognised certificate of compliance" means an access permit or its equivalent issued by a competent national authority in accordance with Article 6(3)(e) of the Nagoya Protocol, that is made available to the Access and Benefit-sharing Clearing-House;

~~(9)~~(12) "Access and Benefit-sharing Clearing-House" means the global information-sharing portal established under Article 14(1) of the Nagoya Protocol.

Article 4

Obligations of users

-1. Utilisation of illegally acquired genetic resources shall be prohibited in the Union.

1. Users shall exercise due diligence to ascertain that genetic resources and traditional knowledge associated with genetic resources used were accessed ~~in accordance~~ with prior informed consent and based on mutually agreed terms as defined by applicable access and benefit-sharing legislation or regulatory requirements and that, ~~where relevant,~~ benefits are fairly and equitably shared upon ~~mutually those~~ agreed terms. Users shall seek, keep, and transfer to subsequent users all information and documents relevant for access and benefit-sharing and for compliance with the provisions of this Regulation.

1a. Genetic resources and associated traditional knowledge shall only be transferred to other users in accordance with the internationally recognised certificate of compliance and mutually agreed terms, or prior informed consent and mutually agreed terms. In the absence of mutually agreed terms or if subsequent users envisage utilising such genetic resources or traditional knowledge under conditions that are not included in the prior terms, those users shall be required to seek mutually agreed terms from the country of origin.

2. Users shall:

(a) seek, keep and transfer to subsequent users information on the internationally recognised certificate of compliance, in the case of genetic resources acquired from Parties to the Nagoya Protocol that have regulated access to their genetic resources in compliance with Article 6 of the Nagoya Protocol, as well as on the content of the mutually agreed terms, and information on:

(1) the date and place of access of genetic resources and traditional knowledge associated with such resources;

- (2) the description of genetic resources or traditional knowledge associated with such resources used, including available unique identifiers;
- (3) the source from which the resources or the knowledge were directly obtained as well as subsequent users of genetic resources or traditional knowledge associated with such resources;
- (4) the presence or absence of rights and obligations related to access and benefit-sharing;

(5) access decisions permits and mutually agreed terms, including benefit-sharing arrangements, where applicable;

(5)(6)the application of access and benefit sharing requirements of specialised international instruments within the meaning of Article 2, that may limit or reduce the user's obligations under this Regulation. In this case the information shall also indicate that the utilisation is covered by the specialised instruments;

- (b) obtain additional information or evidence where uncertainties about the legality of access and use persist; and
 - (c) obtain a proper access permit, establish mutually agreed terms, or discontinue the use where it appears that access was not in accordance with applicable access and benefit-sharing legislation or regulatory requirements.
3. Users shall keep the information relevant for access and benefit-sharing for twenty years after the end of the period of utilisation or subsequent commercialisation.
 4. Users acquiring a genetic resource from a collection listed in the Union register of trusted collections referred to in Article 5(1) shall be considered to have exercised due diligence as regards the seeking of information relevant to access and benefit-sharing for genetic resources and traditional knowledge associated with genetic resources.

4a. The Commission shall be empowered to adopt delegated acts in accordance with Article 14a in order to establish the rules for benefit-sharing in accordance with paragraph 4a by ... 1. Those rules shall require benefit-sharing at least at the level of best practice in the sector concerned and establish conditions for the sharing of non-monetary benefits.

1 OJ: six months after the entry into force of this Regulation.

4b. Users, when negotiating mutually agreed terms with providers of genetic resources or of traditional knowledge associated with genetic resources, shall seek to ensure that such terms contribute to the conservation of biological diversity and the sustainable use of its components and to technology transfer to developing countries.

Article 5

Union trusted collections

- ~~1. The Commission shall establish and maintain a Union register of trusted collections. That register shall be internet based, easily accessible to users, and shall include the collections of genetic resources identified as meeting the criteria of Union trusted collection.~~
- ~~2. Each Member State shall, upon request by a collection under its jurisdiction, consider the inclusion of this collection in the Union register of trusted collections. After verifying that the collection meets the criteria set out in paragraph 3, the Member State shall notify the Commission without delay of that collection's name, contact details, and type. The Commission shall without delay include the information thus received into the Union register of trusted collections.~~
- ~~3. In order for a collection to be included in the Union register of trusted collections, a collection owner 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 use;~~
 - ~~(b) have samples of genetic resources and related information supplied to third persons for their use only with documentation providing evidence that the resources and the information were accessed in accordance with applicable legal requirements and, where relevant, mutually agreed terms for the fair and equitable sharing of benefits;~~
 - ~~(c) keep records of all samples of genetic resources and related information supplied to third persons for their use;~~
 - ~~(d) establish or use unique identifiers for samples of genetic resources supplied to third persons;~~
 - ~~(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 under their jurisdiction included in the Union register of trusted collections effectively applies the measures set out in paragraph 3.

Member States shall inform the Commission without delay if a collection under their jurisdiction included in the Union register no longer complies with paragraph 3.~~
- ~~5. Where there is evidence that a collection included in the Union register of trusted collections does not apply the measures set out in paragraph 3, the Member State concerned shall without delay identify remedial actions in dialogue with the owner of the collection concerned.

The Commission shall remove a collection from the Union register of trusted collections when, in particular on the basis of information provided pursuant to paragraph 4, it has determined that a collection included in the Union register of trusted collections faces important or persistent difficulties to comply with paragraph 3.~~

- ~~6. The Commission shall be empowered to adopt implementing acts to establish the procedures for implementing paragraphs 1 to 5 of this Article. The 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 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. The Commission shall keep the list up to date; particular attention shall be paid to the outermost regions, bearing in mind the significance and fragility of the genetic resources found on their territories, and with a view to preventing any abusive exploitation.
3. The Commission shall designate a focal point on access and benefit-sharing responsible for providing information to applicants seeking access to genetic resources and traditional knowledge associated with such resources in the Union and to liaise with the Secretariat of the Convention on Biological Diversity.

(3a) The focal point designated by the Commission pursuant to paragraph 3, shall ensure consultation with the relevant Union bodies established under, and national authorities implementing, Council Regulation (EC) No 338/97¹.

¹ OJL 61, 3.3.1997, p. 1.

3b. The competent authorities and the focal point on access and benefit-sharing shall provide advice to the public and potential users seeking information on the implementation of this Regulation and of the relevant provisions of the Convention and the Nagoya Protocol in the Union.

Article 7

Monitoring user compliance

- ~~1. Member States and the Commission shall request all recipients of public research funding involving uses of genetic resources and traditional knowledge associated with genetic resources to declare that they will exercise due diligence in accordance with Article 4.~~
2. Users shall declare to the competent authorities established under Article 6(1) that they have fulfilled the obligations under Article 4 and shall submit the related information exercised due diligence in accordance with Article 4 on the occasion of:

(a) establishing prior informed consent and mutually agreed terms;

(b) receiving research funding involving utilisation of genetic resources and traditional knowledge associated with genetic resources;

(c) applying for patents or for new plant variety rights at relevant national, regional or international institutions covering, inter alia, the accessed genetic resources, products, including derivatives, and processes derived from the use of biotechnology, or traditional knowledge associated with the genetic resources;

(d) -requesting market approval for a product developed on the basis of genetic resources or traditional knowledge associated with such resources, or

(e) at the time of commercialisation where a market approval is not required.

3. Competent authorities shall verify the information provided under points (b) to (e) of paragraph 2 and transmit to the Access and Benefit Sharing Clearing House Mechanism, to the Commission and if appropriate to the competent authorities of the State concerned within three months~~Commission every two years~~ the information received ~~on the basis of paragraphs 1 and 2 pursuant to this Article~~. The Commission shall within three months summarise the information received and make it public in an easily accessible, open, internet-based format~~available to the Access and Benefit-sharing Clearing House~~.
4. The Commission shall be empowered to adopt implementing acts to establish the procedures for implementing paragraphs 1, 2 and 3 of this Article. The implementing acts shall be adopted in accordance with the examination procedure referred to in Article 15(2).

Article 8

Best practices

- ~~1. Any association of users may submit an application to the Commission for recognising as best practice a combination of procedures, tools or mechanisms developed and overseen by it. The application shall be supported by evidence and information.~~
- ~~2. Where, on the basis of information and evidence supplied to it by an association of users, 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 set out in Articles 4 and 7, it shall grant recognition as best practice.~~
- ~~3. An association of users shall inform the Commission of any changes or updates made to a recognised best practice for which it was granted recognition in accordance with paragraph 2.~~
- ~~4. If evidence from competent authorities of the Member States or other sources indicates repeated 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 the repeated cases of non-compliance 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 meet the conditions set out in Articles 4 and 7, or when repeated cases of non-compliance by users relate to deficiencies in the practice.~~
- ~~6. The Commission shall establish and keep up to date an internet based register of recognised best practices. That register shall list in one section best practices recognised by the Commission in accordance with paragraph 2 of this Article and display in another section best practices adopted on the basis of Article 20(2) Nagoya Protocol.~~
- ~~7. The Commission shall be empowered to adopt implementing acts to establish the procedures for implementing paragraphs 1 to 5 of this Article. The 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 shall carry out checks to verify if users comply with the requirements set out in Articles 4 and 7.
2. The checks referred to in paragraph 1 of this Article shall be conducted in accordance with a periodically reviewed plan following a risk-based approach of which the key principles shall be laid down by the Commission in accordance with the procedure referred to in Article 15(2). ~~When developing this risk based approach, Member States shall consider that the implementation by a user of a best practice recognised under Article 8(2) of this Regulation or under Article 20(2) of the Nagoya Protocol reduces that user's risk of non-compliance.~~
3. Additional Checks checks may shall be conducted when a competent authority is in possession of relevant information, including on the basis of substantiated concerns provided by third parties, concerning a user's non-compliance ~~of a user~~ with this Regulation.
4. The checks referred to in paragraph 1 shall include at least:
 - (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;
 - (c) on the spot checks, including field audits;

- (d) examination of instances where a user was obliged to make declarations under Article 7.
5. Competent authorities shall accept an internationally recognised certificate of compliance as evidence that the genetic resource it covers has been accessed in accordance with prior informed consent and that mutually agreed terms have been established, as required by the domestic access and benefit-sharing legislation or regulatory requirements of the Party to the Nagoya Protocol providing the prior informed consent. In the event that an internationally recognised certificate is not available, other legally acceptable forms of compliance shall be considered sufficient evidence that the genetic resources covered were legally obtained and that mutually agreed terms were established.
 6. Users shall offer all assistance necessary to facilitate the performance of the checks referred to in paragraph 1, notably as regards access to premises and the presentation of documentation or records.
 7. Without prejudice to Article 11, where, following the checks referred to in paragraphs 1 and 3 of this Article, or following verification under Article 7 (2), shortcomings have been detected, the competent authority shall issue a notice of remedial actions to be taken by the user.
If no positive or satisfactory response is given by the user, and Additionally, depending on the nature of the shortcomings detected, Member States may take immediate interim measures, including inter alia seizure of illegally acquired genetic resources and suspension of specific use activities including commercialisation of products based on genetic resources and associated traditional knowledge. Such interim measures shall be effective, proportionate and dissuasive.
 8. The Commission shall be empowered to adopt ~~implementing-delegated~~ acts in accordance with Article 14a to establish the procedures for implementing paragraphs 1 to 7 of this Article and to define procedural safeguards, such as a right to appeal, with respect to the provisions under Article 7 and Articles 9 to 11. ~~The implementing acts shall be adopted in accordance with the examination procedure referred to in Article 15(2).~~

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 of remedial actions and measures taken under Article 9(7).

Records of all checks shall be kept for at least five years.

2. The information referred to in paragraph 1 shall be made available in accordance with Directive 2003/4/EC in an easily accessible, open, internet-based format.

Article 11

Penalties

1. Member States shall lay down the rules on penalties applicable to infringements of the provisions of Articles 4 and 7 of this Regulation and shall take all measures necessary to ensure that they are implemented.
2. The penalties provided for must be effective, proportionate and dissuasive. Those penalties may include:
 - (a) fines proportional to the value of the use activities related to the genetic resources concerned and that at least effectively deprive those responsible of the economic benefits derived from the infringement;
 - (b) immediate suspension of specific use activities including commercialisation of products based on genetic resources and associated traditional knowledge;
 - (c) confiscation of illegally acquired genetic resources.
3. Member States shall notify the rules referred to in paragraph 1 to the Commission by [date] at the latest and shall notify it without delay of any subsequent amendments affecting them.

Article 12

Cooperation

1. The competent authorities shall cooperate with each other, with the administrative authorities of third countries and with the Commission in order to reinforce effective coordination and ensure compliance of users with this Regulation. Cooperation shall also take place with other relevant actors, including collections, non-governmental organisations and representatives of indigenous and local communities when this is important for the correct implementation of the Nagoya Protocol and this Regulation.
2. The competent authorities shall exchange information on the organisation of their checking system for monitoring user compliance with this Regulation, on serious shortcomings detected through checks referred to in Article 9(14) and Article 10 (1), and on the types of penalties imposed in accordance with Article 11 with the competent authorities of other Member States and with the Commission.

2a. The Commission shall seek arrangements with the European Patent Office and with the World Intellectual Property Organization to ensure that references to genetic resources and their origin are included in patent registrations.

Article 13

Union platform on access and benefit-sharing

1. A Union platform on access to genetic resources and traditional knowledge associated with genetic resources and on fair and equitable benefit-sharing is hereby

established. Member States that plan to adopt rules governing access to their genetic resources shall first conduct an assessment of the impact of those rules and submit the results to the Union platform for consideration under the procedure laid down in paragraph 5 of this Article.

2. The Union platform shall contribute to the streamlining of access conditions at Union level by discussing related issues, including the design and performances of access regimes established in Member States, the promotion of research which contributes to the conservation and sustainable use of biological diversity, particularly in developing countries, including simplified access for non-commercial research, access practices of collections in the Union, access of Union stakeholders in third countries on mutually agreed terms after obtaining prior informed consent, benefit-sharing practices, and the implementation and further development ~~sharing~~ of best practices, and the functioning of dispute settlement arrangements.
3. The Union platform may provide non-binding advice, guidance or opinions on issues under its mandate. Any such advice, guidance or opinions provided shall have due regard for the requirement to involve the relevant indigenous and local communities concerned.
4. Each Member State and the Commission may nominate one regular member for the Union platform. Stakeholders and other experts in matters addressed by this Regulation may be invited as appropriate.
5. The Union platform will take decisions by the consensus of its regular members participating in a meeting. Decisions on procedure may be taken by a two-thirds majority of the regular members participating in a meeting. The first meeting of the Union platform shall adopt by consensus its detailed rules of procedure. The Commission shall prepare, convene and chair the meetings of the platform.

Article 14

Complementary measures

The Commission and the Member States shall, as appropriate:

- (a) support information, awareness raising, and training activities to help stakeholders to understand their obligations under this Regulation;
- (b) support the development of sectoral codes of conduct, model contractual clauses, guidelines and best practices, particularly where they would benefit academic researchers and small and medium-sized enterprises;
- (c) support the development and use of cost-effective communication tools and systems in support of monitoring and tracking the use 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 researchers and small and medium-sized enterprises, in order to facilitate compliance with the requirements of this Regulation.

(da) take measures to support, including through existing research programmes, collections that contribute to the conservation of biological diversity and cultural diversity but which have insufficient means to register their collections in the Union register;

(db) ensure that, in situations where genetic resources and associated traditional knowledge are utilised illegally, or not in compliance with prior informed consent or mutually agreed terms, providers who are competent to grant access to genetic resources and sign mutually agreed terms are entitled to bring an action to prevent or stop such utilisation, including through injunctions, and to seek compensation for any damages resulting therefrom, as well as, where appropriate, for the seizure of the genetic resources concerned;

(dc) encourage users and providers to direct benefits arising from the utilisation or subsequent commercialisation of genetic resources towards the conservation of biological diversity and the sustainable use of its components;

(dd) support, including through capacity-building, upon request, regional cooperation on benefit-sharing regarding transboundary genetic resources and associated traditional knowledge;

(de) consider the necessity for creating catalogues of the available genetic resources originating from each Member State in accordance with Article 7 of the Convention, in order to have a better knowledge of biodiversity;

(df) support research and development of genetic catalogues both within the Union and in third countries.

Article 14a

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The power to adopt delegated acts referred to in Article 4(4b) and Article 9(8) shall be conferred on the Commission for a period of five years from ... 1 . The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.

3. The delegation of power referred to in Article 4(4a) and Article 9(8) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the Official Journal of the European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Article 4(4a) and Article 9(8) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or the Council.

1 OJ please insert date: the date referred to in Article 17(1)

Article 15

Implementing acts

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 opinion of the committee is to be obtained by written procedure, that procedure shall be terminated without result when, within the time-limit for delivery of the opinion, the chair of the committee so decides or a two-thirds majority of committee members so request.
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 Member States' representatives and relevant provider organisations, user associations, inter-governmental and non-governmental organisations as well as representatives of indigenous and local communities in the implementation of this Regulation. Those parties shall contribute, in particular, to defining and reviewing delegated acts pursuant to Article 4(4a) and Article 9(8), and to the implementation of Articles 5, 7 and 8, and any guidelines for establishing mutually agreed terms. The parties shall meet in a consultation forum. The rules of procedure of that forum shall be established by the Commission.

Article 16

Reporting and review

1. Member States shall submit to the Commission, three years after the date of entry into force of this Regulation and every five years thereafter, a report on the application of this Regulation.
2. Not later than one year after the time-limit for submission of the national reports, the Commission shall draw up a report to be submitted to the European Parliament and the Council. The report by the Commission shall include a first assessment of the effectiveness of this Regulation.
3. Every ~~ten~~-five 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 its reporting the Commission shall in particular consider the administrative consequences for specific sectors, public research institutions, small or medium-sized enterprises and micro-enterprises. It shall also consider the need to review the implementation of the provisions of this Regulation concerning traditional knowledge associated with genetic resources in light of developments in other relevant international organizations and the need for further Union action on access to genetic resources and traditional knowledge associated with genetic resources with the view to implementing Article 5.2, Article 6.2, Article 7 and Article 12 of the Nagoya Protocol and respecting the rights of indigenous and local communities.
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 that the Union and its Member States have taken to implement the Nagoya Protocol.

Article 16a

Amendment to Directive 2008/99/EC

Directive 2008/99/EC of the European Parliament and of the Council of 19 November 2008 on the protection of the environment through criminal law 1 is hereby amended, with effect from ... *, as follows:

(1) in Article 3, the following point is added:

‘ (j) Illegal acquiring of genetic resources ’

(2) In Annex A, the following indent is added:

‘ -Regulation (EU) No. .../2013 of the European Parliament and of the Council of ... on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization in the Union ’.

1 OJL 328, 6.12.2008, p. 28.

* OJ: one year after the date of entry into force of this Regulation.

Article 17

Entry into force and application

1. The Commission shall publish a notice in the *Official Journal of the European Union* that the Nagoya Protocol has entered into force. This Regulation shall enter into force on the twentieth day following the publication of that notice.
2. Articles 4 [\(1\) to \(4\)](#), [Article 7](#), and [Article 9](#) shall apply one year after the date of entry into force of this Regulation.
3. This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President